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PANDORA’S HUMIDOR:
TOBACCO PRODUCER LIABILITY IN TORT

by Ellen Wertheimer

INTRODUCTION

The Greek gods, a jealous and temperamental bunch, gave Pandora the famous box to punish humankind for having received the benefit of fire from Prometheus. In order for the gods to attain their goal in giving her the box, it was vital that Pandora open it. Thus, the gods clearly knew that she would, and also knew what would happen and to whom it would happen when she did. Pandora did not disappoint them: she opened the box, despite the warnings she had received not to do so, and she loosed disease and despair upon all humankind.

Clearly, Pandora should not have opened the box. Some responsibility must rest with her for having done so. But a substantial measure of responsibility must also rest with the gods who presented it to her. They created it and gave it to her so that she would open it. They knew that she would disobey their directions. They thus knew perfectly well (a) that Pandora would open the box, (b) what would happen when she did, and (c) that her action would affect the population generally, and not just Pandora.

Tobacco companies\(^2\) gave the world the Pandora’s box contain-
ing the death and disease that tobacco involves, the advertising
to tempt smokers to open it, and the addiction to foreclose them
from closing it again. Just as Pandora was not the only one to be
affected when she opened her box, smokers are not the only ones
affected when they light up. Everyone pays for the perfidy of the
gods in giving Pandora the box and for her idiocy in opening it.
Today, everyone pays for tobacco, whether they use it or not.

The last entity in the box was hope. Hope today has its source
in the new wave of lawsuits against tobacco companies, and the
increased perception that those companies should be compelled
to accept responsibility for the forces they have loosed upon the
world. Pandora may be responsible for opening the box, al-
though it is highly doubtful that she had received a full and
adequate warning of what would happen if she did. Surely if she
had been fully warned, she would have been better equipped to
resist temptation. In any event, however, those who gave Pando-
ra the box for the purpose of having her open it bear a lion's
share of the responsibility. Until the 1990's, they have avoided
taking responsibility for their actions. But the new millennium

3. See, e.g., "Third Wave" Products Liability Litigation Aims For Public Cost
Recoupment, Disease Control and Compensation, Civil Justice Digest, 3 CIV. JUST.
DIG. (1996) (stating that on "May 1, 1996, Maryland became the eighth state to sue
the principal members of the tobacco industry to recoup state Medicare costs for
treatment of smoking-related illnesses . . . [Moreover], in addition to the state
government cases . . . class actions have been filed . . . .").

4. The history of suits filed against tobacco companies has not encouraged
plaintiffs to file suit. Such suits have been long, expensive, and unsuccessful. One
commentator noted:

The case will not be settled, so do not expect it. Prepare for trial from the
first day you undertake the case, because you will try the case, and it is likely
you will have to try it more than once. Whether you are successful or not,
there will be an appeal, unless you abandon the action.

J.D. LEE & JOHN F. VARGO, PRODUCTS LIABILITY PRACTICE GUIDE § 42.07 (1992).

Before Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992), no tobacco compa-
ny had lost or settled a product liability claim involving cigarettes. For a history of
tobacco litigation and its lack of success, see Leila B. Boulton, Comment, Tobacco
Under Fire: Developments in Judicial Responses to Cigarette Smoking Injuries, 36
CATH. U. L. REV. 643, 643-44 n.3 (1987); Bruce A. Levin, The Liability of Tobacco

In Cipollone, 505 U.S. at 504, the Supreme Court upheld an award of $400,000
against a cigarette manufacturer to compensate the decedent's husband for losses
caused by the Liggett Group's breach of express warranty. Id. at 511. This award
may bring the new idea that, just as members of our society are expected to be responsible for their actions, so should tobacco manufacturers. As of April 1997, twenty-one states had filed suit against the tobacco industry seeking medical cost reimbursement from that industry; trial is set to begin on the first of June 1997.\textsuperscript{5} As of this April week, new documents may come to light that make the analogy of the Greek gods, with their jealous and fell intent, all the more apt.\textsuperscript{6}

I. STRICT PRODUCTS LIABILITY

At the beginning of this century, consumers had few remedies against the manufacturers of products which caused them injury.\textsuperscript{7} As the century progressed, so did the perception that manufacturers should stand behind their products by paying for the injuries their products caused.\textsuperscript{8} This perception ripened into

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was small compared to the years of work that had gone into the case. See Blum, \textit{Will Next Round of Smoking Challenges Be Worth Pursuing?}, Nat'l L.J., June 27, 1988, at 3 (observing that by that point in time, the suit had cost $2,000,000 to prosecute); Alix M. Freedman et al., \textit{Liggett Ordered to Pay $400,000 in Damages for Smoker's Death}, WALL ST. J., June 14, 1988, at 3 (noting that $400,000 award followed five years of preparation). For a detailed discussion of the Supreme Court's opinion in \textit{Cipollone}, see Lee & Vargo, supra, § 42.05[4]; Thomas C. Galligan, Jr., \textit{Product Liability — Cigarettes and Cipollone: What's Left? What's Gone?}, 53 LA. L. REV. 713 (1993).


7. In \textit{MacPherson v. Buick Motor Co.}, 111 N.E. 1050 (N.Y. 1916), the New York Court of Appeals held that manufacturers and suppliers of potentially dangerous products are under a duty to all foreseeable users of the product to exercise reasonable care in its manufacture and supply. Prior to \textit{MacPherson}, manufacturer duty was limited to those in privity of contract with the manufacturer.

8. In \textit{Greenman v. Yuba Power Prods.}, 377 P.2d 897, 901 (Cal. 1962), the court stated that "[t]he purpose of [strict] liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves." The focus of strict products liability lies with compensation to be paid by those who create the risk to those who suffer injury when that risk materializes. See Ellen Wertheimer, \textit{Unknowable Dangers and the Death of Strict Products Liability: The Empire Strikes Back}, 60 U. CIN. L. REV. 1183, 1185 (1992) (discussing fairness goal of strict products liability). See also Frank J. Vandall, \textit{Design Defect} in
strict products liability doctrine, and manufacturers became liable for the defective products they produced irrespective of negligence.9

The goals justifying such liability are legion. I will now turn to an examination of some of these goals, with a view toward applying the rationales to the question of whether the tobacco industry should pay for the injuries tobacco causes. Karl Llewellyn asserts that "where the reason stops, there stops the rule."10 I would add to this that where the reason goes, the rule should go also. If holding manufacturers liable in this context would serve the goals of strict products liability, then manufacturers should pay.

A. Strict Products Liability Makes Manufacturers Stand Behind Their Products

One goal of strict products liability is to compel manufacturers to stand behind their products.11 Manufacturers advertise their

9. Section 402A of the Restatement (Second) of Torts clearly envisions liability in the absence of negligence. RESTATEMENT (SECOND) OF TORTS § 402A (1965). Section 402A provides:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation to the seller.


11. See Greenman v. Yuba Power Prod., 377 P.2d 897, 901 (Cal. 1963) (stating the reasons for and goals of strict products liability). Comment c to Restatement (Second) of Torts § 402A (1965) summarizes many of the policy elements behind strict products liability:

On whatever theory, the justification for the strict liability has been said to be
products and hold them out to the public as desirable. The manufacturer of a product should also put its money where its mouth is, and pay for the injuries that its much-vaunted products cause. This leads to the conclusions that a manufacturer should produce products that are as safe as possible, and that when they are not safe, the manufacturer should compensate those injured by them. This compensation becomes a cost of doing business and may be built into the price the manufacturer charges. The fact that the manufacturers will pass on the cost to the consumers of their products further serves the goal of strict products liability, because it means that consumers will pay for the benefit they receive from the availability of a product.

Profit is what remains after the costs of a product have been paid. These costs should include the injuries the products cause; otherwise, the profits reflect a windfall attained when someone else (the consumer, for example) has to pay those costs. The marketplace can only work freely if manufacturers pay the costs generated by their choice of what to produce, and these costs include the injuries which occur through non-negligent use of their products. Strict products liability supports a free market economy and the exercise of free choice. To say that one should

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that the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it; that the public does have a right to and does expect, in the case of products which it needs and for which it is forced to rely upon the seller, that reputable sellers will stand behind their goods; that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.

12. Justice Traynor identified risk distribution as a primary justification for strict liability in Escola v. Coca-Cola Bottling Co., 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring) (reasoning that costs of injuries are costs of doing business). See also W. Page Keeton, Product Liability and the Meaning of Defect, 5 St. Mary's L.J. 30, 35 (1973) (observing that a major reason for strict liability is that manufacturers can serve "effectively as risk distributors"); William L. Prosser, The Assault Upon the Citadel (Strict Liability to the Consumer), 69 Yale L.J. 1099, 1120 (1960), in which Dean Prosser stated: "[U]nder risk-spreading theory[,] the manufacturers, as a group and an industry, should absorb the inevitable losses which must result in a complex civilization from the use of their products, because they are in a better position to do so, and through their prices to pass such losses on to the community at large." But see George L. Priest, Strict Products Liability: The Original Intent, 39 Def. L.J. 279, 286 (1990) (asserting that risk distribution is not a primary goal of strict liability).
take the consequences of one's choices is hardly a radical concept.

If a product is as safe as possible, but remains dangerous, then one might justify imposing the costs of the injuries it causes on society generally, but only if that product benefits society generally. If it does, then forcing society generally to absorb the costs the product generates can be upheld on the ground that the entity which benefits from the product's availability (society) should pay the costs involved. One type of product which fits this paradigm is the vaccine. But if the product is not necessary to society generally, and produces more injury than benefit, then imposing the costs of the injuries it causes on society cannot be justified.

Failing to impose the costs on the manufacturer does not make those costs go away; it simply imposes them on someone else. If the product does not benefit society generally, society generally should not have to pick up the tab for that product's use. If failing to impose liability on the manufacturer leads to the result that society generally ends up paying the costs of the injuries caused by the product, the only possible conclusion is that the manufacturer should pay for the injuries caused by the product. This will lead to an increase in the price of the product, which will further lead to the economically desirable result that those who use the product will pay for that use. This leads us to the next goal of strict products liability: cost spreading.

B. Cost Spreading

Another goal of strict products liability is cost spreading.  

13. See Ellen Wertheimer, Unavoidably Unsafe Products: A Modest Proposal, 2 CHI.-KENT L. REV. 189 (1996) (arguing that those injured by dangerous, non-defective products such as vaccines should be compensated by society generally for their injuries).

14. Vaccines may cause side effects that injure a particular recipient; but they are not defective when the benefit of societal immunity outweighs the cost to the injured individual. See id.; see also Arnold W. Reitze, Jr., Federal Compensation for Vaccination Induced Injuries, 13 B.C. ENVTL. AFF. L. REV. 169, 208 (1986).

15. This goal is based upon the premise that society as a whole suffers more economically when individuals must bear the full burden of their losses and face potential financial ruin. FOWLER v. HARPER ET AL., 3 THE LAW OF TORTS § 13.2, at 132-33 n.7 (1986). Distribution of the costs of injury among all consumers of a particular product protects the individual from disaster; it is preferable to charge all con-
This concept is based on two fundamental ideas. The first is the idea that less total misery is produced when all of the consumers of a particular product pay a higher price for that product than when those who are injured by that product carry the entire weight of those injuries themselves. The second, and perhaps more important, is that cost spreading basically insures that those who benefit from the availability of a potentially dangerous product (by choosing to use it) pay the true costs of that benefit. This happens because consumers will pay a higher price for the products they wish to purchase once the costs of the product are passed on to them by the manufacturers.

With any dangerous product that will injure a certain percentage of those who use it competently, the identity of the unlucky consumer who happens to be injured is largely a matter of

sumers a small price increase than to allow one injured consumer to bear a large burden alone. Guido Calabresi, Some Thoughts on Risk Distribution and the Law of Torts, 70 Yale L.J. 499, 517 (1961).

16. See Calabresi, supra note 15, at 505. Judge Calabresi argues that "the loss should be placed on the party which is most likely to cause the burden to be reflected in the price . . . ." Holding the manufacturer thus has nothing to do with fault, but is rather based on the premise that the manufacturer can most easily alter the product's price to distribute these costs. In Helene Curtis Indus., Inc. v. Pruitt, 385 F.2d 841, 849 (5th Cir. 1967), the court pointed out that "manufacturers are superior risk-bearers because they have the capacity to distribute the losses of the few to the many by the price mechanism." See WILLIAM L. PROSSER, THE LAW OF TORTS § 84, at 506 (1968) ("[The producer] is best able to distribute the risk to the general public by means of prices and insurance."); MARK C. RAHDERT, COVERING ACCIDENT COSTS: INSURANCE, LIABILITY, AND TORT REFORM 28-35 (1995) (elaborating factors involved in an "insurance rationale" for tort liability).

17. The policy of distributing the costs of product injuries by holding the manufacturer liable serves to compel both the manufacturer and the consumer to make production and purchasing decisions based upon the real cost of the product. See Calabresi, supra note 15, at 505, 514; Rahdert, supra note 16, at 33. If a product's price does not reflect its societal costs, its price will be artificially low, and consumers might purchase more of the product than they would if they had to pay the product's true cost. See Gilbert Sandler, Strict Liability and the Need for Legislation, 53 Va. L. Rev. 1509, 1511 (1967) ("[T]he present [liability] system, based on the "fault concept, understates the actual costs of products . . . ."). But see David G. Owen, The Moral Foundations of Product Liability Law: Toward First Principles, 68 Notre Dame L. Rev. 427, 449, 451 (1993). Professor Owen contends that imposing liability upon a faultless party for another's injury is an inequitable policy decision that favors the injured party's interests at the faultless party's expense. Id. at 451. One response to this difficulty is that imposing the costs on the fault-free manufacturer does not leave the costs on that party. Rather, the manufacturer will distribute the burden to consumers of the product through price increases which will be paid by those who benefit from the availability of the product.
chance. If the costs are not spread by holding the manufacturer liable, the costs of the injury fall on the unlucky individual. If, on the other hand, the manufacturer is held liable, then the manufacturer will increase the cost of the product to reflect this, and all who purchase the product will become participants in what amounts to an insurance fund.\(^{18}\) Achieving this result by increasing the price of the product creates a risk pool of those who use the product. If society generally pays the costs, the risk pool will be overinclusive unless society generally benefits from the availability of the product. Of course, the group of contributors to the insurance fund may be underinclusive, because persons in addition to the purchasers may use the product. It will, however, include all purchasers of the product, and will in any event be a closer fit than a risk pool composed of all members of society would be, unless the product provides a uniform benefit to society generally.

C. The Incentive Rationale

Another goal of strict products liability is to provide an incentive to manufacturers to produce the safest product possible.\(^{19}\)

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\(^{18}\) As with more conventional insurance, the contributors to the insurance pool would be those who purchase the product at issue; although coverage would include all those injured by the product.

Various forms of insurance have been the basis for extensive academic discussion since the birth of liability without fault. See, e.g., Fleming James, Jr., *Accident Liability Reconsidered: The Impact of Liability Insurance*, 57 *Yale L.J.* 549, 569 (1948). Arguments in favor of some form of insurance apply to products which are non-defective as well as those which are defective, partly because compensation might not otherwise be available for dangerous, non-defective products. See Marshall S. Shapo, *A Representational Theory of Consumer Protection: Doctrine, Function and Legal Liability for Product Disappointment*, 60 *Va. L. Rev.* 1109, 1376 (1974) ("Such a system would eliminate inequality of treatment for the victims of various kinds of fortuitously caused harms . . . ."); Gary T. Schwartz, *The Beginning and the Possible End of the Rise of Modern American Tort Law*, 26 *Ga. L. Rev.* 601, 631 (1992) ("[T]he larger the number of foreseeable injuries, the more important . . . loss distribution . . . becomes."). This article, however, is limited to tobacco, a dangerous and defective product.

\(^{19}\) In *Phillips v. Kimwood Machine Co.*, 525 P.2d 1033, 1042 (Or. 1974), the court stated that "the imposition of [strict products] liability has a beneficial effect on manufacturers of defective products both in the care they take and in the warning they give." Not all courts have agreed that the incentive rationale applies in any other than the fault context. See *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176 (Mich. 1984). The court stated that "a negligence standard that would reward the careful manufacturer and penalize the careless is more likely to achieve [the] purpose of en-
At first blush, this goal would seem to have little weight if there is no alternative feasible design for the product in question, because no design change will eliminate the dangers. Under this argument, no incentive to design a safer product will work if a safer product cannot be made. Clearly, if the product could be changed in a manner to reduce the danger (for example, by adding filters or changing the composition of the ingredients of the product) then imposing liability for failure to make those changes serves the incentive goal. But what if the product cannot be made safer?

There are those who would argue that the absence of an alternative feasible design should make strict products liability inapplicable to products which cannot be changed to eliminate or reduce the dangers they involve. This argument, however,

couraging the design of safer products].” Id. at 185.


Some economists have challenged strict products liability based on their contention that strict products liability cannot, in fact, provide an incentive to manufacturers to be more careful. See, e.g., Richard A. Posner, Strict Liability: A Comment, 2 J. LEGAL STUD. 205 (1973) (arguing that strict liability standard is presumptively less efficient than alternative standards); Reynold M. Sachs, Negligence or Strict Liability: Is There Really a Difference in Law or Economics?, 8 GA. J. INT’L & COMP. L. 259 (1978) (arguing that strict liability standard threatens efficiency without changing accident and safety levels). While it may be the case that negligence law more directly encourages the exercise of due care, this does not mean that strict products liability cannot retain some of that function as well.

20. But see Indiana Harbor Belt R.R. Co. v. American Cyanamid Co., 916 F.2d 1174 (7th Cir. 1990). In the context of strict liability and ultrahazardous activities, this opinion finds:

By making the actor strictly liable — by denying him in other words an excuse based on his inability to avoid accidents by being more careful — we give him an incentive, missing in a negligence regime, to experiment with methods of preventing accidents that involve not greater exertions of care, assumed to be futile, but instead relocating, changing, or reducing (perhaps to the vanishing point) the activity giving rise to the injury].

Id. at 1177.


Liability is imposed on a manufacturer ... for a design defect because an alternative, feasible, safer design would have lessened or eliminated the injury plaintiff suffered. If no such alternative feasible design existed when the prod-
fails to take into account the operation of market forces. Strict products liability makes sense, even in the absence of an alternative feasible design, because imposing it will allow the market to operate. If a product is not only dangerous but also defective, that is if its dangers outweigh its utility, then imposing liability will require that the manufacturer pay the true costs of the product. If those costs fail to destroy the power of the product to generate a profit, then the manufacturer will continue to produce it. Conversely, a manufacturer who ceases to profit if that manufacturer must pay the true costs of the product, or if consumers stop buying it when its price is increased sufficiently to cover its costs, will stop producing it.

Thus, if there is no alternative feasible design, then the goal of enhanced product safety becomes the purely economic one of encouraging nonproduction if the manufacturer, after paying all the costs of the product, ceases to make a profit. This represents the operation of enhanced safety concerns in tandem with the free marketplace. A defective product is rendered safe in one of two ways: either by a change in its design or by payment of damages to consumers who are injured by it. If the latter course is followed and injured consumers are compensated, the product is safe in the sense that it has caused no uncompensated injuries.

See also James A. Henderson, Jr., Why Creative Judging Won't Save the Products Liability System, 11 Hofstra L. Rev. 845, 850 (1983) (“In [design defect] cases . . . the plaintiff should be required to show that the loss was avoidable . . . by an alternative design.”). A number of state statutes require that the plaintiff show the availability of an alternative feasible design to prevail. See, e.g., LA. REV. STAT. ANN. § 9:2800.56(1)(West 1991); N.J. STAT. ANN. § 2A:58C-3(a)(1)(West 1987); OHIO REV. CODE ANN. § 2307.75(F)(Anderson 1991). Interestingly, the Ohio statute appears to leave the door open to liability in the absence of an alternative feasible design by requiring an alternative feasible design “unless the manufacturer acted unreasonably in introducing the product into trade or commerce.”

For a detailed discussion of product-category liability, which is defined as “strict liability for producing and marketing certain categories of risky products, such as handguns, cigarettes, and alcoholic beverages, without regard to whether such products could be designed or marketed more safely,” see James A. Henderson & Aaron D. Twerski, Closing the American Products Liability Frontier: The Rejection of Liability Without Defect, 66 N.Y.U. L. Rev. 1263, 1329 (1991) (arguing against imposition of such liability); Ellen Wertheimer, The Smoke Gets In Their Eyes: Product Category Liability and Alternative Feasible Designs in the Third Restatement, 61 Tenn. L. Rev. 1429 (1994) (arguing in favor of liability in absence of alternative feasible design if product fails risk-utility test).
If the product ceases to turn a profit, resulting in its unavailability, then the dangers of the product have been eliminated because it can no longer be purchased. The product may not be safer, but the world is.

There are those who would argue that imposing the costs of smoking upon manufacturers will drive them into bankruptcy. The first response to this is that the costs imposed will be passed on to consumers, and thus may have little if any impact upon profits. The second response is more complex. If courts use the fear of bankruptcy as a reason for not imposing liability, what have we gained? If liability is imposed and the manufacturer goes bankrupt, that manufacturer may cease or reduce its production, and those injured by cigarettes will not recover. If liability is not imposed, then production will continue as it is, and those injured by cigarettes will still not be compensated. Indeed, nonliability leads to additional injury because the price of the product need not be increased to reflect its true costs. It takes little imagination to ascertain which result I would advocate.

If a manufacturer is not held liable for the injuries its product causes, then the price of the product remains at an artificially low level. This allows the manufacturer to sell more of the item, assuming that price is related to quantity sold, which in turn leads to additional injuries. From an economic standpoint, the correct price of a product should reflect all its costs. Only then can one accurately assess the level of demand for that product.

22. See Richard C. Ausness, Product Category Liability: A Critical Analysis, 24 N. Ky. L. REV. (1997). Professor Ausness argues that liability in the absence of an alternative feasible design "subjects sellers of inherently dangerous products, such as cigarettes, to potentially devastating liability since their products cannot be made less dangerous." Professor Ausness makes the valid point that driving such sellers into bankruptcy prevents them from paying any damages at all. Unfortunately, as our legal system now operates, the only alternative is non-liability. This means both that the injuries caused by the products are uncompensated and that the manufacturers of the products are able to sell more of their products because the price of the products will be artificially low. Non-liability leads not only to noncompensation, but also to additional injury.

23. The further argument is made that the threat of bankruptcy means that some legislative solution to the need to pay the costs of tobacco should be established. Those who advocate this idea also include the proviso that the damages paid will be limited in some way, for example by excluding pain and suffering, in order to keep the manufacturers healthy. Unless, however, the true costs are imposed, tobacco will receive special protection, a special protection it does not deserve and which no other product of its nature receives.
Yet another reason for strict products liability is simple fairness. The manufacturer creates and controls the danger. The manufacturer profits from the product. Why should consumers be left with the costs of the injuries a dangerous and defective product has inflicted upon them? The obvious answer is that they should not. When the product injures those other than the consumers who use it, the fairness rationale becomes overwhelming.

A price increase in the product to reflect all injuries caused by the product simply requires that those who benefit from the availability of the product pay for their benefit, but distributes the payment equally to all consumers. All consumers of tobacco products benefit equally from access to those products. The injuries should be shared as well.

II. PRODUCTS LIABILITY AND TOBACCO COMPANIES

This article has shown that products liability promotes the economic goal of compelling manufacturers to pay the true costs of the products they make. Failure to impose such liability allows the manufacturer a windfall. Someone must absorb the cost: the cost of the injuries does not go away when the manufacturer escapes liability. In the case of tobacco products, that someone is society as a whole. This hidden tax, unvoted upon and unconscionable to those who pay it, massively supports tobacco companies by allowing them to reap the profits of their business without paying their costs.

The hidden tax of tobacco subsidies paid by everyone range from increased health insurance rates to higher cleaning bills to the need to work overtime to cover for those absent by reason of

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24. The fairness lies both in compensating those injured by products and in making sure that manufacturers do not receive a windfall by being able to charge prices for their products that do not reflect the costs of the products. See Guido Calabresi & Jon T. Hirsch, Toward a Test for Strict Liability in Torts, 81 YALE L.J. 1055, 1084 (1972) (noting that distributional considerations make application of strict liability easier). Strict products liability doctrine spreads the costs of a particular product through the manufacturer to all users of the product. It also represents a societal decision that as between the two innocent parties — the non-negligent manufacturer and the consumer — the manufacturer should bear the costs of injuries inflicted by its products.
their smoking-related diseases. This tax is not merely paid in dollars; it includes the risk of disease and death emanating from secondary tobacco smoke.

There are products, like vaccines, for the dangers of which society should pay, because these products pass any applicable risk utility test and benefit society generally. But tobacco products do not fall into this category because their costs far outweigh their benefits. They are not only dangerous, they are also defective. Thus, the claim of cigarette manufacturers to entitlement to a general societal subsidy rings hollow. In fact, nonliability creates the supreme irony that society, by paying the costs of tobacco use, actually increases demand for cigarettes (and, inevitably, the amount of damage) by keeping the price artificially low.

Let us look at the goals of strict products liability as applied to tobacco companies. If these goals would be met by imposing liability, then failure to do so makes no sense.

A. Manufacturers Should Stand Behind Their Products

This goal seems overwhelming in the case of cigarette manufacturers. There is no other product available today which, when used as directed, kills such a high proportion of its consumers. There is no other product which, when used as directed, “is unequivocally carcinogenic.” There is no other product which,

25. The economic costs of smoking are staggering. In the mid-1980’s, for example, cigarette smoking generated $22 billion each year in health-related costs and $43 billion each year in lost productivity. Marc Z. Edell, Cigarette Litigation: The Second Wave, 22 TORT & INS. L.J. 90, 94 (1986). In the mid-1990’s, smoking was responsible for between 4.2% and 11.5% of all health care costs in the United States. Paul Cotton, Smokers May Pay, But Not Their Own Way, 271 JAMA 644 (1994).


27. Dangerousness is a physical characteristic. Defectiveness is a legal one. “[S]ome products are so dangerous that they create a risk of harm outweighing their usefulness. From that perspective, the term "defect" is a conclusion rather than a test for reaching that conclusion.” O’Brien v. Muskin Corp., 463 A.2d 298 (N.J. 1983).

Not all dangerous products are defective; dangerous products are only defective if their costs outweigh their benefits. Vaccines, for example, are dangerous but not defective. So are knives. See Ellen Wertheimer, Azzarello Agonistes: Bucking the Strict Products Liability Tide, 66 TEMP. L. REV. 419, 437-38 (1993) (discussing difference between danger and defect).

when used as directed, kills some 450,000 Americans each year. The manufacturers in this area profit from their sale of a lethal product. The only way to make them stand behind their product is to impose liability upon them. Otherwise, they profit from its sale without paying its costs.

Cigarette promotion is pervasive. Tobacco companies must generate new smokers in enormous volume, if only to replace those who die. The companies can make no assertions of product safety, and indeed count on their advertisements to counteract any negative information the potential consumer may have re-

NEW ENG. J. MED. 975, 977 (1994).


Under one estimate, 417,000 Americans die from nicotine dependence each year. This is seventy times more than all other drug addictions combined. John R. Hughes & Timothy S. Howard, Nicotine Don't Get No Respect, 271 JAMA 585 (1994) (citing R. Herdman et al., Statement on Smoking-Related Deaths and Financial Costs: Office of Technology Assessment Estimates for 1990, presented at a hearing on preventive health in Washington, D.C. on May 6, 1993).

Furthermore, in the United States in 1990, nearly one in five deaths was attributed to smoking. Carl E. Bartecchi et al., The Human Costs of Tobacco Use, pt. 1, 330 NEW ENG. J. MED. 907 (1994). Even more disturbing, smoking, which was the number one preventable cause of death in the United States in 1990, will cause approximately 30% of the cancer deaths during the 1990s. Id. at 907. It is estimated that smoking causes over 85% of lung cancers, 93% of oral cancers in men and 61% in women, 82% of pharyngeal cancers, 80% of esophageal cancers, 14% of leukemia, and 30% of the 13,500 new cases of cervical cancers occurring in 1993. Id. at 909-10.

Moreover, approximately forty-thousand Americans die each year from the effects of passive smoking. Keil, supra, at A2. According to a study released in June 1994, "tobacco smoke from spouses, co-workers and friends raises the risk of lung cancer for nonsmokers by 30% or more." Mark Jaffe, Study Affirms Risk of Secondhand Smoke, PHILA. INQUIRER, June 8, 1994, at A1. Moreover, passive smoke causes as many as 300,000 cases of bronchitis and pneumonia in children in the United States each year. Larry Margasak, Proposed Curbs on Smoking Gain Key Endorsement, PHILA. INQUIRER, Feb. 8, 1994, at A3. Passive smoke has also been blamed for worsening the asthma of between 200,000 and one million children. Richard A. Daynard, Smoking Out the Enemy: New Developments in Tobacco Litigation, TRIAL, Nov. 1993, at 16 (citing EPA claim).

ceived. Since the usual content of the idea of standing behind one's product involves some aura of product safety, in this sense the concept is clearly inapplicable to tobacco producers. They can, however, make their products safe in the sense of paying for the injuries that they cause. It's the least they can do.

B. Cost Spreading

As the tobacco industry stands now, it is in the extremely fortunate position of reaping the profits but making society generally pay the costs of its products. This happens when the manufacturers escape liability for their product and thus have no need to raise their prices. They can sell their product at an artificially low price, and thus attract more users. But the costs must fall on someone, since nonliability does not make them go away. That someone now includes society generally, a fact which has emerged with greater clarity as the number of state lawsuits against cigarette manufacturers has multiplied.¹

The goals of cost spreading require that cigarette manufacturers be held liable for their product. If society generally pays for the injuries, it means that the pool of those contributing to the product costs is drastically overinclusive, since society generally does not receive a benefit from the availability of tobacco products. Cost spreading requires that those who benefit from a product's availability combine, through increased prices, to pay for the injuries it causes. This in turn mandates that tobacco companies increase their prices to reflect the true costs of what they sell. The fact that tobacco companies adamantly refuse to do this suggests that they are afraid that the increases will lead to decreased use of their products, which in turn implies that the increases necessary to reflect the true costs of their products will be enormous. If this is the case, imposing liability on the financially strapped governmental entities that currently assume much of the burden is all the more indefensible. If forcing smokers to pay the true costs of their habit leads to its demise, that is the free marketplace at work. I am not arguing that liability should be imposed with the regulatory goal of achieving this result, rather that it is possible that, once the costs of smoking have been imposed on smokers, consumption may decrease.

31. See supra note 3 and accompanying text.
Unless tobacco companies are held liable, they will not pass on the costs of their products to those who use them. Apparently, the producers of cigarettes feel that the only way to keep smokers puffing is to have someone else pay for their use of the product. There are three alternative interpretations of producer unwillingness to pass on the true costs of cigarettes to those who smoke. One is that this reluctance stems from a fear that those who smoke would not continue doing so if the price of cigarettes reflected their true cost. If that is the case, then it calls into question the value of the habit. If those who engage in it are not willing to pay for the privilege then they should not have that privilege. The second, related, interpretation is that tobacco companies fear for their ability to attract new smokers if the price of cigarettes rises. Tobacco companies need new smokers, even if only to replace those who die each year. They are clearly willing to fight tooth and nail against any threat to their ability to recruit them.

The third interpretation is that tobacco defendants have gotten away with this (for them) happy state of affairs so long that they are unwilling to give it up. They have made enormous profits without having to pay the costs. It would be demanding too much to ask that they voluntarily take on the liability that they have to date succeeded in dodging. The answer is to force them to do so.

C. The Incentive Rationale

One of the goals of strict products liability has always been to encourage manufacturers to make their products safe.\(^3\) It seems to me that those who support liability for tobacco products have given in on this rationale too easily.\(^3\) It seems intuitively clear that a cigarette with a powerful filter is less likely to cause

\(^3\) See supra note 19 and accompanying text.

3. If tobacco products could be made safer than they are, then they would be defective, even under the Restatement (Third) of Torts definition, because an alternative feasible design would be available. Unfortunately, tobacco products cannot be made safe, and “remain the only consumer product sold legally in the United States that is unequivocally carcinogenic when used as directed.” Thomas D. MacKenzie et al., The Human Costs of Tobacco Use, pt. 2, 330 NEW ENG. J. MED. 975, 977 (1994). There is “no hope of producing or publicizing [a] safer cigarette.” J.D. Lee & John F. Vargo, PRODUCTS LIABILITY PRACTICE GUIDE § 42.07(5) (1992).
injury (or will take longer to do so) than a cigarette without a filter, or one with a less adequate filter. The new information which implies that producers deliberately made their products more dangerous and addictive through cigarette-spiking should lend new life to the application of this goal to tobacco companies.\textsuperscript{34} It should also be possible to develop reduced-nicotine cigarettes.

But even if cigarettes are as safe as they can be made to be, this does not defeat the incentive rationale. A compensated injury, in theory, is no longer an injury. As was discussed earlier, in this sense a product is made safer when the injuries it causes have been paid for. Imposing liability thus will serve the twin objectives of providing a remedy and of creating an incentive to make products as safe as science will allow, thereby reducing the number and extent of the injuries requiring a remedy.

\textbf{D. The Fairness Rationale}

One of the goals of products liability is simple fairness.\textsuperscript{35} One reflection of this goal is cost-spreading itself, which protects the individual consumer of a product from bearing the entire cost of the injuries which that product happens to inflict upon him or her.\textsuperscript{36} Cigarettes cause a certain percentage of smokers to suffer injury. Fairness requires that all smokers contribute to compensating those injured by the availability of the products they wish to purchase.

Another reflection of the fairness goal lies in the fact that, as matters now stand, non-consumers of tobacco products pay many of the costs generated by smokers, but receive no benefit in exchange for their payment. Smokers do not bear the costs their habit generates, at least in the economic sense (they do, of course, pay with their lives). Nor do the injuries stop there: the costs generated by tobacco use go beyond the economic to the physical when passive smokers themselves develop the diseases inflicted by tobacco use. That passive smokers are not compensated is not only indefensible, it is grotesque. Tobacco kills not


\textsuperscript{35} See supra note 24 and accompanying text.

\textsuperscript{36} See supra notes 15-18 and accompanying text.
only those who smoke, but those who do not. Failing to impose
liability upon tobacco companies not only provides them with a
windfall at the expense of the consumer, passive smokers, and
society generally, but it also allows them to kill with impunity.

E. Negligence Doctrine and Tobacco Producers

The trend in recent case law and the Third Restatement of
Torts — a trend I deplore — seems to involve reneging on strict
liability in favor of a return to negligence doctrine. In strict
liability, of course, the plaintiff need not prove negligence on the
part of the manufacturer. If liability is based on negligence, the
plaintiff must prove that the manufacturer acted unreasonably
in order to recover. This next section briefly turns to the ques-
tion of whether the abandonment of strict liability in favor of
negligence would have an impact on the goals behind liability
discussed above. Those who would impose liability for tobacco
products may not need strict liability doctrine in order to prevail.

First, we must ask whether plaintiffs could prevail against
tobacco producers under a negligence-based theory. In other
words, could plaintiffs prove that the manufacturers acted unrea-
sonably? In my view, cigarettes are defective because they fail
any applicable risk-benefit test. Put simply, their dangers out-
weigh their utility. It is also clear that their manufacturers
have been aware of their dangers for decades. Thus, the same

37. Numerous commentators argue that strict products liability in the design
defect context has become merely another form of negligence, albeit couched in other
terms. See, e.g., Jerry Phillips, The Proposed Products Liability Restatement: A Mis-
guided Revision, 10 TOURO L. REV. 151 (1993) (discussing strict liability and negli-
gence doctrines); John F. Vargo, Caveat Emptor: Will the A.L.I. Erode Strict Product
Liability in the Restatement (Third) for Products Liability?, 10 TOURO L. REV. 21, 24-
42 (1993) (discussing doctrines of strict liability and negligence); Ellen Wertheimer,
Unknowable Dangers and the Death of Strict Products Liability: The Empire Strikes
doctrine into negligence doctrine).

38. As is argued in infra, it may be negligent to produce cigarettes at all. Cf.
RE-
STATEMENT (SECOND) OF TORTS § 520 cmt. b (1965).

39. The Tobacco Institute has worked hard to minimize the perception of hazards
from tobacco products, to cloud safety issues or to conceal hazards altogether. See,
e.g., Cipollone v. Liggett Group, Inc., 683 F. Supp. 1487, 1490-91 (D.N.J. 1988), aff'd in
part, rev'd in part, 893 F.2d 541 (3d Cir. 1990), aff'd in part, rev'd in part, 505
U.S. 504 (1992). Even as late as 1986, the Tobacco Institute stated that "eminent
scientists believe that questions relating to smoking and health are unresolved."
Thomas D. MacKenzie et al., The Human Costs of Tobacco Use, pt. 2, 330 NEW ENG.
factors that prove cigarettes defective, plus the addition of manufacturer knowledge, suffice to demonstrate that the manufacturers of these products have acted negligently. Negligence is established by a showing that the costs of a given activity outweigh its benefits. By this standard, cigarette production is negligent conduct. In other words, if the known risks of an activity outweigh the benefits of that activity, the actor is negligent and liable when his or her conduct results in injury. This is tantamount to saying that cigarette production is an unreasonable activity. So be it.

Thus, plaintiffs in lawsuits against tobacco companies will be unaffected by whether the court applies a negligence standard or strict products liability doctrine. Cigarette manufacturers may, of course, have acted worse than negligently, as the materials being released by Liggett seem to imply. In any event, whether a court applies strict liability or negligence theory to tobacco products does not necessarily affect the result that a court will reach. If the goals discussed earlier support liability in the absence of fault, they certainly justify liability in its presence.

The first goal listed above is that of making manufacturers stand behind their products. Liability in negligence likewise serves this objective. The second is that of cost spreading. Negligence based liability likewise serves this goal. The third, the incentive goal, is obviously served by negligence. Indeed, negligence-based doctrine arguably serves this goal even more fully than strict products liability does. The fourth goal is fairness. If it is fair to impose liability on a fault-free defendant, it is a fortiori fair to impose liability on a negligent one.

J. MED. 975, 978 (1994).
40. United States v. Carroll Towing Co., 159 F.2d 169 (2d Cir. 1947) (holding that there is a duty of care to protect others from harm when the burden of taking adequate precautions is less than the product of the probability of the resulting harm and the magnitude of the harm).
41. Section 291 of the Restatement (Second) of Torts provides:
Where an act is one which a reasonable man would recognize as involving a risk of harm to another, the risk is unreasonable and the act is negligent if the risk is of such magnitude as to outweigh what the law regards as the utility of the act or of the particular manner in which it is done.

RESTATEMENT (SECOND) OF TORTS § 291 (1965).
42. See supra notes 6, 38 and accompanying text.
43. See supra note 19.
F. The Identity of the Plaintiffs

Those who actually consume tobacco themselves have much at stake as a result of their actions. I have argued elsewhere that even if failure to warn suits are pre-empted, consumers of tobacco products themselves should be able to file suit against tobacco producers on the ground that tobacco products are defective as manufactured. This will simply force consumers to pay for the total sum of risks created by tobacco use because such liability will trigger price increases. All consumers will pay for the risks to themselves, to all smokers, and to society generally.

But assume for the purpose of argument that consumers may not themselves sue tobacco producers. This does not end the debate. Warnings, even if adequate (and the warnings heretofore on cigarettes have been eminently deficient), cannot foreclose suits by others who suffer from the availability of tobacco products, who never received any warnings and would not have been able to take action on them anyway. These include passive smokers and those entities who must pay for the injuries caused by tobacco, be they public or private. The costs to all of these possible plaintiffs are foreseeable emanations from tobacco use, and should, under the arguments above, be paid for by tobacco producers, and, through them, smokers. It has been many decades since a defendant could successfully argue that liability should only extend to the purchaser of a product.\(^{44}\)

Nor does the identity of the defendants pose any particular problem. As the recent flurry of activity in the courts has shown, there are not that many major tobacco producing companies.\(^{45}\) It should be fairly easy to set up some form of market share system for contribution.\(^{46}\) Even if it is not, however, it cannot justify failing to hold tobacco companies responsible for the massive damage they have loosed upon the nation.

The preceding section has demonstrated that compelling tobac-

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44. See MacPherson v. Buick Motor Co., 111 N.E. 1050 (N.Y. 1916). The court ruled that manufacturers owed a duty of care to all who might be injured by their products, and not just to those in privity with the manufacturer. Id.


co producers to pay for the costs their products generate fulfills
the goals of both strict and negligence-based liability. In addition
to arguing that they should not be liable under products liability
theory, tobacco manufacturers raise various other defenses. It is
to these that this article now turns.

III. DEFENSES RAISED BY TOBACCO COMPANIES

Tobacco companies raise several defenses against the imposi-
tion of strict liability. The first, ludicrous as it sounds, is that
cigarettes are not bad for you. 47 This argument may be dis-
missed as (at best) wishful thinking. If those who make this
argument do not believe what they are saying, then they are
acting fraudulently. If they do believe what they are saying, then
I have a bridge that I would like to sell them.

The second argument, often made in the same breath as the
first, is that smokers assume the risk of their activity. 48 The
fact that cigarette manufacturers argue simultaneously that
cigarettes are not dangerous and that smokers assume all dan-
gers that they involve highlights the massive and deserved lack
of credibility from which executives who make this argument
suffer. How can a consumer assume a risk that the defendant
argues did not exist? If the manufacturers do not know of the
dangers of their product (the most innocent interpretation to
place on the denial of dangers), how can the consumer know of
them? On the other hand, if the manufacturers do know of the
dangers of their product, they have no business denying that
those dangers exist, and have even less business arguing that

47. See supra note 39 and accompanying text. Defendants in cigarette litigation
have argued that there are substantial benefits to smoking. For a discussion of the
benefits of cigarettes and smoking, see generally Douglas N. Jacobson, After Cipollone
v. Liggett Group, Inc.: How Wide Will the Floodgates of Cigarette Litigation Open?, 38
AM. U. L. REV. 1021, 1025 n.29 (1989); C.F. Fenswick, Note, Cipollone v. Liggett
Group, Inc.: Supreme Court Takes Middle Ground in Cigarette Litigation, 67 TUL. L.

48. See James A. Henderson, Jr. & Aaron D. Twerski, Closing the American
Products Liability Frontier: The Rejection of Liability Without Defect, 66 N.Y.U. L.
REV. 1263, 1325-26 nn.253-59 (1991); see also Paugh v. R.J. Reynolds Tobacco Co.,
834 F. Supp. 228, 230 (N.D. Ohio 1993) (precluding plaintiff's recovery because "[t]he
dangers posed by tobacco smoking have long been within the ordinary knowledge
common to the community"). Cf. Note, Plaintiff's Conduct as a Defense to Claims
Against Cigarette Manufacturers, 99 HARV. L. REV. 809 (1986)(discussing why the
assumption of the risk defense should not apply to tobacco cases).
the consumers should know better than to believe them. The assumption of risk argument in this context is tantamount to saying that consumers should know that the tobacco companies are lying when they deny the risk of injury from their product.

Thus, the assumption of the risk argument attains any validity it may have only if the manufacturers concede that their product is dangerous, so dangerous that the precise hazards are a matter of common knowledge. This they are clearly unwilling to do. If the tobacco companies deny that there is any danger from smoking, how can they argue that consumers of tobacco products assume the risks of their conduct?

The assumption of the risk argument suffers from additional infirmities. Assumption of the risk applies as a defense only where the plaintiff subjectively knew of, fully appreciated, and voluntarily confronted the dangers which the defendant contends the plaintiff assumed. Thus, a consumer can only assume the risk of a product’s danger if that consumer is fully informed of the existence and the scope of that danger. There is no evidence whatever that manufacturers of tobacco products have fully informed consumers of the dangers inherent in their products. Indeed, the manufacturers have spent enormous amounts of time and money concealing or minimizing those dangers and in lobbying for the protection of absurdly underinclusive warnings.

49. One of the infirmities is that “assumption of risk is not a favored defense.” Blackburn v. Dorta, 348 So. 2d 287 (Fla. 1977).

50. See Hildebrand v. Minyard, 494 P.2d 1328 (Arizona Ct. App. 1972). The court set out the elements of the assumption of the risk defense. Two of these elements are that the “[p]laintiff must have actual knowledge of the particular risk and appreciate its magnitude,” and that the “plaintiff must voluntarily choose to [encounter] the risk under circumstances that manifest his willingness to accept that particular risk.” Id.

51. In 1965, Congress passed the Federal Cigarette Labeling and Warning Act. Today, the following rotating warnings must appear on cigarette packages and advertisements:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.
SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks To Your Health.
SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.
SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

15 U.S.C. § 1333 (1965). None of these warnings meets the criteria for the assumption of the risk defense. This is because none of them, either individually or en
Moreover, assumption of the risk only works against the plaintiff if the plaintiff is the consumer of the product. It does not work in the context of passive smoke or state health insurance plans. To argue that society generally assumes the risk of paying for tobacco-related injuries by failing to make tobacco use illegal is hardly an argument a tobacco producer would want to make, even if it had any validity, which it does not. Failing to forbid an activity is not the equivalent of agreeing to pay for the injuries that activity causes.

The argument has been made that tobacco products are like fast food, in that both of these inherently cause harm. Since no one would seriously contemplate imposing liability for the sale of cheeseburgers, tobacco companies contend that the analogy serves to protect them from the fate of paying damages. As a preliminary matter, however, it is worth noting that this argument requires the concession that tobacco products cause harm, because it is this propensity that allows the analogy. It is also worth noting that there is no such thing as passive cheeseburger-eating.

But the analogy suffers from more substantive infirmities as well. First, when eaten as part of a reasonable diet, fast food is not harmful. Even when used in moderation, cigarettes are harmful. Thus, the analogy fails as an initial matter. Second, it is highly doubtful that anyone could prove that fast food cheeseburgers caused the harm at issue. A lawsuit against fast food establishments would require evidence that McDonald’s cholesterol, rather than cholesterol ingested from other sources, caused the harm. Thus, analogizing tobacco producers to fast food restaurants fails on causation grounds, because proof that tobacco caused the harm at issue is much more readily available. Third, the magnitude of the harm separates fast food from cigarettes. It is highly doubtful (and there is no evidence that) fast food ingestion will kill one third of all those who start eating such food as teenagers. On the other hand, there is evidence that tobacco masse, conveys the danger to an extent that one can be said to be accepting the risks that smoking involves in making a decision to smoke. Inadequate warnings have never protected manufacturers from liability. The fact that these woefully incomplete and insufficiently terrifying federally mandated warnings can protect cigarette manufacturers from liability for failure to warn reflects an excess of congressional zeal to defend the tobacco industry.
products will kill one third of all persons who start smoking as teenagers. 52 Fourth, I have seen no evidence that McDonald's cheeseburgers are addictive. It is the inability of many smokers to stop that contributes to the danger.

The final defense I wish to discuss is the idea that holding tobacco manufacturers liable for their products somehow interferes with smoker autonomy. 53 The argument is that in making the choice to smoke, a person is exercising his or her autonomy and should not be heard to complain when injury and death result. It should come as no surprise that I reject this particular conclusion. I agree that autonomy requires one to make a choice, and that the selection among alternative courses of conduct must bring with it a willingness to take responsibility for that choice. But defining the consequences of the choice solely in terms of willingness to accept injury and death is too narrow. Instead, I argue that the choice should lie in deciding to smoke and paying for that decision through the increased prices that would result if cigarette prices were increased to reflect their true economic costs. Those who choose to smoke should pay for the availability of the product they wish to use. As the law stands now, those who choose to smoke are subsidized (and arguably encouraged) in their decision because the prices of tobacco products are artificially low. This does not enhance autonomy. It does the opposite: a subsidized decision is not an informed one.

Imposing the costs of smoking on tobacco producers and, through them, on smokers, simply places the responsibility for smoking on those who have chosen to do so. This enhances autonomy, because it allows smokers to make a choice based on full information as to the cost of that choice. To compel smokers to pay for their choice may or may not cause them to make a different one. This is not interfering with autonomy; it is allowing the

52. A study by the American Cancer Society predicts that “at least one third of smokers and [perhaps] as many as one half will die from [smoking related disorders].” Andrew A. Skolnick, Experts at Buenos Aires Conference Predict Pandemic of Tobacco Deaths, 267 JAMA 3255 (1992). “[S]mokers are three times more likely to die before the age of 70 than nonsmokers.” Randi H. Epstein, 40-Year Study Sees Higher Smoking Toll A Report Finds “Much More Extreme” Results in Comparing the Longevity of Smokers and Nonsmokers, PHILA. INQUIRER, Feb. 17, 1993, at A2.

53. See Peter S. Arno et al., Tobacco Industry Strategies To Oppose Federal Regulation, Apr. 24, 1996 JAMA 1258 (1996 WL 10487835)(examining the antiregulatory strategies used by the tobacco industry in the face of new federal initiatives).
free exercise of an informed decision.

It is true that smokers have, at least to some extent, made a choice to begin and to continue smoking. They should pay for their habit, in the form of increased prices. They will then be paying for the injuries caused to the pool of smokers (and non-smokers) generally. The increased cost of cigarettes constitutes the economic value of the privilege of cigarette availability. The purpose of the increased price is to enable manufacturers to reimburse those individuals who happen to be injured for the cost of their injuries. In other words, the pool of smokers contributes to compensate that percentage of smokers that suffers actual injury. Thus, even an injured consumer — one who has at least arguably chosen to smoke — should recover, because that consumer has paid for the coverage through increased prices. 54

There is, as far as I know, no constitutional right to smoke. Smokers should pay the costs of the privilege.

CONCLUSION

If the population generally should pay for the injuries caused by a given product, the population generally should benefit. The fact that the population benefits generally from the immunity conferred by vaccines justifies imposing the costs on the general public when those vaccines cause injury (which they do, but rarely). There is, however, no general benefit derived from smoking. Overall, smoking, and tobacco products generally, cause harm. Because their overall impact is negative, tobacco products are both dangerous and defective. As with all defective products, manufacturers should pay for the harm their products cause. Failing to hold manufacturers liable adds to the death toll by allowing the sale of tobacco products at an artificially low price. No other product, when used as intended, has the grotesque effect tobacco products have. No other manufacturers, producing a lethal product, have escaped liability with such success for so long. It is time for a change.

The gods who gave Pandora her box were immune from suit because they were gods. 55 Tobacco producers can claim no di-

54. Passive smokers should also recover, of course, because smokers have caused their injuries and, by paying the true costs of tobacco products, have paid the necessary amount to allow this to happen.

55. See United States ex rel. Mayo v. Satan And His Staff, 54 F.R.D. 282 (W.D.
vine status. They should pay for the death and disease they have caused.

Pa. 1971) (dismissing suit for failure to prove service of process). See also WILLIAM BLACKSTONE, 1 COMMENTARIES ON THE LAW OF ENGLAND 244, 246 (observing that because the monarch stood at the apex of the feudal pyramid, no court could exercise jurisdiction over the Crown); Russell v. Men of Devon, 2 Term Rep. 671, 100 Eng. Rep. 359 (1788)(discussing concept of sovereign immunity).
PRODUCT CATEGORY LIABILITY:
A CRITICAL ANALYSIS

by Richard C. Ausness¹

INTRODUCTION

Professor Wertheimer has proposed that courts be allowed to hold producers strictly liable for product-related injuries, even though their products are not otherwise defective, as long as the overall risks associated with such products outweigh their benefits.² However, this would subject the sellers of inherently dangerous products, such as cigarettes, to potentially devastating liability since their products cannot be made less dangerous. There are better ways to control the consumption of hazardous products if society wishes to do so.

Part I of this article discusses the scope and purpose of the defect requirement in section 402A³ and in the proposed Restatement (Third) of Torts.⁴ Part II examines the concept of product category liability and chronicles its universal rejection by the courts. Part III analyzes various policy arguments for and against categorical liability. Part IV considers some of the problems associated with using tort law to regulate product safety. Finally, Part V identifies some alternatives to an expansion of tort liability.

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⁴. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1(a) (Tentative Draft No. 2, 1995).
I. STRICT PRODUCTS LIABILITY

A. The Defect Requirement

Strict liability, as codified in section 402A of the Restatement (Second) of Torts, has now largely replaced negligence and implied warranty as the preferred theory of recovery against product sellers. Section 402A imposes strict liability upon any product seller who sells a product which is in a defective condition unreasonably dangerous to a user or consumer or to their property. Under this approach, the focus is theoretically on the product's condition, rather than the manufacturer's conduct. Consequently, an injured party may recover without proving that the product seller was at fault.

However, strict liability is not intended to impose absolute liability. Thus, product sellers are subject to liability only when their products are defective in some way. Courts and com-


6. Section 402A provides:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although (a) the seller has exercised all possible care in the preparation and sale of his product, and (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.


8. See Waterson v. General Motors Corp., 544 A.2d 357, 372 (N.J. 1988) ("The essence of an action in strict liability is that the injured party is relieved of the burden of proving the manufacturer's negligence.").


10. See Caterpillar Tractor Co. v. Beck, 593 P.2d 871, 879 (Alaska 1979) ("A product must be defective as marketed if liability is to attach, and 'defective' must mean something more than a condition causing physical injury."); Michael J. Toke, Note, Categorical Liability for Manifestly Unreasonable Designs: Why the Comment d
mentators\textsuperscript{12} have traditionally divided product defects into three categories: manufacturing defects, design defects and defective warnings. A manufacturing defect is an unintended condition that arises from some mishap in the production process.\textsuperscript{13} A design defect occurs when the entire product line shares a common dangerous characteristic.\textsuperscript{14} Finally, a product that is otherwise properly manufactured may be rendered defective because of inadequate warnings or instructions provided to product users.\textsuperscript{15}

Since no single definition of defect is broad enough to cover every type of dangerous condition,\textsuperscript{16} courts have employed a variety of tests to determine if a product is defective. For example, under the "deviation from the norm test," a product is considered defective if it deviates from the manufacturer's intended design or if it is inferior in workmanship to products of the same description.\textsuperscript{17} A second test, known as the "consumer expectation

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13. See Barker v. Lull Eng’g Co., 573 P.2d 443, 454 (Cal. 1978) (stating that a product with a manufacturing or production defect is "one that differs from the manufacturer’s intended result or from other ostensibly identical units of the same product line"); Caprara v. Chrysler Corp., 417 N.E.2d 545, 552-53 (N.Y. 1981) (explaining that "a defectively manufactured product . . . results from some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction").

14. See Thibault v. Sears, Roebuck & Co., 395 A.2d 843, 846 (N.H. 1978) (“A design defect occurs when the product is manufactured in conformity with the intended design but the design itself poses unreasonable dangers to the consumer.”).


16. See, \textit{e.g.}, Barker, 573 P.2d at 453 (recognizing that the term “defect” “is neither self-defining nor susceptible to a single definition applicable in all contexts”).

17. See O’Brien v. Muskin Corp., 463 A.2d 298, 304 (N.J. 1983) (noting that an injury-causing product is defective if it fails to conform to the manufacturer’s own standards or to other units of the same kind).
"test," is derived from implied warranty principles. According to this test, a product is deemed to be defective if it turns out to be more dangerous than an ordinary consumer would expect it to be. A third test, commonly referred to as the "risk-utility test," provides that a product will be considered defective if the risks associated with the product exceed its overall utility. This test is often used in design defect litigation to treat a product as defective when the utility of the product with an alternative and more safe design outweighs the utility of the product as actually designed.

B. Inherently Dangerous Products

Many products are inherently dangerous. For some products, the danger cannot be eliminated without impairing the product's intended function. For example, the sharp edge of a knife can be hazardous to users of the product, but a knife cannot perform its intended function properly if its blade is dull. Another group of inherently dangerous products is characterized by hazards that are not consciously designed into the product. For example, the carcinogenic properties of asbestos do nothing to enhance its fire retardant qualities. Tobacco also appears to fit
within this category. 26

1. Liability Under Section 402A

In general, it appears that section 402A does not impose strict liability on the sellers of inherently dangerous products as long as a proper warning is given. The first impediment to liability is the requirement that a product be defective. When an attempt was made to delete the word “defective” from a draft version of section 402A during a floor debate in 1961, Dean Prosser, the Reporter for the proposed Restatement, declared that the defect requirement was intended to protect the sellers of whiskey, cigarettes and other inherently dangerous products from liability. 27

The drafters also addressed this issue in comment i to section 402A 28 which purported to define the term “unreasonably dangerous.” In comment i, the drafters declared that “[g]ood whiskey is not unreasonably dangerous merely because it will make some people drunk, and is especially dangerous to alcoholics.” 29 Thus, only “bad whiskey,” such as whiskey contaminated with dangerous levels of fusel oil, could be described as unreasonably dangerous. 30 The drafters also observed that “[g]ood tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful.” 31 To be treated as unreasonably dangerous, tobacco would have to contain “something like marijuana.” 32 Similarly, “good butter” is not to be regarded as unreasonably dangerous simply because it deposits cholesterol in the arteries and leads to heart attacks; only “bad butter,” such as butter contaminated with poisonous fish oil, would qualify for unreasonably dangerous status. 33

According to the drafters of comment i, the reason good whiskey, good tobacco and good butter are not unreasonably dangerous is because the consuming public is aware of the health risks associated with these products. 34 This same reasoning underlies

26. Id.
27. Id. at 861-62.
28. See Restatement (Second) of Torts § 402A cmt. i (1965).
29. Id.
30. Id.
31. Id.
32. Id.
33. Id.
34. Id.
comment g, which defines what is meant by a "defective condition."\textsuperscript{35} In this provision, the drafters state that a product seller is strictly liable "only where a product is, at the time it leaves the seller's hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him."\textsuperscript{36} Presumably, ordinary consumers would be sufficiently familiar with the risks associated with commonly used inherently dangerous products, such as knives, cigarettes and whiskey, that these products would not be regarded as defective according to the criterion set forth in comment g.

It should be mentioned that another provision, comment k,\textsuperscript{37} also deals with inherently dangerous products. Comment k classifies certain products as "unavoidably unsafe" and excludes them from section 402A's strict liability regime.\textsuperscript{38} However, section 402A's legislative history indicates that comment k was primarily concerned with pharmaceutical products.\textsuperscript{39}

2. Liability Under the Third Restatement of Torts

The drafters of the Restatement (Third) of Torts\textsuperscript{40} have also exempted inherently dangerous products from liability. One provision of the new Restatement imposes liability on product

\textsuperscript{35} See Restatement (Second) of Torts § 402A, cmt. g (1965).

\textsuperscript{36} Id.

\textsuperscript{37} Restatement (Second) of Torts § 402A, cmt. k (1965).

\textsuperscript{38} See id. ("There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs."). See generally Richard C. Ausness, Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should Be Applied to the Sellers of Pharmaceutical Products?, 78 Ky. L.J. 705 (1989-90).

\textsuperscript{39} See Page, supra note 22, at 864-66. Since section 402A's adoption, most courts have refused to extend it to other products. See, e.g., Blevins v. Cushman Motors, 551 S.W.2d 602, 608 (Mo. 1977) (holding that golf carts were not unavoidably unsafe products because they could be made safe for their intended use); Netzel v. State Sand & Gravel Co., 186 N.W.2d 258, 264 (Wis. 1971) (declaring that ordinary concrete mix could not be found unavoidably unsafe merely because it contained caustic ingredients). But see Jackson v. Johns-Manville Sales Corp., 727 F.2d 506, 516 (5th Cir. 1984) (suggesting that asbestos products might qualify as unavoidably unsafe), cert. denied, 478 U.S. 1022 (1986); Moran v. Johns-Manville Sales Corp., 691 F.2d 811, 814 (6th Cir. 1982) (also suggesting that asbestos products might qualify as unavoidably unsafe).

\textsuperscript{40} Restatement (Third) of Torts: Products Liability (Tentative Draft No. 2, 1995).
sellers who distribute defective products.\textsuperscript{41} Other provisions enumerate and define the three types of product defect: manufacturing defect, design defect and inadequate instructions or warnings.\textsuperscript{42} Yet, since none of these definitions appear to cover inherently dangerous products, one may reasonably conclude that they are not subject to liability under the new \textit{Restatement}.

It is possible that inherently dangerous products could fall within the category of defectively designed products. However, a product is considered to be defectively designed only if the risk “could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor . . . ”\textsuperscript{43} This alternative design requirement effectively insulates such inherently dangerous products as cigarettes, alcoholic beverages and firearms from design defect liability.\textsuperscript{44} Indeed, in comment \textsc{c} the drafters themselves acknowledge that sellers of inherently dangerous products should not be held strictly liable under the principles of liability set forth in the \textit{Restatement (Third) of Torts}:

The requirement in § 2(b) that plaintiff show a reasonable alternative design applies even though the plaintiff alleges that the category of product sold by the defendant is so dangerous that it should not have been marketed at all. Thus common and widely distributed products such as alcoholic beverages, tobacco, firearms, and above-ground swimming pools may be found to be defective only upon proof of the requisite conditions in § 2(a), § 2(b), or 2(c)\textsuperscript{45}

Thus, it seems clear that the sellers of inherently dangerous products, such as cigarettes, will not be subject to strict liability under the traditional approach of section 402A, or under the liability scheme proposed by the drafters of the \textit{Restatement (Third) of Torts}.

\textsuperscript{41} See \textit{Restatement (Third) of Torts: Products Liability} § 1 (a).
\textsuperscript{42} Id. §§ 1 (b), 2.
\textsuperscript{43} Id. § 2 (b).
\textsuperscript{44} See Wertheimer, supra note 2, at 1443; Toke, supra note 10, at 1200.
\textsuperscript{45} See \textit{Restatement (Third) of Torts: Product Liability} § 2, cmt. c at 21.
II. PRODUCT CATEGORY LIABILITY

Since conventional product liability doctrines do not appear to work very well, plaintiffs have been obliged to develop new liability theories to support their claims against the sellers of inherently dangerous products. The most promising group of theories involves categorical product liability. Under this approach, a court may conclude that an entire product category, such as handguns or cigarettes, is subject to liability even in the absence of a specific defect. 46

A. Theories of Liability

Two theories of categorical product liability have emerged during the past fifteen years: under the first theory, the manufacture and sale of certain types of products is labeled "ultrahazardous"; under the second theory, strict liability is imposed on product sellers if the risks associated with a particular class of product outweigh its utility.

1. The Ultrahazardous Activity Theory

One legal theory that plaintiffs have frequently invoked is the doctrine that individuals or enterprises engaged in ultrahazardous or abnormally dangerous activities should be held strictly liable for any injuries that they cause to others. 47 It has been proposed that this form of strict liability, based on the principle of Rylands v. Fletcher, 48 should be applied to sellers of inherently dangerous products. 49 The "ultrahazardous activity" theory

46. See James A. Henderson, Jr. & Aaron D. Twerski, Closing the American Products Liability Frontier: The Rejection of Liability Without Defect, 66 N.Y.U. L. REV. 1263, 1297 (1991) [hereinafter Frontier] (explaining that "once a category is identified as appropriate for strict liability, by implication all the products within that category would be measured according to a no-defect strict liability standard . . . ").
47. This theory of strict liability was first suggested by an English court in Rylands v. Fletcher, L.R. 3 H.L. (1868). In the United States, it was incorporated into the Restatement of Torts, which imposed strict liability on those who engaged in "ultrahazardous" activities. See RESTATEMENT OF TORTS §§ 519-520 (1939). The Restatement (Second) of Torts broadened the scope of strict liability to include "abnormally dangerous" activities. See RESTATEMENT (SECOND) OF TORTS §§ 519-20 (1977).
has often been invoked by those who have been injured by handguns or other firearms.\textsuperscript{50}

For a variety of reasons, however, almost no court has been willing to find that the manufacture or sale of firearms is an ultrahazardous activity.\textsuperscript{61} First of all courts have been reluctant to broaden the scope of a doctrine which has traditionally been limited to landowner liability.\textsuperscript{52} Second, they have been unwilling to extend strict liability to an activity that is a matter of common usage.\textsuperscript{53} Finally, they have been concerned about the possible economic effects of such a liability rule.\textsuperscript{54}
2. The Risk-Utility Theory

The risk-utility theory is even more popular with plaintiffs. According to this concept, manufacturers and other sellers may be held strictly liable under section 402A even in the absence of a conventional defect. Such products are considered "defective" because the accident costs that they generate outweigh the benefits that the public derives from their use and consumption. During the past decade or so, plaintiffs have invoked this theory in connection with such inherently dangerous products as above-ground swimming pools, trail bikes, firearms, tobacco products, alcoholic beverages and asbestos. However,
plaintiffs have been successful in only three instances.\textsuperscript{63}

\textbf{a. Cases Applying the Risk-Utility Theory}

One of the first cases to recognize product category liability was \textit{O'Brien v. Muskin Corp.},\textsuperscript{64} decided by the New Jersey Supreme Court in 1983. \textit{O'Brien} involved a lawsuit by an individual who was injured while diving into a shallow above-ground swimming pool.\textsuperscript{65} The injured party brought suit against Muskin Corporation, the manufacturer of the swimming pool, alleging that the product was defectively designed because its vinyl liner was too slippery.\textsuperscript{66} The trial court refused to submit the design defect claim to the jury and the plaintiff appealed.\textsuperscript{67} On appeal, the \textit{O'Brien} court acknowledged that it was appropriate to consider available alternative designs as part of a risk-utility analysis\textsuperscript{68} However, the court also declared that there are some products which are so dangerous and so useless that the risks associated with their use outweigh their benefits.\textsuperscript{69} In such instances, product sellers should bear the cost of liability for harm to injured consumers even though no safer alternative is available.\textsuperscript{70} The court then concluded that “the trial court should have permitted the jury to consider whether, because of the dimensions of the pool and the slipperiness of the bottom, the risks of injury so outweighed the [pool’s] utility . . . as to constitute a defect.”\textsuperscript{71} In the court’s words:

\begin{quote}
viewing the evidence in the light most favorable to plaintiff, even if there are no alternative methods of making bottoms for above-ground pools, the jury might have found that the risk posed by the pool outweighed its utility.\textsuperscript{72}
\end{quote}

\begin{thebibliography}{99}
\bibitem{halphen} See \textit{Halphen}, 484 So. 2d at 110; \textit{Kelley v. R.G. Indus., Inc.}, 497 A.2d 1143 (Md. 1985); \textit{O'Brien v. Muskin Corp.}, 463 A.2d 298 (N.J. 1983).
\bibitem{obrien} 463 A.2d 298 (N.J. 1983).
\bibitem{muskin} \textit{Id}. at 302. The plaintiff was injured when he struck his head on the bottom of the pool. \textit{Id}.
\bibitem{muskin2} \textit{Id}.
\bibitem{muskin3} \textit{Id}. at 303.
\bibitem{muskin4} \textit{Id}. at 305 (“The assessment of the utility of a design involves the consideration of available alternatives.”).
\bibitem{muskin5} \textit{Id}. at 306.
\bibitem{muskin6} \textit{Id}.
\bibitem{muskin7} \textit{Id}.
\bibitem{muskin8} \textit{Id}.
\end{thebibliography}
The second case when strict liability was imposed on an entire product category was *Kelley v. R.G. Industries, Inc.* In *Kelley*, the victim of a grocery store robbery brought suit against the manufacturer of the "Saturday Night Special" handgun that was used by the perpetrator of the crime. The plaintiff contended that the manufacturer was subject to strict liability under the provisions of section 402A. The Maryland Supreme Court acknowledged that the handgun in question was not defective under the consumer expectation test because a consumer would expect a handgun to have the capacity to fire a bullet. Further, the handgun was not defective under conventional risk-utility analysis because nothing went wrong with the product. However, the court went on to consider whether manufacturers and sellers of handguns might be strictly liable to gunshot victims on a categorical basis.

The court did not engage in any sort of formal risk-utility analysis. Instead, it examined various gun control statutes to see if Congress or the state legislature had reached any conclusions about the risks and benefits of handguns. This examination led the court to conclude that the existence of state statutory provisions expressly allowing private persons to own and carry handguns indicated that such activities were not contrary to public policy. Presumably, this meant that the risks of handguns in general did not outweigh their utility. For this reason, the court declined to increase the burden of manufacturer liability on all handguns. However, the court then acknowledged an

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73. 497 A.2d 1143 (Md. 1985).
74. See H. Todd Iveson, *Manufacturers' Liability to Victims of Handgun Crime: A Common Law Approach*, 51 FORDHAM L. REV. 771, 791-92 (1983) (stating that the risks of Saturday Night Specials are great because they are "easily concealable" and "relatively inexpensive," and that their countervailing utility is minimal because the poor quality of manufacture "precludes their use for most legitimate purposes").
75. See *Kelley*, 497 A.2d at 1144-45.
76. *Id.* at 1147-48.
77. *Id.* at 1148.
78. *Id.* at 1148-49.
79. *Id.* at 1150 (acknowledging that "the fact that a handgun manufacturer or marketer generally would not be liable for gunshot injuries . . . under previously recognized principles of strict liability is not necessarily dispositive").
80. *Id.* at 1151-53.
81. *Id.* at 1152-53.
82. *Id.* at 1153 (stating that "to impose strict liability upon the manufacturers or
exception for a limited category of handguns. Specifically, the court determined that the treatment of Saturday Night Specials in state and federal gun control statutes indicated that such weapons were largely unfit for any legitimate use. In addition, the court found that the manufacturers and sellers of Saturday Night Specials were well aware that the principal use for their products was criminal activity. Consequently, the court concluded that it was appropriate to place such weapons in a special category for purposes of civil liability.

The third case when a court applied a risk-utility analysis to achieve categorical product liability was *Halphen v. Johns-Manville Sales Corp.* The injured party in *Halphen* allegedly died as the result of exposure to asbestos and his widow brought suit against an asbestos manufacturer. The case was tried in federal district court and the jury found in the plaintiff's favor. The federal appeals court first affirmed the lower court's judgment, but then certified to the Louisiana Supreme Court the question of whether, under state law, the defendant could be held liable notwithstanding the fact that the inherent risks associated with the product were scientifically unknowable at the time it was marketed.

The Louisiana court declared that an injured party could recover against the seller under principles of strict liability if the product was unreasonably dangerous because of a manufacturing defect, an inadequate warning or an unsafe design. However, the court also declared that some products could be considered "unreasonably dangerous per se." According to the *Halphen* court, a product is unreasonably dangerous per se "if a reason-

marketers of handguns for gunshot injuries resulting from the misuse of handguns by others, would be contrary to Maryland public policy as set forth by the Legislature").

83. *Id.*
84. *Id.* at 1158.
85. *Id.* at 1159.
86. *Id.* (holding that it is consistent with public policy to hold manufacturers and marketers of Saturday Night Specials strictly liable to victims of gunshot injuries that result from criminal use of their products).
87. 484 So. 2d 110 (La. 1986).
88. *Id.* at 112.
89. *Id.* at 112-13.
90. *Id.* at 113.
91. *Id.* at 114-15.
92. *Id.* at 113.
able person would conclude that the danger-in-fact of the product, whether foreseeable or not, outweighs the utility of the product. The court also pointed out that a hindsight test would be used to evaluate a product's risks and benefits for purposes of determining whether it would be subject to categorical liability. Specifically, the court stated that:

[...]his theory considers the product's danger-in-fact, not whether the manufacturer perceived or could have perceived the danger, because the theory's purpose is to evaluate the product itself, not the manufacturer's conduct. Likewise, the benefits are those actually found to flow from the use of the product, rather than as perceived at the time the product was designed and marketed.

The Halphen court concluded that if a plaintiff proved that a product was unreasonably dangerous per se, it would not matter that the case could have been tried as a conventional design defect case. In reaching that conclusion, the court thereby suggested that categorical liability would not be limited to products that were inherently dangerous.

O'Brien, Kelley, and Halphen are the only cases in which courts have held that categorical liability can be imposed upon product sellers within the framework of section 402A. However, each of these cases generated intense criticism at the time they were decided and each was eventually overruled by legislation.

b. Cases Rejecting the Risk-Utility Theory

The vast majority of courts have refused to accept the notion of categorical product liability based on a risk-utility analysis.

93. Id. at 114.
94. Id.
95. Id.
96. Id.
97. Id.
99. See Grossman, supra note 55, at 398 ("When confronted with real world cases, the courts have persistently refused to embrace categorical liability.").
Products where this approach has been rejected include firearms, alcoholic beverages and, of more importance, tobacco products. Some of the cases which have rejected categorical liability for cigarettes are discussed in more detail below.

In Gunsalus v. Celotex Corp., a former asbestos worker brought suit in federal court against various asbestos manufacturers and a cigarette company, alleging that the synergistic effect of smoking and working with asbestos products caused him to develop lung cancer. The plaintiff argued that the defendant's cigarettes were defectively designed and that they failed the risk-utility test. The federal district court dis

100. See Shipman v. Jennings Firearms, Inc., 791 F.2d 1532, 1533-34 (11th Cir. 1986) (recognizing that "Florida law will not apply ... strict products liability ... to a gun manufacturer who produces and distributes weapons that perform as intended and designed"); Perkins v. F.I.E. Corp., 762 F.2d 1250, 1274 (5th Cir. 1985) (stating that "[n]o court in this jurisdiction has ever applied a general risk/utility analysis to a well-made product that functioned precisely as it was designed to do"); Armijo v. Ex Cam, Inc., 656 F. Supp. 771, 773 (D.N.M. 1987), aff'd, 843 F.2d 406 (10th Cir. 1988) (stating its belief "that New Mexico courts would follow the overwhelming weight of authority which rejects strict products liability as a theory for holding handgun manufacturers liable for the criminal misuse of their products"); Richardson v. Holland, 741 S.W.2d 751, 754 (Mo. Ct. App. 1987) (acknowledging that "[t]he cases uniformly hold that the doctrine of strict liability under the doctrine of 402A is not applicable unless there is some malfunction due to an improper or inadequate design or defect in manufacturing"). See also Knott v. Liberty Jewelry & Loan, Inc., 748 P.2d 661, 664 (Wash. Ct. App. 1988); Delahanty v. Hinckley, 564 A.2d 758, 762 (D.C. 1989); Riordan v. International Armament Corp., 477 N.E.2d 1293, 1299 (Ill. App. Ct. 1985).


102. See Kotler v. American Tobacco Co., 926 F.2d 1217, 1225 (1st Cir. 1990), vacated, 505 U.S. 1215, rea'd on remand, 981 F.2d 7 (1st Cir. 1992) ("It is illogical to say that a product is defective in its generic form when 'defect' has historically been measured in reference to the availability, or at least the feasibility, of safer alternatives"); Roysdon v. R.J. Reynolds Tobacco Co., 849 F.2d 230, 236 (6th Cir. 1988) ("Because the record contains no evidence whatever that the use of the defendant's cigarettes presents risks greater than those known to be associated with smoking, we find that a reasonable jury could not find that the cigarettes were defective"); Miller v. Brown & Williamson Tobacco Corp., 679 F. Supp. 485, 489 (E.D. Pa.), aff'd, 856 F.2d 184 (3d Cir. 1988) (concluding that "Pennsylvania courts have not adopted, and will not adopt, the risk-utility theory of liability as the present state of the law"). See also Gunsalus v. Celotex Corp., 674 F. Supp. 1149, 1159 (E.D. Pa. 1987); Hite v. R.J. Reynolds Tobacco Co., 578 A.2d 417, 421 (Pa. Super. Ct. 1990).


104. Id. at 1151.

105. Id. at 1157.
missed the design defect claim because the plaintiff failed to
show that the cigarettes were defective in any way.\footnote{106}

Liability under the plaintiff’s second claim was predicated on
the theory that “the risks caused by cigarettes outweigh their
social utility.”\footnote{107} The court, however, concluded that Pennsylva-
nia courts would refuse to recognize a claim based on categorical
liability.\footnote{108} Accordingly, the Gunsalus court granted the
defendant’s motion for summary judgment on the plaintiff’s risk-
utility claim.\footnote{109}

Similarly, in Gianitsis v. American Brands, Inc.,\footnote{110} the plain-
tiff sought damages from several tobacco manufacturers and
distributors, claiming that smoking caused his lung cancer.\footnote{111}
In his complaint, the plaintiff contended that “the risks associat-
ed with smoking an ordinary cigarette, far outweigh the social
value or utility of cigarettes to our society.”\footnote{112}

The court declared that, as an initial matter, the plaintiff
must show that the product in question was defective.\footnote{113} This
meant that the product must have contained either a manufac-
turing flaw, a defective design or an inadequate warning.\footnote{114}
Only after establishing the existence of a defect would the plain-
tiff need to prove that the defect in question made the product
unreasonably dangerous.\footnote{115} In the court’s view, the risk-utility
test, as formulated by Dean Wade,\footnote{116} was only relevant to the
question of whether the product was unreasonably danger-
ous.\footnote{117} Consequently, since the plaintiff did not show the ciga-
rettes to be defective, the court concluded as a matter of law,
that the plaintiff could not recover simply by proving that the

\footnotesize{106. Id. at 1158-59. The court also ruled that any claim based on failure to warn
was preempted by the Federal Cigarette Labeling and Advertising Act, 15 U.S.C.
§§ 1331-1341 (1988). Id.
108. Id.
109. Id.
111. Id. at 854.
112. Id. at 855.
113. Id. at 856 (stating that the basis of any 402A claim is an allegation of a
defect associated with the product).
114. Id.
115. Id.
116. See John W. Wade, On the Nature of Strict Tort Liability for Products, 44
risks of this product outweighed its utility.118

Finally, in Kotler v. American Tobacco Co.,119 the widow of a
smoker who had died of lung cancer brought suit against several
cigarette companies on the theories of negligence, breach of war-
renty and misrepresentation.120 A federal district court, applying
Massachusetts law, ruled in favor the defendants.121 On ap-
peal, the plaintiff argued that a design defect claim was cogniza-
bale under Massachusetts law on the basis of its inherently dan-
gerous characteristics.122 According to the plaintiff, "when one
balances risk against utility, cigarettes per se are so unreason-
ably dangerous as to be actionably defective."123

While Massachusetts did not recognize strict liability in tort,
the federal appeals court observed that state warranty law was
"congruent in nearly all respects with the principles expressed in
Restatement (Second) of Torts § 402A (1965)."124 Accordingly,
the court applied a tort liability analysis while utilizing the rhet-
oric of warranty law. Applying these principles to the plaintiff's
case, the court concluded that in order to maintain a claim for
defective design under warranty theory, the plaintiff must estab-
lish the existence of a safer alternative design.125 Moreover, the
Kotler court flatly refused to change the existing case law to
allow a risk-utility test to be used.126 Specifically, the court
stated that:

[i]t is illogical to say that a product is defective in its generic
form when "defect" has historically been measured in reference to

118. Id. at 859.
119. 926 F.2d 1217 (1st Cir. 1990).
120. Id. at 1219-20.
121. First, the district court held that all claims based on inadequate warnings
subsequent to 1966 were preempted by the Federal Cigarette Labeling and Advertis-
Supp. 15, 18 (D. Mass. 1987). The court later dismissed the plaintiff's design defect
claim because no evidence had been produced that the cigarettes were defective in a
manner beyond the inherent characteristics of tobacco. See Kotler v. American Tobac-
co Co., 731 F. Supp. 50, 55-57 (D. Mass. 1990). The case was eventually tried on a
negligence theory and resulted in a jury verdict for the remaining defendant. Kotler,
926 F.2d at 1220.
122. Kotler, 926 F.2d at 1224.
123. Id. (emphasis added).
124. Id. (quoting Back v. Wickes Corp., 378 N.E.2d 964, 968 (1978)).
125. Id. at 1225 (holding that "a design defect case premised on breach of war-
ranty is . . . dependent on proof of the existence of a safer alternative design").
126. Id.
the availability, or at least the feasibility, of safer alternatives.\textsuperscript{127} Accordingly, the federal appeals court upheld the lower court's dismissal of the plaintiff's design defect claims.\textsuperscript{128}

3. The Doctrinal Argument Against Product Category Liability

As the foregoing discussion has shown, injured parties must prove that a product is defective in order to recover against a product seller. Furthermore, this requirement cannot be satisfied by merely showing that the product is inherently dangerous.\textsuperscript{129} Instead, the plaintiff must be able to point to some sort of modification or alternative design that would have made the product safer without changing its inherent nature or function.\textsuperscript{130} Thus, the doctrine of strict products liability, at least in its conventional form, appears to offer little support for the imposition of categorical liability on product sellers. Nor can the traditional rules with respect to ultrahazardous or abnormally dangerous activities be stretched to extend categorical liability to inherently dangerous products.\textsuperscript{131} Consequently, given the present state of the law, it seems unlikely that cigarette smokers will be able to recover against tobacco companies for smoking-related injuries.

Of course, courts could depart from existing doctrine and recognize categorical liability as a new theory of recovery for injured consumers. This would permit smokers to argue that the risks of ordinary cigarettes outweigh their social utility. However, most courts seem to be unwilling to embrace categorical liability in the absence of a compelling public policy basis to do so. Accordingly, the next part of this article will consider policy arguments for and against the imposition of categorical liability on cigarette manufacturers.

\textsuperscript{127} Id.
\textsuperscript{128} Id. at 1226.
\textsuperscript{129} This assumes, of course, that the danger is a matter of common knowledge or that the product seller has provided an adequate warning.
\textsuperscript{130} See \textit{e.g.}, Kotler, 926 F.2d at 1225.
\textsuperscript{131} See \textit{supra} notes 51-54 and accompanying text.
III. POLICY CONSIDERATIONS

Those who favor the imposition of categorical liability upon tobacco companies have relied upon various policy arguments to support their position. However, opponents of such liability have raised policy concerns of their own.

A. The Case for Product Category Liability

Proponents of categorical liability contend that subjecting tobacco companies to categorical liability will reduce accident costs by forcing these companies to internalize the costs of smoking-related injuries. They also claim that it is desirable to hold cigarette companies liable for smoking-related injuries because they can reduce the cost of such injuries to individual victims and spread them among the smoking public. Finally, they argue that imposing liability on cigarette manufacturers will prevent them from receiving an unmerited windfall and will punish them for their antisocial behavior.

1. Accident Cost Avoidance

Conventional wisdom assumes that accident costs will be reduced to an optimal level if product sellers are held liable to consumers for product-related injuries. In the absence of such liability, producers have little incentive to make their products safer; however, when producers are required to compensate injured consumers, they have an incentive to avoid such liability by investing more resources in product safety. A manufacturer will spend money on accident cost avoidance as long as the marginal cost of additional accident cost reduction is less than the marginal reduction of expected tort liability. The same

132. See discussion infra part III.A.1.
133. See discussion infra part III.A.2.
134. See discussion infra part III.A.3.
135. See George L. Priest, The Invention of Enterprise Liability: A Critical History of the Intellectual Foundations of Modern Tort Law, 14 J. LEGAL STUD. 461, 520 (1985) ("Society will benefit from internalizing the costs of operation to product manufacturers, including losses from resulting product-related injuries.").
136. See Craig Brown, Deterrence and Accident Compensation Schemes, 17 W. ONT. L. REV. 111, 128 (1978) (explaining that "[s]trict liability] provides an incentive for those engaged in a particular activity to make it safer, for by doing so, their costs will be lower").
137. See James A. Henderson, Jr., Product Liability and the Passage of Time: The
manufacturer, however, will choose to pay damages to injured parties when the marginal cost of additional accident cost avoidance exceeds the marginal benefit of further accident cost savings. Of course, tort liability will have little effect on manufacturer behavior if cigarettes are inherently dangerous and cannot be made any safer. However, even in this situation, tort liability can have an indirect effect on accident costs. This is because inherently dangerous products cost less and are thus in higher demand than market forces would ordinarily dictate if the price of the product does not reflect the true costs of production, including accident costs associated with the use or consumption of the product. But tort liability forces the sellers of inherently dangerous products to raise their prices in order to offset the costs of increased liability and this, in turn, causes the demand for such products to decline. As use and consumption fall, so do the accident costs associated with such products.

This analysis seems to apply nicely to cigarettes: at the pres-
ent time, the price of cigarettes does not reflect the full health costs of smoking because a substantial share of these costs are shifted to nonsmokers. Consequently, smokers “overconsume” tobacco products, thereby causing society to expend more resources on smoking-related health care than are justified by the economic benefits of smoking. However, if some of the health costs of smoking are shifted to tobacco companies, they will be forced to raise their prices, with a concomitant decrease in consumption and smoking-related injuries.

2. Risk Spreading

Conventional wisdom assumes that the economic dislocation associated with product-related injuries can be lessened if accident costs are spread among a large group instead of being borne entirely by individual victims. When product-related injuries are involved, product sellers are in a better position than consumers to spread these losses. In a normally competitive market, producers can compensate those who are injured by their products (either directly or through the purchase of liability insurance), and can pass these costs on to their customers in the form of higher prices.

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144. See Note, Plaintiff’s Conduct as a Defense to Claims Against Cigarette Manufacturers, 99 HARV. L. REV. 809, 823 (1986) (stating that “[t]hose smoking-related health care costs not paid for by public programs are largely absorbed into private-sector loss spreading mechanisms—like pooled health insurance—and are consequently not reflected in the price of cigarettes . . . .”).

145. Id. at 824.

146. Id.

147. See Stanley Ingber, Rethinking Intangible Injuries: A Focus on Remedy, 73 CAL. L. REV. 772, 794 (1985) (“Spreading the impact of loss over time or among a class of individuals will decrease economic dislocation, thereby reducing secondary costs.”).

148. See Sheila L. Birnbaum, Unmasking the Test for Design Defect: From Negligence [to Warranty] to Strict Liability to Negligence, 33 VAND. L. REV. 593, 596 (1980) (explaining that “[t]he manufacturer can spread risk through insurance and price adjustments, whereas the individual might suffer a crushing blow underwriting the loss himself”); Kathleen M. McLeod, Note, The Great American Smokeout: Holding Cigarette Manufacturers Liable for Failing to Provide Adequate Warnings of the Hazards of Smoking, 27 B.C. L. REV. 1033, 1072 (1986) (stating that a principle purpose of the imposition of strict liability is to place the cost of injury on the manufacturer who can spread the cost among all consumers by adjusting the price of the product).

This risk-spreading rationale appears to support the imposition of liability on cigarette companies. The market for tobacco products is large: at least fifty million Americans presently smoke150 and tobacco companies sell more than 600 billion cigarettes a year.151 Moreover, despite the public concern about health risks, the tobacco industry continues to be highly profitable.152 For these reasons, tobacco companies should be easily able to spread accident costs.

3. Moral Issues

Some commentators argue that moral considerations have a significant role to play in the law of products liability.153 One important moral consideration is corrective justice, which is concerned with rectifying wrongful gains and losses.154 The principle of corrective justice requires those who profit from wrongdoing to compensate those who are injured as the result of their improper conduct.155 From this perspective, it can be argued that cigarette manufacturers who profit from the sale of a dangerous product are obliged, as a matter of corrective justice, to compensate those who are injured from the consumption of tobacco products.156

150. See Note, supra note 144, at 809 n.5.
152. See Clara Sue Ross, Comment, Judicial and Legislative Control of the Tobacco Industry: Toward a Smoke-Free Society?, 56 U. CIN. L. REV. 317, 332 (1987) ("The tobacco industry in the United States ranks among the top five industries in terms of sales, assets, and profits.").
156. See Wertheimer, supra note 2, at 1447 (stating that "[c]igarette manufacturers . . . receive a windfall because they collect profits on sales of their product, but do not pay its true costs").
B. The Case Against Product Category Liability

Most commentators agree that the sellers of dangerous products ought to pay for the injuries that their products cause to innocent consumers. However, there is little agreement about whether this objective can best be achieved by subjecting producers to product category liability. This section identifies some of the arguments against the imposition of categorical liability.

1. Accident Cost Avoidance

As mentioned earlier, the imposition of categorical liability upon product sellers is supposed to force them to raise prices, which will thereby lower consumer demand for dangerous products and reduce product-related accident costs.157 Unfortunately, however, subjecting sellers to such liability may actually increase accident costs in some circumstances. Specifically, consumers will turn to substitutes if the price of a product or activity substantially rises because of government regulation or increased tort liability.158 This substitution is a manifestation of the "theory of the second best."159 The effect can be beneficial if consumers seek less dangerous alternatives to the activity or product in question; however, accident costs may actually increase if consumers choose more dangerous substitutes.160 For example, deaths and injuries from the consumption of contaminated whiskey rose dramatically during the Prohibition period because drinkers who were unable to purchase liquor legally purchased bootleg whiskey instead.161

It is hard to say what smokers would do if the price of cigarettes increased enormously or if tobacco companies were driven out of business by overwhelming tort liability.162 Given the ad-

157. See discussion supra part III.A.1.
158. See Frontier, supra note 46, at 1291 (explaining that a system of regulation "increases the liability costs of the regulated firms to the point where they and the consumers with whom they deal turn to new patterns of essentially unregulable behavior to escape the higher liability costs of the regulated markets").
159. For a more detailed discussion of the theory of the second best, see Boundaries, supra note 143, at 1059-65.
160. See Peter Huber, Safety and the Second Best: The Hazards of Public Risk Management in the Courts, 85 COLUM. L. REV. 277, 292 (1985) ("Patchy, erratic risk internalization may impose greater costs on the safer substitutes within particular markets, and so may encourage a shift in consumption toward the more hazardous.").
161. See Frontier, supra note 46, at 1291 n.105.
162. See Mary Griffen, Note, The Smoldering Issue in Cipollone v. Liggett Group,
dictive nature of cigarettes, it is possible that frustrated smokers would turn to bootleg products if cigarettes became difficult to obtain at reasonable prices. However, a more likely scenario is that new cigarette companies would enter the market. Since existing tobacco companies would immediately feel the effects of enhanced tort liability, they would have to raise their prices at once. However, new producers would not have to worry about liability for many years and, therefore, could sell their cigarettes for less. This, in turn, would force existing companies to lower their prices or leave the market. In either event, cigarette prices would not rise as predicted by the theory of market deterrence. Thus, cigarette consumption would not decrease nor would smoking-related illnesses decline.

2. Risk Spreading

It was suggested above that product sellers could spread risks better than consumers. This view, however, has not gone unchallenged. For example, it has been pointed out that tort law often duplicates other loss-spreading mechanisms such as private insurance and workers compensation. Furthermore,

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163. See Ross, supra note 152, at 319.
164. See Gregory P. Taxin, Tobacco Industry Liability for Cigarette-Related Injuries: "Smokers, Give It Up!", 16 J. PROD. & TOXICS LIAB. 221, 247 (1994) (stating that "products produced by legitimate, going concerns will include the expected cost of harm done by cigarettes, but cigarettes produced by those who expect their liability to be zero . . . will not include the 'true' cost of smoking").
165. For example, existing tobacco companies might leave the American market to the new cigarette companies and concentrate their marketing efforts overseas.
166. See James E. Britain, Product Honesty Is the Best Policy: A Comparison of Doctors' and Manufacturers' Duty to Disclose Drug Risks and the Importance of Consumer Expectations in Determining Product Defect, 79 NW. U. L. REV. 342, 410 (1984) (declaring that "[t]he blithe assumption underlying loss spreading arguments that manufacturers are in a better position than consumers to both bear and spread losses has never been empirically verified").
167. See George L. Priest, The Continuing Crisis in Liability, 1 PROD. LIAB. L.J. 243, 248 (1989) (stating that "[t]oday, the compensation provided by the legal system is largely redundant. Workers filing 60% of products liability claims are already covered for disability losses and full medical expenses through workers' compensation. Most ordinary consumers have private insurance or qualify for government health and income maintenance programs"); Stephen D. Sugarman, Serious Tort Reform, 24
the tort system is regressive because every consumer pays the same "premium" for protection against injury, but wealthier claimants tend to receive higher damage awards. Of more importance, for risk spreading to work properly, the losses involved must not exceed the resources of the risk spreader. As the recent experience of the asbestos industry demonstrates, accident costs cannot be spread effectively when the legal system retroactively imposes massive liability upon an industry. When faced with such overwhelming liability, product sellers invariably seek protection in bankruptcy. When this occurs, only few victims will be fully compensated and many will receive inadequate compensation or nothing at all. Consequently, if cigarette companies are subjected to excessive liability, they may be unable to function effectively as loss spreaders.

There is yet another reason why product category liability will not promote risk spreading. As mentioned earlier, under some circumstances, the imposition of categorical liability will encourage the entry of new sellers into the market because they will not be subject to tort liability for many years to come. Some of these firms may choose to market their products for ten or twenty years and then go out of business before any of their customers begin to develop smoking-related illnesses. Of course, if this occurs, there will be no funds available to compensate smokers when they eventually become ill and file claims. In this author's view, it is not unlikely that new entrants into the cigarette market will adopt such hit-and-run tactics, leaving their former customers high and dry.

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168. See George L. Priest, Modern Tort Law and Its Reform, 22 Val. U. L. Rev. 1, 17 (1987) ("Tort law's lumping of low-income consumers and high-income consumers into the same insurance pool and charging them a similar premium for insurance forces low-income consumers to subsidize high-income consumers.").


170. See Smoking-Related Injuries, supra note 154, at 1120.

171. See discussion supra part III.B.1.

172. See Taxin, supra note 164, at 247 (arguing that some manufacturers "will plan on being long gone by the time a cause of action ripens").
Thus, while risk spreading is viewed as an attractive goal by many, there is no assurance that product category liability will improve the chances of compensation for injured consumers. Indeed, if the legal system imposes excessive liability on product sellers, their ability to spread losses may be completely destroyed.

3. Moral Issues

Moral concerns do not provide much support for a general rule of product category liability because the moral positions of product sellers and product users vary according to the product in question. However, principles of corrective justice appear to support the imposition of some liability upon tobacco companies. For more than a century, tobacco companies have sold a dangerous product to the public. Despite growing scientific evidence that smoking causes lung cancer and other diseases, cigarette companies failed to provide any warnings about the health risks of smoking until required to do so by statute. Even now, the tobacco industry continues to deny that smoking is hazardous. Other practices, if true, such as directing cigarette advertising at children and regulating nicotine levels in cigarettes, are also morally wrong. Consequently, the level of wrongdoing attributable to tobacco companies may be sufficient to give rise to an obligation to compensate.

However, the duty to compensate may also be affected by the moral position of the victim. In the case of smokers, this position

173. See Wertheimer, supra note 2, at 1447.
174. See Marc Z. Edell, Cigarette Litigation: The Second Wave, 22 TORT & INS. L.J. 90, 97 (1986) (declaring that medical literature "confirms the fact that the medical and scientific community was concerned with the potential cancer-causing effects of tobacco products as early as the 1920s, and certainly by the late 1930s medical and scientific research demonstrated a strong association between cigarette smoking and cancer").
176. See McLeod, supra note 148, at 1066-67 ("[C]igarette manufacturers deny the health hazards of smoking and challenge any medical studies as 'biased' and 'unscientific'.")
177. According to the FDA, advertising by tobacco companies has created a "pervasive and positive imagery that has for decades helped to foster a youth market for tobacco products." 60 Fed. Reg. 41,314, 41,326 (1995).
PRODUCT CATEGORY LIABILITY

is somewhat ambiguous. Arguably, many consumers were not really aware of the actual health risks of smoking when they began to smoke.179 Moreover, once individuals have taken up the habit, the addictive nature of tobacco has made it very difficult for many of them to stop smoking. On the other hand, cigarette packages have contained health warnings for more than thirty years. Thus smokers cannot claim to be ignorant of the dangers of smoking.180 Furthermore, while smoking is habit-forming, and perhaps even addictive, millions of smokers have successfully quit over the past three decades.181

Furthermore, if smokers are allowed to recover under a theory of product category liability, they will not only seek compensation for medical expenses and lost wages, but they will also demand large sums for pain and suffering and punitive damages. Considering that injured smokers are at least partly responsible for their situation, a more limited level of compensation seems appropriate.

IV. THE USE OF TORT LIABILITY TO CONTROL THE CONSUMPTION OF INHERENTLY DANGEROUS PRODUCTS

Even if we conclude that some products, such as cigarettes, are so inherently dangerous that society should discourage their consumption, it remains to be seen whether tort law should be used for this purpose. First, it is difficult to apply the risk-utility analysis as a liability standard. Second, courts are not competent to make decisions about what products are suitable for consumers. Third, tort law is an extremely expensive way to regulate product safety.

179. See McLeod, supra note 148, at 1061 (claiming that “even today, despite the accumulation of scientific evidence . . . the American public remains remarkably unaware of the specific dangers of cigarette smoking”).
180. See Donald W. Garner, Cigarette Dependency and Civil Liability: A Modest Proposal, 53 S. Cal. L. Rev. 1423, 1429 (1980) (“The days when plaintiff could honestly claim that he did not know that cigarettes are injurious are over.”).
A. Problems with the Liability Standard

Under the risk-utility test, a product is regarded as defective if the risks associated with a product as designed outweigh the benefits of the same product equipped with a feasible alternative design. In this context, the risk-utility test is reasonably manageable because the fact-finder is ordinarily required to compare a specific aspect of the product's design with a relatively close substitute. In contrast, the risk-utility analysis is much more difficult to apply to an entire category of products. This is partly because it is very hard for private litigants to obtain reliable information about the overall costs and benefits of products. Take the case of cigarettes. The costs of smoking are known in a general sort of way. Smoking is known to cause lung cancer and may be responsible for other forms of cancer as well; smoking also contributes to heart disease; and, finally, smoking has also been linked to a variety of chronic obstructive lung diseases. However, it is virtually impossible to quantify these costs in dollar terms. Estimates of the annual health care costs attributable to smoking range from $13 billion to $22 billion, while estimates of productivity losses due to smoking vary even more widely. It is even more difficult to put a dollar value on smoking-related deaths or to the pain and suffering that is inflicted on the victims of smoking-related illnesses.

Quantifying the benefit side of smoking is even more problematic. Smoking does give pleasure. However, this benefit is hedonic and, therefore, not easily monetizable. One way to measure the utility of smoking is to calculate the amount of money that consumers are willing to pay for tobacco products. However,

182. See supra notes 20-21 and accompanying text.
183. See Frontier, supra note 46, at 1305.
184. See generally Taxin, supra note 164, at 222-33 (describing the various health effects of smoking); Michael K. Mahoney, Comment, Coughing Up the Cash: Should Medicaid Provide for Independent State Recovery Against Third-Party Tortfeasors Such as the Tobacco Industry?, 24 B.C. ENVTL. AFF. L. REV. 233, 235-36 (1996) (also describing the health effects of smoking).
185. See, e.g., Mahoney, supra note 184, at 238 ($21.9 billion); McLeod, supra note 148, at 1072 n.317 ($13 billion).
187. See Griffin, supra note 162, at 616.
even if one could calculate the actual retail sales price of all cigarettes sold in America during a given period, this figure would not necessarily represent the true utility of smoking because consumers might actually be willing to pay much more for cigarettes. The difference between the price consumers are willing to pay for a product and the price they actually pay in the market is known as the "consumer surplus." Unless we can calculate this consumer surplus, we cannot determine the utility of smoking for purposes of risk-utility analysis.

B. Institutional Competence

The vagueness of the risk-utility test potentially allows courts and juries to exercise enormous power over the economic welfare of entire industries. As numerous courts and commentators have observed, it is better that important social decisions be made by other institutions of government. The adversarial nature of the litigation process, limited resources, and restrictive rules of evidence all limit the courts' access to information and public input. This makes them social engineers.

190. See Kotler v. American Tobacco Co., 731 F. Supp. 50, 53 (D. Mass.), aff'd, 926 F.2d 1217 (1st Cir. 1990) (arguing that "the risk/utility theory is a radical doctrine which imprudently arrogates to the judicial process some very significant societal determinations").
191. See, e.g., Patterson v. Rohm Gesellschaft, 608 F. Supp. 1206, 1216 (N.D. Tex. 1985) ("Moreover, the judicial system is, at best, ill-equipped to deal with the emotional issues of handgun control."); Hilberg v. F.W. Woolworth Co., 761 P.2d 236, 241 (Colo. Ct. App. 1988), overruled on other grounds by Casebolt v. Cowan, 829 P.2d 352 (Colo. 1992) ("Questions concerning the social or societal utility of firearms and how and by whom they may be possessed and used are major public policy questions which properly reside with constitutional assemblies and legislative bodies.").
192. See, e.g., Grossman, supra note 55, at 407 (acknowledging that "the court system does not possess the necessary tools to make fair and rational categorical assessments as called for by categorical liability, and that . . . assessments, therefore, should be left to the legislature"); Larsen, supra note 189, at 2061; Toke, supra note 10, at 1210.
193. See Toke, supra note 10, at 1209 ("The judiciary, however, lacks the instruments or techniques needed to ascertain and evaluate vast amounts of relevant social and behavioral data."); Note, Handguns and Products Liability, 97 HARV. L. REV. 1912, 1925 (1984) ("Courts are designed to handle discrete cases on the basis of an evidentiary record; they are not efficient regulators. They cannot continually check
In contrast, legislative bodies and administrative agencies are better equipped to address broader social issues such as those associated with product safety. 194

C. Litigation Costs

In comparison to other regulatory mechanisms, another problem with the tort system is its high operating cost. 195 According to one estimate, plaintiffs spend between $7 billion and $9 billion each year in legal fees and expenses, while defendants and their insurers spend another $8 billion to $10 billion to defend against claims. 196

Furthermore, there is reason to believe that litigation costs would be particularly high if cigarette companies were suddenly subjected to tort liability. In the first place, the imposition of product category liability would generate a massive number of lawsuits. 197 Moreover, many of these suits would involve multiple parties. 198 Finally, lawsuits against tobacco companies would require the adjudication of complicated causation issues. 199

V. ALTERNATIVES TO PRODUCT CATEGORY LIABILITY

There are a number of approaches that are more promising than product category liability. These approaches include increased government regulation, narrowly-targeted statutory compensation schemes, and increased taxation of dangerous products.

the effects of their decisions and make fine alterations as needed.


195. See JOHN G. FLEMING, THE AMERICAN TORT PROCESS 18 (1988) ("The most negative feature of the tort system is its staggering overhead cost.").

196. See JAMES S. KAKALIK & NICOLAS M. PACE, COSTS AND COMPENSATION PAID IN TORT LITIGATION vii-viii (Rand Institute for Civil Justice 1986).

197. See Smoking-Related Injuries, supra note 154, at 1121.

198. Id. at 1121-22.

199. See Frontier, supra note 46, at 1303 ("The questions whether the plaintiff's illness was caused by smoking and, if so, which producers' products are implicated, in many cases, would defy coherent resolution.").
A. Government Regulation

If society is concerned with reducing product-related accident costs, it should consider direct regulation as an alternative to increased tort liability. Tort rules are often vague and uncertain, and therefore often send weak signals to product sellers. In contrast, regulatory agencies have the necessary competence and resources to make informed decisions about product safety; their regulations are uniform and specific; and they have the means to monitor and enforce compliance.200

In the past, tobacco products have not been subject to product safety regulation by the federal government except in the area of health warnings.201 Recently, however, the Food and Drug Administration began to regulate the advertising, distribution and sale of tobacco products to children and adolescents.202 Although one may question the FDA’s existing authority to regulate cigarettes as medical devices,203 there is little doubt that Congress has the power to regulate tobacco products if it chooses to do so. Such regulations could take the form of required warnings or disclosures, control over nicotine content, required safety devices such as filters, or quality standards for tobacco.

B. Statutory Compensation Schemes

If compensation is an important goal, a narrowly-focused compensation scheme might serve this purpose better than tort law. Tort law is much more expensive to operate than compensation mechanisms like social security and workers compensation.204 Tort victims typically receive less than half of the money paid out by defendants to settle claims,205 while private health in-

203. See Noah, supra note 178, at 21 (“Even assuming that the nicotine in tobacco products falls within the FDA’s authority over drugs, the treatment of such products as medical devices seems tenuous.”).
204. See Stephen D. Sugarman, Doing Away with Tort Law, 73 CAL. L. REV. 555, 596 (1985) (“[T]he tort system is fabulously expensive to operate in comparison to modern compensation systems.”).
205. See Robert L. Rabin, Some Reflections on the Process of Tort Reform, 25 SAN
Insurance plans and workers compensation systems require much less than that to operate. It would certainly be feasible to set up a system, modeled after the federal Black Lung program, under which tobacco companies could be assessed a certain amount to compensate injured smokers according to a specific compensation formula.

A more modest compensation scheme might rely on Medicare and Medicaid programs. Recently, a number of states have sued tobacco companies to recover medical costs for smoking-related illnesses that they have paid out through their Medicaid programs. Regardless of the outcome of these suits, Congress might enact appropriate legislation to require tobacco companies to pay for some of the Medicaid and Medicare costs that are attributable to smoking.

C. Taxation

At present, both the states and the federal government levy excise taxes upon tobacco products. However, the revenues from these taxes are not earmarked for any particular purpose, but instead go into a general fund. It would be possible, and perhaps desirable, to increase these taxes substantially and dedicate them to the funding of Medicare, Medicaid, and other programs that treat smoking-related injuries. This would ensure

DIEGO L. REV. 13, 35 (1988) ("Reduced to a single figure, injury victims were receiving less than half of every dollar expended by the system on accident claims.").

206. See ROBERT E. LITAN, THE LIABILITY EXPLOSION AND AMERICAN TRADE PERFORMANCE: MYTHS AND REALITIES, IN TORT LAW AND THE PUBLIC INTEREST 127, 135 (Peter H. Schuck, ed. 1991) ("In contrast, ‘transaction costs’ consume 30% of the costs of the workers compensation system, 15% of health insurance, and just 1% of the social security system.").

207. See Smoking-Related Injuries, supra note 154, at 1124-33 (describing a proposed compensation system for smoking-related injuries).

208. See Mahoney, supra note 184, at 239-44 (describing state suits against tobacco companies).


211. See Ahron Leichtman, The Top Ten Ways to Attack the Tobacco Industry and
that tobacco companies pay for some of the social costs of smoking. At the same time, however, tax rates could be kept low enough to prevent tobacco companies from going out of business.

CONCLUSION

As a general proposition, product sellers should be made to pay for the injuries caused by their products. However, tort law is a crude, and often ineffective, tool for this purpose. In their present form, tort law principles effectively immunize the sellers of inherently dangerous products from liability as long as they properly warn consumers about these unavoidable risks. Professor Wertheimer proposes to remedy this deficiency by allowing courts to subject product sellers to liability when product-related risks outweigh benefits. If this approach is accepted, courts would be able employ this risk-utility analysis to impose liability on tobacco companies. Although this extension of tort liability would force tobacco companies to bear a share of the social costs associated with their products, in the long run it would have a variety of undesirable consequences.

Win the War Against Smoking, 13 ST. LOUIS U. PUB. L. REV. 729, 741 (arguing that “tobacco tax revenues should be earmarked for specific anti-tobacco or health-related purposes”).
BEGINNING THE ENDGAME:
THE SEARCH FOR AN INJURY COMPENSATION SYSTEM
ALTERNATIVE TO TORT LIABILITY FOR TOBACCO-RELATED HARMs

by Paul A. LeBel*

The reference to an endgame in the title of this contribution to the Symposium is meant to sound both an optimistic and a pessimistic note. The good news, one might argue, is that the key policy makers of our society have begun to think seriously about the many ramifications of a more widespread and detailed appreciation of the relationship between the use of tobacco products and the resultant adverse effects on health. The bad news is that as we are poised to engage in the endgame, much of our thought seems to be confined within the molds that offer little promise for arriving at the most socially responsible outcome to that game.

Legal developments in the safety and liability portions of the tobacco arena are currently progressing on six fronts.¹ In litigation to impose liability on members of the industry, there are claims to recover damages for harm to smokers as individual litigants and as members of classes of smokers,² claims to recover damages for harm attributable to exposure to environmental (or second-hand) tobacco smoke,³ and claims by public authorities to recover the costs of publicly funded health care for tobacco-related health problems.⁴ On the regulatory front, there are efforts at the federal, state, and local levels to control access

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1. Paul A. LeBel, "Of Deaths Put On By C Cunning and Forced Cause": Reality Bites The Tobacco Industry, 38 WM. & MARY L. REV. 605, 615-33 (1997) (hereinafter cited as Tobacco Deaths). Criminal investigations are also proceeding at state and federal levels, but those are beyond the scope of this article, except to the extent that they might serve as a source of additional information about the industry and of additional pressure to reach closure on some of the outstanding safety and liability issues.

2. Id. at 618-23.

3. Id. at 625-26.

4. Id. at 626-29.
to tobacco products, to expand the information that is available about those products, and (to a considerably lesser extent) to affect the content of tobacco products.

With the exception of the innovative use of Medicaid subrogation claims by the state attorneys general in nearly half of the states, the litigation strategies that are being used involve efforts to shape standard tort doctrines and procedural devices to fit the demands of the tobacco context. Assuming that the substantive elements and the procedures can be made to accommodate liability for harm — in this case, harm caused by a product that is more accurately characterized as lethal rather than as defective — it is not at all clear that the public interest is best served by transferring great amounts of wealth from the tobacco industry to smokers and their heirs. The daunting prospect of adjudicating tobacco tort claims by the hundreds of thousands calls into question whether we are capable of learning anything from the experience of mass injury litigation in such settings as asbestos, Bendectin, and silicone gel breast implants claims.

On the regulatory front, even the more robust regulatory strategies for tobacco are distinctive for their refusal to follow through on the full implications of the lethal and addictive nature of the products. If nicotine is an addictive drug, and if it is delivered to consumers in a carcinogenic and cardiopulmonary risky manner, then the cautionary approach by the regulatory agencies is more a testament to the political realities than it is evidence of a principled consistency in regulatory concern. We

5. Id. at 631-33.
6. Id. at 629-31.
7. Id. at 633.
10. The Food and Drug Administration has concluded that it is addictive. 61 FED. REG. 44,661 (1996).
12. Professor O'Reilly's contribution to this symposium makes a compelling argument for the proposition that the agency is not required to go farther and faster than it has. James T. O'Reilly, Tobacco and the Regulatory Earthquake: Why FDA
have entered into the endgame, one might conclude, but we seem to be resigned to playing by using the questionable moves of the conventional model of tort liability and a deferential approach to an industry that still possesses considerable political influence.

The principal papers and commentaries presented in this Symposium offer many insightful views of quite distinguished people whose thoughts on tobacco litigation and regulation will advance the public debate and the legal understanding on this significant topic. My own views are deeply sympathetic on a number of levels to those who are advocating an enhanced liability exposure for the tobacco industry and to those who are supporting both the federal regulatory regime about to go into place and some even more robust efforts by states and municipalities on disclosure and on use. Nevertheless, and I hope not just to be contrarian, I propose to come at the current posture of the legal relationship between the nation’s health and the tobacco industry from a different perspective. Instead of beginning with the litigation and regulatory models and working out the conceptual and the practical difficulties of applying them to the tobacco-related harm problem, I will start with the notion that thinking at the systemic level about injury compensation can lead us toward an approach that, if not superior to current paradigms, will at least help to inform the debate about the next round of legal responses to the problem.

This is admittedly not the first effort at devising a compensation program for tobacco-related harms. For at least two decades, legal scholars have reacted to concerns about the appropriateness of tort remedies in the cigarette context by offering suggestions for creating an alternative method of resolving those claims and of lowering the incidence of harm associated with the products. This occasion for looking anew at the possibility of con-
Structuring a compensation system for tobacco-related harms is the result of the convergence of three developments: first, a growing body of federal and state experience with compensation programs in other settings; second, a sense of frustration that the lessons of such mass tort litigation experiences as the asbestos cases are having such little impact on the planning for the resolution of the tobacco injury problem; and third, a belief that the disclosure of the internal workings of the tobacco industry will prompt a call for serious action sooner rather than later. For those reasons, the time is ripe for investing in a proactive approach to sketching the contours of an injury compensation for tobacco-related harms.

The ways in which a society deals with its citizens who have suffered injuries because of exposure to external sources of risk can be a telling indicator of the notions of justice that prevail in that society. Injuries can be viewed as occasions for applying notions of corrective justice, returning the victims as close as we can to the status quo ante, or they can be seen as opportunities for engaging in a more sweeping exercise in distributive justice, using the intervention in the post-accident setting as an occasion for redressing other inequalities. Accidental harm can evoke communitarian principles, under which the burden of dealing with the consequences of the harm is spread over a wide base, or it can be seen as a matter for the injury victim to deal with under a more atomistic view of the person as an isolated unit, with strongly individualistic notions of personal responsibility and of culpability providing the critical concepts underlying a scheme for allocating losses.

When one examines the multiple techniques of providing compensation for injury in this society at the end of this millennium, one gets a perhaps unintended but probably quite accurate sense of the philosophical pluralism, if not muddle, that underlies a significant segment of American law and public policy. Compensation for harm is accomplished through a wide variety of tech-

\[\text{References}\]

niques and mechanisms, some created by legislative intervention and others produced through the accretion of a centuries-long common law decision making process. Against that background, it is more appropriate to think of looking at multiple systems from which guidance might be sought in addressing a particular injury problem, than it is to think that one can identify a single organizing principle.\textsuperscript{19}

The driving force behind this article is a belief that the current situation with regard to tobacco-related harms offers an occasion for devising an injury compensation system that should be better able to accommodate the specific demands created by that situation than we would obtain by manipulating tort doctrines or by exercising regulatory authority that would likely be met with considerable political resistance that could produce a backlash that impacts other vitally important regulatory initiatives and liability doctrines. Such a system will be shown to deviate from our conventional understanding of tort law remedies in substantial ways.\textsuperscript{20} Indeed, labeling an approach as a search for an optimum injury compensation system implies in the present day terminology that one is looking for an alternative or a supplement to a traditional tort litigation model of providing compensation.

In its broadest usage, the term “injury compensation systems” should encompass the full range of programs and mechanisms that can provide compensation to injured people. The oldest of the injury compensation systems in our legal heritage was what we would now describe as a first-party process, in which the injured person was generally required to draw on his or her own resources, including in many instances a network of extended family and charitable resources, to alleviate the consequences of a harm.

By the middle of the Nineteenth Century, a general body of


\textsuperscript{20}. A previous exercise along these lines in the drunk driving accident setting is PAUL A. LEBEL, \textit{JOHN BARLEYCORN MUST PAY: COMPENSATING THE VICTIMS OF DRINKING DRIVERS} (1992). The problem posed by second-hand smoke was alluded to in that work as potentially susceptible to a compensation system solution. \textit{Id.} at 331-34.
tort law rules and principles had taken shape and assumed a growing significance as a system for the allocation of at least some losses from the victim to those whose conduct was responsible (usually their negligent conduct) for contributing to the harm. The compensation that was obtainable under these traditional tort rules tended to reflect a number of doctrinal features: (a) the ability to characterize as negligent (or even more highly culpable) the conduct of the person from whom compensation was sought; (b) the identification of a quite specific and particularistic causal relationship between that fault and the harm for which compensation was sought; (c) an ability to characterize the injured person as being close to innocent in the production of the harm; (d) a skeptical attitude toward harm that was not tangible; (e) a process of determining legal responsibility that required individual adjudication of the issues in controversy; and (f) placement on the party seeking to relieve the burdens of production of legally sufficient evidence and persuasion by a preponderance of the evidence.

The Twentieth Century has seen an expansion, and more recently some contraction as well, in the scope of tort law as an injury compensation system. Strict liability has emerged as a viable theory of responsibility in some significant injury contexts. While strict liability in its modern incarnation was initially thought to be appropriate in the case of the most dangerous activities, liability that was not ostensibly based on fault enjoyed a three decade expansion in the realm of products liability claims. Recent developments in that field, however, reflect a considerable retreat from the full implications of applying truly strict liability in all but the simplest of product injury cases. More attenuated connections to an individual's harm have supported legal responsibility in a few exceptional situations.

21. See, e.g., RESTATEMENT (SECOND) OF TORTS § 519 (1977) (translating the “unsuccessful containment” idea of Rylands v. Fletcher into a contemporary principle of liability for harm caused by abnormally dangerous activities).


Comparative responsibility has flourished as a replacement for the traditional notion of tort liability as an all-or-nothing proposition. The legal system has shown a greater willingness to consider harms other than readily apparent physical injury as deserving of compensation. In some instances, resolution of tort claims on a basis other than case-by-case adjudication has been approved, although again recent developments suggest a growing reluctance to consider such adjudicatory methods as appropriate in the settings where they might have the most significant impact. Finally, the burdens of production and persuasion have been eased for plaintiffs in some situations or imposed on defendants after a relatively minimal showing by plaintiffs.

Although the extensive modification of traditional tort law has been a significant part of the compensation picture of the last fifty years, the most noteworthy injury compensation development in this century has been the introduction of a number of legislative compensation schemes that treat some types of injuries to individuals as problems that require more of a social

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Eli Lilly & Co., 539 N.E.2d 1069 (N.Y. 1989), cert. denied, 493 U.S. 944 (1989) (furthest reach of market share theory, refusing to allow manufacturers of DES to exculpate themselves by disproving possibility of having caused the particular plaintiff’s harm).


27. See, e.g., In Re “Agent Orange” Prod. Liab. Litig., 597 F. Supp. 740 (E.D.N.Y. 1984) (fairness opinion approving class settlement of claims that would have been unable to establish basis of liability as individual claims).


29. See, e.g., Barker v. Lull Eng’g Co., 573 P.2d 443 (Cal. 1978) (permitting plaintiff in design defect litigation to make minimal showing of causal relationship between design feature and harm, and then imposing burden of justification of that design feature on defendant); Feldman v. Lederle Labs., 479 A.2d 374 (N.J. 1984) (imposing on pharmaceutical company the burden of proving that knowledge of the risk of a prescription drug was not within the scientific state of the art at the time of distribution).
solution than is likely to be obtained in the tort system. The most significant of these alternative and supplemental compensation programs — the workers’ compensation systems at the state and federal levels — traces its roots to Nineteenth Century Europe, and has been well established in the United States since the second decade of this century. In recent years, compensation programs have proliferated as legislatures have sought to divert categories of harms from being adjudicated by the tort litigation process. In a development that may be somewhat more surprising, courts in the mass injury setting have now entered into the process of compensation program creation, utilizing a variety of procedural vehicles such as class action settlements, and jurisdictional devices such as bankruptcy reorganization plan approval, to accomplish that goal.

As we approach the Twenty-first Century, the phenomenon of an injury compensation program that acts as an alternative or a supplement to traditional tort liability has assumed a newly vigorous role. The most useful conceptual underpinnings of an effort to construct an innovative compensation program are likely to be found in the three-quarters of a century experience in providing compensation for workplace harm under the workers’ compensation systems adopted in each of the states. That experience offers a significant insight both into the nature of the issues that are raised by compensating for injuries outside of the traditional tort arena and into the feasible contours of the resolutions of those issues. A good deal of the narrowly-focused injury compensation program legislation in recent years draws from the workers’ compensation experience, in both positive (benefiting

30. These systems are qualitatively different from no-fault insurance legislation, which have the effect of treating harms as purely private insurance matters rather than as requiring a social solution.


32. See, e.g., In Re Silicone Gel Breast Implant Prods. Liab. Litig., 1994 U.S. Dist. LEXIS 12521 (M.D. Ala. 1994). A revised settlement had to be fashioned after the bankruptcy petition by Dow Corning changed the amount and the sources of the funding available.

from the lessons in workers’ compensation) and negative (failing to break through the confines of that experience) ways. The most recent of the significant conceptual advances in the law of injury compensation today occurs in the judicial arena, and one can take advantage of those developments as well by drawing on the experiences of the end-stage of the most innovative mass tort litigation to expand the range of options that one can put on the table when confronted with a new (or newly addressed) injury compensation problem.

A good deal of the innovation in the law of injury compensation in the last quarter-century has appeared to operate from the premise that specific inadequacies of traditional tort law can be remedied by a more or less radical departure from the tort litigation model. Too many of these systems, however, particularly those that have been created through the judicial process, seem to be engaged in re-inventing the wheel. In a sense, the injury compensation system creative process appears mainly to have looked vertically to the tort model, and seems to have had as its primary focus an attempt to avoid the more unsatisfactory features of that model.

The search for an optimum compensation system would benefit from the introduction of a different perspective on the developments in this area of law and policy. Such a search would look horizontally across the range of legislative and judicial compensation systems to identify the lessons that can be learned from the experience of other systems and that can then be extended to this new context if it is thought to be suitable for some deviation from a tort litigation vehicle for injury compensation.

I. THE GOALS AND THE ESSENTIAL ELEMENTS OF AN INJURY COMPENSATION SYSTEM

The developing law of injury compensation systems is one of the most explicitly instrumental bodies of rules and processes in American jurisprudence. Legislatures and courts are generally inclined to turn to a search for an injury compensation system only when some significant problem is perceived with the ability of traditional tort litigation to accomplish its function of providing appropriate levels of compensation to those who legitimately deserve to be compensated. An important part of understanding this body of law, then, consists of an appreciation of when and why case-by-case litigation of individual tort claims is thought to
be inadequate. The starting point for the crafting of most of the programs currently in place thus seems to be an examination of what was occurring in the tort arena's disposition of claims arising from these injuries and an exploration of what were thought to be the drawbacks to that disposition. For that reason, the initial decision to move in the direction of an injury compensation system and the shape of the system that is constructed each might be characterized as responsive or reactive to a disappointment with the operation of the tort system.

Equally important in the development of an injury compensation system as the sense of when a resort to tort law falls short, however, is an explicit identification of what an injury compensation system can hope to accomplish. It is only when the goals are known and the possible tensions among them are appreciated that it is possible to make informed policy choices about how to structure a particular compensation program. Although there can be differences of opinion about the terminology to describe and the priority to assign to them, the goals of an injury compensation system can usefully be understood as occupying four distinct categories: the compensation for loss, the enhancement of safety, the achievement of administrative efficiency, and the imposition of an appropriate internalization of injury costs.

34. A recent study of the Federal Employers' Liability Act offered the following statement of the goals of an injury compensation system:

Overall goals of injury compensation involve equity, efficiency, and incentives. Ideally, an injury compensation system should be equitable to the injured worker, should provide benefits in an efficient manner, and should be structured so that each party has incentives to reduce both injuries and the costs of those injuries that occur.

A system's efficiency and incentive structure can be assessed objectively, but the fairness of any particular system depends on more subjective perspectives or social philosophies of individuals or groups. The criteria that may be considered in judging the fairness of a particular injury compensation system, however, can be defined and investigated. They include the extent of coverage, including who and what is compensated; the level of the compensation for losses; the speed with which the losses are compensated; the certainty with which they are compensated; and who bears the costs of compensation.

A. The First Goal — Compensation for Loss

To compensate for an injury is to take steps to offset the adverse consequences attributable to the injury. Unlike the case in such legal regimes as property and contracts, the nature of the harm addressed by tort law generally does not lend itself to remedies that restore the aggrieved person to the original state before the other person interfered with her or his rights. For the most part, our legal system accomplishes a compensatory function in the tort arena by requiring a party to make a monetary payment to the injured person or to someone who has incurred an expense or suffered a loss because of the injury to the victim.

Similar limitations in the ability to restore the injury victim to a pre-injury status exist when one resorts to a compensation system outside of the tort arena. Perhaps the greatest advantage of an injury compensation system is the ability to focus attention and direct funds that anticipate and alleviate the impact of prospective harms, as opposed to the predominantly retrospective focus of the tort liability system. Compensation programs can be constructed in particular contexts recognizing that some of the population will certainly be adversely affected in the future, and that some of those who are injured will certainly continue to incur losses after the initial injury. An injury compensation system enables a society and its legal system to get ahead of the curve instead of continually playing catch-up in addressing an injury problem.

Compensation can be structured to cover a variety of losses, and it can extend to a range of people who are related to the victim in different ways. Major distinctions can be drawn among the types of compensation to highlight the options in choosing which of multiple compensatory goals are realistically achievable in a particular context.

The basic theoretical distinction in compensation is between direct and indirect costs of injury.\(^{35}\) Within the category of direct costs we find such items of loss as physical harm suffered in an incident, loss of income due to the inability to work, physical pain and suffering, and mental or emotional harm. Indirect costs

\(^{35}\) Judge Calabresi characterizes this distinction as one between "primary" and "secondary" accident costs. GUIDO CALABRESI, THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS 26-28 (1970).
of injury include such matters as the loss of economic support to those who depend on the flow of income supplied by the injured party, loss of emotional support that would have been provided by the victim, and loss of companionship or consortium as a result of the injury. A rough counterpart of this distinction within traditional tort doctrine would be a distinction between claims by the victim of the tortious conduct and derivative claims that flow from a relationship to that victim.

The characteristic feature of injury compensation systems created by legislatures is their tendency to restrict compensation to pecuniary losses. The largest system, workers' compensation, typically limits benefits to medical and rehabilitation expenses incurred as a result of a workplace injury or occupational disease, a partial replacement of wage loss during periods of disability due to that injury or disease, and death benefits to those who are actually dependent on the deceased worker. The state programs to replace the part of the medical malpractice system that would otherwise apply in birth-related neurological injury incidents similarly exclude non-pecuniary loss from the compensation that is provided.\(^{36}\) One of the compelling justifications for restricting compensation in this way has to be the recognition that when limited funds are available, the highest priority use of the funds is to alleviate the consequences of the injury that are most likely to produce disadvantageous social effects, as the victim's personal resources would have to be diverted from their other beneficial uses and devoted to dealing with the harm.

The federal childhood vaccine injury compensation program is distinctive among injury compensation systems in its allowance of recovery for pain and suffering, with that recovery capped at $250,000.\(^ {37}\) That compensation program has an opt-out provision, giving the vaccine injury victim an election to pursue a tort remedy following exhaustion of the statutory process,\(^ {38}\) and is thus distinguishable from the exclusivity model that is common to most other compensation systems. Allowing recovery for pain and suffering, even if modest in amount by comparison to tort re-

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36. See, e.g., VA. CODE ANN. § 38.2-5009 (Michie 1994) (authorizing compensation for actual medically necessary and reasonable care expenses, lost earnings, and the expenses of obtaining compensation).
covery standards, could play an important role in reducing the disincentive to accept the award decision that has been made within the compensation program. This would in turn lower the social costs of operating a compensation program and a tort litigation system for resolving the same claims.

Because the relevant comparison when creating most injury compensation systems is to the tort liability system, there are limits on how much of a variation can exist between tort compensation and the benefits available under the new system. Too large a difference can raise concerns about depriving potential tort litigants of a remedy without providing some corresponding gain. If the difference narrows too much, however, one might question what is achieved by the creation of the new system.

For the broad-scale social contract arrangement of the workers' compensation systems, the trade-off metaphor offers a realistic and comforting image. Both categories of parties to the contract — employers and employees — receive and give up something of value under the system, with the public interest being served as well by the diversion of workplace harms into a compensation system that provides swifter and surer compensation at a lower expense than would be true within the tort system.

For the more narrowly tailored compensation programs of recent vintage, the smallest levels of benefits that are available tend to be found in the programs in which the likelihood of receiving any compensation in the tort system is lowest. Agent Orange victims who would have been unable to establish causation on an individual basis thus were able to get quite modest payments under a compensation program that awarded relief to the class of people who were exposed to the herbicide.39 Similarly, the divergence between the size of tort awards and the benefits available in the compensation program established for Dalkon Shield victims as part of the A. H. Robins bankruptcy reorganization plan were greatest for the class of claimants who proved none of the elements that would have been necessary had they pursued a tort remedy.40 In contrast, those claimants who

were thought to have the most viable tort claims were treated (in
theory, at least) as if they would be given their full measure of
tort damages from the compensation program.\[41\]

B. The Second Goal — Safety Enhancement

The first-order justification for a compensation program is its
delivery of funds to people whose injuries have left them or their
dependents at some disadvantage. As such, a program that oper-
ated only with a corrective or distributive aim could still be justi-
fied by pointing to its ability to reach that first-order goal. The
case for a compensation program is likely to be strengthened,
however, if it can be shown to have a positive effect in enhancing
safety by reducing the frequency or the severity of injuries.

Probably the most effective way of achieving a safety goal is
action that is directed at the injury-producing conduct. Regula-
tion of workplace practices\[42\] and consumer product bans\[43\] are
examples of this sort of safety-related action, as are the setting
of highway speed limits\[44\] and the installation of occupant pro-
tection systems in automobiles.\[45\] This kind of "specific deter-
rence"\[46\] of risks of harm requires a level of understanding of
the magnitude of the injury problem and the contributions of the
various factors that play a role in its size and severity that is
often difficult if not impossible to appreciate until the problem
has blossomed into a social and legal crisis. In a real sense, then,
the legal decision maker who anticipates a risk but is unsure of
how best to address it through direct regulation is encountering
an open-textured situation characterized by the handicaps identi-
fied by Herbert Hart as associated with the legal authority who
would prefer to govern through pre-announced rules: "relative
ignorance of fact . . . [and] relative indeterminacy of aim."\[47\] The

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41. Id. at 636-46.
sumer products).
45. 49 C.F.R. § 571.208 (1994) (Federal Motor Vehicle Safety Standard for occu-
pant protection systems).
46. The term is Calabresi's, and is used to distinguish the direct effect of reg-
ulation from the indirect effect of exposure to liability, referred to as "general deter-
rence." Calabresi, supra note 35, at 95.
striking feature of the world in which people suffer injury is that events require decisions to be made after the fact about which there was prior ignorance and when the indeterminate aim to avoid harm could not realistically have been accomplished.

In contrast to the use of direct regulatory action to avoid harm, injury compensation programs produce their safety effects indirectly, if at all. Compensation obligations force an entity that might otherwise be legally and financially indifferent to the consequences of its action to take into account the accident costs for which it will be held responsible. Employers who are liable for workers' compensation benefits for injuries that entail no realistic exposure to tort liability are thus unable to be legally indifferent to those harms, and they may respond to that workers' compensation obligation by taking steps to lower the risk of harm. Compensation obligations may also induce a previously insufficiently interested third party to become involved in making decisions for safety. To use the workplace setting again, the contractual obligation to indemnify the employer for its workers' compensation liability can induce the workers' compensation insurance carrier to take two steps that would be expected to increase safety. First, it can tailor insurance premiums to the risk that the employer is actually posing to its work force, and second, it can conduct an inspection program to recommend or demand changes in work practices to lower the risk of employees suffering harm for which it is ultimately going to be responsible. Indirect lowering of accident costs can occur, therefore, whenever the party who controls the risk modifies its behavior in order to lower its exposure to the payment obligation.

One of the insights of the economic analysis of liability for product-related harms has been the safety effect that can occur even when the party in control of the risk lacks an economic incentive to lower the risk. If the expected liability costs were lower than the investment necessary to avoid the liability, the party would be acting rationally, all else aside, in paying its damages as they occur rather than changing its behavior to avoid liability. In such a situation, however, the imposition of legal responsibility for the harm suffered by the victims can cause the price of the goods or services posing the risk to rise above what it would be in the absence of a compensation responsibility. If the price increase depresses demand, then one would expect fewer harms attributable to that risk to occur.
The emphasis in that last statement is necessary to highlight the limit on what is being claimed for the effect of an increased price. It is not necessarily true that the net effect of lower demand for a risky product is a decrease in overall harm. The empirical question that needs to be answered is how will the needs of the consumers who are priced away from the product now be met. If the answer is that those consumers will now engage in riskier behavior, the final judgement about whether there has been a net social safety gain will require a calculation of the accident losses that are prevented by the consumers' reaction to the higher priced product and the accident losses that are caused by the consumers' reaction to the higher priced product.

The fact that harms associated with alternative means of satisfying consumer desire might increase does not necessarily undercut the argument for attempting to obtain the safety gain attributable to the price increase that is associated with an imposition of legal responsibility for the harm. The net effect may still be positive in the sense that the harms attributable to whatever the consumers select as an alternative are more susceptible to direct regulation, or are easier to accommodate within existing legal and insurance regimes, or for some other reason pose less of a social problem than the harms associated with the product in question.

Two points about the relationship between an obligation to compensate for harm and a predicted enhancement of safety need to be kept in mind. First, the actual effects of an imposition of legal responsibility for harm are likely to be complex and to vary from setting to setting. Second, the fact that empirical questions need to be answered should not detract from raising the hypothesis that the implementation of a new injury compensation system proposal can achieve a safety goal as well as provide

48. Professor Ausness refers to this as an example of the economic phenomenon of the "second best." Richard C. Ausness, Product Category Liability: A Critical Analysis, 24 N. KY. L. REV. 423 (1997). The most obvious instance of this kind of effect is when consumers are priced out of the market for a safer but more expensive product and choose as a substitute a product that is less expensive but more dangerous. That does not seem to be a plausible scenario for tobacco products. A different way in which the effect might occur, however, is that consumers change the manner of use of the more expensive product so that the risk is magnified. For a discussion of how smoker behavior might change in a way that enhances the riskiness, see LeBel, Tobacco Deaths, at 639-40.
compensation to those who are injured.

C. The Third Goal — Administrative Efficiency

Compensating for injury can require activity by a variety of public and private institutions, each of which involves an expenditure of some resources — money, time, energy — to make the two most critical determinations: whether a claimant is entitled to compensation, and if so, what benefits should be paid. A goal of administrative efficiency serves as a constraint on the achievement of compensatory and safety goals: society as a whole is not well served when the cost of administering a compensation system rises to a level that exceeds the compensation and safety gains associated with the system. Efficiency may not be the most important criterion with which to assess a compensation program, but accomplishments on other dimensions would have to be extraordinarily important to justify a system that cost considerably more to administer than it provided in compensation and safety.49

The strongest lesson one can learn from the administrative experience of injury compensation systems is the cost of precision. In the tort system, there is considerable momentum toward increasingly refined allocations of responsibility. Under comparative negligence affirmative defenses, for example, fault must be apportioned between plaintiffs and defendants. The fault shares of parties, and in some cases non-parties as well, must be determined to apply a comparative fault contribution rule in a joint and several liability setting. If joint and several liability is replaced, in whole or in part, with a proportional liability scheme, the share of responsibility of each person who contributed to the occurrence of the harm becomes even more critical to the determination of the extent to which a plaintiff will be compensated.

The precision sought in these comparative responsibility doctrines comes at a price. The decision making demand on the fact finder becomes more complicated, and one might expect the presentation of evidence and arguments to be affected accordingly.

49. This is, of course, one of the more compelling arguments in the arsenal of the critics of contemporary tort law, at least in such routine settings as the litigation of responsibility for losses suffered in automobile accidents. See generally JEFFREY O'CONNELL, THE INJURY INDUSTRY AND THE REMEDY OF NO-FAULT INSURANCE (1971).
The risk of confusion and genuine error should rise as juries are presented with more complex decision making tasks. The ability of parties and their attorneys to predict outcomes would be another factor that is affected by the introduction of new variables in the outcome. Although it is not clear that this would necessarily impede settlement, it is likely to increase the uncertainty in which settlement valuations of claims take place.

Simplifying the determinations that a compensation system must make can reduce the cost of administering the system considerably. In the Agent Orange program, for example, virtually all of the particularistic causation determinations were eliminated by the decision to treat the simple fact of exposure to the herbicide in Vietnam as the initial threshold element. Sophisticated medical and vocational determinations of the nature of harm and the degree of disability can similarly be eliminated with rough categorical decisions about harm and benefit amounts. Issues that would appear to matter a great deal in the normal human reaction to an incident, such as who was at fault, might be pushed to the background or out of the picture altogether in a compensation system, as is true of the workers' compensation system.

Along with the simplified determinations that can be built into the threshold entitlement elements, a compensation system's efficiency can be increased by adopting decision making processes that deviate from the intensive scrutiny associated with the litigation model. Decisions can be made within an administrative process that resembles claims processing of the insurance industry more than it does the fact finding of civil litigation. To retain the administrative efficiency gains obtained at that first level of decision making, an injury compensation system can structure the further review of those decisions to minimize the chance that some later stage will reintroduce the trial-type process that was avoided in the first instance.

While it is clear that the price of precision in making determinations can be lowered, the decision making efficiency itself co-

50. One can imagine, for example, that the complexity of the litigation decisions increases the anticipated cost of litigating a claim, so that the expected return is lowered, making settlement more attractive.

mes at a cost that may be significant. An important part of the motivation for the comparative responsibility movement in tort law is a sense of fairness that is offended by asking only whether or not questions without going on to ask how much questions as well. The creators of an injury compensation system might anticipate the charge of unfairly refusing to make fine discriminations among types of conduct and degrees of harm by making it clear what is the central aim of the system, and then structuring the delivery of benefits so that there is a strong correlation between the process that is used and the aim that is sought.

One other feature of administrative efficiency needs to be considered. The discussion so far has focused on the costs of making decisions within the compensation system. The manner in which the compensation system is coordinated with other systems and programs can have a significant effect on what the society as a whole invests in the solution of the injury problem. A desire to eliminate what appears to be wasteful expenditure of judicial resources can help to justify the abolition of the collateral source rule in tort law, for example. Instead of quantifying and determining responsibility for categories of harms that have been covered by other sources, a legal system might conclude that the best use of the civil justice system is to compensate for harm for which there is no other coverage.

Injury compensation systems can address this issue in a number of ways, with two models at opposite ends of the spectrum. The injury compensation system can be set up so that the entitlement to benefits is triggered only if other sources of compensation prove to be inadequate in a particular case. Under this model, the administrative costs of the compensation system would only be incurred when absolutely essential to accomplish the aims of the program. On the other hand, the injury compensation system can be established so that it is the compensation source of first resort, allowing society to avoid expenditures of resources in the other arenas in which the effects of the harm would have to be addressed. Compensation systems can thus be structured so that they are supplemental or exclusive sources of compensation.

What needs to be understood is that there are two sources of justice concerns in creating an injury compensation system. An appearance of diverting legitimate claims from a tort liability regime where those claims would receive more generous treat-
ment than they are given in the compensation system may seem unfair to the claimant. An appearance of extracting funds from entities who would bear no realistic exposure to tort liability may seem unfair to the parties who contribute to the financing of the compensation system. The most realistic prospects for an injury compensation system arise when there is a convergence of interests of the affected parties and the society as a whole, so that a responsible compromise can be brokered to accommodate the competing interests to the greatest extent feasible.

D. The Fourth Goal — Appropriate Cost Internalization

Internalization of injury costs may initially strike an observer more as a process by which other goals are achieved rather than as an independent goal itself. It is certainly true that safety effects, for example, can be traced to a decision that a particular industry must take injury costs into account when it makes decisions about how much to invest in safety. A legal system that imposes a compensation obligation on that industry uses the cost internalization process to induce producers and consumers to act in ways that promote greater safety.

Although the instrumental nature of cost internalization is clear, there is nonetheless some additional analytical clarity that can be achieved by focusing briefly on cost internalization as an end in itself. The starting point for a cost internalization analysis is Guido Calabresi's question, "What is a cost of what?" That question is a matter of causation, asking when we can identify one factor as a cause of another. In the realms of theology and metaphysics, such an inquiry would look ultimately to first causes and draw on quite subtle distinctions. In the law of injury compensation, fortunately, the causal answer that underlies an appropriate measure of cost internalization is obtainable from a more concrete identification of burdens and benefits.

Achieving appropriate cost internalization as a goal for an injury compensation system is actually the converse of Judge

52. See CALABRESI, supra note 35, at 133.
53. THOMAS AQUINAS, 1 SUMMA THEOLOGICA 33 (1948 ed.) (Q. 2, art. 3: proof of existence of God by reference to first efficient cause).
54. ARISTOTLE, METAPHYSICS, IN 2 COMPLETE WORKS 1552, 1555-57 (J. BARNES ed. 1984) (distinctions among four senses of causation).
Calabresi's prescription to avoid externalities. The goal is to create a rough correspondence between those who enjoy the benefits of an activity and those who bear the burdens. When the activity is the manufacture or the distribution of a product that has the capacity to injure, the appropriate focus is on whether the losses associated with those injuries are included within the costs of the industry distributing the product. If they are so internalized, then the price of the product will reflect the injury costs as part of the social cost of the product, and production and demand levels will be set accordingly. If they are not internalized, then production and demand levels for the product will be inflated. Furthermore, in the absence of cost internalization, the injury costs that are externalized onto the victims will have to be borne by some segment of the population other than the producers and, through them, the full class of consumers of the product. It is the absence of cost internalization, not its appropriate utilization, that leads to injury costs being spread across society as a whole.

Within the contemporary law of products liability, even when the liability that is being imposed is putatively strict, the defectiveness analysis specifically and deliberately narrows the benefits and burdens comparison. The focus is on the risk that the product poses to the user or others and the benefits that the product offers to the consumers and others exposed to the risk. The overall economic benefit of the product is supposed to be excluded from the analysis, as is the economic burden associated with decreasing the availability or the affordability of the product. It matters to that analysis, for example, whether people who would benefit from an unavoidably risky prescription drug are deprived of that benefit; it is not supposed to matter whether the pharmaceutical industry must downsize its workforce as a response to the exposure to products liability.

Approaching an injury problem through the vehicle of an injury compensation system provides room for thinking comprehensively and systemically about the overall social good that can be accomplished through the program. Determinations that are in

the broader public interest may be easier to make in the course of global solutions to problems than they are in the more piece-meal fashion of the adjudicatory process. Those who inquire about the effect of liability on the farm economies of tobacco growing states or the industrial economies of cigarette manufacturing states are met with indifference in the liability theories of tort law. Such concerns are legitimately incorporated into a consideration of the optimal social solution to a widespread social problem.

E. The Essential Elements of an Injury Compensation System

As the preceding discussion of the goals of an injury compensation system suggests, the emerging law of injury compensation systems draws on a variety of statutory and regulatory enactments and common law precedent, dealing with a wide range of substantive, procedural and remedial issues. Although one might be tempted to abandon an attempt to systematize and synthesize such a hodge-podge of programs, that temptation can be resisted if one keeps focused on a core of five major issues that the study or the creation of any injury compensation system will be required to address.57

i. The defining issue for an injury compensation system is what is the basis of entitlement to compensation.

The entitlement to compensation sets the parameters for the system. More than any other element of a compensation program, the basis of entitlement captures the essential aim of the program and defines how much flexibility there is likely to be in the construction of the other elements of the program.

The basic question at the heart of an injury compensation program is the identification of the injury compensation problem. The creation of a system requires careful thought about the nature of the problem, and of how it is possible to address it in this

57. As is true of statements of the goals of an injury compensation system, different commentators might choose among various terms for the essential issues that need to be addressed. In a recently published proposal for a compensation program in the contaminated blood products setting, Professor Andrew Klein has identified the major components of the program as jurisdiction, funding, compensation, and access to the tort system. Andrew R. Klein, A Legislative Alternative to "No Cause" Liability in Blood Products Litigation, 12 YALE J. ON REG. 107 (1995).
manner. Is the problem that too many harms are occurring? Is the problem that too many injured parties are being left to their own devices to deal with the consequences of the harm? Is the problem that the litigation system reaches too many results thought to be socially undesirable? Is the problem that the litigation system reaches generally appropriate results but at an unacceptable cost? Is the problem the lack of a prospective focus, so that the injury compensation system could be seen as trying to get ahead of the curve of a massive number of claims instead of playing catch-up in the way that the tort litigation system generally does? The shape of the program will be responsive to the answers to these different questions.

Compensation programs can be set up so that they resemble the zero-based proof attitude of the litigation system, in which the decision maker begins with a clean slate and nothing happens until the claimant satisfies an evidentiary burden that is fact specific to the claim. Much of the attractiveness of the compensation system approach lies in the ability to make appropriate decisions without a high investment in fact finding, and in order to realize that attraction, the entitlement to compensation would have to be set in a more categorical way. Presumptions of entitlement built into the system from the start are a quite useful way of streamlining the process, as are predetermined levels of benefits for particular showings of harm.

ii. Once the threshold for obtaining compensation has been determined, the next issue that needs to be addressed is what is the compensation that the system will provide to those who cross that threshold.

Given the genesis of many injury compensation systems in particular dissatisfactions with the tort system in place at the time the system is created, it is not surprising that the questions

58. See, e.g., 42 U.S.C. § 300aa-14 (1994) (Vaccine Injury Table containing conditions and time of onset to qualify as a vaccine-related injury for purposes of compensation under the National Childhood Vaccine Injury Compensation Act).

59. The intermediate group of claimants in the Dalkon Shield compensation program, those with proof of the use of the device and medical evidence of their conditions but who faced problems with alternative causes of their conditions, were compensated according to a schedule resembling a workers' compensation schedule for loss of body parts. RONALD J. SOBOL, BENDING THE LAW: THE STORY OF THE DALKON SHIELD BANKRUPTCY 313 (1991).
at this stage of system creation tend to turn on how closely the compensation will correspond to the damages that would be available if the claimant were successful in a tort action.

The basic choices to be made on this element of the system involve different sets of variables. One of the variables is the level of compensation: should the system attempt to provide total compensation or should there instead be an acknowledgment that the compensation is only partial. Another variable is the position that the compensation system occupies in the universe of potential sources of compensation: is the system the payor of first resort or is it instead a compensation source that comes into operation only for otherwise uncompensated harm. Related to that variable is the choice of whether to extinguish other claims that may arise out of the incident or exposure giving rise to the harm or to allow tort actions to proceed against those who occupy a third party status to the relationship between the injury victim and the enterprise that is held responsible through the compensation program.

The interaction between those sets of variables can help to shape the program. The availability of, and the likelihood of success on, third party claims can relieve some of the financial pressure on the compensation system, for example, which can in turn affect the level of benefits that can be afforded for those who do not have access to a third party recovery. Similarly, a decision to make the program a supplemental source of compensation can affect the demands that are placed on the funds that are available, opening up further possibilities for deciding what harm is compensable in what amounts.

If the claimant is given options of accepting the award made within the compensation system or pursuing a tort remedy, then the compensation that is available within the system has to be generous enough to provide an incentive to accept the system's award. That generosity is, of course, less needed as the prospect of success in the tort litigation declines.

iii. Given the basis and the nature of compensation, the creators of an injury compensation system must decide what is the source of the funds for compensation.

The workers' compensation system employs a variety of techniques for assuring adequate funding for claims for compensa-
Some states create funding bodies from which compensation is paid, but the predominant mode of financing workers' compensation benefits is insurance obtained on the commercial market or, in the case of the more financially sound entities, self-insurance. When the decisions about compensation make the system resemble a social welfare benefit more than a liability determination, it is probably best to see the source of funds as a tax on the enterprise that has produced the harm.

The appropriate taxing unit is a decision that has to be made in the construction of a compensation program. Childhood vaccines, for example, are taxed on each dose produced by the pharmaceutical industry, but the tax rate varies among the vaccines according to the risk of injury associated with each vaccine. If the risk is generally uniform across the enterprise that is being held responsible for financing the program, then the cost of administration of the system can be kept lower due to the absence of a need to make differential risk determinations affecting the financial obligations of individual contributors to the funding of the program. At the outset of a program where the risk variation is a matter of uncertainty, cost effectiveness in administration may call for an initial uniform assessment, with an on-going and periodic review process to determine whether the rate should be changed to reflect actual claims experience.

iv. An injury compensation system must address the question of what procedures are to be used for making the two critical determinations: whether compensation should be awarded, and if so, how much compensation an individual claimant should receive.

One of the major advantages of an injury compensation system is the opportunity to lower the costs of making the critical determinations of whether and how much compensation should be awarded. Although some states direct contested workers' compensation cases to the trial court of general jurisdiction, it is more common to find the first level of decisions made by administrative agencies, with subsequent judicial review in a trial court or, more commonly, directly to an appellate court. Compens-
sation programs may set up special administrative bodies to make the decisions, as was the case with the Dalkon Shield Claimants' Trust. The creation of a new compensation program may involve subcontracting the decision making to an outside body, as in the Agent Orange experience, which might seem a particularly attractive option when the decisions are essentially insurance payment matters rather than complicated or contestable factual determinations. Decisions can also be made within a currently existing judicial structure, as with the special masters of the Court of Federal Claims or within the bankruptcy process in the federal district courts.

v. Finally, an injury compensation system must contain a clear process for determining how the compensation provided within the system is to be coordinated with the tort system and with collateral sources of compensation for the harm covered by the system.

The options on this component of an injury compensation system include three basic models. Drawing on the experience with workers' compensation systems, the benefits available under the new system can be considered the exclusive remedy that is available to the injured person. The federal vaccine injury program employs a model of election following exhaustion; the injured person is required to proceed into the compensation program, but at its termination, the claimant is entitled to reject the result obtained within the system and pursue a tort remedy, albeit under a tort regime that is altered by substantive and procedural requirements set out in the legislation. The new compensation system might also be seen as a supplement to the existing tort liability system, stepping in to provide compensation for those who are not compensated or who are undercompensated under the prevailing doctrines of tort law.

63. 42 U.S.C. § 300aa-12 (1994) (conferring jurisdiction on Court of Federal Claims to determine entitlement and amount of compensation under the National Childhood Vaccine Injury Compensation Program).
64. Professor Eades' commentary suggests that the compensation program funded by a tax on tobacco products, along with regulatory efforts, "should be merely an adjunct to the traditional tort system." Eades, supra note 8, at 495. In an earlier effort to construct a system for compensating victims of drunk drivers, the author
II. SOME PRELIMINARY THOUGHTS ON THE CONTOURS OF AN INJURY COMPENSATION SYSTEM FOR TOBACCO-RELATED HARMs

Taking the general observations of the preceding section about the genesis of injury compensation systems and applying them to the situation we find when we examine the current legal posture of the tobacco industry in this country raises more questions than it provides answers. Approaching the issue in a systematic way and at a systemic level should, however, offer some instruction about what are — and perhaps even more importantly, what are not — useful avenues to pursue.

When one considers the goals of an injury compensation system, some are easier to achieve in a tobacco setting than others. At first glance, compensation would appear to be considerably more difficult to accomplish than would the achievement of the goals of reducing the risk of harm and of forcing the industry to internalize the costs of tobacco-related harms into the industry's operating expense. Containing within manageable levels the administrative expenses of any program established to provide those benefits is also problematic in any system that would attempt to provide a counterpart to tort damages for individual victims of tobacco-related harms.

Compensation of tobacco product users for their individual harm is difficult to reconcile with tobacco-related harms on both a conceptual and a practical level. One of the more distinctive features of tobacco-related harms is that the bulk of those harms occur to the people who voluntarily begin to use the products which, at least for some time now, have been accompanied by warnings of the risks that these harms will occur. In this sense, then, much of the harm that tobacco causes cannot be characterized as occurring to people who fit the traditional understanding of “innocent victims.” This aspect of the problem raises two possibilities, in the sense that there are two different routes we might follow.

The first possible response is that a compensation system needs to be devised in such a way as to exclude from access to

chose this option. LeBEL, supra note 20, at 290-92. On reflection, it is not clear that the same choice would be made by the author even in that setting today, given legitimate concerns about duplication of decision making tasks and the resultant higher costs of administration, compared to an exclusivity model.
the compensation provided by the system the "willing participants" in the risky behavior that leads to the harm. Such a response is deeply embedded in traditional tort ways of thinking about injury compensation. The defense of assumption of risk raised a total bar to recovery for more than a century of our experience with fault-based jurisprudence. In the pockets of strict liability for abnormally dangerous activities, assumption of the risk that made the activity abnormally dangerous has remained a defense. As a strict tort liability theory emerged for products cases, the product user's unreasonable decision to use the product knowing of the defective condition was retained as an affirmative defense. 65

A reluctance to expend limited resources on those who knowingly encounter a risk for no good reason is responsive to a fundamental notion of personal responsibility. Indeed, in an earlier work on compensating the victims of intoxicated drivers, the author specifically excluded from a new compensation system proposal any possibility of recovery by the drinking drivers or those whose claims were derived from the drinking drivers. 66 That kind of restriction in the tobacco setting would not necessarily leave the system with nothing to do. Passive smoking victims who are injured by environmental tobacco smoke would constitute a presumably large class of persons who fit the profile of classic innocent victims.

It would thus be possible to design a system that excluded claims for compensation by the users of tobacco products. The question then becomes whether we should do that, or whether instead there is something about the tobacco injury context that undermines this initial reluctance to include product users within the class of those who are entitled to compensation of some sort. The possibility of finding that contextual peculiarity is heightened if we consider the second response to the issue of whether smokers should be treated as willing participants rather than as innocent victims.

The second and different response to the characterization question is that the moral responsibility for the adverse effects on the nation's health is so widely disproportionate when one considers the tobacco industry and the users of its products that

65. Restatement (Second) of Torts § 402A cmt. n (1965).
66. LeBel, supra note 20, at 297-99.
any qualms that we might have about rewarding people for their bad behavior should be set aside. It is one thing for society to view with special disfavor a driver who chooses to become intoxicated and then exposes himself and others to the enhanced risk of death on the highway. It is quite another thing for society to view with the same level of disapproval people who succumb to the sophisticated marketing efforts that result in the addiction of the youngest segment of the consuming population to the products whose full risks are unlikely to be conveyed by the manufacturers or appreciated by the consumers at the critical and vulnerable age when lifestyle choices are being made. The bipolar world of willing participants and innocent victims fails to capture the reality of a consuming population who became addicted at a time when in every way except for the government-mandated warnings the industry downplayed and denied the health risk.

Support for a response that is more tolerant of the choices initially made by those who are injured can be found both in contemporary tort law and in the experience of other compensation systems that have been developed as alternatives to tort litigation. One of the most widely adopted modifications in tort doctrine in recent years has been the shift in the treatment of plaintiffs' conduct defenses from total bars to recovery to bases for comparative reductions in the amount of recovery. A frequently adopted corollary to the comparative negligence doctrine has been the limitation of the assumption of risk defense to those situations in which the decision to encounter the known risk was unreasonable, viewed in objective terms. Within workers' compensation, the injury compensation system with which we have the longest experience, it has long been the case that only the most egregious fault on the part of the injured employee would act as a barrier to a full entitlement to the benefits of the compensation system.

The experience of opening access to compensation for those whose fault has contributed to their harm would be a stronger precedent to follow if other goals would be accomplished by doing so, and if the most problematic forms of compensation were adequately addressed. When one looks at those other goals in the tobacco setting, the grounds of support for expanding the range of compensation to include some of the harms suffered by tobacco product users become apparent.

Achieving an appropriate measure of cost internalization in
the tobacco setting is a goal that is going to be met in the near future only if there are litigation breakthroughs of one sort or another, or if a specially tailored program is adopted to shift some of the costs of those harms to the industry. With very few exceptions, the harms attributable to the use of tobacco products have been successfully externalized by the industry that manufactures and distributes those products. A curious feature of the contemporary tobacco litigation scene is that significant costs are being internalized by the industry, but those sums in the tens (or hundreds) of millions of dollars are the costs of defending against any legal responsibility for the harm that the products have caused. Acknowledging that responsibility and then participating in an appropriately designed compensation system would divert that socially wasteful expenditure into channels that would actually accomplish some public good.

A compensation program that was limited to environmental tobacco smoke victims would be the easiest to justify on cost internalization grounds. For those harms of smoking, the burdens of dealing with the consequences of the product's use are visited on a segment of the population that enjoy none of the benefits of that use. Shifting the costs of their harms to the industry would be in accord with the classical restorative justice notions embodied in contemporary economic ideas of matching benefits and burdens through cost internalization mechanisms of private and public law.

An injury compensation system that reached more broadly so that the harms of product users who in some sense share the responsibility for their health-impaired condition could be compensated also has analogical support on cost internalization grounds. In the workers' compensation setting, for instance, careless workers and their resultant injuries are seen as an inevitable incident of the employment enterprise, and the costs of those injuries are thought to be appropriately incorporated into the operating costs of the employing enterprise and then into the prices paid for the goods and services of that enterprise.

A quite similar line of thinking would be applicable to a tobacco injury compensation system that included product users among its beneficiaries. Smoking-related harms are the most

67. In a discussion following the presentation of the papers at this Symposium, the figure of $600 million dollars in defense costs annually was mentioned.
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predictable, indeed certain, of the consequences of distributing cigarettes, and a legal system that allowed the industry to continue to externalize the costs of those harms would allow the industry to understate its costs of operation significantly.

Because those costs have to be allocated somewhere, treating them as matters for the tobacco industry to internalize would relieve the financial burden on some other sources of public and private compensation. Including smokers as persons whose harms were included within the scope of a tobacco injury compensation system would make explicit what is implicit in the compensation provided to injured consumers through products liability litigation. Part of the price of the product reflects access to a system for shifting accident costs away from the victim and for spreading those costs over a different base than the one that would bear the costs if they were not shifted. Automobiles, for example, are marginally more expensive because a potential recovery of damages for harm caused by defective automobiles is part of the package obtained by the purchaser. Likewise tobacco products could be priced at a level that reflects the opportunity for those harmed by the products to recover some of the costs of those harms.

Cost internalization in this sense is appropriately seen as a form of insurance, albeit one that operates more as a tax than a voluntary decision to purchase coverage in the commercial insurance market. Two questions follow from that understanding, however. First, is the cost being internalized by the appropriate enterprise? Second, is the system by which compensation is provided the most appropriate method for delivering the compensation? Each of those questions is answered in large part by considering in the tobacco setting the remaining goals of an injury compensation system. The risk reduction objective points strongly toward the tobacco industry as an appropriate institution on which to impose some of the costs of the harm caused by tobacco products, while the administrative efficiency goal is best served by a compensation system that is financed through a

specially earmarked tax on tobacco products that is used to address a limited segment of the financial consequences of tobacco-related harms.

The safety enhancement goal for a compensation system in the tobacco setting is more readily achievable than virtually any other objective. An increase in the cost of the tobacco product is likely to produce a corresponding decrease in demand, particularly among the younger users who are at the critical age when they are most likely to become addicted long-term users. Whatever method is used to force the industry to internalize the costs of the harm that their products cause will almost certainly have as a beneficial effect a reduction in the volume of those harms.

This exercise in thinking through the options for an injury compensation system grew out of a set of reflections on the rapidly changing legal posture of the tobacco industry in the summer of 1996.69 The most promising of the developments surveyed in that article was a surtax on tobacco products enacted through voter referendum in three states.70 The revenues from that supplemental excise tax were earmarked for special programs that would lower the cost of tobacco harms, both by supporting efforts to lower the smoking rate and by subsidizing measures to treat people with smoking-related health problems.

That kind of tax increase supporting particular programs is an eminently defensible piece of social policy. It accomplishes some shifting of injury costs to the industry that has, for the most part, successfully externalized those costs, and it does so in a way that may increase the price to reflect its social cost more than is currently the case. The lesson that emerges from the economic analysis of injury compensation is that the tax increase itself is likely to produce a beneficial effect if demand for the products declines. The search for an appropriate compensation program begins from that point, but it remains the most powerful justification for addressing the tobacco injury problem through a vehicle outside of the traditional tort litigation system.

Administrative efficiency, if not viewed as a fully independent goal, at least serves as an important side constraint on the methods that are used to achieve other ends. In the tobacco setting,

69. LeBel, supra note 1.
70. The state referenda were passed in California in 1988, in Massachusetts in 1992, and in Arizona in 1994. See id. at 635-47.
the foundation for collecting the funds for an effective compensation program is already in place, in the form of the excise tax structure that is imposed on tobacco products by the federal and state governments. Distribution of funds to those harmed by the products is more problematic, largely because the phenomenal marketing success enjoyed by the industry has made the occurrence of those harms quite widespread.

Administrative efficiency notions play a role in making the centrally shaping decision of whether an injury compensation system in the tobacco setting should exclude claims by those who use the products. The effects of consumption of tobacco products are not signature diseases in the sense that asbestosis is uniquely attributable to exposure to asbestos fibers. What that means is that a smoker who presents a particular health problem may have multiple factors in his or her personal history and the environment that arguably contribute to that problem.

The multiplicity of causal factors could lead to a decision to exclude smokers from access to the compensation program for tobacco-related harms in the absence of a showing of predominance of smoking as a causal explanation of the claimant's condition. Such a decision would, however, understate the complicity of the tobacco industry in the health risk that its product users face. More promising as a source of guidance in this setting is the experience in the workers' compensation setting of attributing responsibility and thus opening access to the program as long as there is a minimal showing that the relevant factor (in this case it would be the use of the tobacco products rather than the occupational exposure to harmful substances) was a significant contributing factor to the claimant's current condition.

Drawing on those functional considerations, and appreciating the tensions between and among various goals in the tobacco-related harm setting, a tentative shape for a tobacco injury com-

71. At least not yet. One of the evidentiary issues in Brown & Williamson Tobacco Corp. v. Carter, 680 So. 2d 546 (Fla. Dist. Ct. App. 1996) was whether the kind of cancer that the plaintiff suffered was consistent with exposure to the tobacco smoke byproducts. Medical science may become capable of specifically linking tobacco use and particular cancers in the future.

72. See, e.g., Rutledge v. Tultex Corp., 301 S.E.2d 359 (N.C. 1983) (occupational disease established if claimant shows that workplace exposure to cotton dust significantly contributed to the development of the disease; exposure does not have to be sole cause of disease).
Compensation program begins to emerge. The remainder of this section of the article will sketch the major elements of this initial approach to constructing an injury compensation system in this complex and politically charged environment.

The most realistic and manageable method of establishing a basis of entitlement to benefits from a tobacco injury compensation program would be for the creator of the program to construct a schedule of harms comparable to the Vaccine Injury Table in the National Childhood Vaccine Injury Compensation Act. In that legislation, Congress established a list of conditions related to each of the vaccines covered by the Act, with a time within which each condition would normally be expected to occur if it were in fact vaccine related. The occurrence of the first onset or a substantial aggravation of one of the Table conditions within the period specified in the Table creates a presumption that the victim is entitled to compensation under the Act. In the absence of the presumption from the Vaccine Injury Table, the claimant bears the burden of proving that he or she has suffered a vaccine-related injury.

No one would suggest that the task of creating such a tobacco harm schedule is anything but breathtakingly complex, but it is perhaps the most critical preliminary step in fashioning a system that is manageable and affordable. The experience in administering the Black Lung Act suggests that time and energy invested in setting the right threshold at the outset would be more than repaid in the avoidance of subsequent difficulties in determining access to compensation in a way that does not convert the system into a general health insurance program.

Once a working definition of tobacco harm is accomplished through the construction of a tobacco harm schedule, the question becomes what is to be done with what has been identified as tobacco-related harm. Monetary payments made to individuals seem to be the least justifiable use of the funds that would become available in a tobacco injury compensation program. The maximum attainment of the multiple goals of the system would

be best achieved if the benefits were instead used to supplement the privately and publicly financed health care resources available to the population at large. Drawing on but expanding the theory underlying the claims by the state attorneys general, that the use of tobacco products has produced a health care cost that is being subsidized by various segments of the population, the compensation from this program could be provided in the categories which follow.

A. For victims who suffer harms on the tobacco harm schedule and who are covered by health insurance, benefits would be provided to reimburse the victim for the difference between the actual cost of the health care for those harms and the insurance coverage that is available to the individual.

This benefit of the compensation program would generally fall into two categories. For individuals whose insurance coverage has not been exhausted, the compensation would be in the amounts of the deductibles or co-payments required for the health care. These benefits would be available both for privately insured individuals and for those who are covered by Medicare. For those individuals whose health care has exhausted the major medical provisions of their insurance, the compensation would be in the amount of the health care expenditures, in the same way that uninsured individuals would be compensated below.

B. For uninsured victims of harms on the tobacco harm schedule, benefits would take the form of payments to the health care providers who perform care for those harms.

For this category of benefits, the program would act as a substitute for the Medicaid agency within the state where the care is provided. Instead of treating the health care as a public expense, the injury compensation system would treat it as an expense attributable to the tobacco industry to be funded through the compensation program. Payments would be made to the providers, not to the victims, and the payments would be made for the services as they are provided, eliminating any need to determine a lump-sum amount for future medical expenses.
C. For tobacco-related deaths, as determined according to the tobacco harm schedule, a death benefit of a modest amount would be payable to the estate of the decedent.

The purpose of this form of payment is largely symbolic, but experience in the law of injury compensation systems has suggested that symbolic payments can produce a beneficial effect. The most important social fact about tobacco products is that when used in their intended ways, they produce disabling and fatal conditions. The sort of "terminal benefit" contemplated in this provision of the tobacco injury compensation program acknowledges the role that tobacco products play in the pathology of the American public.

As an incidental positive effect, the death benefit undercuts the curious argument that tobacco deaths actually produce a public good in the form of deaths that lower the long-term health care costs of people who would live longer were it not for their tobacco-related harm. Tobacco deaths themselves would become part of the cost of the product that the industry would be required to internalize, not some sort of perverse public benefit that the industry is providing to the nation.

Missing from this list of items that would be compensated by the tobacco injury compensation program is any payment to the tobacco victim for two items of loss: those that are pecuniary in nature but covered by some other funding source, and those that are non-pecuniary in nature. For smokers, such an exclusion could be justified on the ground previously raised, namely, that there are limited funds with which to try to accomplish a set of objectives and the lowest priority claim on those funds is the compensation of those who participated in the production of their harm.

For non-smokers, a different justification would have to be sought. Their participation in the harm is involuntary in all but the most formalistic way. It would be exceedingly harsh, for example, to hold that flight attendants chose to be exposed to

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77. In his fairness opinion in the Agent Orange litigation, Judge Weinstein used quotes from Frazer's *The Golden Bough* and from Abraham Lincoln's Second Inaugural Address in support of the proposition that public acknowledgement could be as significant as private compensation in the process of reaching closure of mass injury claims. In Re "Agent Orange" Prod. Liab. Litig., 597 F. Supp. 740, 857, 862 (E.D.N.Y. 1984).
concentrated environmental tobacco smoke as part of their employment, and that they could always have elected other work if they really objected to the exposure.

If there is to be any accommodation by the compensation program of claims for benefits that compensate for personal injury as such, it would be in the context of claims by non-smokers who have been harmed by exposure to the smoke from other people's use of cigarettes. Within an injury compensation system, those claims would present difficult scientific issues about causation, at least in the short run. That suggests that, again perhaps only in the short run, the appropriate view of the injury compensation system for this class of claimants is as a limited supplement to the other sources of compensation, rather than as a substitute for the wider range and larger size of the awards that might be obtainable in a tort recovery.

Financing the compensation system for tobacco-related harms is easily accomplished through a tax on tobacco products, with the revenue earmarked for this purpose. As described in a recent publication, such a tax would have two positive effects in the tobacco setting. First, it would generate funds to support the compensatory aim of the proposal, with an expectation that the drain on other sources of funding for those same purposes could be lightened. Second, it would increase the price of the tobacco products so that the market signals received by consumers would at least somewhat more closely correspond to the actual social cost of those products, with whatever beneficial health effect such a rise in price might produce in the form of a lower demand for the products.

III. CONCLUSION

The description of these remarks as “preliminary thoughts” is accurate for two reasons. First, there is a good deal to be done, especially in the empirical and epidemiological fields, before the next step of actually crafting a compensation program would be feasible. But second, and more importantly, this is an attempt to lower the rhetorical and economic stakes in the debate about what to do when we know as much as we now know about the risk of injury and death from the use of tobacco products. It

78. LeBel, supra note 1, at 638-41.
ought not be a vain hope that once we have moved beyond the name calling and the finger pointing, we can enter into a conversation about how to play an endgame that has at its core the interest of the public as a whole rather than just the self-interest of the various parties who are most directly affected by the outcome. Serious consideration of an injury compensation system as an alternative to the tort litigation model could be a step in that direction.
A COMMENT ON PROFESSOR PAUL A. LEBEL'S IDEAS FOR A TOBACCO INJURIES COMPENSATION SYSTEM

by Ronald W. Eades

I. THE ISSUES

The debate over tobacco seems to occupy a substantial amount of time in the United States. The struggle in the debate between the economic benefit of the tobacco industry and the horrible losses due to tobacco consumption has a "death grip" on society and seems impossible to resolve. When individual smokers have brought actions against the tobacco companies, they have routinely lost. Whether judgment for the defense was based on the idea that tobacco is not defective, or a federal preemption theory, the results have been the same. Into that battle, states have begun to sue tobacco companies. These actions are usually brought in an effort by the states to recover their costs in providing health care for citizens who have been the victims of tobacco related diseases. The state claims are presently being filed and will be in the courts for years to come. Those claims will also have substantial difficulty in getting a remedy from the tobacco companies for the losses. In order for the states to prevail, novel legal arguments must be advanced to reverse the years of successful defense of tobacco litigation. Ultimately, the costs of litigation, risk of loss by plaintiffs, absence of compensation for the truly harmed, and all of the other risks associated with liti-

1. Professor of Law, School of Law, University of Louisville. Rhodes College, B.A.; University of Memphis, J.D.; Harvard Law School, LL.M.
2. See Richard L. Rabin, A Sociolegal History of the Tobacco Tort Litigation, 44 STAN. L. REV. 853 (1992). This is an excellent history of the tobacco litigation.
6. Id.
7. Id.
8. Part of the action that had been filed by California was dismissed due to difficult issues of causation. 25 Prod. Safety & Liab. Rep. (BNA) 227 (Mar. 7, 1997).
nigation may suggest that other remedies be sought.

Professor Paul A. LeBel has suggested a possible move from a tort system to a compensation system. LeBel's argument is actually a suggestion that a broad tax and benefit scheme may be the solution. Some care must be exercised to review the problems with tobacco litigation in both the individual and state format, and then consider the idea of a compensation system that is supported by taxation. It would not appear, however, that the time has come to reject completely a tort remedy in favor of a tax remedy. Although such a tax remedy may have some benefits, a more effective model would use the tax remedy in conjunction with the important remedies that a novel tort approach could provide.

II. PROBLEMS WITH SEEKING TORT REMEDIES

A. Actions by Individual Smokers

Individual smokers have sought recovery from tobacco companies using traditional tort theories. These actions, however, have been unsuccessful for the plaintiffs. The tobacco companies have benefited from a series of tort and legislative theories that have provided something approaching immunity from action.

The first theory, simple as it is, that has protected the tobacco companies is the argument that tobacco products are not defective when they cause disease. In an early landmark decision, Judge Goodrich of the Third Circuit wrote a concurring opinion that would frame the issue.

If a man buys whiskey and drinks too much of it and gets some liver trouble as a result I do not think the manufacturer is liable unless (1) the manufacturer tells the customer the whiskey will not hurt him or (2) the whiskey is adulterated whiskey — made with methyl alcohol, for instance. The same surely is true of one who churns and sells butter to a customer who should be on a

10. Id.
12. Id.
13. See infra notes 14-26 and accompanying text.
nonfat diet. The same is true, likewise, as to one who roasts and sells salted peanuts to a customer who should be on a no-salt diet. Surely if the butter and the peanuts are pure there is no liability if the cholesterol count rises dangerously. In this case there was no claim that Chesterfields are not made of commercially satisfactory tobacco.\footnote{Pritchard v. Liggett & Myers Tobacco Co., 295 F.2d 292, 302 (3d Cir. 1961) (Goodrich, J., concurring).}

That theory was adopted by the Restatement.\footnote{RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (1965).} The comments to the Restatement (Second) of Torts, using a consumer expectation theory, state, "Good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful; but tobacco containing something like marijuana may be unreasonably dangerous."\footnote{Id.} It is clear, therefore, that in order to find a defective condition for tobacco, there must be some foreign substance present in the product.\footnote{Id. at 366.}

The classic case on the issue of adulterated tobacco was the poor plaintiff who found a toe in his chewing tobacco.\footnote{Pillars v. R. J. Reynolds Tobacco Co., 78 So. 365 (Miss. 1918). The case is a negligence claim and is not, therefore, directly supportive of the issue in strict liability. It should be noted, however, that the case allows the use of res ipsa loquitur upon finding the toe, and relieves the plaintiff of the burden of proving the conduct that was the breach of reasonable care. Even if the case is not direct precedence for strict liability, it does offer an example of the willingness of the courts to allow a remedy where the cause of harm is adulterated tobacco.} In reflecting on the reasons that the plaintiff should be allowed to recover, the court opined, "We can imagine no reason why, with ordinary care, human toes could not be left out of chewing tobacco, and if toes are found in chewing tobacco, it seems to us that somebody has been very careless."\footnote{Id. at 366. Although the plaintiff in the case did not develop the catastrophic illness that one usually associates with tobacco, he did develop symptoms of pto-maine from this errant toe. See also Liggett & Myers Tobacco Co. v. Rankin, 54 S.W.2d 612 (Ky. 1932) (involving the discovery of a wooly worm in a plug of chewing tobacco).}

Where, therefore, some adulterating foreign substance is found in the tobacco, there may
be a claim for relief. Tobacco in its natural condition, however, is not defective.

If the injured plaintiff seeks to use the idea of a failure to adequately warn of the risks associated with tobacco, modern federal statutes will act to bar recovery. When Congress, during the 1960's, began to require the tobacco industry to warn of risks associated with the product, a special defense was created. The statutes expressly preempted state law, and the tobacco industry had only to follow the federal statutes. Since the industry has followed those statutes, its use of the federally mandated warnings cannot be challenged as a matter of state tort law. As such, a claim based upon a failure to warn under a state's adoption of Restatement (Second) of Torts section 402A is barred by the federal preemption.

Even if the injured plaintiff could persuade the court to find a duty in light of a defective product or a failure to warn, issues of causation and affirmative defenses would continue to defeat the claims. Speaking of plaintiff's attorneys in the tobacco litigation, it has been said, "First, and, with the benefit of hindsight, most obviously, they simply failed to grasp how intensely most jurors would react to damage claims by individuals who were aware of the risks associated with smoking and nonetheless chose to continue the activity over a long time period." The problem, of course, is that smokers have been exposed to warnings appearing directly on the tobacco packages. Those warnings indicated that use of the product may be hazardous. These warnings have been a part of the consumption of the product for over 30

21. Id.
22. See supra notes 14-21 and accompanying text.
25. Id.
26. Id. at 524.
27. Rabin, supra note 2, at 871.
29. Id.
Plaintiffs are confronted with the defense that they, themselves, were the cause of their own harm or that they contributed to that harm.

B. Actions Brought by States

When states began to bring their own actions, in order to seek recovery for costs of Medicare and Medicaid payments, they found themselves faced with many of the same problems that the individual claimants encountered. Because of the nature of the claim by the states, they may, in fact, be faced with the same defenses that the tobacco industry has been using against the individual smokers.

The actions by the states will appear to be in the nature of subrogation claims. The states will be suing for the damages that have been paid to care for injuries to the individual smoker. If the courts perceive those claims as similar to subrogation claims, then the states will be held to be subject to the same defenses mentioned above. It is a well known principle of subrogation, that the party seeking the remedy must "stand in the shoes" of the party who originally had the claim. The states may find that when they "stand in the shoes" of the smokers, tobacco is still not defective, there is no duty to warn, and that the issues of causation and comparative fault will defeat the claim.

To counter the defenses, the states could try a novel approach to the litigation based on older principles. The public authority has always enjoyed the right to seek a remedy where the public health, safety, morals, or convenience was threatened. This ac-

30. Id.

31. There have even been cases, of course, that challenged whether the long term smoking caused the cancer. Pritchard v. Liggett & Myers Tobacco Co., 295 F.2d 292, 296 (3d Cir. 1961).


33. Id.

34. For two essays which debate the issues in tobacco litigation see Susan Nial, Stop the Plunder, 3 THE BRANDEIS BRIEF 4 (1996); Barbara Caulfield, The End Does not Justify the Means, 3 THE BRANDEIS BRIEF 5 (1996).
tion can be brought as a claim for public nuisance. Under this theory, the state would not be seeking to redress the individual smokers' claims, but would be seeking a remedy for the injury to the state. In fact, examples of public nuisance actions could be instructive. Whereas the subrogation claims usually require that the plaintiff "stand in the shoes" of the real injured party, public nuisance claims may be brought even where the real "injured" parties would prefer no actions be brought. A traditional form of public nuisance case was an action by a public authority to remove a bawdy house. Similarly, funeral homes, in certain neighborhoods, were also declared to be a public nuisance. Although the owners and customers of such establishments may have welcomed their existence, the public authority would have the right to seek damages and ultimately remove the businesses.

In order to determine whether there was substantial harm caused by the nuisance, and thereby decide that a remedy was appropriate, the courts would have to perform something like a risk/utility analysis. One of the best examples of such a process can be found in the historical cases arising out of Ducktown, Tennessee. When the copper plants in that region were a cause of concern to individual local residents, the courts did not find the harm sufficient to allow an equitable remedy. When, however, the state of Georgia brought a claim, declaring that the whole state was at risk because of the pollution, the United States Supreme Court took a different view. The risk to the entire state of Georgia was greater than the utility of the industry.

A similar theory could be considered by the states in the to-

35. For examples of definitions of public nuisance, see Leonardson v. City of East Lansing, 896 F.2d 190, 191-92 n.1 (6th Cir. 1990); Stone Container Corp. v. Stapler, 83 So. 2d 283, 287 (Ala. 1955).
37. See infra notes 37-38 and accompanying text.
40. See supra note 38-39.
41. Madison v. Ducktown Sulphur, Copper & Iron Co., 83 S.W. 658 (Tenn. 1904).
42. Id.
43. Id.
45. Id.
bacco litigation. Although the risk of harm to an individual smoker, especially where that smoker knowingly encountered that risk, could be considered substantially less than the utility of the industry as a whole. Where, however, numerous states allege that substantial harm is being done throughout the nation, the risk of such massive disease could be held to outweigh the value of the tobacco industry.

III. TAX SUPPORTED COMPENSATION SCHEME

A. Possibilities

Professor LeBel has suggested that an alternative approach to solve some of the problems of remedying tobacco related injuries would be a compensation system supported by taxes. 46 The underlying hope with this plan is that it would reduce smoking while providing a fund to pay for the physical harm caused. 47 In short, LeBel would suggest that a broad tax and benefit scheme would remedy most of the tobacco related problems. 48 Although some benefits may be derived from such a program, it is questionable whether such a program could accomplish its own stated goals. Such a tax plan could be useful, but should not be seen as the sole remedy. It should, and could, be used in conjunction with tort remedies.

B. The Benefits

As society has become more complex, the tort system has suffered increasing difficulty in providing a remedy for injuries caused. When tort law was concerned with the problem of one wagon running over a poor, frightened donkey with fettered fore legs, the courts could fashion rules that worked. 49 All the parties could be brought to court, and the issues were clear. The modern possibility of multiple plaintiffs, multiple defendants,
difficult questions of causation, and hard questions of damages all combine to place tremendous stress on the system. In times when the tort system has failed, the possibility of a compensation system has been suggested. The most obvious example, of course, is Workers' Compensation. When the tort system was unable to handle the problems of work place injuries, compensation systems came into vogue. Although not a true tax and benefit scheme, such compensation systems provide many of the same benefits. They provide a fund to cover the cost of injuries, and, in addition, such systems act as a deterrent to undesirable conduct. Employers' insurance premiums are, in some ways, accident experience rated. When there are fewer injuries, the premiums go down.

A tobacco tax and benefit scheme could provide such benefits. It could be assumed that, in terms of simple economics, the price of tobacco has an impact on the ability of consumers to purchase. If the price was driven higher by taxes, then the consumption of that product would drop. The high taxes could then be directed to pay medical costs associated with the product. As taxes went higher, smoking would drop and, in the future, cause the amount of money available for medical costs to drop; a reduction in smoking should also cause a reduction in the medical costs themselves. The rates of taxes could be adjusted at regular inter-

50. See, e.g., Sindel v. Abbot Lab., 607 P.2d 924 (Cal. 1980); In re Agent Orange Product Liab. Litig., 996 F.2d 1425 (2d Cir. 1993).


53. For a good early discussion of the purposes of Workers' Compensation, see Ives v. South Buffalo Ry. Co., 201 N.Y. 271 (1911). Social Security is also a good example of a tax and benefit system. Seeking to accomplish a universal goal of providing security for the population, the whole population shares in the costs by way of a tax.

54. Workers' Compensation systems, however, do not stand as the sole protection against work place injuries. Federal and state safety regulations, private disability insurance, and even tort recovery against third party tortfeasors remain an important part of the legal structure that protects against such injuries. The treatment of alcoholic beverages by the law may ultimately be the best example to follow for tobacco products. State and federal regulations and state and federal taxation, together with the availability of tort recovery for many of the injuries associated with the use of alcohol, provide the type of remedies that should be considered for tobacco.

55. Obviously, substantial research and study should be conducted in this area. Mere speculation on the relationships of rate of taxes, rate of smoking, and medical costs should not be a substitute to valid studies when the nation considers a major
vals to insure that the consumption of tobacco continued to decline while sufficient money was collected to pay for remaining health care costs.

C. The Risks

Unfortunately, no one scheme will provide the ultimate answer for this problem. Even a casual observer would recognize all possible solutions have flaws. The possible flaw in the tobacco tax and benefit scheme is that it may not reduce smoking to a substantial degree, and that the tax may not provide any benefits.

Professor LeBel has to admit that the increased costs of tobacco may not cause substantially reduced consumption. The current price of tobacco is subject to numerous factors. Those factors include price supports, international sales, ability to buy international tobacco, and a sizeable profit. It would be possible for the tobacco industry to absorb a substantial tax before having to raise the price of the final product to the consumer. In addition, a product like tobacco may not behave in the market place in the same manner as other products. The fact that tobacco has an addictive nature, may encourage consumers to continue purchasing the product above a price that would have forced other products off the market.

Also, the goal of using tax resources to pay tobacco related health care costs may not be attainable. It would be hoped that

56. Workers’ Compensation, for example, remains a problem. States routinely review costs and impacts on business that are caused by the system. Social Security is also a major topic of conversation in government. The perceived conflict between a balanced budget and Social Security benefits is a matter of constant debate.

57. LeBel, supra note 9, at 639-41.

58. There appears to be continuing debate about whether tobacco is “addictive” or a “habit.” Regardless of which of these adjectives correctly describes the product, the impact on purchasing practices should be the same.

59. Interestingly enough, however, a high tax may drive off the young smoker. Peer pressure or appearances, as opposed to addiction, may be the motivating force for the young smoker. As such, the young smoker may approach the tobacco products in the same way that most consumers approach other non-necessary goods. If the product gets too expensive, the young smoker may opt to avoid tobacco and purchase other “young, socially driven” products. Such young smokers may switch from tobacco products to designer jeans. LeBel, supra note 9, at 640. If the high prices drove off the young smoker, the ultimate goal of smoking reduction would be reached. It would just take much longer than expected.
such tax money would be set aside to pay costs related to tobacco injuries. This could be accomplished by payments to private insurers or to federally funded health care systems.\textsuperscript{60} Unfortunately, the old issue of causation would inevitably arise. There is a continuing debate over the extent tobacco plays in specific injuries. Whether the issue arises when an individual plaintiff seeks recovery or an insurer tries to take advantage of a fund, the questions are the same.\textsuperscript{61} Substantial work would be required to determine what types of injuries would receive compensation from the new fund, and what types would be excluded. The fact that some injuries may be the result of tobacco and other environmental factors could make the issue impossible to resolve. In addition, there would be claims that those who voluntarily smoked should be excluded while those who were injured by "second hand" smoke could recover. Such a decision would remove the largest portion of the injuries from the avenue of recovery. There would be continuing debate over whether some injuries were being over compensated while others were being under compensated. The causation issue would merely move from tort law to tax law; it would not be solved.\textsuperscript{62}

An attempt could be made to dedicate the fund to health care generally. This would, of course, remove the causation issue. The tobacco tax could be shared among health care costs in any manner determined by the legislative body enacting the tax. However, this does not appear to be totally satisfactory.\textsuperscript{63} The further

\textsuperscript{60} Those federally funded health care systems could include Medicare, Medicaid, and Veteran’s Administration.

\textsuperscript{61} Trying to use a schedule of harms or some presumption of a claim would not resolve all problems. Those familiar with Black Lung injuries associated with the coal industry recognize that there is a continuing problem with identifying the cause of the harm and a sufficient severity of harm in order to allow recovery. The experience with this problem in Kentucky would be instructive. Kentucky has used a variety of legislated techniques to try to provide a remedy for the disease. Questions remain, however, as to what extent is there an actual disability and to what extent did the coal and not some other environmental factors cause the harm. See RONALD W. EADES, KENTUCKY WORKERS’ COMPENSATION 116-17 (3d ed. 1995). In Newberg v. Reynolds, 831 S.W.2d 170 (Ky. 1992), there was a claim by the employer that the impairment was due to cigarette smoking and not the coal dust.

\textsuperscript{62} Professor LeBel admits this problem when he refers to the issue of trying to determine who would be entitled to the compensation. LeBel, \textit{supra} note 9, at 642.

\textsuperscript{63} The idea of providing a general benefit to the public for the harm created by tobacco raises an interesting historical/jurisprudential problem. Although the problem is outside the scope of this discussion, it bears some notation. The traditional method
the money moves away from a single purpose, the greater the likelihood of it not being used for health care. In addition, the further the money moves away from its intended purpose, the less likely one is to get general public support for the tax.

A final problem may be one of responsibility. Law has taken a general drift away from personal and corporate responsibility for actions. The tax and benefit scheme could reduce smoking and provide a fund for health care. It would, however, place that cost and burden on the general public, while allowing the tobacco industry to avoid the ultimate responsibility. Tort law, for all
of its faults, places the cost directly on the person with primary responsibility. Although the defendant in a tort claim may be able to shift that cost in a products liability action by raising prices, the burden to find that relief is on the defendant. The tax and benefit scheme places the burden of finding relief on the government, and ultimately the tax payer.

IV. SOME SOLUTIONS

With the level of injury and death that is routinely associated with tobacco products, some solution must be found. To borrow liberally from the landmark case dealing with a toe in chewing tobacco, something must be done to ease the suffering. If something is not done, "it seems to us that somebody has been very careless." Even if the "moral" or "fair" answer were to place the cost of injuries upon the tobacco industry through the use of tort law, that answer is not currently accepted by the courts. The courts seem inclined to interpret products liability law in a manner that is sympathetic with the industry. This rejection of liability of the tobacco industry should not lead to a general rejection of attempts to apply traditional tort law to such cases. It should, instead, lead to greater creativity in the analysis of tobacco cases. The use of nuisance law is merely one example of such creativity. In addition, compensation programs should be studied and considered. Professor LeBel's tax and benefit scheme provides some interesting possibilities. If careful economic research in the possible problem areas suggests that the goals of such a program could be reached, then the tax scheme should be implemented. However, the tax should not be considered as the only program. An attempt to pass a tax or compensation system

institutional materials of our legal system not a single universally accepted theory of morality. Rather, we find a condition . . . refer[red] to as a moral pluralism." Paul A. LeBel, An Interested Response to a "Wholly Disinterested Assessment": LeBel on Summers on LeBel on Summers on . . . Er . . . Um . . . Oh, Yeah . . . Fuller, 85 MICH. L. REV. 1914, 1922 (1987) (referring to R. DWORKIN, LAW'S EMPIRE 213 (1986)). This is merely to suggest that injuries produce costs to society as a whole. A simple solution would be to burden those who generate the cost with the responsibility of, in the first instance, finding a remedy for those costs. Professor LeBel discusses this issue when he reviews the problem of "internalizing" the cost of injury by the tobacco company.

68. Pillars v. R. J. Reynolds Tobacco Co., 78 So. 365, 366 (Miss. 1918).
while prohibiting the growth and expansion of tort recovery should be avoided. LeBel's tax scheme should be merely an adjunct to the traditional tort system. 69

69. A compensation system and the tort system should not be considered as the only two remedies. State and federal officials should also consider regulation of the industry.
I. INTRODUCTION

The tobacco product control regulations adopted by the Food and Drug Administration (FDA) in 1996 are the inevitable product of decades of movement among Congress, courts and agency power. These movements may be compared to the tectonic plate shifts in geophysics, giant movements in the earth that inevitably produce earthquakes. The regulatory earthquake of FDA rules colliding with the power of tobacco companies could be portrayed as the collision between "merchants of death" protecting their right to sell fatally addictive products and the "national nanny" bureaucracy that is interfering with consumers' lifestyle choices. This paper posits that the FDA's rules will be sustained, will go into force and that the Supreme Court's ultimate decision on the rulemaking authority of the FDA will broaden the authority of other administrative agencies to self-expand their powers to define key jurisdictional terms.

The scope of this article is focused solely on legal definitions, and no more. Neurotransmitter dependence on cotinine molecules entering the brain is a topic for biomedical scientists; lung pathology and vascular damage is a topic for pathologists; and the nuances of advertising issues are to be debated by experts on the nuances of constitutional liberties. This paper focuses on the FDA's definitional authority over drugs and medical devices, and the likely judicial acceptance of its decision to regulate cigarettes as drug delivery devices.¹

¹. Adjunct Professor of Law, University of Cincinnati College of Law; J.D. 1974 University of Virginia, B.A. 1969 Boston College. The views expressed are those of the author alone.


³. Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products are Nicotine Delivery Devices under the Federal Food Drug and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. 44,619 (1996) (to be codified at 21 C.F.R. § 897) (hereinafter the citation will be to the Federal Register page without repetition).
No issue has ever galvanized food and drug lawyers in the same manner as the issue of tobacco. Lawyers on each side of this issue are ideologically polarized, with the public health advocates on one side and the freedom-to-sell libertarians on the other. The irony is that the sweeping power claimed by today's FDA was created, in an earlier public life, by lawyers who are tobacco's most astute defenders today. This paper concludes that the broad FDA definitional authority which is key to the FDA's legal analysis will be sustained in the courts and the tobacco "drug delivery" rules will be upheld.

1. THE LEGAL ISSUE: THE POWER TO DEFINE

The critical issue here is the administrative agency's power to define objects within a statutory scheme. To define, in this purely legal context, is to regulate. This is not Darwin or Audubon naming exotic fauna in a wilderness, nor is it Kant or Bentham philosophizing about terminology, nor is it a Biblical Creator endowing names upon man and woman. Defining by regulation does not mean creating or changing the object; an endangered species is no less a species, and a wetland is no less wet or dry, because of the government rule. Defining does not mean imposing a term upon the public consciousness; "drug delivery device" is not what one would colloquially call a cigarette, but the cardboard containers for pizza were not considered "food" until an appellate court agreed with the FDA's definition of them as food.4

The essence of the FDA's definitional regulation is the finding that cigarettes are medical devices because they deliver a drug, nicotine, to the brain.5 The FDA staked out this position with the longest and most comprehensive supporting brief in the history of the FDA, published in the Federal Register.6 The brief, stated as a jurisdictional explanation,7 gives the agency's comprehensive explication of its history and of the "device" definitional option,8 which it chose to exercise in its discretion-

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7. Id.
ary capacity as a regulatory agency. This definitional term was then immediately assailed by the tobacco industry’s counsel and their spokesmen. No ordinary definition could ever draw such a degree of attention. Many millions of dollars in legal fees are arrayed on tobacco’s side of this definitional struggle. Current and former members of the tobacco industry’s legal firms have published critiques of the rules, but the bulk of the industry rationale is recorded in the thousands of pages of the FDA administrative record.10

The reason this definitional conflict was inevitable is that the FDA has enjoyed an unprecedented accretion of broad definitional authority over decades of judicial deference. The term “deference” here means reluctance of courts to halt a rulemaking proceeding of a federal administrative agency. Deference is a frequent reality in the relationships between agencies and courts, but the FDA receives more than normal deference.11

Institutionally, the federal judiciary does not wish to make the fine distinctions in health science or regulation for which specialized health agencies were created. For as long as non-scientist lawyers have sat on the federal bench, there has been reluctance by judges to define the definitional scope of “drug” status once the medical and chemical experts of the FDA have spoken. The FDA does not always win definitional


10. FDA Docket 95N-0253 contains the 500,000 comments that were received. See John Henkel, How to Comment on Proposals and Submit Petitions, 30 FDA CONSUMER 6 (1996).


12. See, e.g., United States v. 484 Bags, More or Less, 423 F.2d 839 (5th Cir. 1970).

13. The same is true of medical devices, the category in which FDA has classified cigarettes; note that prior to the 1976 medical device amendments, courts deferred to the broad FDA definition of "drug" for a product that today would have been a medical device. United States v. An Article of Drug . . . Bacto-Unidisk . . ., 394 U.S. 784 (1969).
arguments, but its triumphs are so dominant in force and prestige that its defeats have been rare. The FDA is "presumed immune" from judicial reshuffling of the agency's priorities.

2. WHO AND WHY IS THE FDA?

The FDA is a 9,300-employee federal administrative agency with a budget of close to $1 billion and a jurisdictional reach unparalleled among other federal agencies, reaching over $1 trillion in products. The FDA exists for a well-defined public health purpose: to protect the public from harm arising out of exposure to products such as drugs. The 1,475 employees in the FDA's Center for Drug Evaluation and Research regulate pharmaceuticals, over the counter drugs and their ingredients; the 1,058 employees of the Center for Devices and Radiological Health regulate medical devices and diagnostic products.

The FDA's scientific renown among world health agencies has led many other nations to accept FDA judgments about the regulatory status of products. That is one of the factors leading tobacco firms to fight the FDA so vigorously. The FDA's statutory authorities include the Federal Food Drug and Cosmetic Act and more than a dozen other statutes. For purposes of this paper, we will focus on the Food Drug and Cosmetic Act's human drug authorities of the FDA, but the reader should recognize that the agency's multiple functions in other areas have contributed legal and policy precedents which also help to illuminate the cigarette decision.

14. See, e.g., Northwest Tissue Ctr. v. Shalala, 1 F.3d 522 (7th Cir. 1993); Scott v. FDA, 728 F.2d 322 (6th Cir. 1984); Almay, Inc. v. Califano, 569 F.2d 674 (D.C. Cir. 1977).
17. Id.
18. Id. at 1.
19. Id. at 19.
20. Id.
22. Many of these statutes are reprinted in JAMES T. O'REILLY, 2 FOOD AND DRUG ADMINISTRATION app. at A (2d ed. 1993).
3. WHAT DID THE FDA CONCLUDE IN ITS RULEMAKING?

In its 1996 final rules, the FDA defined cigarettes as "drug delivery devices" subject to regulation by the FDA. This is the central regulatory decision of this massive rulemaking, and the final rule was accompanied by an unusually lengthy "Jurisdictional Determination." The combined 886-page publication that accompanied the two page final rule has been very controversial. The cigarettes, as medical devices, deliver nicotine by inhalation, and the nicotine has drug effects; the FDA concluded that the cigarette is a combination drug and delivery device. The FDA received what was perhaps the largest number of rulemaking comments in the history of federal administrative law.

Nicotine has long been recognized as a drug, and is listed as such in the officially recognized lists of drugs. The FDA opted to treat the cigarette, a wrapped tube of tobacco leaves, as a combination device, by the inhalation of which the nicotine drug could reach the brain. Alternative options were considered by the FDA, but rejected.

The FDA final rulemaking process concluded with final regulations published on August 28, 1996 and the issues were immediately litigated. The litigation is expected to reach the Supreme Court in 1998 or 1999.

II. FDA EMPOWERMENT THROUGH ACCRETION OF DIFFERENCE

28. 500,000 comments were received, see Henkel, supra note 10.
31. Id.
1. HISTORY OF THE FDA’S JURISDICTIONAL POWER

The governmental power to define health-regulated products is older than the FDA itself. Regulation of animal feed content was a politically necessary addition to the laissez-faire economies of the agricultural states in the late 19th century when cheating on feed and seeds could cause a serious hazard and an economic blow to the farmers. Agricultural fraud cases led to the creation of state chemists who had the authority to standardize feed materials. The Federal Agriculture Department’s Bureau of Chemistry was created in 1862, and the first food and drug law was recommended in 1880. By the turn of the last century, public outcry over canned meats led to the creation of a food regulatory function for the Bureaus of Chemistry in states, and ultimately to the Pure Food and Drugs Act of 1906.

Congress passed the 1912 Sherley Amendment to fix the Supreme Court’s earliest finding of a definitional lack of authority for the FDA. The amendment overcame the Supreme Court’s United States v. Johnson precedent that allowed falsity in drug claims so long as ingredients were truthfully stated. Later laws in 1930 allowed the FDA to define certain quality standards for foods.

The definitional role of the FDA exists as a surrogate for the inability of drug consumers to define and characterize their active drug ingredients. The FDA makes technical decisions that the public is not capable of making, such as the definition of the proper set of pharmaceutical additives that can be used in formulating an AIDS vaccine. While some courts gently implore the FDA to be more specific in its categorization and definition of such findings as “manageable risks,” courts do not venture their own definitions.

37. 221 U.S. 488 (1911).
38. See the historical review in James T. O'Reilly, 1 Food and Drug Administration § 3.03 (2d ed. 1993).
2. THE "CONSTITUTION" PRINCIPLE AT THE FDA

The eminent drug law expert Peter Hutt, now a senior partner of the Tobacco Institute's principal law firm, authored the preeminent statement of FDA jurisdiction in 1973:

Congress obviously knew in 1938 that it could not foresee future developments, and that it must proceed primarily by establishing general principles, permitting implementation within broad parameters, if regulation in this important area was to be effective. In this respect, the Act must be regarded as a constitution. It establishes a set of fundamental objectives . . . . The mission of the Food and Drug Administration is to implement those objectives through the most effective and efficient controls that can be devised.\(^{42}\)

If the statute is a constitution then the FDA can reach anywhere and regulate anything not proscribed by Congress. It follows from Hutt's constitution theory that the FDA can assume "jurisdiction to determine its jurisdiction." Critics might claim that this principle is administrative law's equivalent of a "perpetual motion machine": the laws of physics cannot tolerate an unlimited power source, yet here the courts can be tolerant. Only Congress can rein in such a powerful agency, since the courts have declined to control its jurisdictional adventures.

3. THE SUPREME COURT AWARDS THE FDA GREAT DEFERENCE

In one day during the Supreme Court's 1973 Term, four decisions were issued that collectively reached the high water mark of deference to definitional choices by an agency.\(^ {43}\) The FDA swept to victory in all four cases and obtained from the Supreme Court the power to determine its crucial jurisdictional term, "new drug,"\(^ {44}\) virtually without court interference.

The Supreme Court held that the definitional processes of the

\(^{42}\) Peter Hutt, Philosophy of Regulation Under the Federal Food Drug & Cosmetic Act, 28 FOOD DRUG COSM. L.J. 177, 178-79 (1973) (emphasis added).


Food Drug & Cosmetic Act "strongly suggest that Congress desired that the administrative agency make [the] determination" of definitional scope of the key operating terms of its statute.\textsuperscript{45} For the FDA, the ability to make determinations of what drugs are "new" drugs is the keystone of the regulatory system for pharmaceutical products.\textsuperscript{46} In the quartet of cases, challengers protested to the courts about the FDA's definitional treatment of their generic drugs when compared to the "pioneer" drugs that held approved new drug applications. The Supreme Court responded: "The heart of the new [drug] procedures designed by Congress is the grant of primary jurisdiction to FDA, the expert agency it created."\textsuperscript{47} FDA Chief Counsel, Peter Hutt observed while at the FDA that, after the 1973 decisions, any appeal to courts from an FDA decision regarding new drug status would be "of a very limited nature."\textsuperscript{48} The FDA had won a landmark concession of its extraordinary scope of self-determined jurisdictional powers.

From this font of authority, amply expressed by the FDA in 1996 by hundreds of Federal Register pages on the tobacco issue,\textsuperscript{49} flowed the deference that will probably sustain the FDA's jurisdictional and definitional choices about cigarettes.

\textbf{4. IMPLEMENTING THE POST-1973 DEFERENTIAL DIRECTION}

After the 1973 quartet of Supreme Court new drug decisions, the federal case law has overwhelmingly supported the FDA,\textsuperscript{50} including a trio of Supreme Court decisions approving the FDA's view of drug use in lethal injection executions,\textsuperscript{51} accepting the

\begin{itemize}
  \item \textsuperscript{45} \textit{Bentex Pharmaceuticals, Inc.}, 412 U.S. at 652.
  \item \textsuperscript{46} For the history of the term, see \textit{JAMES T. O'Reilly, 1 FOOD AND DRUG ADMINISTRATION} § 13.05 (2d ed. 1993).
  \item \textsuperscript{47} \textit{Hynson, Westcott & Dunning, Inc.}, 412 U.S. at 627.
  \item \textsuperscript{48} Hutt, \textit{supra} note 42 at 665.
  \item \textsuperscript{50} When the Supreme Court revisited the related issues in 1979 and 1983, the outcome was the same deference to FDA definitions of new drugs. \textit{See} United States v. Rutherford, 442 U.S. 544 (1979) and United States v. Generix Drug Corp., 460 U.S. 453 (1983). Lower courts consistently exhibit this deference. \textit{E.g.}, Henley v. FDA, 77 F.3d 616, 620-22 (2d Cir. 1996).
  \item \textsuperscript{51} \textit{Heckler v. Chaney}, 470 U.S. 821 (1985).
\end{itemize}
FDA's view of what generic drugs are considered "new," and upholding the FDA's ability to decide what drugs are safe enough to be sold in commerce to terminally ill patients. The lower courts have read the message to defer to the FDA's definitional decisions, and their subsequent cases increased the degree of deference to FDA definitions. Thus, as the Court of Appeals for the District of Columbia Circuit has held, it is not necessary for the FDA to have express statutory authority for regulations; it is enough that there be "compatibility . . . with the whole statutory scheme."

A nuance of the court/FDA co-defining scope developed when the Second Circuit explored "general recognition" of drugs in the 1980 Premo decision. While a court could not enter the FDA's realm of safety and efficacy decisions, the court said it would have concurrent jurisdiction, with the FDA in the lead role, deciding which drugs are "generally recognized" by experts to be safe and effective. Note, however, that this concurrent or co-defining role was premised on the ability of a court to hear expert witness testimony about the specific drug. The use of trial type hearings to find which drugs are "generally recognized . . . by experts" is a fact-gathering exercise, in which the "facts" include expert pharmacologists' opinions. The 1996 FDA cigarette determinations are those of "drug" or "device" status, made upon a voluminous rulemaking record, for which no live witness testimony is likely to be essential to the decision. So the tobacco decision could have been forecast in 1973 and after, as a predictable jurisprudential progression from the Supreme Court's deference to FDA.

52. Generix Drug, 460 U.S. at 453.
53. Rutherford, 442 U.S. at 544.
56. Premo Pharmaceutical Labs. v. United States, 629 F.2d 795, 803 (2d Cir. 1980).
57. The statutory term "generally recognized" is explored in detail in JAMES T. O'REILLY, 1 FOOD AND DRUG ADMINISTRATION § 13.05 (2d ed. 1993 & Supp. 1996).
58. Premo Pharmaceutical Labs., 629 F.2d at 799.
5. DEFERENCE IN ENFORCEMENT RUNS ONE WAY

Definitional empowerment of the FDA in enforcement cases has been a significant trend favoring the FDA over many years. This has complemented the separate line of cases disputing product status in the non-enforcement context, discussed in the preceding section. The FDA protects public health interests, and courts are supportive of that mission in the enforcement context. An ordinary court in an ordinary administrative rulemaking case has incentives to limit the reach of agency powers. However, appellate courts have held that, in FDA enforcement cases, the interpretive power of the court may be used to define coverage more stringently than the FDA has done, but not more loosely, because of the public health nature of the FDA enforcement mission.

This judicial self-restraint, a one-way toughening of the authority, is relevant to the judicial attitude toward tobacco regulatory controls. For example, a shipment of imported coffee when compared to an FDA sanitation standard showed some contamination deficiencies, and the FDA seized the coffee. The Fifth Circuit ruled in the seizure case that when a court reviews FDA interpretations of public health statutes, the judge could read the law more tightly (and thus protect the public more), but that the converse is not true: the trial court could not loosen the reins of regulation by redefining FDA norms. That Fifth Circuit view suggested that the court could go deeper into the control of contaminants, but that trial judges would not be free to loosen the public health protective standards. If the FDA said 100 maggots in a coffee bag would be enough to define the bag as “adulterated food,” then the court could tighten the definition to condemn a bag with 50, but could not loosen the regulation and allow up to 200 maggots. The analogy can be drawn from coffee to cigarettes, because FDA is given broad definitional deference in defining contamination in enforcement and in defining terms in rulemaking. A court that attempts to un-define the FDA's “medical device” status choices would be working against the one-way principle of the Fifth Circuit decision.

60. United States v. 484 Bags, More or Less, 423 F.2d 839, 842 (5th Cir. 1970).
61. Id.
6. THE DRUG AND DEVICE DEFINITIONS

The FDA has declared cigarettes to be medical devices for the delivery of the drug nicotine.\(^1\) The Food Drug & Cosmetic Act\(^2\) shows a conscious congressional choice to establish parallel language for both the "drug" and "medical device" definitions.\(^3\) Each looks in the alternative at one of two tests, examining first the claims made for the product and then the product's effects on a structure or function of the body.\(^4\) The parallel definitions are differentiated by the type of action the product has on the body — those that break down biochemically are drugs, while those without this metabolizing effect are medical devices.\(^5\) Conscious parallelism suggests the FDA will enjoy in the tobacco case the deferential weight of cases that have involved either drug or device definitional conflicts.

Congress created the medical device definition in 1938\(^6\) to reach a category of health products that were not "drugs" and were almost a catch-all category, intending that by so defining the class, some non-chemical "health" products could be regulated more adequately by the FDA and prosecutions could be brought against fraudulent marketers of such products.\(^7\) The actual set of "medical devices" today was selected by an advisory committee in the mid-1970s. After adoption of 1976 legislation expanding medical device power, that advisory committee report became the basis for other committee classifications from which the FDA wrote its medical device rules.\(^8\) In light of tobacco lobbyists' protests that only Congress could declare medical device status of cigarettes, it is significant that Congress regulated virtually no devices by name in its 1976 enactment.\(^9\) Congress was loose and deferential in empowering the FDA with the clas-

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63. 21 U.S.C. § 321(g), (h) (1994).
64. CHARLES DUNN, FOOD DRUG & COSMETIC ACT 26, 287 (1938).
66. This is found in 21 U.S.C. § 321(h) and was clarified in the 1976 medical device amendments, Pub. L. No. 94-295, 90 Stat. 539 (1976).
68. CHARLES DUNN, FOOD DRUG & COSMETIC ACT, 26, 287, 477 (1938).
69. See JAMES T. O'REILLY, 1 FOOD AND DRUG ADMINISTRATION § 18.04 (2d ed. 1993 & Supp. 1996) (the historical background of the Cooper Committee report and the subsequent advisory committees).
70. Id.
sification of various products.

The 1938 definitional decision, preserved in today's statute,\(^7\) keeps drugs and devices on a parallel course of regulation. Under that parallel scheme, as applied to the 1996 tobacco rules, nicotine is the metabolized drug and cigarettes are the device, the physical object which aids in nicotine's delivery to the brain.\(^7\) The FDA's extensive elaboration of the "drug delivery device" categorization of cigarettes in 1996 makes a very credible case that the drug, nicotine, is delivered by the device, the cigarette.\(^7\)

The medical device statutory definition is satisfied by showing either that the product affects the body's "structure or function" or that the claims made for it represented the product to have a therapeutic, curative or preventive effect.\(^7\) Much of the tobacco industry rebuttal submission asserts that there was no intention of today's marketers to make health claims.\(^7\) Though the courts in the older *Fairfax Cigarettes* case and one other\(^7\) held that claims could make a cigarette into a "drug," the fact that today's cigarette marketers are disavowing any claims of health benefit does not diminish their "device" status.\(^7\) The FDA correctly observed that the intended use of a device is not solely determined by promotional claims.\(^7\) The focus of the FDA's argument is not on claims but on the co-equal alternative, effects on body function, in the statutory standard.\(^7\) If there is an actual effect on body function from the cigarette's delivery of the nicotine, that is enough for device status of the cigarette.\(^8\) The FDA could regulate under either theory without the need for both to apply.

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74. 21 U.S.C. § 321(h) is stated in the alternative.
75. See, e.g., Comments of the smokeless tobacco industry in FDA Docket 95N-0253, 61 Fed. Reg. 44,488 (1996). The industry comments are so large that the FDA will, upon request, deliver them in a computer CD-ROM disk rather than printing out over 3,000 pages of the comments.
Combining the use of this “function and effect” norm under the statute with the broad definitional deference that the courts accord the FDA as discussed above, the FDA’s 1996 tobacco products regulatory statement\(^{61}\) creates a powerful basis for courts to uphold FDA control of the cigarette and related products as medical devices.

### III. CONGRESS AND DEFERENCE TO THE FDA

#### 1. COULD CONGRESS ACT AGAINST TOBACCO?

Virtually every participant in the legal debate recognizes that under its commerce powers\(^{82}\) Congress could adopt a statute that would expressly regulate tobacco as a drug delivery device. Congress knows how to act specifically about one particular substance in amending the Food Drug & Cosmetic Act.\(^{83}\) When enough votes amass to overcome the lobbying force of the tobacco industry, Congress can confirm or codify the FDA’s view of tobacco.

Alternatively, Congress could change the Food Drug & Cosmetic Act to declare cigarettes a drug delivery device by law or the statute could be changed to exclude tobacco, as the tobacco lobby has successfully done in many other statutes.\(^{84}\) A third alternative is that Congress could remain silent, as it has. Nonetheless, there is no doubt that Congress could act.

#### 2. HOW COULD THE FDA’S RULE BE REVERSED BY CONGRESS?

The FDA could be stopped by Congress from regulating cigarettes. Congress has a number of options to overcome the FDA’s decision to control cigarettes, if a consensus among elected Senators and Representatives would provide the political will to preserve cigarettes’ pre-1996 unregulated status.

The Congress could adopt legislation to directly amend the Food Drug & Cosmetic Act to expressly exclude cigarettes or to draw a boundary that forbids cigarette regulation as medical

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82. U.S. CONST. art. I, § 8, cl. 3.
This could be a simple statutory change like the cosmetic definition's simple exclusion of "soap" or it could be an extensive amendment resulting from the lengthy negotiation of special terms in alternative statutory language.

Congress could use the newly enacted Congressional Review Act to adopt a "joint resolution of disapproval" that both removes the final tobacco rule and forbids the FDA from adopting a similar rule until Congress provides new statutory authority. This is an extremely potent legislative review weapon, but the constitutional command for bicameral adoption and presentment requires that the President and majorities in both houses concur in the removal of such authority. In the tobacco rulemaking, the President made the ultimate choice about FDA cigarette regulatory decision, since the announcements of the FDA rules took place at the White House with President Clinton as principal speaker. One could predict that his veto would be used to preserve such a high profile executive branch rule against any joint resolution of disapproval and the likely threat of a veto will require the tobacco advocates to secure a two-thirds majority in each house of Congress for the override.

The Congressional Review Act provides that if Congress voted to reject an FDA tobacco rule and the joint resolution of disapproval survived a possible veto, then the FDA could not adopt a substitute rule on tobacco until new legislative authority was granted. Thus, Congress could veto the tobacco rule and

87. See, e.g., saccharin's closely negotiated carcinogen warning provisions that permitted the product to remain on the market. 21 U.S.C. § 343(o) (1994).
89. The adoption of such a joint resolution eliminates the FDA's ability to adopt a rule on the same subject until Congress has passed new legislative authority for the FDA. 5 U.S.C. § 801(b)(2) (1996).
90. U.S. CONST. art. I, § 7, cl. 3.
93. 5 U.S.C. § 801(b)(2) (1996). Adopting a joint resolution eliminates the FDA's ability to adopt a rule on the same subject until Congress has passed new legislative
the FDA would be barred from acting against tobacco products.\textsuperscript{94} The 1996 legislation excludes courts from considering the failure to overturn a rule after a Congressional Review Act legislative veto fails to win adoption,\textsuperscript{95} but prior case law has upheld the FDA’s authority where Congress was on notice of a substantive rule and failed to change it by legislation.\textsuperscript{96}

Congress could also remove appropriations authority for cigarette controls by the FDA; this use of the riders on appropriations bills had been commonplace before the 1996 adoption of the “line item veto” authority of the President.\textsuperscript{97} Eliminating the authority to spend money enforcing the rule does not strike it from the Code of Federal Regulations, however, and this is an imperfect solution at best.

3. WILL CONGRESS OVERRIDE THE FDA?

The FDA should not wait for Congress to decide the jurisdictional status of cigarettes. The political reality of legislating in a highly complex and controversial field is that Congress cannot make health decisions on specific issues, except in rare cases. So federal administrative agencies exist to micro-determine the sub-issues in fields that Congress has macro-determined will need regulatory control of some kind. The problems of limited time, limited knowledge and complexity of subject matter all militate against any expectation that Congress will, by itself, create a detailed regulatory system for tobacco. It is possible that Congress could accept a compromise, but not in time before the 1996 rules go into effect.

In the 1996 cigarette regulations, the FDA is micro-defining the “drug delivery device” term under a broad delegation of authority to regulate medical devices, which the FDA considers to be justified.\textsuperscript{98} It is reasonable to expect that no legislative override of the FDA rule will occur by either a joint resolution of disapproval or new substantive legislation.

\begin{itemize}
\item \textsuperscript{94} Id.
\item \textsuperscript{95} 5 U.S.C. § 801(g) (1996).
\item \textsuperscript{96} United States v. Tuente Livestock, 888 F. Supp. 1416, 1423-24 (S.D. Ohio 1995).
\item \textsuperscript{97} Line item veto authority is found in 2 U.S.C. § 681 (1996).
\item \textsuperscript{98} 61 Fed. Reg. 45,219 (1996).
\end{itemize}
4. DOES LEGISLATORS' INACTIVITY PRECLUDE REGULATORS' ACTION?

Congress has the power to regulate expressly, but it does not follow that the desuetude of Congress means the FDA cannot act. Many years after the congressional enactments, the FDA has found that its 'constitution' is broad enough for its new assertion of dormant statutory authorities.99 Gridlock in Congress does not deprive an agency of jurisdiction, unless Congress has spoken to the issue by removing that dormant jurisdiction. Congress has not so spoken.

5. WAS THE DELEGATION OF POWER FROM CONGRESS TOO BROAD?

The Congress has not given the FDA any explicit power to regulate cigarettes. The FDA found the implicit authority in its statute.100 Critics of the jurisdictional decision could assert that Congress gave too broad a delegation of authority to the FDA, and this could be argued to be an excessive, standardless delegation of legislative power to an executive branch agency, and therefore a violation of the constitutional separation of powers.101

The nondelegation line of cases from the 1930s102 have not been actively followed in constitutional case law in recent years.103 The 1930's decisions in which excessive delegation of legislative power was invalidated had concerned economic regulation by "New Deal" agencies.104 By contrast, the cigarette rulemaking is a health regulatory choice made by an agency and has consequential but not inherent economic effects.105

99. Hutt, supra note 42.
103. See PETER STRAUSS ET AL., ADMINISTRATIVE LAW CASES AND COMMENTS 82 (9th ed. 1995).
104. The question in Schechter arose from administrative control of poultry sale standards, while regulation of oil production was debated in the case that became Panama Oil.
105. The FDA did not regulate the industry's pricing but did restrain its advertis-
Furthermore, "excessive delegation" suggests desuetude and apathy on the part of a lax Congress in defining terms. Since the drug and device definitions have been evolving throughout the 1906, 1938, 1962, 1988, 1990 and 1994 statutory enactments, there is an ample set of foundation materials from which the particularity of the delegation to the FDA has been adequately established. The Congress did not simply give away all possible authority and let the FDA decide how to use that authority; only an open-ended, standardless abdication of power would warrant constitutional challenges to the "device" definition.

Even if non-delegation concepts were still ascendant, they would probably not apply. Since the term "drug" has been interpreted through ample bodies of precedent, modified by Congress and clarified by extensive rulemaking and guidance documents, it is extremely unlikely that a current federal court would invalidate the "drug" portion of the Food Drug & Cosmetic Act as applied to nicotine, for lack of adequate delegation of standards from which the regulator and court could understand the intentions of the Congress. A similar result for the parallel definition of "devices" is probable.

IV. ADMINISTRATIVE ISSUES

1. DOES PAST INACTIVITY BY THE FDA PRECLUDE THE NEW CONSTRUCTION?

Changes in construction of a statute are relatively frequent occurrences; judicial interference is seldom granted. Case law overwhelmingly allows agencies to find belated authority in statutes that the agency had not previously asserted. Waiver of a
dormant statutory power is not assumed. Estoppel against agencies from reliance upon a past policy is rarely accepted by the courts, and the case for estoppel seems even weaker in rulemaking settings.

FDA inconsistency about the definitional status of cigarettes is an argument made by tobacco’s defenders: having not regulated cigarettes in the past, the FDA should not regulate today. But the FDA’s change in views is more a product of evolution of the scientific understanding of tobacco addiction, rather than illegal evasiveness by an untrustworthy set of devious bureaucrats. Widespread scientific acceptance of the addictive properties of cigarettes has been confirmed by the in-court admission by a large cigarette manufacturer that the product is in fact addictive. The FDA’s ability to change its view and regulate where it has not regulated before is established in the case law of the FDA. To rule otherwise would have frozen the FDA in a time warp according to the knowledge of 1906 or 1938, until and unless special legislation added each new drug to the agency’s list of regulable entities.

2. IS THIS BROAD DEFERENCE AVAILABLE TO ALL AGENCIES?

Deference to agency rulemaking that interprets ambiguous terms is well accepted. The deference principle has its limitations, but the FDA tends to fare much better than other agencies in deferential acceptance of its rulemaking authority. Judges

110. See, e.g., Office of Personnel Management v. Richmond, 496 U.S. 414, 434 (1990) ("[t]his Court has never upheld an assertion of estoppel against the Government by a claimant seeking public funds.").


112. See supra notes 9, 27, 74.

113. The FDA’s prior decision not to regulate cigarettes had been upheld. Action on Smoking and Health v. Harris, 655 F.2d 236 (D.C. Cir. 1980).


117. National Confectioners Ass’n v. Califano, 569 F.2d 690, 694 (D.C. Cir. 1978) (holding that FDA can find in its statutes authority not previously asserted).


119. See generally JAMES T. O’REILLY, 1 FOOD & DRUG ADMINISTRATION § 4.02 (2d
are not willing to become health risk assessors. Reluctance to second-guess FDA health related decisions has been a historic pattern of behavior among most federal judges. Indeed, since FDA cases are litigated to conclusion so infrequently, few federal judges may experience more than one FDA case per decade of service.

The FDA's unique position has not been matched by other safety agencies. The product regulatory controls of the Consumer Product Safety Commission, Environmental Protection Agency and National Highway Traffic Safety Administration have not fared as well in the courts.

3. COULD LIMITING THE FDA HERE AVOID FUTURE ARBITRARINESS?

The Congress gave the FDA a delegation of broad authority; as the Supreme Court observed, the definitional portions of the Act "strongly suggest that Congress desired that the administrative agency make [the] determination" of product status. In theory, if the FDA exceeds the limits of its jurisdiction, and then if the courts do not rein in the agency's reach for new authority, the potential for arbitrariness exists in subsequent FDA rulemaking projects. "Quis custodiet custodies?" or "who guards the guardians," as the Romans would ask, becomes a policy problem. The combination of delegation plus deference could result in this potent agency growing even more powerful.

If the FDA can regulate this product, where will regulators stop? The scenario matches the tobacco industry's policy arguments against judicial deference to the FDA. There would be a serious risk to the political legitimacy of our federal administrative agency system if an agency were given unlimited discretion

120. See, e.g., Abbott Labs. v. Young, 920 F.2d 984 (D.C. Cir. 1990).
121. In the decade preceding the 1973 Supreme Court decisions, for example, the FDA won by default or consent orders 99.7% of district court cases under its most commonly used authority, product seizure. Hutt, supra note 42 at 186.
and no checks and balances existed.

The political critique is valid in part: when left to its own choices, the executive branch may choose to take advantage of the lack of will by Congress and the lack of comfort by the courts, and usurp too much regulatory control power by exceeding reasonable regulatory boundaries. Power abhors a vacuum. Congress has lacked the will to deal with the huge death rate of cigarette smokers; an agency has taken on the role of public health crusader; but the courts are uncomfortable with the suggestion that they should intervene to reverse the FDA’s science choices. The strongest advocates for cigarettes would assert that future regulatory controls could run rampant over individual liberties, unless the FDA is forced to stop its war against citizens who choose to use cigarettes.

The assertions that the sky of individual liberties will fall if cigarettes are controlled tend to overlook the pragmatic reality of balancing powers. The FDA has chosen a politically tenable and legally strong posture in its published rule; if the rule lacked any political support, the executive branch’s only elected official would not have championed its cause so publicly as did the President. Furthermore, if the FDA failed to have a legally strong position, the Supreme Court or a lower court would find a gap in the jurisdictional claim and would invalidate the rule, leaving no federal health agency able to impact the death and addiction concerns. So the likely FDA response to such a charge would probably be that adequate checks against arbitrariness exist and the FDA is seeking deference, not invincibility, for its rulemaking powers.

4. MUST THE FDA GO ALL THE WAY TO A BAN?

Once the FDA has imposed its jurisdictional coverage of cigarettes by means of definitional controls, must the agency also proceed to the next step and totally ban cigarettes? No. The medical device categorization allows a device that has serious health risks to remain on the market with labeling and marketing controls. Medical device bans are few, device controls,

127. The case for a ban would be greater if the FDA had classified cigarettes as "new drugs," 21 U.S.C. § 321 (1994), for the required proof of safety could not be
including marketing constraints, are more likely choices and the FDA has taken stringent control action. The FDA is not required to take any particular enforcement action against any regulated products, as the Supreme Court confirmed in the Chaney case when it upheld the FDA's refusal to prosecute a drug product's unapproved uses. The FDA's discretion in the medical devices field was implicitly confirmed in the 1996 Lohr decision, which interpreted the statutory authority of the FDA over medical device standard-setting.

Because the FDA gave full consideration to banning cigarettes and chose its course of action with exceedingly fine detail, the courts are very likely to defer to its choice among alternative definitions of "medical device." If a third party challenger wanted the FDA to impose greater controls on tobacco products, that party would presumably either assert that FDA action had been "unreasonably delayed" or that the FDA's decision was arbitrary and capricious. Such claims fail in most cases, because courts allow discretionary choices to be made by administrative enforcers. That type of challenge to non-regulatory choices amounts to a form of mandamus, in its assertion that the agency ignored a legal duty to take action. The prerequisite to such a mandamus, "a duty owed to the plaintiff," i.e. the statutory duty to ban cigarettes, is not found anywhere in the assembled in light of the overwhelming record against tobacco.

128. Though the FDA has statutory authority to ban devices, this has been rarely employed. 21 U.S.C. § 360(f) (1994).

129. Heckler v. Chaney, 470 U.S. 821 (1985) (holding that the FDA cannot be ordered by a court to bring enforcement of the "new drug" definition against drugs that are being used for a purpose not recognized among the safe and effective uses approved on its label).


131. See supra note 6 and accompanying text. The vast length of the rulemaking publication and the huge administrative record belies claims of arbitrary haste on the part of the FDA.


135. The agency's statutory duty to act or regulate in a certain way is a prerequisite to a court order compelling the act. 28 U.S.C. § 1361 (1994); Howard Brill, The Citizen's Relief Against Inactive Federal Officials, 16 AKRON L. REV. 339 (1983).

federal statutes.

The Administrative Procedure Act's (APA) requirement that a challenger show that the FDA "unlawfully withheld or unreasonably delayed" a new drug decision or other ban is a high barrier.\textsuperscript{137} Absent more congressional action, FDA has acted, there is no FDA action "unlawfully withheld," especially in light of \textit{Chaney},\textsuperscript{138} and there is no deadline against which to compare delays. Apart from the APA, there are no statutory rights sufficient to win for a challenger a court order that the FDA must ban cigarettes. Here, the FDA painstakingly took regulatory action but did not go as far as some tobacco opponents preferred. The likelihood of success for such a challenge to the less-than-ban strategy is very small.

V. POLICY CHOICES AND LESSONS

1. \textbf{THE POLICY CHOICE: SHOULD FDA REGULATE, SINCE IT CAN DO SO?}

One's policy preferences play a role in how one answers this question. The preceding sections affirm FDA power to regulate; now the question is whether FDA should do so. (Other articles in this issue address the advertising issues regarding how to regulate.) The FDA is a public health agency headed by a physician; tobacco addiction is a proven killer; and no other product approaches its consequences as a leading cause of death. Other federal agencies that might like to regulate have been systematically excluded by effective lobbying from the tobacco industry. The use of medical device authority for control of the death rate is an available option, as discussed above.

The agency that invokes a well-reasoned and discretionary power, in contrast to a mere ministerial use of a mandatory power, deserves support for its courageous choice. Using its best and brightest experts, the FDA has built an impressive administrative record supporting its rulemaking. The author concludes that the FDA should do what it lawfully can do to prevent tobacco deaths, and that this rule should be affirmed on appeal.


2. WHAT DOES THE TOBACCO RULEMAKING TEACH ADMINISTRATIVE LAWYERS?

There are three lessons that future scholars of administrative law are likely to find in the cigarette rulemaking.

First, the resource demands of a major challenge to a major rule can be enormous. The massively-endowed opponents in the tobacco industry, capable of fielding a virtual all-star team of former agency lawyers, are intimidating foes. They can pose an agency head's worst nightmare. To win against the deepest "bench" of any adversarial team in the history of FDA law will be a daunting task for the FDA and its Justice Department colleagues. The contest is not over until the Supreme Court upholds or invalidates the final rules, or denies certiorari after a convincing Fourth Circuit decision in the pending North Carolina federal court litigation. Even then, observers expect peripheral issues to be litigated in enforcement proceedings, but the main event is likely to be a Supreme Court split decision in 1998 or 1999.

Second, no real prioritization of all the public health missions in product safety can occur without addressing the leading product-related cause of death: cigarettes. FDA managers as health regulators simply had to attack the tobacco-related death rate if they were to legitimately claim to be defending the health of the public. There was no way to immunize from regulation this one proven cause of millions of deaths, while blithely pursuing other regulations to govern smaller risks from each mere part per million of minor exposures to a food additive or pharmaceutical impurity.

Third — and this finding may be presumptuous until the Supreme Court speaks to tobacco in 1998 or 1999 — a well-reasoned administrative rulemaking can take advantage of accretions of past power, to utilize definitions in order to reach places "where legislators feared to tread." The courts' and the Congress' willingness to let the FDA accrete jurisdiction was neither right nor wrong in itself. Separation of powers is a concept which the branches of government could bend to a particular case of need. Since the Congress and courts have created an atmosphere of great deference toward FDA definitions, a prudent agency manager will fill the gaps with regulatory controls on the topmost priority targets. Conversely, an agency on a short leash with a poor track record in court dares not reach beyond explicit dele-
gations. In the climate of long-building deference, the tobacco rulemaking is a landmark and not an aberration.

VI. EPILOGUE

As this article went to press, the FDA won the contested issue of jurisdiction in the district court on April 25, 1997. In Coyne Beahn, Inc., v. FDA,\textsuperscript{139} the court rejected tobacco industry claims that congressional approval is a prerequisite to agency adoption of regulations. The court applied deferential norms to the FDA's claim of jurisdiction over non-therapeutic medical devices such as cigarettes.\textsuperscript{140} Medical device definitions, construed after extensive examination of the issues, adequately capture the type of product which delivers the drug nicotine.\textsuperscript{141} The court was hesitant to agree that the FDA has "unfettered discretion to apply the regulatory authority of its choice to combination products" but deferred to the agency's choice by applying\textit{Chevron} principles discussed earlier in this article.\textsuperscript{142} The FDA did not prevail on a lesser issue, the applicability of the restricted device authority to control advertising, but by using that statutory issue the court escaped the more difficult constitutional issues which will be addressed further in the inevitable Fourth Circuit and Supreme Court appeals. The predictions of this article, at least at the lower court level, have proven remarkably accurate.

VII. CONCLUSION

A rose by any other name is still a rose, but an agency with power to define terms has broad power to regulate. Cigarettes are just the latest of thousands of medical devices to be regulated by the Food and Drug Administration. The content and use of a rolled tube of chemically-treated paper can determine whether it remains unregulated, or with tobacco inside, whether it is a drug delivery device subject to marketing controls as a medical device.

Scholars in future years, perhaps in 2027, will look back at the

\textsuperscript{139} 1997 U.S. Dist. LEXIS 5453 (M.D.N.C. 1997).
\textsuperscript{140} Id. at *47.
\textsuperscript{141} Id. at *57.
\textsuperscript{142} Id. at *61.
1997 conflict over the tobacco rulemaking as an administrative rulemaking that was either a classic landmark, or the greatest failed attempt at control in all of the 20th century's history of health regulation. This is an important test of how broad the empowerment of agencies is and how broadly the courts' jurisdictional deference should expand.

The FDA has acted courageously in pursuing the most wealthy and powerful opponent in agency history. It was wise to take so long and so cautious an approach. This has been a titanic struggle, one with literally life and death stakes for younger smokers. The expertise of a specialized administrative bar has never been so richly amassed against the lawyers of one specialized agency. No other client could have purchased the firepower that was arrayed against the FDA's jurisdiction in this case.

When the smoke clears, the decades of gradual accretion of self-determined definitional authority to the FDA will be viewed as the source of the FDA's victory. Other agencies, and other Congresses, will learn from this example of definitional empowerment of the bureaucracy. This regulatory earthquake will have raised more questions about deference to agency jurisdictional choices than its probable Supreme Court denouement will settle.
FDA'S REGULATION OF TOBACCO PRODUCTS: A FLAGRANT DISREGARD OF CONGRESSIONAL INTENT

by John E. Jevicky, Esq.¹

I. INTRODUCTION

The Constitution grants Congress the power to "make all Laws which shall be necessary and proper"² while the Executive "shall take Care that the Laws be faithfully executed."³ These two statements from the Constitution reflect perhaps one of the most fundamental and basic concepts of our system of government: Separation of Powers. It is the duty of Congress to determine what laws are needed, to enact those laws, and to delegate, if necessary, the power to execute and enforce them. The United States Food and Drug Administration (hereinafter "FDA") is an agency which operates under the Executive branch of our federal government. It carries out the Executive's or President's obligation to "take Care" that all laws enacted by Congress are faithfully executed. To faithfully execute these laws, FDA must respect and follow the Congressional intent reflected in the language of the laws. Congress, in order to protect the health and safety of American citizens, found it necessary and proper to create the Federal Food, Drug and Cosmetic Act (hereinafter "FDCA").⁴ Congress also found it necessary and proper to delegate to FDA the authority to execute the FDCA⁵ and to promulgate regulations for the efficient enforcement of that Act.⁶ On August 28, 1996, FDA, however, promulgated illegal tobacco regulations, violating not only the intent of the Congress, but also

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². U.S. Const. art. I, § 8, cl. 18.
³. Id. at art. II, § 3.
⁶. Id. at § 371(a).
challenging a fundamental premise of our form of constitutional government.

FDA issued a final rule that purports to regulate nicotine-containing cigarettes and smokeless tobacco products as drug delivery devices.\(^7\) The asserted basis for regulation is that these tobacco “devices” deliver nicotine, a drug, into the bloodstream.\(^8\) The primary focus of FDA’s new tobacco regulations is on the advertising, sale, and distribution of cigarettes and smokeless tobacco products to children and adolescents.\(^9\) In its notice of proposed rule-making in August, 1995, FDA provided an analysis of its jurisdiction to regulate tobacco and tobacco products.\(^10\) FDA asserted that because nicotine is addictive and has pharmacological effects on the structure and function of the body, the nicotine in tobacco products is a “drug” under the FDCA.\(^11\) Based upon this finding and upon FDA’s belief that cigarette manufacturers intend for people to become addicted to nicotine, FDA further asserted that cigarettes and smokeless tobacco products are drug delivery devices because they deliver doses of nicotine into the human body. Despite Congressional intent to the contrary, FDA has granted to itself the power to regulate cigarettes as drug/medical device combination products.\(^12\)

FDA has exceeded the scope of its delegated authority in these tobacco regulations. While the courts have generally shown deference to the expertise of FDA, they do not accept broad constructions of the agency’s jurisdiction to regulate that go beyond the jurisdiction granted by Congress. The Supreme Court has stated that in interpreting the FDCA, it is their function to “construct what Congress has written. After all, Congress expresses its purpose by words. It is for us to ascertain — neither to add nor to subtract, neither to delete nor to distort.”\(^13\) Consistent with this function, the courts should not defer to FDA’s interpre-

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8. Id. at 44,397.
9. Id. at 44,397-99.
12. Id. at 45,205.
tation of its jurisdiction under the FDCA because FDA has distorted the Act.

II. INTENT OF CONGRESS FOR REGULATING TOBACCO PRODUCTS

There is no section of the FDCA that explicitly mentions cigarettes or tobacco products as falling within the jurisdiction of FDA as "drugs" or "medical devices." The regulation of cigarettes as drug-delivery devices is the result of FDA's "sudden discovery," after sixty years, that it does, in fact, have jurisdiction to regulate tobacco products. However, Congress specifically reserved for itself the authority to regulate tobacco many years ago. Furthermore, FDA's long-standing policy was that it had no jurisdiction over tobacco products. FDA's most recent interpretation of the FDCA stretches the definitional provisions of the Act beyond even the broadest, most liberal interpretation of what Congress intended.

A. Historical Exclusion of FDA from Regulation of Tobacco

FDA's attempt to regulate cigarettes and smokeless tobacco products as drug delivery devices violates Congress' clearly expressed intent to reserve for itself the power to regulate tobacco and tobacco products. Congress has never granted FDA any jurisdiction over tobacco products. Despite numerous attempts in Congress over the last ninety years to place tobacco products within the reach of FDA, all such attempts have failed. Congress has repeatedly and consistently rejected all efforts to grant FDA authority to regulate cigarettes used for smoking pleasure. Furthermore, Congress itself has enacted statutes regulating tobacco products and has given authority to enforce such statutes to agencies other than FDA.

In 1906, Congress' enactment of the Pure Food and Drugs Act gave no authority over tobacco products to FDA's predecessor, the Bureau of Chemistry. In 1914, the Bureau of Chemistry decided that, even though cigarette smoking was already widespread, tobacco not labeled for a medicinal purpose did not fall within the jurisdiction of the Pure Food & Drugs Act:

Tobacco and its preparations, when labeled in such a manner as to indicate their use for the cure, mitigation, or prevention of disease, are drugs within the meaning of the act, and, as such, are subject to the provisions thereof.

On the other hand, tobacco and its preparations which are not so labeled and are used for smoking or chewing or as snuff and not for medicinal purposes are not subject to the provisions of the act. 16

In 1929, anti-tobacco groups, already aware of health risks associated with smoking, introduced legislation that would have placed tobacco within the reach of the Pure Food & Drugs Act. 16 This attempt failed.

In 1938, Congress enacted the FDCA. For the first time, Congress granted premarket approval authority over new drugs. Still there was no expression by Congress of an intent to encompass tobacco products within the scope of the FDCA. Further, in 1956 and 1963, bills were introduced in Congress that would have expanded the FDCA in order to grant FDA jurisdiction over cigarettes and tobacco products. 17 These bills failed to pass.

In 1964, the Surgeon General issued a report that listed the health risks associated with smoking. 18 The report was adopted by the Department of Health, Education and Welfare. 19 One of the principal findings of the report was that smoking was a health hazard of sufficient import to warrant remedial action. 20 The report also included the following significant findings: nicotine is habit forming; from age 12 and up, there is a regular increase in the incidence of smoking; and smoking contributes to the onset of such diseases as lung cancer, chronic bronchitis, emphysema, cardiovascular diseases, and other cancers. 21 Evi-

17. H.R. 11280, 84th Cong., 2d Sess. (1956) (proposal to amend the FDCA with respect to the manufacture, use and shipment of tobacco products); H.R. 5973, 88th Cong., 1st Sess. (1963) (proposal to amend the FDCA to make that act applicable to smoking products); S. 1682, 88th Cong., 1st Sess. (1963).
20. Id.
dence of serious health risks associated with tobacco use has been in existence almost as long as the FDCA itself, and certainly since the issuance of the Surgeon General's 1964 report. Accordingly, FDA's statement that its ability to assert jurisdiction over cigarettes is based on "dramatic new evidence" is grossly misleading.

Indeed, if there were ever a time to recognize FDA's authority to regulate tobacco products, the four hundred page report by the Surgeon General should have established such authority. In fact, this report prompted a proposal in Congress to extend FDA's jurisdiction under the FDCA to include tobacco products. However, instead of seizing the opportunity to extend FDA's powers over tobacco products, Congress chose to enact the Federal Cigarette Labeling and Advertising Act (hereinafter "FCLAA"). In making the decision to enact the FCLAA, Congress weighed the interests of the tobacco industry and individual consumers. Congress recognized the serious health risks associated with smoking. However, it concluded that individuals "must be safeguarded in [their] freedom of choice — that [they have] the right to choose to smoke or not to smoke." Thus, Congress determined that the best approach to address the health risks of smoking was through label warnings under the FCLAA — not to extend FDA's regulatory powers.

In order to inform the public about the health risks associated with smoking, the FCLAA requires manufacturers to use warning labels and forbids manufacturers from advertising on any medium of electronic communication. The express purpose of the FCLAA is to "establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health." This is a clear statement by Congress that the FCLAA preempts any type of health or safety issue that would otherwise fall under the FDCA.

Interestingly, Congress granted enforcement authority under the FCLAA to the Federal Trade Commission (hereinafter "FTC")

26. Id. at § 1335.
27. Id. at § 1331 (emphasis added).
exclusively.\textsuperscript{28} FDA was given no regulatory role under this "comprehensive federal program." In fact, Congress explicitly stated that no other entity could require any labeling or advertising not required by the Act.\textsuperscript{29} FDA's tobacco regulations are in direct conflict with the FCLAA. Its assertion of jurisdiction is a flagrant disregard of the intent and laws of Congress.

The Congressional denial of FDA authority to regulate tobacco products did not end with the enactment of the FCLAA in 1969. Congress clearly reserved the power to regulate tobacco in 1976 when it stated that, "the clear mandate of Congress is that the basic regulation of tobacco and tobacco products is governed by the legislation dealing with the subject, the Cigarette Labeling and Advertising Act of 1969, and that any further regulation in this sensitive area must be reserved for specific Congressional action."\textsuperscript{30} Congressional intent could not be more clear — only Congress has the authority to regulate tobacco products. In that same year, Congress amended the FDCA to give FDA premarket approval authority over medical devices and to establish a threeteried regulatory classification system for ensuring the safety and efficacy of medical devices.\textsuperscript{31}

Noticeably absent from the new definitions section was any mention of tobacco products. Taken together, these Congressional enactments of 1976 — two specifically addressing tobacco and tobacco products and another specifically amending the FDCA to comprehensively regulate medical devices — are clear and unambiguous expressions of Congress that it did not intend for FDA to regulate tobacco and tobacco products either as drugs or medical devices.

Consistent with this view, Congress has repeatedly rejected any effort to extend the regulatory powers of FDA to tobacco and tobacco products. Since 1976, Congress has denied proposals to extend FDA jurisdiction over tobacco products at least eight times over a 16 year period: 1977,\textsuperscript{32} 1978,\textsuperscript{33} 1979,\textsuperscript{34} 1984,\textsuperscript{35}

\begin{itemize}
  \item \textsuperscript{28} See 15 U.S.C. §§ 1336-1337.
  \item \textsuperscript{29} Id. at § 1334.
  \item \textsuperscript{30} S. REP. NO. 251, 94th Cong., 2d Sess. 43 (1976). This statement was made at the time Congress amended the Federal Hazardous Substances Act to exclude tobacco products from the definition of hazardous substance. Congress also excluded tobacco products from the definition of chemical substance in the Toxic Substances Control Act, 15 U.S.C. §§ 2601-2629 (1976).
  \item \textsuperscript{31} Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976).
  \item \textsuperscript{32} H.R. 2419, 95th Cong., 1st Sess. (1977) (proposal to amend the FDCA to

As further evidence of Congress' intent to retain sole regulatory control over tobacco and tobacco products, in 1986, it enacted the Comprehensive Smokeless Tobacco Health Education Act (hereinafter "CSTHEA") to regulate smokeless tobacco products. 40 Not surprisingly, FDA was granted no regulatory role under this Act. Finally, in 1992, Congress enacted the Alcohol, Drug Abuse, and Mental Health Amendments Reorganization Act (hereinafter "ADAMHA"). 41 This Act specifically addressed the issue of youth smoking — the primary focus of FDA final rule — but gave the FDA no power to regulate. 42

33. S. 3317, 95th Cong., 2d Sess. (1978) (proposal to amend the FDCA and FCLAA to provide for health warning labels on cigarettes).
34. H.R. 279, 96th Cong., 1st Sess. (1979) (proposal to amend the FDCA to authorize regulation of tobacco products).
35. H.R. REP. No. 805, 98th Cong., 2d Sess. 12 (1984) (stating that, with the exception of the FCLAA, federal laws that protect the public from hazardous food, drugs and consumer products do not apply to cigarettes).
38. H.R. 4350, 102d Cong., 2d Sess. (1992) (proposal to amend the FDCA to regulate the manufacture, sale, promotion, and distribution of tobacco products); S. 2298, 102d Cong., 2d Sess. (1992) (proposal to amend the FDCA to regulate the sale and distribution of tobacco products).
40. Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. §§ 4401-4408 (Supp. 1997). This Act expressly preempts any Federal Agency from requiring any statement, beyond that required by the Act, relating to the use of smokeless tobacco on a label or advertisement. Id. at § 4406.
B. Comprehensive Regulation Exists without FDA Final Rule

Despite whatever value one might find in FDA's objective of curtailing adolescent smoking, the final rule is redundant, creates an overlapping federal scheme of regulation, and is contrary to Congress' clearly expressed intent that regulation "in this sensitive area must be reserved for specific Congressional action." 43

Consistent with reserving for itself the right to regulate tobacco and tobacco products, Congress has created a comprehensive program to regulate the manufacture, distribution, packaging and sale of these products. The majority of this regulation exists within FCLAA and CSTHEA. Additionally, the problem of youth smoking is addressed in ADAMHA. Furthermore, all fifty states have regulations regarding tobacco and tobacco products. The states restrict tobacco use by minors, have certain licensing requirements, and have restrictions on vending machines and loose cigarette sales.

Under the FCLAA, the FTC is granted enforcement authority; under the CSTHEA it is the Secretary of Health and Human Services (hereinafter "HHS") and the FTC. Additionally, there are other administrative agencies in the federal government to which Congress has delegated certain regulatory powers over tobacco and tobacco products. For example, the Bureau of Alcohol, Tobacco and Firearms has the authority to collect excise taxes on tobacco products and to regulate the manufacture of tobacco products. 44 The Secretary of HHS must report to Congress every three years on the addictive property of tobacco and recommend any legislation or administrative action. 45 The Department of Agriculture has the authority to set marketing quotas and price levels for tobacco, 46 and the Internal Revenue Service has the authority to implement taxes for the sale of cigarettes. 47 Conspicuously absent from the list of administrative agencies with explicit regulatory authority over practically all aspects of cigarettes and tobacco products is FDA. Obviously it was never Congress' intent for FDA to have jurisdiction over

47. I.R.C. § 5701(b) (1994).
tobacco products under the FDCA.

Finally, FDA's tobacco regulations add nothing to the extensive federal and state regulatory scheme. FDA's regulations address cigarette sales, labeling and advertising. 48 These are areas of regulation that have been addressed by the federal and state governments for many years. Because the final rule adds nothing to, and simply overlaps, the comprehensive program of regulation already in place, it is clear that FDA's attempt to assert jurisdiction over tobacco and tobacco products is nothing more than a thinly veiled attempt to broaden its powers and to move forward the personal and political agendas of the Clinton Administration and FDA's policy-makers. 49

III. INTERPRETATIONS OF CONGRESSIONAL INTENT BY FDA

Since the enactment of the FDCA in 1938, FDA has asserted jurisdiction over cigarettes only when they are accompanied by therapeutic claims by the manufacturers. 50 Such an approach is consistent with the intent of Congress. Now, however, FDA is reversing sixty years of interpretation because it believes it has sufficient evidence to show that manufacturers intend for cigarettes to be used to affect the structure and function of the body, and are thus within the scope of the FDCA.

A. FDA's Historical Interpretation of the FDCA

Since 1914, FDA or its predecessor agency has adhered to the clear position that it lacked any authority to regulate tobacco products. In 1972, FDA Commissioner Charles Edwards testified before Congress that "the regulation of cigarettes is the domain of Congress" and that it "would be inconsistent with clear congressional intent" for FDA to regulate tobacco products. 51 Obvi-

49. See Judi Hasson, Debate Centers on Economy, Government Role, USA TODAY, Oct. 7, 1996, at 12A.
50. See United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes, 113 F. Supp. 336, 337 (D.N.J. 1953) (FDA could regulate cigarettes when manufacturer claimed that they would reduce risk of colds and other infections); United States v. 354 Bulk Cartons * * * Trim Reducing-Aid Cigarettes, 178 F. Supp. 847, 851 (D.N.J. 1959) (FDA could regulate cigarettes that purportedly suppressed appetite because they affected the structure and function of the body).
51. Public Health Cigarette Amendments of 1971: Hearings on S. 1454 Before the
ously, then Commissioner Edwards read and followed the same expressions of Congressional intent cited in Section II of this article. He recognized that there was no "gap" in the FDCA that allowed regulation of tobacco products by FDA.

Furthermore, Peter Hutt, a drug law expert with the Tobacco Institute's principal law firm, who has been quoted as saying the FDCA is a constitution and should be interpreted as such, recognized that even constitution-like statutes have limits when he testified that:

Congress decided in 1970 that cigarettes should not be banned, that they should be allowed to remain in commerce with the warning decided on by Congress, and we therefore feel that we have no basis for making any kind of determination literally contrary to the congressional determination.\(^52\)

Consistent with the statements of Commissioner Edwards and Mr. Hutt, in 1977, FDA denied a citizen's petition to assert agency jurisdiction over nicotine-containing cigarettes. The citizen's petition, filed by Action on Smoking and Health, asserted that nicotine-containing cigarettes affected a function of the body and challenged FDA's refusal to assert jurisdiction over cigarettes.\(^53\)

In denying the petition, FDA stated that:

[T]here is no evidence in the legislative history [of the Medical Device Amendments of 1976] that Congress intended to include cigarettes within the definition of "device" nor does the legislative history contain any discussion of a possibility that cigarettes were "devices" within the prior definition.

The amendments were thoroughly considered, and the legislative history discusses the types of products intended to be regulated and the types of health hazards with respect to which the amendments were intended to provide authority. Cigarettes are not mentioned even though Congress was aware of the considerable public discussion of the health hazards of cigarette smoking. It is, therefore, not reasonable to consider cigarettes as "devices" when there was no discussion in the legislative history of congressional intent to provide jurisdiction over cigarettes or to provide authority suitable to the regulation of cigarettes.\(^54\)

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\(^{52}\) Consumer Subcomm. of the Senate Comm. on Commerce, 92d Cong., 2d Sess. 240 (1972).

\(^{53}\) Id. at 242.

\(^{53}\) Action on Smoking and Health v. Harris, 655 F.2d 236 (D.C. Cir. 1980).

\(^{54}\) Letter from Mark Novitch, FDA Deputy Commissioner, to John Banzhaf, III,
The District of Columbia Circuit Court agreed with the Commissioner's decision.\(^{55}\) The court stated that “Congress has been made repeatedly aware that FDA cannot assert jurisdiction over cigarettes absent health claims made by manufacturers or vendors;”\(^{56}\) “[i]f the statute requires expansion, that is the job of Congress.”\(^{57}\)

**B. FDA is Limited by its Interpretation of the FDCA**

Courts have traditionally deferred to FDA in its interpretations of the FDCA. Although such deference may exist, “courts are the final authorities on issues of statutory construction . . . and are not obliged to stand aside and rubber-stamp their affirmance of administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute.”\(^{58}\) Furthermore, “[i]n [the Court’s] anxiety to effectuate the congressional purpose of protecting the public, [it] must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.”\(^{59}\)

Also, courts give “great weight to the longstanding interpretation [of a] statute by [the] agency charged with its administration.”\(^{60}\) For the past sixty years, FDA has stated that, in the absence of health claims by the manufacturers, it has no jurisdiction over cigarettes. In this situation, “congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress.”\(^{61}\) FDA has consistently stated that Congress through the FDCA did not grant FDA jurisdiction over tobacco products. Congress has amended the FDCA many times with full knowledge of FDA’s construction and interpretation of the Act, and FDA “is

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55. *Harris*, 655 F.2d at 239.
56. *Id.* at 241.
57. *Id.* at 243.
61. *Id.*
not now free to read a new . . . meaning into the Act.\textsuperscript{62}

In \textit{United States v. Rutherford},\textsuperscript{63} the Supreme Court held that there was no exception to FDA premarket approval under the FDCA for drugs used by terminally ill patients.\textsuperscript{64} FDA's long-standing interpretation of the Act was that it did not exist solely to protect patients with curable diseases.\textsuperscript{65} The Court stated that great weight would be given to this long-standing interpretation, especially when that interpretation involved an issue of considerable public controversy.\textsuperscript{66} The Court took this analysis one step further when it stated that "once an agency's statutory construction has been 'fully brought to the attention of the public and the Congress,' and the latter has not sought to alter that interpretation although it has amended the statute in other respects, then presumably the legislative intent has been correctly discerned."\textsuperscript{67}

Furthermore, the Supreme Court, in \textit{Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.},\textsuperscript{68} developed a two-step test by which courts review an agency's construction of the statute it administers.\textsuperscript{69} The first question is "whether Congress has directly spoken to the precise question at issue."\textsuperscript{70} If Congress has expressed its intention on the precise question at issue, then "that intention is the law and must be given effect."\textsuperscript{71} If, however, Congressional intent is ambiguous, the court must turn to the second prong and ask "whether the agency's answer is based on a permissible construction of the statute."\textsuperscript{72}

Under this analysis, it is clear that FDA has exceeded the scope of its jurisdiction. Congress has specifically and unambiguously spoken to the precise question of FDA's jurisdiction over tobacco products. The message Congress sent to FDA over the last ninety years is clear: absent a health claim by a manufacturer or vendor, FDA has no jurisdiction over tobacco or tobacco

\begin{thebibliography}{99}
\item 62. \textit{Id.} at 289.
\item 63. 442 U.S. 544 (1979).
\item 64. \textit{Id.}
\item 65. \textit{Id.} at 552.
\item 66. \textit{Id.} at 554.
\item 67. \textit{Id.}
\item 68. 467 U.S. 837 (1984).
\item 69. \textit{Id.} at 842-43.
\item 70. \textit{Id.}
\item 71. \textit{Id.} at 843 n.9.
\item 72. \textit{Id.} at 843.
\end{thebibliography}
products. Furthermore, FDA’s denial of jurisdiction over these products has been long-standing and is well-established. The FDCA has been amended many times, and Congress has never taken the opportunity to change FDA’s interpretation of its jurisdiction under the Act.

IV. INTENT OF TOBACCO MANUFACTURERS

The FDCA definition of a “drug” includes an article, other than food, “intended to affect the structure or any function of the body.” 73 Similarly, the FDCA definition of a “device” includes an instrument or other related article which is “intended to affect the structure or any function of the body . . . and which does not achieve its primary intended purposes through chemical action within or on the body . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes.” 74 In determining whether a product falls within these definitions, “[t]he vendors’ intent in selling the product to the public is the key element in this statutory definition.” 75 The requisite intent to affect the body exists if the manufacturers or vendors make health claims about their products or it may be inferred from labeling, promotional material, advertising, and any other relevant source. 76 Without the requisite intent of the vendor or manufacturer, FDA’s authority over products in interstate commerce would be almost unlimited.

Under the FDCA definitions of drug and device, the manufacturer’s intent determines whether a product falls within the jurisdiction of FDA. The agency focuses upon the manufacturer’s representations in making this determination. 77 The Action on Smoking and Health v. Harris court discussed two ways to present evidence of a manufacturer’s intent — subjective vendor claims or objective evidence such as labeling, promotional material, and advertising. 78 “Clearly, it is well established that the intended use of a product, within the meaning of the Act, is

76. Action on Smoking and Health v. Harris, 655 F.2d 236, 239 (D.C. Cir. 1980).
77. Id.
78. Id.
determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source. 79

It is and always has been clear that cigarettes can only be regulated by FDA if the manufacturer makes health claims. In the only two cases in which FDA was able to assert jurisdiction over cigarettes, the manufacturers made representations concerning beneficial health effects of their cigarettes. In *United States v. 46 Cartons*, 80 the manufacturer claimed that the cigarettes helped prevent respiratory diseases and numerous other infections. 81 The district court concluded that these cigarettes were drugs within the meaning of the FDCA because the manufacturer’s representations evidenced an intent for the cigarettes to be used in the cure, mitigation, treatment, and prevention of disease. 82 Likewise, in *United States v. 354 Bulk Cartons*, 83 the manufacturer claimed that the cigarettes helped the smoker to lose weight by acting as an appetite suppressant. 84 The court, once again, based its finding that these cigarettes were drugs on the intent of the manufacturer. 85 The manufacturer intended for the cigarettes to affect the structure and functions of the body by reducing the appetite (function) thereby achieving a reduction in body weight (structure). These two cases establish the test for determining whether a product is drug or a device: whether the manufacturer’s representations establish an intent to cure or treat a disease or to affect the structure or function of the body.

FDA’s tobacco regulations state that it has jurisdiction over cigarettes because the manufacturers intend for the cigarettes to affect the structure or function of the body. However, FDA’s construction of “intent” severely distorts the meaning of the word as used in the FDCA and as interpreted by the courts. FDA was unable to develop any evidence of the manufacturers’ intent to affect the structure or function of the body as that phrase has

79. Id. (internal quotations and citations omitted).
81. Id. at 337.
82. Id.
84. Id.
85. Id. at 851. The label on the cigarettes said, “trim reducing-aid cigarettes,” and an advertisement read, “Overweight? Lose weight without pills or diet. Smoke Trim reducing-aid cigarettes.” Id. at 849.
always been interpreted. The reason is that the tobacco companies do not promote or intend for their products to be used for any such purpose. In the case of cigarettes, they are intended for smoking pleasure. There is no evidence of subjective or objective intent of tobacco manufacturers to promote anything other than that cigarettes provide smoking pleasure. There is also no evidence of subjective or objective intent to affect the structure or function of the body. The labels, advertisements, and promotional materials of tobacco products make no mention anywhere of any possible health benefits. Therefore, FDA redefined "intent" in order to bring tobacco within its reach. In doing so, FDA is regulating backwards: the product must fit within the statute; the statute should not be stretched and twisted to fit the product.

FDA now argues that the objective intent standard may be satisfied by evidence of a consumer's actual use and the manufacturer's knowledge of that use, regardless of whether the manufacturer made any health claims. Under this analysis, even though cigarette manufacturers claim only that cigarettes provide smoking pleasure, the "intent" element is satisfied by the consequences of consumer use, i.e., nicotine addiction and other pharmacological effects. This is not what Congress intended. The court in FTC v. Liggett & Myers Tobacco Co. analyzed the "intent to affect" requirement in holding that cigarettes were not drugs within the meaning of the FTC Act:

Anything which stimulates any of the senses may be said, in some perhaps insignificant degree, to affect the functions of the body of man. Consequently any article which, used in the manner anticipated by the manufacturer thereof, comes into contact with any of the senses may be said to be an article "intended to affect the functions of the body of man."

Surely, the legislators did not mean to be as all-inclusive as a literal interpretation of this clause would compel us to be . . . .

Congress, had the matter been considered, would not have

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86. 61 Fed. Reg. at 45,203.
87. Id. at 41,483.
89. The definition of "drug" is the same in both the FTC Act and the FDCA.
intended cigarettes to be included as an article "intended to affect the functions of the body of man" or in any other definition of "drug."\textsuperscript{90}

Under its new rule, FDA is essentially rewriting the FDCA to serve its own purposes. Once the smoke clears, however, it will be seen that Congress intended for the FDCA to be applied as written. And, as written, it requires representations by the manufacturer that cigarettes are intended to affect the structure and function of the body. If there is a need to regulate tobacco products because of health risks, Congress knows how to amend the Act to include tobacco products or to extend the definition of "drug" or "device" such that tobacco products would fall within the jurisdiction of FDA.

Regulating products based on actual consumer use is an absurd stretch of the jurisdictional definitions. Under FDA's new construction of the Act, if a manufacturer of wool coats becomes aware that a consumer wears its wool coat, not because it keeps him warm, but because he likes the smell and feel of the coat and that it makes him feel good to wear it, all of which affect his senses and thereby his psychological well-being, i.e., functions of the body, it could be regulated as a drug.\textsuperscript{91}

V. CONCLUSION

In \textit{Youngstown Sheet and Tube Co. v. Sawyer},\textsuperscript{92} Justice Jackson, in his concurring opinion, observed:

When the President takes measures incompatible with the expressed or implied will of Congress, his power is at its lowest ebb, for then he can rely only upon his own constitutional powers minus any constitutional power of Congress over the matter. Courts can sustain exclusive Presidential control in such a case only by disabling the Congress from acting upon the subject. Presidential claim to a power at once so conclusive and preclusive must be scrutinized with caution for what is at stake is the equilibrium established by our constitutional systems.\textsuperscript{93}

\textsuperscript{90.} \textit{Liggett & Myers}, 108 F. Supp. at 576-77.

\textsuperscript{91.} The coat might also be considered a medical device because it affects the structure or function of the body by assisting in the maintenance of body temperature. Under FDA's interpretation, there is no product that might not be caught in its regulatory net.

\textsuperscript{92.} 343 U.S. 579 (1952).

\textsuperscript{93.} \textit{Id.} at 637-38 (Jackson, J., concurring) (internal footnote omitted).
 Regulation of tobacco products is a subject matter exclusively within the separate power of Congress. The President, through FDA or any other agency, is limited to faithfully executing the laws enacted by Congress, including the FDCA or any statute that addresses tobacco products. FDA's tobacco regulations exceed the authority granted to it by Congress. At no time in the history of the FDCA has Congress granted to FDA or the President the general authority to regulate tobacco products under the FDCA. To the contrary, Congress has reserved to itself the power to regulate tobacco products or has delegated such regulatory powers to agencies other than FDA. The constitutional obligation of the President and FDA to faithfully execute the laws of Congress requires a respect and adherence to the intent of Congress expressed in the language of the laws it enacts. FDA's tobacco regulations are illegal assertions of power and demonstrate a flagrant disregard of clear Congressional intent.
Honest, I really was the first one. You can look it up: George Washington Law Review, March 1971, in an article entitled The First Amendment in the Marketplace: Commercial Speech and the Values of Free Expression. Five years before the Supreme Court held that commercial speech was deserving of First Amendment protection, long before any scholarly commentator had even intimated that commercial speech was worthy of consideration as "speech" for purposes of the constitutional guarantee, there I was, arguing that because commercial speech "advances [the individual] towards the intangible goal of rational self-fulfillment," it was properly characterized as protected expression.
There are, no doubt, many scholars even today who would equate my boast of having made such an original contribution to First Amendment theory with the claims of having invented the Edsel or managed Bob Dole's presidential campaign. It is certainly true that many commentators today remain unconvinced concerning the First Amendment value of commercial speech. However, a long line of Supreme Court decisions recognizing the First Amendment status of commercial speech should at least be deemed probative evidence of my sanity.

Though given the commercial speech doctrine's extremely troubled beginnings, I might be accused of an unrealistic level of expectation, I must admit to substantial frustration as result of the half-hearted nature of the Court's commercial speech protection. Even after the Court extended a meaningful level of constitutional protection to commercial speech, in numerous decisions the level of protection afforded to commercial speech stood barely above the minimal protective level provided to economic or commercial conduct under the Fifth Amendment's substantive due process protection. Such a diluted form of constitutional guarantee resulted largely from what I deemed to be fundamental flaws in the theoretical underpinnings of the Court's initial decision to extend First Amendment protection to commercial speech. The Court in Virginia Board relied fundamentally on the economic benefits that advertising may have on society and on its indirect implications for the political and economic systems. In so doing, the Court ignored the true free speech values served by commercial speech.

doing it serves an important function as a catalyst in the achievement of personal self-realization." Id. at 472.


7. See, e.g., Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 456 (1978) (allowing regulation of commercial speech where damage "may" occur or that harm is "likely"); Friedman v. Rogers, 440 U.S. 1, 13 (1979) (allowing regulation of commercial speech when there exists a "possibility" of harm).

8. As to the minimal level of constitutional protection provided by economic substantive due process, see, e.g., Ferguson v. Skrupa, 372 U.S. 726 (1963).

9. See MARTIN H. REDISH, FREEDOM OF EXPRESSION: A CRITICAL ANALYSIS 60-68
In its 1993 decision *City of Cincinnati v. Discovery Network*, the Court appeared quietly to signal a dramatic shift in its commercial speech analysis. There the Court refused to accept the argument that commercial speech could be regulated under circumstances in which non-commercial speech could not, because commercial speech was somehow less worthy a form of expression. Commercial speech was to be distinguished from traditionally protected expression, the Court found, only in those situations in which commercial speech presented a unique danger of harm. Though apparently few noticed, by effectively equating the value of commercial speech with that of more traditionally protected forms of expression the Court in *Discovery Network* was challenging fundamental assumptions that had been made in a number of important Supreme Court precedents.

Last term, the Court appeared to reject the “step child” status of commercial speech in everything but name. Though its decision in *44 Liquormart, Inc. v. Rhode Island* is burdened by the confusion normally associated with the absence of a majority opinion, two of the opinions filed in that case, representing the views of four Justices, openly advocate full First Amendment protection for commercial speech. Indeed, the opinion announcing the judgment of the Court actually suggested that commercial speech lay at the historical core of the First Amendment.

My first reaction to this decision, not surprisingly, was a feeling of both satisfaction and vindication that has been matched
only by my reaction to Northwestern finally going to the Rose Bowl in 1996. My second reaction, however, was concern that once again, the Justices had failed to provide an adequate theoretical grounding to support such a significant doctrinal move. The purpose of this article, then, is to reconsider the theoretical arguments both for and against the extension of full First Amendment protection to commercial speech, in order to demonstrate the validity and wisdom of the doctrinal extension seemingly signaled in *44 Liquormart*.

Such a reconsideration differs in several important respects from my analysis some twenty-six years ago, largely because the nature of the modern conceptual attacks on commercial speech protection have evolved in a manner far different from the theoretical defense of commercial speech's exclusion from constitutional protection that I had anticipated at that point. Few jurists or commentators today would, I think, defend commercial speech's second class status simply on the grounds that the subject matter of such speech falls beneath First Amendment concerns. If such reasoning had been accepted, its logic would necessarily have excluded from full First Amendment protection such expression as Consumer Reports Magazine and the comments of consumer protection advocates criticizing commercial products — a conclusion the Supreme Court has, not surprisingly, been unwilling to reach. 17 The theoretical awkwardness of this truncation of the commercial speech doctrine, however, significantly weakens the theoretical attack on full commercial speech protection. 18 In fact, in light of this alteration in analysis, most of these attacks — much like similar attacks against obscenity protection — 19 may be deconstructed into little more than a result-oriented attempt to stifle advocacy of a particular ideological perspective or point of view. 20 The First Amendment guarantee cannot be allowed to be manipulated in such a man-

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18. See discussion infra text at notes 72-117.

19. In previous writing, I have argued that while obscenity regulation has been justified by the Supreme Court on the grounds that it fails to contribute to the marketplace of ideas, in reality it represents governmental condemnation of the lifestyle embodied in obscenity. Redish, supra note 9, at 69-70.

20. See discussion infra text at notes 84-117.
ner, if it is not to degenerate into nothing more than a manipulative tool of those who exercise political power.

Such an ulterior result orientation is nowhere more evident than in the current debate concerning the constitutionality of restrictions on the advertising of tobacco products. The arguments that are generally employed to support the constitutionality of such restrictions are inconsistent with fundamental precepts of both free speech theory and doctrine in all areas of First Amendment interpretation other than commercial speech regulation.21 When carefully scrutinized, then, these arguments amount to little more than the fear that citizens will be persuaded by particular expression, and a desire to prevent such a result by stifling that expression. In virtually no other area of free speech doctrine could such an argument be accepted today,22 and with good reason. Such suppression undermines the basic notions underlying democratic theory.23

In no area of commercial speech regulation is this anti-democratic reasoning more transparently evident than in the proposed restriction of tobacco advertising. In seeking to suppress the advertising of tobacco products seen by large numbers of adults,24 government is attempting to suppress the advocacy of lawful personal choices that are deemed to be both unpopular and unwise. As such, they inescapably reflect governmental mistrust of individuals' ability to make lawful decisions on the basis of free and open debate.25 Examination of the smoking

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21. See discussion infra text at notes 84-106.
23. See discussion infra text at notes 107-117.
24. While it is true that speech aimed at minors does not receive full First Amendment protection [see, e.g., Ginsberg v. New York, 390 U.S. 629 (1968)], regulations recently imposed by the Food and Drug Administration on tobacco advertising extend well beyond the limited context of minors. It is well established that expression aimed at adults cannot be regulated on the grounds that it is also seen or heard by minors. See, e.g., Sable Communications of Cal., Inc. v. FCC, 492 U.S. 115, 131 (1989) (restricting phone-sex services held unconstitutional because the statute "has the invalid effect of limiting the content of adult telephone conversations to that which is suitable for children to hear."); Butler v. Michigan, 352 U.S. 380, 383 (1957) (statute making it an offense to make available to the general public materials found to have potentially harmful influence on minors held unconstitutional because statute is "not reasonably restricted to the evil with which it is said to deal.").
25. For a more detailed discussion of this point, see Martin H. Redish, Tobacco Advertising and the First Amendment, 81 IOWA L. REV. 589, 604-07 (1996).
controversy, then, can reveal much about the artificiality of the commercial speech distinction.

Hopefully, the decision in *44 Liquormart* will usher in a new era in commercial speech protection, one in which governmental regulation of truthful commercial speech will be recognized as the serious threat to First Amendment values that it actually is. If so, however, the theoretical basis for the extension of full First Amendment protection to commercial speech will probably require considerably more analytical fortification than the Justices have to date provided. In this article, I hope at least to begin to supply that theoretical support.

The next section of this article will describe the *44 Liquormart* decision, and explore its potential impact on the commercial speech distinction. The section that follows will explore the theoretical arguments for and against the continued second-class status of commercial speech within the First Amendment hierarchy, concluding that no legitimate theoretical basis exists to support such a status. Finally, the article will focus on the smoking controversy as a microcosm of the commercial speech issue, in an attempt to underscore the truly ominous implications for free speech protection to which a finding of the constitutionality of tobacco advertising regulation would give rise. As the analysis will demonstrate, whatever victory some might believe would result from such a decision would likely prove to be a Pyrrhic one indeed.

II. *44 Liquormart* and the Future of the Commercial Speech Distinction

A. Pre-*44 Liquormart* Commercial Speech Doctrine: A Brief Overview

Although the Supreme Court first extended substantial First Amendment protection to commercial speech in *Virginia State*
In the early years of such protection the Court afforded "commercial speech a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values." As a result, the Court on occasion upheld speech regulations that would quite probably have been deemed unconstitutional in the regulation of noncommercial expression.

In Central Hudson Gas & Electric Corp. v. Public Service Commission, the Court established a four-part test to determine the constitutionality of commercial speech regulation: (1) was the speech false or misleading (If so, it could constitutionally be regulated); (2) does the government regulation further a substantial interest; (3) does the regulation directly advance that interest; and (4) could the governmental interest be equally served "by a more limited restriction on commercial speech" None of the test's factors appears to authorize a reviewing court to take into account the nature of the regulation's specific impact on First Amendment concerns. For example, at no point does the test ask whether the "substantial" governmental interest may be outweighed by the restriction on expression — an inquiry that is universally undertaken in traditional First Amendment analysis. Evidence that the test established in Central Hudson does not provide a level of protection equivalent to that provided by traditional First Amendment standards can be found in the

33. See, e.g., id. at 457 (upholding commercial speech regulation when it has been demonstrated only that damage "may" occur); id. at 464 (mere likelihood of harm sufficient to justify regulation); Friedman v. Rogers, 440 U.S. 1, 13 (1979) (upholding regulation of commercial speech where there is a "possibility" of harm).
34. 447 U.S. 557 (1980).
35. Id. at 563-64.
36. See, e.g., United States v. O'Brien, 391 U.S. 367, 376-77 (1968) (describing level of governmental interest required to regulate substance of protected expression as "compelling", "substantial", "subordinating", "paramount", "cogent" and "strong"). See also Brandenburg v. Ohio, 395 U.S. 444, 447 (1969) (upholding regulation of advocacy of unlawful conduct only when "advocacy is directed to inciting or producing imminent lawless action and is likely to incite or produce such action.").
37. It should be emphasized that while the Central Hudson test has undoubtedly failed to provide a level of constitutional protection equal to that afforded non-commercial speech, its protection is nevertheless considerably more than insignificant. See, e.g., Edenfield v. Faye, 507 U.S. 761 (1993) (state interest must be served in direct and effective way); Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 648 (1985) (requiring more than "tenuous" supporting evidence); Rubin v. Coors Brewing
Court's dictum in that very decision accepting the propriety of a paternalistic and manipulative rationale for regulating commercial expression. 38

Commercial speech protection reached its post-Virginia Board low point in Posadas de P.R. Associates v. Tourism Co. of Puerto Rico. 39 There the Court propounded the highly dubious — and now discredited — theory that the greater power to regulate conduct logically included within it the lesser power to regulate expression promoting that conduct. 40 Such reasoning, of course, would effectively do away with the Central Hudson test, which provided considerably greater protection to commercial speech than is afforded to commercial conduct under the Fifth and Fourteenth Amendments' due process clauses. 41 Subsequent decisions, however, appeared to take a considerably more protective approach. 42 But it was not until 44 Liquormart that a number of the Justices explicitly adopted the view that the protection given commercial speech, in most cases, would approach the stringent level of protection afforded traditional categories of expression.

38. Central Hudson, 447 U.S. at 569-70 (noting that ban on electric utility's promotional advertising directly advanced the state's substantial interest in reducing electricity consumption).


40. See Martin H. Redish, Product Health Claims and the First Amendment: Scientific Expression and the Twilight Zone of Commercial Speech, 43 Vand. L. Rev. 1433, 1441-42 (1990) (arguing that Posadas actually has reversed the 'greater' and the 'lesser.' [The] logic effectively reduces the greater first amendment protection of expression to the considerably lesser fifth amendment protection afforded commercial conduct.)


42. Posadas, 478 U.S. at 345-46.

43. See Central Hudson, 447 U.S. at 566; see discussion supra text at notes 34-38.


45. See the opinions of Justice Stevens, speaking for three Justices, and of Justice Thomas. 44 Liquormart, 116 S. Ct. at 1495, 1515. See discussion infra text at notes 47-67.

46. Recall the exceptions recognized in 44 Liquormart for regulations of both false advertising and harassing commercial speech. See supra note 26; see discussion infra text at notes 57-59.
B. The 44 Liquormart Decision

In 44 Liquormart, the Supreme Court held unconstitutional Rhode Island statutes prohibiting the advertising of liquor prices other than at the location of sale. Four separate opinions were written. Justice Stevens, announcing the judgment of the Court, spoke for three Justices when he wrote:

Advertising has been a part of our culture throughout our history. Even in colonial days, the public relied on "commercial speech" for vital information about the market . . . . Indeed, commercial messages played such a central role in public life prior to the Founding that Benjamin Franklin authored his early defense of a free press in support of his decision to print, of all things, an advertisement for voyages to Barbados.47

While Justice Stevens accepted that commercial speech may constitutionally be regulated in order to avoid deceptive advertising or to "restrict some forms of aggressive sales practices that have the potential to exert 'undue influence' over consumers,"48 he concluded that, "when a State entirely prohibits the dissemination of truthful, nonmisleading messages for reasons unrelated to the preservation of a fair bargaining process, there is far less reason to depart from the rigorous review that the First Amendment generally demands."49 Justice Stevens also put an end to the Court's flirtation with the specious logic of Posadas:

Contrary to the assumption made in Posadas, we think it quite clear that banning speech may sometimes prove far more intrusive than banning conduct . . . . [W]e reject the assumption that words are necessarily less vital to freedom than actions, or that logic somehow proves that the power to prohibit an activity is necessarily "greater" than the power to suppress speech about it.50

Despite its largely protective tone, there is an illogic in Justice Stevens' revised analysis of commercial speech protection. On the one hand, his opinion rejects the arguments that the Court had previously relied upon to justify a reduced level of protection for

47. 44 Liquormart, 116 S. Ct. at 1504.
48. Id. at 1506.
49. Id. at 1507.
50. Id. at 1512.
commercial speech, and recognizes the central role such speech has played in societal development. On the other hand, he is apparently willing to measure regulations of commercial speech that are related "to the preservation of a fair bargaining process" by means of a considerably less stringent review than normally afforded to regulations of speech. The problem with this analysis is Justice Stevens' failure to recognize that the increased harm of the commercial speech in no way alters the value of the speech being regulated, any more than does the presence of significant danger caused by political speech — for example, advocacy of imminent governmental overthrow — is thought somehow either to reduce the value of that expression or to alter the applicable constitutional standard of protection.

To be sure, unless one believes that full First Amendment protection necessarily implies absolute protection — and the Supreme Court most definitely does not — the mere fact that particular expression receives full protection does not automatically imply that government is powerless to regulate it. Full protection, rather, means only that government must establish a truly compelling interest in order to justify restriction of expression. Thus, Justice Stevens could reasonably conclude that in certain instances protection of the bargaining process constitutes the requisite compelling governmental interest, and therefore justifies regulation of even fully protected commercial speech. However, it amounts to a non-sequitur to reason that because particular speech causes serious harm, the speech is to be judged by a less protective standard. Presumably, the category of speech must be deemed to have the same value, regardless of the harm it causes. There exists no logical basis for drawing an inverse correlation between the two. Hence, Justice Stevens

51. Id. at 1507-08.
52. Id.
53. Id. at 1507.
could quite probably have reached similar results, simply by applying a compelling interest test. After all, even in the category of political expression, conscious falsehoods may be penalized and physical harassment prohibited. In any event, it is important to recall that at least when commercial speech is being regulated for some reason other than protection of the bargaining process, Justice Stevens and the two Justices joining his opinion made clear that they would provide full constitutional protection to such expression.

Justice Thomas, in a separate concurring opinion, expressed the view that "in cases . . . in which the government's asserted interest is to keep legal users of a product or service ignorant in order to manipulate their choices in the marketplace, the balancing test adopted in Central Hudson . . . should not be applied . . . . Rather, such an 'interest' is per se illegitimate and can no more justify regulation of 'commercial' speech than it can justify regulation of 'noncommercial' speech." In reaching this conclusion, he emphasized the importance of free dissemination of information about commercial choices in a market economy; the antipaternalistic premises of the First Amendment; the impropriety of manipulating consumer choices or public opinion through the suppression of accurate 'commercial' information; the near impossibility of severing 'commercial' speech from speech necessary to democratic decisionmaking; and the dangers of permitting the government to do correctly what it might not have been able to muster the political support to do openly.

Thus, four members of the Court in 44 Liquormart adopted the view that at least under most circumstances, commercial speech is to be treated fungibly with traditionally protected categories of expression in terms of the standard of review. Even

57. See, e.g., New York Times Co. v. Sullivan, 376 U.S. 254, 279-80 (1964) (holding that defamation of public officials are unprotected by the First Amendment when made either with knowledge of falsity or reckless disregard of truth or falsity).
60. Id. at 1515 (Thomas, J., concurring).
61. Id. at 1516 (Thomas, J., concurring).
62. Id. at 1517 (Thomas, J., concurring).
63. Justice Scalia, concurring separately, initially inquired what history would say about the issue, and found no evidence. He therefore believed the issue should be resolved under current doctrinal standards, and agreed that the Rhode Island laws
Justice O'Connor, who — speaking for four Justices — refused to accept Justice Stevens' equation of commercial and non-commercial speech, both rejected the Posadas logic and appeared to apply a highly speech-protective version of the Central Hudson test.

There can be little question that the decision in *Liquormart* represents a dramatic breakthrough in commercial speech theory. Though they differed as to their reasoning, all members of the Court adopted a considerably more protective approach to commercial speech than previous decisions generally had held.

To the Court's credit, the opinions in *Liquormart* contain considerably more thoughtful analysis of commercial speech theory than either the Court's summary and conclusory rejection of First Amendment protection that I was forced to deal with in 1971 or the reasoning it employed in initially extending such protection. At no point in the opinions, however, do the Justices engage in a thorough critical overview of the theoretical arguments for and against the continued second class status of commercial speech. Perhaps that would be too much to expect of a judicial opinion in any event. But as close as the Court has now come to placing commercial speech on the same plane as more traditionally protected expression, such a theoretical reconsideration is most certainly in order.

As in 1971, my view today is that commercial speech serves the values of free speech protection as much or more than does any category of fully protected expression. In many ways, however, both commercial speech doctrine and theory have evolved so as actually to make my task in establishing that proposition considerably easier than it was in the months immediately following were unconstitutional when measured under those standards. *Liquormart*, 116 S. Ct. at 1515 (Scalia, J., concurring).


65. *Id.* at 1521 (O'Connor, J., concurring).

66. *See discussion supra* text at notes 47-59.


68. *See discussion supra* text at notes 13-16.


my law school gradation. Today, careful examination reveals that without question, none of the remaining arguments relied upon to justify commercial speech's second class status justifies the distinction's continued existence.

III. RETHINKING THE COMMERCIAL SPEECH DISTINCTION: CRITIQUING THE JUSTIFICATIONS

A. The Nature of the Subject Matter

Since at the time I published my initial work on commercial speech the issue had never been debated in either the judicial decisions or the scholarly literature, I was forced to anticipate the serious theoretical defenses that could conceivably be made to support the total exclusion of commercial speech from the scope of the First Amendment. Though since that time the Supreme Court has made clear that the First Amendment does, in fact, extend to commercial speech, it is likely that many of the very same arguments would today be relied upon to justify reduced protection for such speech. Ironically, however, the primary justification for reducing protection of commercial speech that I had anticipated at that time is no longer seriously put forward in most quarters. That argument is, simply, that the subject matter involved in commercial speech — namely, the comparative merits and advantages of competing commercial products and services — is somehow "beneath" the legitimate concerns of the First Amendment. Instead, the theory asserts, the focus of the First Amendment is, and should be, on matters of greater political or artistic significance.

There exist two conceivable variations on this argument. One views the First Amendment as protecting solely (or at least primarily) political expression, and reduces or excludes protection for commercial speech for no reason other than that it is something other than political expression. Under this variant, com-

72. See discussion supra text at notes 2-3.
73. Redish, supra note 1, at 434-41.
74. See discussion infra text at notes 31-46.
75. See Thomas Jackson & John Jeffries, Commercial Speech: Economic Due Process and the First Amendment, 65 VA. L. REV. 1 (1979) (arguing that subject of commercial speech is, as a general matter, beneath First Amendment concerns).
mercial speech is deemed to be no better or worse than numerous other forms of expression, such as literary expression or speech concerning scientific or purely social matters. The other variant recognizes that the First Amendment protects considerably more than merely political speech, including art, literature, and science, but excludes commercial speech from the reach of the First Amendment because such expression concerns mundane matters of property and economic rights, not a subject worthy of the constitutional guarantee. After all, the argument runs, the issue of whether a consumer should brush her teeth with Crest or Colgate hardly rises to the level of grand political debate.

In response to these anticipated contentions, I argued that commercial speech may serve the very same values as are fostered by political expression, in that it facilitates an individual's "private self-governing" process. It thereby assists in attainment of the values of individual autonomy and self-realization. I therefore concluded that any distinction between commercial speech and political expression for purposes of First Amendment protection was irrational. The Supreme Court, however, effectively circumvented my defense, by choosing not to reduce protection for all expression concerned with the sale of commercial products or services. Rather, it confined the category of "commercial speech" — for which merely reduced protection was to be provided — only to that speech which "does no more than propose a commercial transaction."

77. See Jackson & Jeffries, supra note 75, at 7-8:
The first amendment guarantee of freedom of speech and press protects only certain identifiable values. Chief among them is effective self-government. Additionally, the first amendment may protect the opportunity for individual self-fulfillment through free expression. Neither value is implicated by governmental regulation of commercial speech.

78. See id. at 14 ("Whatever else it may mean, the concept of a first amendment right of personal autonomy in matters of first amendment right of personal autonomy in matters of belief and expression stops short of a seller hawking his wares.").


80. Redish, supra note 1, at 443-48.

conveniently excludes the expression of information or opinion about commercial products or services by anyone other than the seller. Thus, Ralph Nader's criticism of the Chevrolet Corvair would today receive full protection, even though it concerns exclusively the merits of a commercial product, while Chevrolet's arguments urging purchase of the Corvair would receive only the reduced protection of the *Central Hudson* test, at least to the extent its arguments can be properly characterized as "the promotion of a commercial transaction."\(^{82}\)

The Court has thus conceded that at least the *subject matter* of commercial speech may properly be deemed worthy of full First Amendment protection.\(^{83}\) The reasons for the reduced level of constitutional protection afforded to such speech, then, must turn on the unique presence of one or more additional factors. The remainder of this section considers arguments supporting the relevance of those additional factors.

**B. "Heartiness" and Objective Verifiability**

In *Virginia Board*, the Court suggested two reasons to explain the "common sense" distinction between commercial speech and traditionally protected forms of expression. First, "[t]he truth of commercial speech ... may be more easily verifiable by its disseminator than ... news reporting or political commentary."\(^{84}\) Second, "[s]ince advertising is the *sine qua non* of commercial profits, there is little likelihood of it being chilled by proper regulation."\(^{85}\) Justice Stevens in *44 Liquormart* expressed serious doubt about these rationales,\(^{86}\) and with good reason.

Three fallacies plague both of these suggested distinctions. Initially, even if one were to assume their accuracy, *at most* they represent grounds to distinguish First Amendment protection for

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82. There exists substantial confusion in Supreme Court doctrine as to the extent to which corporate speech must directly propose a commercial transaction in order to qualify as "commercial speech." See Redish, *supra* note 40, at 1448-53.
85. *Id.*
The doctrine of "New York Times Co. v. Sullivan." We need not fear chilling truthful advertising by prohibiting false advertising, the argument proceeds, because advertising claims involve factual assertions that are verifiable with relative ease. In any event, the existence of a profit incentive will preclude such a chill. When, however, the issue turns to the constitutionality of blanket prohibitions on truthful commercial speech, the "heartiness" and "verifiability" rationales are rendered wholly irrelevant: What difference could it possibly make that a commercial enterprise may have an increased incentive to advertise due to a profit motive, if the government has completely prohibited it from advertising?

Moreover, it would be absurd to suggest that the existence of a personal or economic incentive behind expression is somehow uniquely confined to commercial advertising. The ultimate irony in such a position is that the speech sought to be penalized in the New York Times case itself — where the Court waxed eloquent about the dangers of a chilling effect on free expression that might be caused by defamation actions — came in the form of a paid-for advertisement appearing in the Times. Surely, much political speech is motivated by considerations of personal benefit. Somehow, that fact does not cause the Supreme Court to be less concerned about the possible chill that defamation suits might create to deter such expression. It is difficult to understand why a different standard should be applied to commercial expression.

Similarly, it is by no means obvious that claims made in commercial speech are necessarily more objectively verifiable than those made in the political realm. Often, political speech is composed, not assertions of normative political theory but rather simple statements of allegedly objective fact. Surely, the assertions contained in Consumer Reports Magazine are no more or less objectively verifiable than are the claims of commercial advertisers. Yet under the commercial speech doctrine, the former

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88. Id. at 278-79.
89. Id. at 256.
90. See Redish, supra note 1, at 448-58.
C. The Speech-Action Dichotomy

Perhaps the Court's focus on the proposal of a commercial transaction as the defining element of commercial speech can be grounded on the well established speech-action dichotomy: both textually and theoretically, the First Amendment protects speech, not actions.91 To the extent commercial expression is "linked inextricably" to the commercial transactions themselves,92 perhaps the speech can be deemed to collapse into the non-speech commercial transaction itself, and its status as protected speech thereby diluted.93 But while this argument could, at most, arguably have relevance to promotion at the point of sale,94 to suggest that speech which advocates action automatically renders that speech the equivalent of action itself would defy both conceptual reality and at least seventy years of the Supreme Court's First Amendment jurisprudence.95 Speech that advocates action is for that reason no less classifiable as 'speech,' for purposes of the First Amendment protection. Thus, the speech-action dichotomy fails to justify the commercial speech distinction.

D. The Corporate Nature of the Speaker

Yet another conceivable rationale for the commercial speech distinction is the fact that the speaker in the context of commercial promotions will invariably be a corporate entity.96 It is the view of a number of commentators that the values traditionally served by the protection of free speech are inapplicable in the

92. See, e.g., Friedman v. Rogers, 440 U.S. 1, 10 n.9 (1979).
94. Even at the point of sale, it should be noted, the speech promoting the sale is arguably still sufficiently distinct from the actual sale as to remain fully protected speech.
96. To the extent the speaker is not a corporation, of course, this rationale is inapplicable.
context of corporate speech. 97

Purely as a doctrinal matter, however, it would, to say the
least, be awkward for the Supreme Court to rely on the corpo-
rate nature of the speaker to justify reduced protection for com-
mercial speech. The Court has long held that in matters of gen-
eral public interest, corporations have available to them the "full
panoply" of free speech rights. 98 While the Court has on occa-
sion wavered in its resolve on this issue, 99 its decisions recog-
nizing the free speech rights of corporations remain good
law. 100 The Court, then, could hardly ground its reduced protec-
tion of commercial speech on the corporate nature of the adver-
tiser. 101

Moreover, purely as a theoretical matter, a speaker's corporate
status should in no way diminish the level of First Amendment
protection accorded its expression. The primary argument
against the protection of corporate speech is that such expression
is not the product of free will, but rather a slavish, robot-like
response to market forces. 102 Even if one were to accept these
assertions, however, it would not follow that corporate speech is
beneath First Amendment concerns. According to respected pre-
cepts of free speech theory, at least a significant portion of the
value served by free expression is the benefit received by the
reader, viewer or listener. 103 But if one important rationale for
free speech protection is the speech's value to the listener or
reader, then logically neither the motivation for the speech nor
its effect on the speaker should be dispositive of its First Amend-
ment status.

97. In particular, see Baker, supra note 5.
Amendment right not to be required to mail newsletter with utility bill); First Nat'l
under First Amendment).
prohibiting corporations from making expenditures from their general treasuries held
constitutional).
100. See Redish, supra note 40, at 1448-53.
101. The combination of the Court's case of the commercial speech distinction and
its full protection of noncommercial corporate speech, not surprisingly, leads to a
good deal of doctrinal confusion. See supra note 82.
102. See Baker, supra note 5.
103. See, e.g., ALEXANDER MEIKLEJOHN, POLITICAL FREEDOM; THE CONSTITUTIONAL
Moreover, the view of corporate expression as something other than the exercise of free will is unduly myopic, for it completely ignores the exercise of free will that enters into the formation of the corporate entity in the first place. The entire history of the American corporation is tied to the democratic goal of personal self-development and advancement. Thus, it is appropriate to view the corporation's speech as a means of facilitating the self-development of those who formed and operate the corporation. Thus, corporate expression is deserving of full First Amendment protection. The corporate nature of the speaker therefore may not be relied upon to rationalize the commercial speech distinction.

E. Speaker Self-Interest

The most obvious rationale to support the Supreme Court's distinction, for purposes of the level of First Amendment protection, between commercial advertising on the one hand and Consumer Reports' Magazine commentary on the other is the presumed objectivity of the latter. A commercial advertiser, quite obviously, possesses an economic interest in persuading the listener or reader to buy its product. Consumer Reports, on the other hand, can reasonably be presumed to have no special interest in the readers' acceptance of its findings. Such a distinction, however, cannot withstand close analytical scrutiny.

In no other area of First Amendment construction does a speaker's lack of objectivity or the presence of a speaker's personal interest in gaining acceptance of her speech in any way reduce the constitutional protection afforded to that expression. A candidate for political office, for example, obviously lacks objectivity of expression, yet her speech — quite correctly — is afforded full First Amendment protection. The same could be said of...
the speech of countless private interest groups who seek to influence the shaping of public opinion. In fact, it is likely an accurate statement to assert that most contributions to public debate today are motivated out of one personal interest or another. This hardly leads to their reduction in First Amendment protection. It is unclear, then, why the very same factor should be deemed to reduce the protection given to commercial advertising.

If one were starting from first principles, one might, I suppose, fashion a normative free speech theory that consciously chose to exclude from protection personally motivated or non-objective expression. Such a theory would presumably draw upon the civic republican or communitarian traditions, which condemn the pursuit of pure private interest in favor of a focus on the public interest. As I have detailed elsewhere, however, such a theory of free expression is totally inconsistent with the historical and philosophical traditions of the democratic system, premised on a fundamental belief in individual respect and dignity, as well as a belief in the autonomy of the mind.

Moreover, purely as a practical matter, any free speech theory that excludes protection for self-interested speech would effectively turn our existing political structure on its head. It is an undisputed fact of modern political life that individuals often speak in order to promote their own interests through the governing process, either by convincing those in power to take or not to take certain actions, or convincing the electorate to replace those in power. Exclusion of such speech from the scope of the First Amendment would leave precious little expression in the protected category.

The existence of self-interest as a recognized motivating force for expression, it should be emphasized, does not necessarily equate to the caricaturish pluralism both described and attacked


by the public choice theorists. We are not necessarily talking about a mechanistic, non-deliberative pursuit of selfish interests. The concept, rather, is that by means of his rational processes the individual may determine what actions or results will serve his personal interests most effectively, and, by means of communication, seek to persuade others to allow or bring about such results. In this sense, self-interested communication serves as both a symbol of individual integrity and an essential facilitator in the process of personal self-realization.

There are good reasons to protect self-interested speech. As political scientist Jane Mansbridge has shown, to be truly effective a truly communitarian society must be relatively confined and homogeneous, where individuals possess a shared substantive goal. In contrast, in a large, heterogeneous society such as ours, the primary benefit of a democratic system is to enable individuals to protect their own interests from threats posed by the government or by other private interests — a system which Professor Mansbridge calls “adversary democracy.”

The greatest irony in the widespread disdain for self-interested expression inherent in the commercial speech distinction is the fact that in many other aspects of legal and political culture our society actually places a premium on self-interest. Indeed, the entire premise of our largely capitalistic economic system is the belief that reliance on self-interest will maximize societal welfare. The central assumption of capitalism, of course, is that the individual’s incentive to maximize profits will lead to the creation of improvements in products and services.

Within our society’s legal structure, the system’s choice to adopt the adversary system implicitly signals a recognition of the potentially beneficial impact of self-interest. Rather than rely on objective and disinterested government officials to conduct the factual investigation in a case, the adversary system employs individuals whose almost sole responsibility is to protect and further the interest of the client. When an attorney makes an argument to a court, presumably the judge is (or should be) fully aware that the argument is made not necessarily because the

109. See supra notes 124, 125.
110. See generally JANE MANSBRIDGE, BEYOND ADVERSARY DEMOCRACY (1980).
111. Id.
112. See discussion supra text at note 124.
attorney believes it to be morally, factually or legally correct, but because the acceptance of the argument would help the attorney win the case. Presumably, the judge will, with appropriate skepticism, discount the persuasiveness of the argument in light of the attorney's obvious self-interest in gaining its acceptance. It surely does not follow, however, that the judge will or should automatically ignore the argument, or that the argument may be objectively compelling, despite the attorney's self-interest. The attorney was given the incentive to develop the argument, because of the very self-interest that the adversary system has imposed. Implicit in the establishment of the adversary system, then, is the recognition that the presence of self-interest may well lead to a broader societal benefit.

Similarly, the entire law of standing in federal court pursuant to Article III is premised on a societal preference for self-interest as an assurance of litigant seriousness of both purpose and motivation. The Supreme Court has made clear that pure ideological interest provides an insufficient basis on which to establish constitutional standing. To be sure, in part this "private rights" model of adjudication is premised on notions of separation of powers. But it also derives from the assumption that the presence of self-interest will provide the necessary incentive to assure full preparation of a case.

Far from the anti-social negative force described by republican and communitarian scholars, then, pursuit of self-interest is widely recognized as a very positive force towards the betterment of society — a fact recognized in all other aspects of free speech theory. One can only wonder, then, why an exception is recognized in the area of commercial advertising. Why, indeed.

116. See Brilmayer, supra note 113.
117. See supra note 106.
F. Deconstructing the Commercial Speech Exception: The Ideological Rationale

I am sure that there are at least some scholars and jurists who actually believe one-or more of the fallacious rationales for the commercial speech distinction that I have just described. Respect for these individuals, however, should make one quite dubious of such a conclusion. The arguments are simply too blatantly flawed on their face to allow them to be taken seriously. Once one chooses to define the concept of “commercial speech” by reference to a factor other than its subject matter — which the Supreme Court has quite clearly done — the remaining conceivable rationales suffer from a blatant inconsistency with either established precepts of First Amendment thought or widely held notions of American political theory. The only other conceivable explanation for the reduced level of First Amendment protection afforded commercial advertising, then, is some sort of ideologically based distaste for, or rejection of, the value of the commercial promotion of a product or service.

This ideological rationale can take one of two forms. First, it may represent a generic ideological rejection of the capitalistic system out of which commercial advertising grows. Second, it may constitute a narrower form of ideological analysis that condemns the particular product or service being promoted by the commercial advertising sought to be regulated. The thinking behind this narrower rationale is presumably that, as a practical matter, the only individuals who are likely to promote the product or activity are those who are selling it. Thus, to stop the commercial advertising is tantamount to effectively halting all promotion of the use of the product or service. Under such an approach, it would make perfect sense to extend full protection to the speech of those attacking the product or service, but no

118. See discussion supra text at notes 84-117.
119. It should be emphasized that even were the definition of “commercial speech” broadened to include all expression concerning the relative merits of commercial products and services, the arguments against extending full First Amendment protection to such expression are unpersuasive. See Redish, supra note 1; see discussion supra text at note 81.
120. See discussion supra text at notes 81-83.
121. See discussion supra text at notes 84-105.
122. See discussion supra text at notes 106-117.
protection or only limited protection to speech promoting its purchase or use, simply because the former furthers the predetermined ideological goal while the latter undermines it.

Alternatively, one who wishes to halt or reduce the use of a product or service might reason that it would be impractical to expect to control non-commercial promotion of the product or service, because of the well established First Amendment prohibition on viewpoint-based regulations of expression. The most that could be hoped for, then, would be to hide behind the constitutional smoke screen that is the commercial speech distinction, in order to impose at least a limited form of viewpoint-based regulation. These two strategies, it should be noted, are by no means conceptually exclusive. Which rationale would apply would be determined largely by the likelihood that product promotion would come from an additional source or sources other than commercial promotion.

The problem with this ideological rationale, of course, is that it is blatantly and fundamentally inconsistent with the basic premises of both a system of free expression and the democratic structure of which it is a central element. Surely, the Supreme Court today would not countenance a law restricting pro-socialist expression on the grounds that the Court does not believe in socialism, or uphold a law restricting anti-socialist expression because it was pro-socialist. Under such a blatantly viewpoint-based structure, the control of expression would be reduced to nothing more than a struggle for political power. For whichever side attains political power would presumably be able to constitutionally shut off the expression it found to be ideologically distasteful.

The so-called "neutral principles" theory of constitutional interpretation advocated by Herbert Wechsler many years ago has come under strong attack in recent years (perhaps not coincidentally, on occasion by the very same commentators who would likely deny constitutional protection to commercial

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speech). Yet if there exists any area of constitutional analysis where it is essential that constitutional rules are established and followed without concern for the identity of the particular views or parties involved in the litigation, it is free expression. The ideological neutrality of the system of free expression is essential to that system's very existence; without it, the system will inevitably implode.

It is, of course, impossible to delve into the minds of those who urge rejection of full protection for commercial speech. It therefore could be deemed presumptuous to question their motivations. Yet many of those who fall within this category are associated with the Critical Legal Studies movement, an epistemological perspective that rejects the viability of legal analysis divorced from purely political considerations and a political ideology extremely antagonistic to the capitalistic interests associated with commercial advertising. It thus should not seem farfetched to suggest that the rejection or reduction of First Amendment protection for commercial advertising, unjustifiable on any principled basis of free speech theory, ultimately amounts to little more than an ideologically-grounded (and thus wholly unacceptable) critique.

Reliance on such ideological motivations effectively reduces free speech doctrine to a Hobbesian state of nature, in which there exists a "war of all against all." In such circumstances, whichever ideological camp attains political power may, quite legitimately, suppress the speech of its opposition on no grounds


The [Critical Legal Studies] critique of legal rules and reasoning is well known. Rules since they are indeterminate and manipulable, can generate practically any result in a given situation.

Rights, a special kind of rule, receive particularly harsh criticism from Critical Legal Scholars (Crits) Rights legitimize unfair power arrangements, acting like pressure valves to allow only so much injustice. With much fanfare, the powerful periodically distribute rights as proof that the system is fair and just, and then quietly deny rights through narrow construction, nonenforcement, or delay.

Rights, Crits argue, are never promulgated in genuinely important areas such as economic justice. They protect only ephemeral things, like the right to speak or worship. When even these rights become threatening, they are limited.
127. See discussion supra text at notes 72-117.
other than naked dislike of the political viewpoints expressed in that speech. As Hobbes warned us, however, life in such a constitutional state of nature is likely to be "nasty, brutish and short." Ideology can therefore never play a theoretically proper part in justifying governmental restriction of expression.

G. Rationalizing the Commercial Speech Distinction: A Summary

Once one rejects subject matter as a rationale for reducing First Amendment protection for commercial speech, the remaining rationales fall as quickly and easily as a stack of dominoes. More importantly, exclusion of subject matter as the defining factor of commercial speech inescapably reveals an ideological rationale behind the commercial speech distinction: It is not that the debate over the merits of commercial products or services falls beyond the scope of the First Amendment, but rather that the expression of those advocating one side of that debate is deemed unworthy of such protection.

The greatest irony in all this is that it effectively underscores the inherent difficulty in distinguishing between commercial and political expression in the first place. As I first warned in 1971, speech does not come in neat, severable units. The operation of commercial enterprises and the quality of their products and services give rise to inescapable social and political implications. The very fact that those who seek to reduce free speech protection for "commercial speech" are today so anxious to exclude from that less protected category expression about such products and services other than advertising tends to confirm the inherently ideological message of all commercial speech.

IV. THE SMOKING CONTROVERSY: THE COMMERCIAL SPEECH DISTINCTION IN MICRO COSM

Much as the Spanish Civil War served as a testing ground for the weapons that were to later to be employed in considerably broader theatres of combat, the issue of the First Amendment protection for tobacco advertising can serve as a measuring stick.

128. THOMAS HOBBES, LEVITAN (1651).
129. See discussion supra text at notes 72-117.
130. See Redish, supra note 1.
131. See discussion supra Part III.A.
for the overall theoretical grounding of the commercial speech distinction. For the arguments against full First Amendment protection for tobacco advertising underscore every one of the theoretical flaws underlying the commercial speech distinction.

In previous writing, I have argued that even under the relatively reduced protection afforded to commercial speech by pre-44 Liquormart First Amendment doctrine, most restrictions on tobacco advertising should be deemed unconstitutional. The focus of the present analysis, however, is quite different. My point here, rather, is that the political and social context of the proposed regulation of tobacco advertising demonstrates the entire unworkability of the commercial speech distinction in the first place.

No one could seriously dispute that today smoking is a social and political issue of enormous intensity and import. The smoking controversy involves a variety of heavily contested issues, implicating questions of scientific theory, individual free choice, social responsibility, and the scope of governmental power — issues that constitute the very meat of the expression traditionally receiving full First Amendment protection. In order to demonstrate the point, one need only inquire whether First Amendment protection would be extended to the commentary of anti-tobacco activists either asserting the scientific case for the link between smoking and illness or urging individuals not to smoke. The answer, quite obviously, is that such expression both would and should receive full First Amendment protection. Presumably, even the most ardent advocate of a narrow, politically-based First Amendment would be forced to concede that such expression lies at the core of free speech protection, because it implicates expression at the very center of the political process. The scientific, social and moral issues surrounding the smoking controversy, then, would have to be viewed as central to the values of free expression. But if this is true for the expression of those advocating that individuals refrain from smoking, it logically must be equally true for speech advocating that people smoke. The label of “political speech” cannot rationally be attributed only to one side of a debate.

If there is one unbending principle of First Amendment theory

and doctrine, it is that government may not shut off one side of a political debate because of disagreement with the position sought to be expressed. 133 To uphold such a restriction would allow government to skew the democratic process in order to achieve a preordained result. It would, moreover, reflect government's mistrust of its citizens' ability to make lawful choices on the basis of free and open debate. 134 Additionally, selective governmental suppression of speech on the basis of government's perception of the speech's wisdom or persuasiveness undermines the basic premises of governmental epistemological humility, without which the First Amendment cannot survive. 135 Yet the consequence of — indeed, the motivating force behind — the regulation of tobacco advertising is that one side of this important public controversy is stifled so that only the expression of other side can be heard.

The reduced level of protection for tobacco advertising cannot be justified on the basis of the subject matter of the advertisements, because the expression urging individuals not to smoke, of course, deals with the exact same subject matter. Nor can it be justified on the basis of the self-interest of the tobacco companies, because self-interest has never been thought to justify reduced protection for expression that is part of a public debate (nor could it, without significantly disrupting the system of free expression). 136

It could be argued that even were one to concede — as one must — that the smoking controversy implicates a matter of legitimate public debate, it does not logically follow that tobacco advertising constitutes a real contribution to the debate. The advertisements provide no concrete information, the argument would proceed. Rather, they convey nothing more than the frivolous and misleading idea that smoking is a pleasurable activity that increases the individual's personal attractiveness and social acceptability. 137 The flaw in this reasoning, however, is evident

133. See supra note 123.
135. I have explored the concept of epistemological humility and its relationship to First Amendment theory in Redish, supra note 40, at 1443-44.
136. See discussion supra text at notes 106-117.
on the argument's face. Ironically, this attack on tobacco advertising itself constitutes proof that such advertising represents a contribution to the smoking debate. Far from failing to contribute to a public debate, the advertisements constitute advocacy of one very clear choice in the smoking controversy. Especially once the required warnings are included, the advertisements can be read to urge individuals to risk the possibility of future health injury in order to obtain certain largely intangible benefits, in the same manner as numerous other risk-producing activities.

Even were there not such an intense controversy over the ills of smoking, it would be difficult to distinguish such appeals from debate concerning social and political issues traditionally subjected to full First Amendment protection. They constitute suggestions concerning fundamental lifestyle choices available to the individual. When existence of the intense public controversy over smoking is recognized, regulation of such advocacy takes on the ominous character of governmentally orchestrated suppression and mind control, the very type of regulation of expression the First Amendment has been widely construed to preclude. The fact that the government finds the arguments made in advocating a lawful activity to be unpersuasive or unwise, of course, makes such advocacy no less part of the public debate. There can be little question, then, that tobacco advertising is today the subject of potential regulation for the very reason that it conveys an unpopular (albeit perfectly lawful) social message that challenges the views of those who presently hold political power. Far from being justified as merely regulations of the expression of "a seller hawking his wares," then, the restriction of tobacco advertising in reality represents the most ominous form of thought suppression.

Once it is recognized that the regulation of tobacco advertising constitutes governmental suppression of an unpopular social message, the arguments traditionally relied upon to reduce protection for commercial speech disintegrate. The facts that tobacco advertising may not provide a complete picture concerning the dangers of tobacco use or that the tobacco industry's promotions are motivated out of concern for profits, in no way dis-

139. See Blasi & Monaghan, supra note 137.
140. See generally Baker, supra note 5.
tistinguish the tobacco industry's message from the overwhelming majority of fully protected contributions to public debate. Thus, the argument that tobacco advertising misleadingly fails to provide a complete picture no more justifies reduced protection than it does in any other area of speech regulation. Bob Dole's campaign speeches were no more likely to point out the Democratic Administration's positive accomplishments than President Clinton's addresses were likely to highlight the legislative successes of the Republican Congress. When Vice-President Gore spoke passionately at the 1996 Democratic Convention of the death of his sister from lung cancer, he neglected also to mention that for many years afterward he continued to operate a tobacco farm. A welfare mother speaking about her recent welfare cutbacks is no more likely in her speech to take note of the cutbacks' beneficial impact of the national deficit than the National Rifle Association is to devote attention in its literature to the number of accidental deaths caused by hand gun use. Moreover, in all of these cases, no one would expect behavior that is any different. Virtually no contribution to public debate is free of personal motivation or bias. Nor do virtually any such contributions even purport to convey either a complete or objective portrayal of the issues.

The system seeks to deal with the negative consequences possibly flowing from these factors in a number of ways. Initially, recipients of such contributions to public debate will generally be expected to discount their arguments in light of the speaker's self-interest. Secondly, the concept of a free marketplace in ideas and information presumes that the arguments and facts unlisted by one group of speakers will be provided by competing groups of speakers. Ironically, as in both the legal and economic spheres, the implicit assumption is that the existence of self-interest will induce counter-speech. Thus, the very factor that is widely relied upon to justify reduced constitutional protection for commercial speech actually serves as the theoretical linchpin for the successful operation of the marketplace of ideas.

To be sure, reliance on the marketplace to assure that all aspects of an issue are adequately explored in the course of public debate will prove unreliable in certain instances. But it is for this reason that government may itself choose to contribute to public debate, by warning the public of what it deems the erroneous or unwise positions already taken in the course of that
debate. It does not follow, however, that government may skew the debate by means of outright suppression. Such a cure would most assuredly be considerably more harmful than the disease. At least in the specific context of the smoking controversy, concern about the absence of counter-speech is, of course, moot. The fear of an expressive imbalance could hardly justify suppression of the tobacco industry’s position, since no one could reasonably dispute the empirical reality of the widespread — indeed, pervasive — availability of the anti-smoking position.

V. CONCLUSION

The puzzling (and frustrating) element in the foregoing analysis is that virtually no free speech scholar (at least those lacking an overriding ideologically based result orientation) would suggest that either the personal interest of the speaker or the biased and incomplete nature of expression somehow reduces the level of First Amendment protection given to traditional contributions to public debate. Nor would the market’s possible failure to portray all viewpoints ever be allowed to justify suppression of popularly held positions. Fundamental precepts of free speech theory obviously preclude such governmental tinkering with the expressive marketplace. Yet when commercial advertising is involved, for some reason, factors that are routinely ignored in First Amendment analysis appear — inconsistently — to assume overriding theoretical importance.

Recognition of the important role that commercial advertising plays in the shaping of social attitudes and values manifested in Liquormart logically dictates according such expression full First Amendment protection. Neither distaste for the message, the existence of the advertiser’s self-interest, nor the concededly non-objective nature of the expression can any more

141. While several scholars have raised concerns over the First Amendment implications of government speech [see, e.g., MARTE G. YUDOFF, WHEN GOVERNMENT SPEAKS 42 (1983)], it would simply be unworkable to erect a system in which government could not attempt to educate or persuade the public. See Martin H. Redish & Daryl Kessler, Government Subsidies and Free Expression, 80 MINN. L. REV. 543, 569 (1996).

142. To the extent the system of free expression were to respond at all to the possibility of such market failure, it would be exclusively by means of a constitutionally dictated right of access.

143. See discussion supra text at notes 47-49.
justify suppression than it does in the case of traditionally protected advocacy.

The smoking controversy is just that — a controversy. Not all contributions to that controversy need take the form of objective expression or speech that is consistent with the accepted governmental orthodoxy. Under accepted First Amendment precepts, protected speech may be self-interested, incomplete and even irrational. Contributions to public debate that come in the form of commercial advertising thus differ in no meaningful way from traditionally protected contributions. There is therefore no principled theoretical basis on which to distinguish commercial advertising from any other type of fully protected expression.
SMOKING AND SELF-REALIZATION: A REPLY TO PROFESSOR REDISH

by John T. Valauri

I. INTRODUCTION

It is an honor and a challenge to have the opportunity to reply to Professor Redish's presentation at this symposium. It is an honor because he is the prophet of constitutional protection for commercial speech. He took up cudgels for this cause over a quarter century ago, at a time when few in the academy or on the bench shared his sentiments. But, it is a challenge because he has persevered and (largely) prevailed. He is no longer a prophet crying in the wilderness, but rather one now recognized in the law reviews and the court reporters.

If this program had taken place just a few years ago, I could have relied on Supreme Court precedent, *Posadas de Puerto Rico Associates v. Tourism Company of Puerto Rico*, concerning the advertising of casino gambling, to argue that the undoubted governmental power to ban the manufacture of tobacco products also includes the power to ban the advertising of tobacco products. Now, this case lies in tatters, cruelly cut back and criticized by a Court that has effectively overruled it.

In its stead stands a case on liquor price advertising, *44 Liquormart, Inc. v. Rhode Island*, that all but quotes from Professor Redish's brief. Justice Stevens' plurality opinion denies that the power to prohibit manufacturing implies the right to ban advertising. It functionally removes the secondclass status of commercial speech in First Amendment law by no longer deferring to state representations regarding the purpose and efficacy of regulatory measures impacting that speech. In addition, it

4. "The text of the First Amendment makes clear that the Constitution presumes that attempts to regulate speech are more dangerous than attempts to regulate conduct." *Id.* at 1512.
promises to sternly judge any regulation that would keep consumers in the dark by banning truthful, nonmisleading commercial speech for paternalistic reasons.\(^5\)

II. THE SELF-REALIZATION MODEL

The chief reason for Professor Redish's success in his crusade to win greater First Amendment status for commercial speech is his presentation of a unifying principle to explain and justify equal protection for advertising—the model of self-realization. Traditional theories of free speech based protection on the role of expression in democratic self-government.\(^6\) As commercial speech appeared to play no essential role in political debate and democracy, but rather, to relate more to private decisionmaking, it seemed natural to deny it the higher constitutional protection accorded political speech.

Professor Redish's master move is to offer a new, broader rationale for the protection of speech, one which makes the exclusion of commercial speech from full protection seem arbitrary and unnatural. Where the terms of older defenses of free speech were social and political, arguing for free speech as necessary for democracy, the new self-realization model operates instead at the individual level, emphasizing self-rule (or autonomy) and self-development.\(^7\)

As with older theories of free speech, the self-realization model bases protection on a single value. But while this value is related to the traditional political self-government rationale, it is also significantly broader. The older view limits heightened protection to expression involved in or related to the political process. The Redish model expands it to cover any expression that might aid in individual self-development. Traditional notions of the marketplace of ideas, nonsuppression of truthful information, and

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5. "[W]hen a State entirely prohibits the dissemination of truthful, nonmisleading commercial messages for reasons unrelated to the preservation of a fair bargaining process, there is far less reason to depart from the rigorous review that the First Amendment generally demands." *Id.* at 1507.

6. Traditional First Amendment doctrine is summed up by Alexander Meiklejohn, one of its classic exponents, who wrote, "The principle of the freedom of speech springs from the necessities of the program of self-government." ALEXANDER MEIKLEJOHN, POLITICAL FREEDOM 27 (1965).

7. For an early exposition of this theory, see Martin H. Redish, *supra* note 1, at 438-43.
rational decisionmaking are retained, but now given greater scope and wider play.

The effect of the switch to this newer, broader theory of free expression is readily seen in the constitutional treatment afforded commercial speech. From the perspective of the political model of free speech rights, as purely commercial speech plays little role in the exposition and debate of political ideas, (political speech might be about commercial matters, but it does more than propose a commercial transaction), it receives scant constitutional protection. Under the self-realization model, advertising deserves substantial constitutional protection since advertising provides information which is more useful in life decisions than what is available from other sources. ⁸

III. LUDWIG WITTGENSTEIN, MEET JOE CAMEL

If Professor Redish's self-realization theory of the constitutional protection of speech does such a good job of unifying and explaining expanding Supreme Court doctrine, why, then, am I so uneasy about its application in the area of cigarette advertising, especially to minors? This is more than an instance of hard cases making bad law. It goes, I believe, to a mismatch or dissonance between the model's source and its applications. The single value of self-realization just does not have the same force in all contexts. Instead, a more flexible approach is called for.

My predicament puts me in mind of a philosophical legend I heard in my youth concerning Ludwig Wittgenstein, arguably the most influential philosopher of the twentieth century (at least in anglophone countries). Wittgenstein is famed for having two philosophies, one early and the other late, separated by a period of doubt and turmoil.

In his earlier years, Wittgenstein maintained the picture theory of meaning. To oversimplify somewhat, the picture theory of meaning holds that each sentence is a picture of a fact (or at least a potential fact). ⁹ Wittgenstein eventually came to reject

⁸. "Information received in the commercial context . . . is specifically designed to assist the individual in the decision-making process." *Id.* at 445.

this theory of meaning as inadequate and abandoned it for a theory of meaning as use.

What caused this crisis in Wittgenstein's philosophy? Philosophical lore traces the change, at least in part, to a conversation he had with an Italian economist, a colleague at Cambridge University in England. As was his wont, Wittgenstein vigorously expounded his picture theory of meaning to the colleague, arguing that sentences are pictures of facts. In reply, the colleague made a vulgar Neapolitan hand gesture at Wittgenstein and then calmly asked, "Tell me, what fact does that depict?"

Stunned at the response, Wittgenstein repented of his picture theory of meaning, spent several years in doubt and reflection on a mountainside in Norway, and returned to philosophy with a very different theory of meaning. The new theory he developed was meaning as use, which said that the varieties of linguistic meaning were as numerous and diverse as the jobs to which language can be put.10

Now, I neither seek nor expect such a Damascene conversion from Professor Redish. But I do hope that we can embark upon a productive dialogue about the limits of the self-realization model of free speech protection, especially in the context of cigarette advertising directed at minors. Let us start by assuming that we are looking upon a Joe Camel billboard across the street from an elementary or junior high school. Please tell me what self it realizes. Is self-realization even the first notion that springs to mind in this situation?

My point here is that, like Wittgenstein's picture theory of meaning, the self-realization model oversimplifies the uses of language. Now, Professor Redish may reply that he has recognized that there are many different sorts of expression. But his theory cannot account for them in terms of constitutional protection. The purposes of cigarette advertising often differ quite starkly from the provision of information to rational adults to aid them in their personal decisionmaking in the pursuit of self-development.

IV. SMOKING AND SELF-REALIZATION

To put this discussion in a more specific contemporary context, consider the recent admissions made by the Liggett Group, Inc., one of America's major cigarette makers. As part of an agreement to settle a lawsuit brought by twenty-two states, Liggett made these admissions:

(1) Cigarette smoking is addictive.
(2) Cigarette smoking causes cancer.
(3) Cigarette makers have directed marketing efforts at minors.\(^{11}\)

In these circumstances, what restrictions may government constitutionally place on cigarette advertising and why? I contend that it may ban cigarette advertising directed at minors. Furthermore, I believe that, despite some statements tending toward the contrary position, such a limited ban can be reconciled with both Professor Redish's self-realization model of free speech protection and recent United States Supreme Court commercial speech decisions, most notably 44 Liquormart. Both assume a process of free-flowing information and rational, adult decisionmaking which simply does not apply in the youth smoking situation.

So, on one hand, the plurality in 44 Liquormart finds that, "[c]ommercial speech bans not only hinder consumer choice, but also impede public debate over central issues of public policy."\(^{12}\) Yet, earlier it allows that, "[w]hen a State regulates commercial messages to protect consumers from misleading, deceptive, or aggressive sales practices . . . the purpose of its regulation is consistent with the reasons for according constitutional protection to commercial speech and therefore justifies less than strict review."\(^{13}\) Likewise, Professor Redish last year said that, "[s]upression of tobacco advertising is properly seen . . . as a dangerous manifestation of governmental mistrust of citizens' abilities to absorb and judge the expression of competing viewpoints."\(^{14}\) Yet, in 1971, he conceded that, "[i]t may nevertheless

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13. Id. at 1507.
be agreed that the public health interest justifies a prohibition of cigarette advertising as it is currently constituted.”

Contrasting views like these indicate to me the preferability of a continuum of constitutional commercial speech protection, rather than a bright line test where one size fits all. And under this view, minor-targeted cigarette advertising would fall very much to the lesser protection end of the spectrum.

This question would be substantially easier to resolve if one could readily distinguish minor-targeted advertising from information sought by adult smokers. But I have no confidence in the feasibility of making a clear and clean division between the two categories. Some significant overlap is inevitable. Professor Redish is likely to insist in this case that adults should not be reduced to hearing only expression that is suitable for children and that choice of modes of expression is an important First Amendment value.”

In contrast, I would argue that the governmental interest in preventing the harm caused by this speech, (the seduction of another generation of nicotine addicts and the resultant health problems and costs), the small amount of speech covered, the questionable value of such speech, the availability of adequate alternative means to reach adult smokers, and the absence of truly less restrictive alternatives all justify the constitutionality of the limited restriction proposed. Moreover, I suggest that such a ban is consistent with a flexible theory of self-realization and a reasonable reading of recent Supreme Court commercial speech precedent.

V. TAKING SELF-REALIZATION SERIOUSLY

Finally, let me reformulate the core of my disagreement with Professor Redish in a different way, one that arises out of a fundamental ambiguity in his basic notion of self-realization. Now, his concept is intended to be ambiguous between two interpretations, the “development of the individuals’ [sic] powers and abili-

15. Martin H. Redish, supra note 1, at 467.
ties" and "the individual's control of his or her own destiny through making life-affecting decisions." 17

The problem with this ambiguous definition of self-realization is that these two interpretations of self-realization can, and often do, conflict. The notion of a bad or wrong choice, for example, is an important element of the first interpretation, but is a contradiction in terms under the second.

How does Professor Redish resolve this conflict? He gives it little, if any, explicit attention. In practice, though, he opts for the second interpretation, rather than the first, wherever they would come into conflict. So, for example, shortly after introducing these two interpretations, he says, "[a]ny external determination that certain expression fosters self-realization more than any other is itself a violation of the individual's free will, recognition of which is inherent in the self-realization principle." 18

But does my choice, by the very fact that it is mine, foster self-realization? Is not this the sort of formalism that has caused the liberty of contract rationale of *Lochner v. New York* 19 to be so universally criticized? A choice that is formally free, but practically constrained, is not truly free or self-realizing.

Professor Redish may counter by replying that the bakers in *Lochner* could not control their own destiny and freely decide because of external economic pressures and, thus, the liberty of contract doctrine violated, rather than actualized, their free will.

Let us put external factors to one side. Absent external constraint, is my choice, simply because it is mine, by definition free and self-realizing? Professor Redish, I believe, would say yes. I would say no, and that his second interpretation is a necessary, but not a sufficient, condition of autonomy or self-realization. Instead, the two notions that Professor Redish calls alternative interpretation of self-realization are better understood as dual criteria of autonomy or self-realization.

The difference between Professor Redish's view of self-realization and mine is as simple as the distinction between liberty and license or as metaphysical as the Kantian distinction between Wille and Willkür. 20 This distinction is especially crucial here in

18. Id. at 12.
19. 198 U.S. 45 (1905).
20. See IMMANUEL KANT, THE METAPHYSICS OF MORALS 42 (Mary Gregor trans.,
the case of cigarette advertising given the addictive character and cancer-causing effects of cigarette smoking, along with the directed marketing of cigarettes at minors. Such advertising would probably pass scrutiny under Professor Redish's version of self-realization, but not under my dual criteria version.

There is neither the time nor the space here to resolve this difference, if in fact it can be resolved. Philosophers have failed to do so for generations. My point is merely to raise it as another hurdle which Professor Redish's theory must clear to carry the day.


21. See supra note 11 and accompanying text.
In 1560, the French Ambassador to Portugal, Jean Nicot, introduced an American herb to the civilized world, extolling its curative powers. The "American herb" subsequently was christened "Nicotiana," the scientific name for tobacco, to pay homage to Nicot and his endowment to the world. In a relatively short period of time, Nicotiana's pernicious effects became apparent. Pope Urban VII excommunicated all parishioners using tobacco on church grounds, by proclaiming that "[t]he use of ... tobacco has gained so strong a hold on persons of both sexes ... that ... during the actual celebration of holy mass, they do not shrink from taking tobacco through the mouth or nostrils, thus soiling the altar linen and infecting the church with its noxious fumes...." The Pope's admonitions were corroborated in the early 1600's by King James I of England, who wrote that tobacco was "a custome lothsome to the Eye, hateful to the Nose, harmful to the Braine, dangerous to the Lungs, and, in the black stinking Fume thereof, nearest resembling the horrible Stygian Smoke of the Pit that is bottomless." The declarations of the King and Pope were quite prophetic. In 1954, a scientist at Memorial Sloan-Kettering Cancer Center detected that tobacco tar caused cancerous tumors in mice. As a result, scores of law suits were initiated by injured smokers against the cigarette manufacturers for the deleterious effects of

2. Id.
4. Richards, supra note 1, at 4 (quoting A Counterblaste to Tobacco (1604), quoted in Consumer Protection Gains and Setbacks, EDITORIAL RES. REP. 70 (1978) and reprinted in A ROYAL RHETORICIAN (Robert S. Rait ed. 1900)).
their products. The well-financed and contentious tobacco companies ferociously battled the plaintiffs, who relied upon the traditional common law principles of warranty and negligence.

The courts essentially obliterated the plaintiffs' claims for smoking-related injuries as quickly as they were filed. On the issue of negligence, the courts determined that the risk of harm from cigarette smoking was not sufficiently foreseeable, thus, eliminating an essential element of the negligence cause of action. Additionally, even though an implied warranty of merchantability does not require a showing of fault, the courts required the plaintiffs to make fault-like showings, to wit foreseeability and reliance. By reducing the warranty theory to "nothing more than one of negligence," the plaintiffs were unable to establish that it was sufficiently foreseeable that cigarette smoking caused cancer.

In 1962, to address the public's concern, the Surgeon General convened an advisory committee to examine the health hazards of smoking. The advisory committee's report stated as its central conclusion that "[c]igarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action." In response to the advisory committee's report, the tobacco industry announced that it "accept[ed] an interest in people's health as a basic responsibility, paramount to every other consideration in [its] business." To manifest its compassion, the tobacco industry publicized that it would fund a completely "autonomous" research center, the Tobacco Industry Research Committee, to investigate and disclose to the public any data concerning tobacco use and health.

During this same era, the American Law Institute unveiled

7. Id. at 857-58.
13. Id.
section 402A of the Restatement (Second) of Torts, which established the doctrine of strict products liability. However, this new theory of liability did little to ameliorate the injured plaintiffs' prospects of recovery. To state a cause of action under a strict products liability theory, the plaintiff must prove that the product is "unreasonably dangerous" and "defective." Conscious that the "unreasonably dangerous" element would present a serious threat to the tobacco industry, the American Law Institute created an exemption for "good tobacco."

The American Law Institute provided plaintiffs with a cause of action against manufacturers of cigarettes, but concealed it in the fine print. For that reason, section 402A and comment i "stopped the cigarette products liability litigation in its tracks." In spite of the Restatement's position on tobacco, the onslaught against the cigarette manufacturers persisted. The incessant litigation created such a cacophony that the Supreme Court of the United States resolved to establish some guidelines for litigants in Cipollone v. Liggett Group, Inc. In Cipollone, Rose Cipollone smoked, except during her first pregnancy in the 1940's, between one and two packs of cigarettes each day for more than thirty-eight years. In 1981, she was diagnosed as having lung cancer which necessitated the removal of a lung. Mrs. Cipollone, nevertheless, continued to smoke secretly until her cancer was diagnosed as being terminal in 1983. In 1983, the year before she died, she and her husband, Antonio, filed a

14. See Restatement (Second) of Torts § 402A (1965) ("One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property . . . .").
15. Id.
16. See Restatement (Second) of Torts § 402A cmt. i (1965) ("The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer . . . . Good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful; but tobacco containing something like marijuana may be unreasonably dangerous.").
20. Id.
21. Id.
products liability suit in the federal court in New Jersey against the manufacturers of the cigarettes that she had smoked. The Cipollones' complaint relied upon such theories as failure to warn, breach of express warranty, fraudulent misrepresentation and conspiracy to defraud.

The jury found that the manufacturer had failed to adequately warn of the health effects of smoking and that it had breached its express warranties made prior to 1966. However, the jury also found that Rose Cipollone "voluntarily and unreasonably encountered a known danger by smoking cigarettes," and held her eighty-percent responsible for her injuries. In effect, the jury's resolution nullified Rose's award because New Jersey's modified-comparative fault law disallows recovery by those individuals responsible for greater than fifty-one percent of their injuries.

With regard to Antonio Cipollone's claims, the jury awarded him $400,000 as compensation for the harm he suffered as a result of his wife's illness and death. Both sides appealed.

The Supreme Court of the United States granted the petition for certiorari to consider the preemptive effect of the Federal Cigarette Labeling and Advertising Act of 1965 and the Public Health Cigarette Smoking Act of 1969. The 1965 Act "mandated warnings on cigarette packages . . . but barred the requirement of such warnings in cigarette advertising . . . ." Section two of the 1965 Act asserted that the statute's purposes were to adequately inform the public of the perils of smoking and to protect the national economy from the burden of nonuniform cigarette labeling and advertising regulations. To accomplish this purpose, the "Act made it unlawful to sell or distribute any

23. Id.
24. Id. at 554.
25. Id.
26. Id.
27. Cipollone, 893 F.2d at 555.
30. Id. (quoting Cigarette Act, supra note 29, § 1331).
cigarettes in the United States unless the package bore a conspicuous label stating: 'CAUTION: CIGARETTE SMOKING MAY BE HAZARDOUS TO YOUR HEALTH.'

Moreover, section five of the Act, entitled "Preemption," averred as follows:

(a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package.
(b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

In 1969, Congress amended the 1965 Act by enacting the Public Health Cigarette Smoking Act of 1969, which strengthened the warning label by requiring the phrase: Cigarette smoking is "IS DANGEROUS" vis-a-vis "MAY BE DANGEROUS" to your health. Further, the 1969 Act proscribed cigarette advertising in "any medium of electronic communication subject to [FCC] jurisdiction," and revised the preemption provision by supplanting the original section 5(b) with a provision that asserted: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act."

The Court interpreted section five of the 1965 and 1969 Acts to be determinative of the preemptive scope of the law. Consequently, although the 1965 Act did not preempt state law damage actions, the 1969 Act preempted essentially all failure to warn claims relating to the advertising or promotion of cigarettes. To explain its reasoning, the Court enunciated as follows:

To establish liability for a failure to warn, petitioner must show that "a warning is necessary to make a product . . . reasonably

31. Id. (alteration in original) (quoting Cigarette Act, supra note 29, § 1333 (Supp. III 1965-67)).
32. Id. at 514 (discussing Cigarette Act, supra note 29, §§ 1334-35).
33. Id. at 504 (quoting Cigarette Act, supra note 29, § 1333 (1970)).
34. Cipollone, 505 U.S. at 515 (quoting Cigarette Act, supra note 29, § 1335 (1970)).
35. Id.
36. Id. at 518 (citing Cigarette Act, supra note 29, § 1334).
37. Id. at 524.
safe, suitable and fit for its intended use," that respondents failed to provide such a warning, and that that failure was a proximate cause of petitioner's injury. In this case, petitioner offered two closely related theories concerning the failure to warn: first, that respondents "were negligent in the manner [that] they tested, researched, sold, promoted, and advertised" their cigarettes; and second, that respondents failed to provide "adequate warnings of the health consequences of cigarette smoking." Petitioner's claims are pre-empted to the extent that they rely on a state-law "requirement or prohibition . . . with respect to . . . advertising or promotion." Thus, insofar as claims under either failure-to-warn theory require a showing that respondents' post-1969 advertising or promotions should have included additional, or more clearly stated, warnings, those claims are pre-empted. The Act does not, however, pre-empt petitioner's claims that rely solely on respondents' testing or research practices or other actions unrelated to advertising or promotion. 38

The Court's ruling was significantly beneficial for future plaintiffs, because it permitted substantial flexibility regarding state law claims. 39 The Court affirmed the fact that the 1969 Act did not "preempt state-law obligations to avoid marketing cigarettes with manufacturing defects or to use a demonstrably safer alternative design for cigarettes." 40 Accordingly, if the plaintiff can establish that a safer alternative cigarette was available, but that the manufacturer did not market it because it would result in lower sales, then the plaintiff will have a cause of action under a design alternative theory. In addition, the Court would allow state law claims that relied upon the manufacturer's "testing or research practices or other actions unrelated to advertising or promotion." 41 This second cause of action would be applicable if a state's consumer protection statute required cigarette manufacturers to disclose to the state administrative agency certain hazards discovered during testing or research, and the manufacturer failed to comply. 42

Moreover, the Court authorized a breach of express warranty claim, because "the 'requirement[s]' imposed by an express war-

38.  Cipollone, 505 U.S. at 524-25.
39. Id. at 530-31.
40. Id. at 523.
41. Id. at 524-25.
42. Id. at 528.
ranty claim are not ‘imposed under State law,’ but rather imposed by the warrantor” in its advertisements. The Court also approved a state law claim for fraudulent misrepresentation. As a result, if the plaintiff can prove that the cigarette manufacturers possessed knowledge of tobacco’s pernicious effects and conspired to conceal or misrepresent that knowledge in its advertising, then the plaintiff’s claim will not be preempted by the federal law. The final state law claim sanctioned by the Court was for conspiracy to misrepresent or conceal material facts. This cause of action is very important to the plaintiff because if he or she can show that the manufacturers engaged in conversations concerning the risks associated with smoking, then the plaintiff, under either a theory of fraud or deceit may be able to recover punitive damages. Further, under the conspiracy theory, each coconspirator is treated as an agent of the other, consequently, making a very strong argument for joint and several liability.

Despite the Court’s pivotal ruling in Cipollone, the “lawyers for the Liggett Group persuaded the Supreme Court to order a retrial that the plaintiffs could not afford.” The Liggett Group had already expended $75 million opposing the Cipollones and was prepared to disburse even more. Meanwhile, on the plaintiffs’ side, both Rose and Antonio Cipollone were dead and “[n]either their son nor the lawyers handling the cases, who had

43. Cipollone, 505 U.S. at 525-26.
44. Id. at 527.
45. Id. at 527-31.
46. Id. at 530.
47. See RESTATEMENT (SECOND) OF TORTS § 876 (1979).
For harm resulting to a third person from the tortious conduct of another, one is subject to liability if he (a) does a tortious act in concert with the other or pursuant to a common design with him, or (b) knows that the other’s conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself, or (c) gives substantial assistance to the other in accomplishing a tortious result and his own conduct, separately considered, constitutes a breach of duty to the third person.

expended more than $5 million in time and $1 million in out-of-pocket expenses in their cigarette litigation, wanted to continue the fight. Hence, the case was discontinued. 

Prior to 1996, there had been more than eight-hundred anti-smoking lawsuits filed, but the cigarette manufacturers had never paid a single dollar in damages. The tobacco industry’s pugnacious litigation strategy had prevailed for over forty years. As one lawyer for R.J. Reynolds boasted:

[T]he industry’s hard-ball tactics have made the litigation [of these cases] “extremely burdensome and expensive for plaintiffs’ lawyers . . . . To paraphrase General George Patton, the way we won these cases was not by spending all of [R.J.] Reynolds’s money, but by making the enemy spend all of his.”

Despite Liggett Group’s successful defense in the Cipollone suit, the attorneys representing the Cipollones were able to discover damaging internal company documents which demonstrated that the industry had been aware of the serious health hazards of cigarette smoking, but had conspired to withhold them and wage a public relations campaign aimed at discrediting tobacco’s critics. Additionally, in 1994, the New York Times obtained minutes of a Brown & Williamson company meeting held in 1967 at which a chief researcher stressed that the industry’s real business was not tobacco but the sale of nicotine. These documents revealed that the cigarette manufacturers had been cognizant of nicotine’s addictive qualities for nearly thirty years.

Also occurring in 1994, testimony before Representative Henry Waxman’s Subcommittee on Health and the Environment di-

52. Christopher John Farley, Cough Up That Cash, TIME, Mar. 6, 1995, at 47.
54. See Alan Farnham, Tobacco’s Last Gasp? (Tobacco Companies Accused of Hiding Dangers of Smoking from Public), FORTUNE, May 23, 1988, at 9.
56. Id.
vulged that the tobacco industry, with the aid of the public relations firm of Hill and Knowlton, created the Tobacco Industry Research Committee (now the Council for Tobacco Research [hereinafter CTR]) as a ruse.57 Under the guise of furnishing aid and assistance to the research effort, the industry launched a monumental public relations campaign to counter mounting evidence linking tobacco to lung cancer.58 In response, the executive director of CTR, Dr. James Glenn, testified that CTR was independent of the industry and that there was no causal link between smoking and health diseases.59 This testimony directly contradicted a Wall Street Journal investigation which had reported that CTR was at the center of "the longest-running misinformation campaign in United States business history."60

The degeneration of the industry's credibility continued when Brown & Williamson's Chief, Thomas Sandefur,61 Philip Morris' President, William Campbell,62 and other industry CEOs intransigently declined to admit to Representative Waxman's Subcommittee on Health and the Environment that smoking was addictive, even as the aforementioned internal company memos revealed that cigarette manufacturers had long understood and

Congressman Henry Waxman explained that, in response to the mounting scientific evidence linking smoking to health diseases, the tobacco industry retained the public relations firm of Hill & Knowlton in 1953. Hill & Knowlton recommended that the tobacco industry create the Council for Tobacco Research to research and present to the public scientific evidence negating the link between smoking and health diseases.


hidden nicotine's addictive properties. The industry's blatant obstinacy before Congress swayed the tide of public sentiment and presaged an onslaught of epic proportions.

After watching the cigarette executives testify before Congress that nicotine is not addictive, the American Medical Association pronounced as follows:

[U]nequivocal evidence [existed that] the US public has been duped by the tobacco industry. [The AMA urged that] [a]ll avenues of individual and collective redress should be pursued through the judicial system, [and specifically supported government efforts to recoup the] billions of dollars in excess medical costs from tobacco-related diseases borne by Medicare, Medicaid, and the Department of Veterans Affairs.

The testimony of the industry's CEOs also infuriated Florida native Grady Carter, who had smoked for forty-four years and, as a result, contracted lung cancer in 1991. Carter subsequently sued Brown & Williamson for failure to warn and strict liability. In an unprecedented occurrence, the jury was permitted to inspect internal documents belonging to Brown & Williamson, which indicated that the industry had known for years that cigarette smoking presented serious health risks and that nicotine is addictive. The documents severely hampered Brown & Williamson's standard position: that smokers were accountable for their own illnesses because they had engaged in the habit knowing full well the risks they were taking. In the first post-Cipollone plaintiff verdict, the jury awarded Grady Carter $750,000, although, Brown & Williamson indicated that it would appeal.

On another front, four old law school friends from Ole Miss, including the Attorney General of Mississippi, discovered a chink in the tobacco companies' armor. Reasoning that the State did

63. See Farley, supra note 52, at 47.
64. See American Medical Association Publishes Analysis of Disputed Tobacco Papers, Calls for Redress Through Courts, Civ. JUST. DIG., Summer 1996, at 1.
68. Id.
69. Henry Weinstein & Jack Nelson, States Gather Forces to Take on Tobacco
not smoke but had suffered considerable damage from tobacco-related illnesses, the State of Mississippi in May, 1994 filed suit against the tobacco industry to recoup the “tens of millions of dollars it spends each year to provide medical care to victims of tobacco-related illnesses.”\(^7\)0 The suit “names thirteen tobacco companies, six tobacco wholesalers, and tobacco trade associations and public relations consultants. Specifically, it seeks to reimburse the state for providing health care to victims of tobacco-related illness through programs such as the state insurance plan, Medicaid, medical assistance for the aged, and indigent care.”\(^7\)1

The suit alleges that “[t]he defendants have known for decades of the lethal dangers of smoking their cigarette products.”\(^7\)2 Further, the complaint maintains that the cigarette manufacturers concealed from and misled the public about information demonstrating the dangers of smoking.\(^7\)3 “The state’s suit seeks unspecified damages for restitution and unjust enrichment, indemnity, common law public nuisance, and injunctive relief.”\(^7\)4 The Mississippi suit is scheduled to go to trial on June 2, 1997.\(^7\)5

By implementing said causes of action, Mississippi has outflanked the cigarette manufacturers by circumventing the traditional legal theories associated with products liability. This gambit has effectively eliminated the industry’s favorite defenses of assumption-of-the-risk and contributory negligence, because Mississippi did not smoke and had no choice in providing health care to its citizens suffering from tobacco-related illnesses.\(^7\)6 Moreover, Mississippi’s strategy denies the cigarette manufacturers a jury trial, because, in equity, there is no right to a trial by

\(^7\)0 State of Mississippi’ Sues Tobacco Industry, MEALEY’S LITIG. REP.: TOXIC TORTS, June 16, 1994, at 5 (citing State v. American Tobacco Co., No. 94-1429 (Jackson County Ct. 1994)).

\(^7\)1 Id.

\(^7\)2 Id.

\(^7\)3 Id.

\(^7\)4 Id.

\(^7\)5 Gail Appleson, Cigarette Maker Hopes to Settle Medicaid Suits, ORANGE COUNTY REG., Jan. 10, 1997, at C6.

First, Mississippi maintains that the cigarette manufacturers have been unjustly enriched by not having to shoulder the enormous health care costs associated with their deleterious products. Consequently, "the State is entitled to restitution because it conferred a benefit on the tobacco industry, satisfied its debt, performed its duty, and saved it from expense and loss." The Restatement of Restitution permits "recovery by one who is forced to supply things or services to satisfy the requirements of public decency, health or safety, and to avert a public health crisis. The State did just that by paying the costs of the public health crisis which the tobacco industry created."

Second, Mississippi claims that it is an innocent third-party, legally obligated to incur the medical expenses of indigent smokers. In support of this proposition, Mississippi relies upon the Restatement of Restitution, which provides: "[t]he concept of indemnity calls for a shifting of loss, or a portion of it, unfairly borne by one party who was under a duty to pay for the loss for which the other is primarily responsible." Therefore, Mississippi should be indemnified for its losses by shifting the costs of tobacco-related illnesses to the cigarette makers.

Third, Mississippi alleges that the cigarette manufacturers are creating a public nuisance. Public nuisance is a theory which grants states broad authority to protect against conduct that is "an unreasonable interference with a right common to the general public." The Restatement (Second) of Torts asserts that public health is just such a right. The nation's courts consistently have allowed government entities to recover their expenditures associated with abating a public nuisance. Since Mississippi

77. Id.
78. Id.
79. Id. (citing RESTATEMENT OF RESTITUTION § 1 cmt. b (1937)).
80. MOORE & MIKHAIL, supra note 76, at 192 (citing RESTATEMENT OF RESTITUTION § 1 (1937)).
81. Id.
82. Id. (quoting the RESTATEMENT OF RESTITUTION § 76 (1937)).
83. Id.
84. Id.
85. MOORE & MIKHAIL, supra note 76, at 192 (quoting RESTATEMENT (SECOND) OF TORTS § 821B(1) (1979)).
87. See MOORE & MIKHAIL, supra note 76, at 192; see also New York v.
has acted to abate a public nuisance created by the cigarette manufacturers by providing health care to indigent smokers, it is entitled to recover its expenditures.\textsuperscript{88}

Fourth, Mississippi requests injunctive relief to protect the State's children.\textsuperscript{89} “This claim is aimed at stopping the industry from targeting children in advertising and promotions and from selling cigarettes to minors.”\textsuperscript{90} The State contends that “[t]he industry is creating successive generations of addicted smokers, many of whom will ultimately get sick and create a health care crisis for, and a tremendous burden on, the State.”\textsuperscript{91} Accordingly, the court of equity should provide such relief.\textsuperscript{92}

The Mississippi action has been followed by similar suits brought by twenty-two states and more than a dozen municipalities.\textsuperscript{93} In addition to the aforementioned claims, the State of Minnesota is utilizing its strong antitrust statute by accusing “the industry of conspiring to suppress research into a safer cigarette.”\textsuperscript{94} Comparably, Florida's legislature engendered an Act which countenanced the recoupment of Medicaid expenditures and eliminated all affirmative defenses.\textsuperscript{95} The states' suits pres-
ent a significant threat to the industry because "the legal theories available to the states are so powerful." 96

These "powerful legal theories," which previously had not been employed in the customary tobacco products liability litigation, have the industry's attorneys scrambling to find new defenses. The traditional defense that smokers had assumed any risks involved with smoking and were guilty of contributory negligence is of no relevance in state recoupment actions based in equity. 97 It is this very feature of the states' equitable claims that presents the industry with what may prove to be an insuperable obstacle to avoid accountability.

An additional dilemma for the tobacco industry is that they are no longer king-of-the-financial mountain. 98 Northeastern University Law Professor Richard Daynard, chair of the Tobacco Products Liability Project, explicates as follows:

This king-of-the-mountain game [that the industry has] played is a game that would be played by a schoolyard bully. . . . After you've beaten a couple of kids up, nobody dares take you on. But the moment the kids say, 'We can take him if we band together,' the bully is finished. 99

The potential for billion dollar settlements and commensurate legal fees is "attracting the top guns of tort law," 100 and is eroding the king's mountain. The majority of the states "that have filed suit have entered into contingent fee contracts with private attorneys rather than financing and managing the cases entirely by themselves." 101 This flexibility enables the states to attract the preeminent attorneys and their sophisticated firms. 102 Accordingly, the states are equipped with the resources to assail the fifty billion dollar a year industry and its dilatory tactics.

97. MOORE & MIKHAIL, supra note 76, at 192.
98. See Gleick, supra note 49, at 54.
99. Id. (quoting Northeastern University Law Professor Richard Daynard).
100. Id.
Graham Kelder and Richard A. Daynard, who are the managing attorney and chair of the Tobacco Products Liability Project, respectively, assert that the states present a grave threat to the tobacco industry in the Medicaid suits, for the following reasons:

(1) a well-financed nationwide consortium of plaintiff attorneys who will share expenses and information; ... 
(3) the absence of blameworthy plaintiffs (especially the state governments), thus avoiding previously successful defenses; 
(4) abundant evidence of industry wrongdoing, originating within the industry itself and uncovered by investigative reporters; and 
(5) new facts on nicotine's addictive properties. 103

"The current round of attacks on the tobacco industry is better thought out, better funded and better organized than at any time in history. And it comes at a time when the tobacco industry is more vulnerable than ever, given the disclosures from inside the industry." 104

At the center of the Medicaid cases is the contention that the cigarette companies have known since the early 1950's that their products were dangerous to people's health, but have suppressed information about the hazards and the addictive character of nicotine. 105 During the pretrial discovery phase of the Medicaid suits, the states have unearthed a surfeit of damaging evidence. In November, 1995, the vice president for research and development at Brown & Williamson Tobacco Company, Jeffrey Wigand, shocked the nation when he turned whistle-blower. 106 During a deposition in Mississippi's Medicaid suit against the industry, 107 Wigand divulged that "former B&W chief Thomas Sandefur [had] acknowledged nicotine's addictive power," and, in anticipation of litigation, Sandefur had a "company lawyer de-
letel] 12 pages from the minutes of a meeting attended by Wigand and other top scientists from B&W's affiliates in which there was discussion of developing a 'safer cigarette.'

Wigand is the consummate witness because he "can personalize the story and give . . . firsthand evidence . . . as to how the industry was conducting its business and what its motivations were." Following Jeffrey Wigand's lead, two former scientists and an ex-production manager of Philip Morris publicly stated that Philip Morris President William "Campbell and the company were aware of nicotine's addictiveness and deliberately controlled nicotine levels to satisfy smokers." These statements directly contradict Campbell's 1994 testimony before Congress, where he stated: "Philip Morris does not manipulate or independently control the level of nicotine in our products." Philip Morris attorneys retort that Campbell did not say that tobacco is not addictive, instead, he said that he did not believe it is additive; a "personal viewpoint he has every right to hold.

In October, 1996, attorneys representing the State of Minnesota discovered provocative internal company documents belonging to British American Tobacco Co., the parent company of Brown & Williamson. The aforesaid documents, dated May 16, 1980, stated that the company needed to change its position because "our integrity is seriously in question over our position on causation," a position that is implausible "in the eyes of the ordinary man in the street." Another memo, entitled "A New Company

109. Gleick, supra note 49, at 54 (quoting Scott Ballin of the Coalition on Smoking or Health).
110. Blum, supra note 107, at A6. Nicotine levels are controlled by the use of additional ammonia, which, in turn, increases the proportion of "free" nicotine contained within the cigarette. David Phelps, State: What's in a Cigarette?, STAR-TRIB., Nov. 27, 1996, at 1D (quoting a 1973 R.J. Reynolds memorandum). This "free" nicotine is rapidly absorbed by the smoker and instantly perceived as a nicotine "kick." Id. Presumably, an enjoyable event for the smoker.
114. Id.
Approach to the Smoking and Health Issue," espoused that "smoking is addictive/habituative in addition to being an additional [health] risk and many smokers would like to give up the habit if they could."115 These memoranda are yet another example of how the cigarette industry willfully suppressed information concerning the health hazards of smoking.

The incriminating testimony of the whistle-blowers and the ubiquitous internal company documents have precipitated five grand jury investigations into the possibility of perjury and malfeasance charges being filed by federal prosecutors against Sandefur, Campbell, and the other industry executives, who declared under oath during the 1994 Waxman hearings that nicotine is not addictive.116

The prevalence of whistle-blowers, incriminating corporate memoranda and the growing number of states joining the lawsuit also caused one of the cigarette makers to blink. In an unprecedented maneuver, the Liggett Group, the smallest of America's top five cigarette manufacturers, broke ranks with the other cigarette makers by settling five117 Medicaid recoupment suits brought by state attorneys general.118 The March, 1996 settlement amounted to thirty-one million dollars, to be paid over twenty-five years.119 The settlement provided two pools of money, "a larger one for the five original states and a smaller one for subsequent filers."120 Minnesota declined to settle, explaining that it was a splendid arrangement for Liggett and R.J. Reynolds but offered the states very little.121

Cupidity, not magnanimity, lay "behind [Bennett] LeBow's peace pact with the anti-smokers."122 LeBow, who controls the Liggett Group, was vying for control of R.J. Reynolds, the second largest cigarette maker.123 LeBow theorized that if R.J.
Reynolds merged with Liggett, it would also become part of the settlement, thus, circumscribing its losses should the industry one day lose the cases. However, Liggett's proposed takeover of R.J. Reynolds foundered, and the "reaction to the settlement has been mixed."  

More important, by settling, LeBow has broken the tobacco industry's united front against the state attorneys general. The devastating corollary of this arrangement was that "Liggett agreed to hand over key files—files that anti-smoking forces hope will prove that the industry suppressed evidence that nicotine is addictive." Moreover, on January 10, 1997, the Wall Street Journal reported that LeBow was attempting to "settle virtually all the current and future liability lawsuits hanging over his company" by offering to release thirty years of sensitive industry documents. The proposal was "discussed . . . with representatives of attorneys general around the country . . ." The disclosure of this information could prove cataclysmic for those cigarette manufacturers resolved to stand and fight the states.

To further chum the waters, in June, 1996, a bill was introduced to allow the states to retain a portion of their recoveries. Under current federal law, any Medicaid money recouped by the states would have to be returned to the federal government. To create a financial incentive for the states, Senator Frank Lautenberg, D-N.J., introduced a bill that would permit states to retain thirty-three percent of any awards eventually won. If the bill passes, it also will compel the state attorneys general to file suit or explain to their constituents why neighboring states are receiving millions of dollars in restitution

124. Id.
126. See Levinson, supra note 122, at 38.
127. Id.
131. Id.
132. Id.
for their taxpayers.\footnote{133}{See Gleick, supra note 49, at 54.}

The pressure on the industry is increasing daily. It is spending tens of millions of dollars annually defending itself, and "[t]he total potential liability is in excess of $30 billion, more than the combined shareholder equity of the two largest U.S. tobacco companies: Philip Morris Companies, Inc. and RJR Nabisco Holdings Corp."\footnote{134}{Susan Adams, Where There's Smoke, There's Lawyers, Forbes, Dec. 16, 1996, at 74.} Though the industry continues to deny that it is interested in settling, substantial evidence indicates that is just what they intend to do.\footnote{135}{Mike France, Big Tobacco May Be Ready to Deal, Bus. Wk., Oct. 7, 1996, at 150. With the insurance companies feverishly laboring to find a legal basis to deny coverage, it is hypothesized that the tobacco companies are under increased pressure to settle. "[D]efense costs will force individual tobacco companies to turn to their insurance policies, including product liability and commercial general liability, both of which contain broad duty-to-defend provisions with typically unlimited defense limits." Dan Lonkevich, Insurers, Tobacco Players Prepare for Coverage War, Nat’l Underwriter Prop. & Casualty-Risk & Benefits Mgmt., Nov. 18, 1996, at 3. Veteran attorneys generally agree that "future coverage disputes are inevitable considering the ever-growing number of . . . tobacco-related Medicaid cost reimbursement suits . . . ." Id.}

North Carolina Attorney General Michael F. Easley has said that the cigarette manufacturers "have asked to use his office as a vehicle through which they can communicate with the other [attorneys general]—especially those with whom they have pending litigation—because it’s just hard to communicate once the suit is filed."\footnote{136}{France, supra note 135, at 150.}

Moreover, numerous plaintiffs’ attorneys articulate that “since mid-August they have received phone calls from lawyers, lobbyists, and politicians claiming to represent the industry and trying to lay the groundwork for a possible settlement.”\footnote{137}{France, supra note 135, at 150 ("Washington-based John Coale of Coale & Van Susteren says he had a 20-minute conversation with an industry lobbyist in mid-September who wanted to know whether he would be willing to go along with a deal brokered by Congress.").} A settlement “would likely require the manufacturers to shell out billions for injured smokers and teenage-prevention programs. In exchange, Big Tobacco would receive immunity from legal liability, in effect ridding itself in one fell swoop of its many lawsuits.”\footnote{138}{Id.}

In September, 1996, Lon West, a securities analyst, attended
private meetings with attorneys from R.J. Reynolds and Philip Morris during which he was told:

[T]hey would be interested in a global settlement in order “to limit the downside risk, get out from under the cloud of litigation, and carry on with business” . . . . While those same lawyers denied the existence of any current negotiations, they did discuss legislative precedents for a global settlement, citing the 1969 Federal Coal Mine Health & Safety Act and the 1986 National Childhood Vaccine Injury Act as proof that a congressional grant of immunity to an industry is plausible . . . .

Gary D. Black, a tobacco analyst, stated that the industry could fund a settlement by increasing the price of its cigarettes by twenty-five cents per pack, which would yield at least six billion dollars a year — a figure that reflects a decrease in consumption due to the higher price. Hence, it is apparent that the cigarette manufacturers could afford a global settlement and that Congress has the puissance to make it happen.

Today, it is common knowledge that tobacco contains nicotine, an extremely addictive drug “so addictive, in fact, that when patients in drug treatment facilities [were] asked what drug they need[ed] most, the vast majority list[ed] tobacco first, ahead of heroin, methadone, alcohol, and other drugs that brought them into the program.” Furthermore, scientists have demonstrated conclusively a direct link between lung cancer and benzo(a)pyrene, a chemical commonly found in cigarette smoke. Although the recent study establishes the causal link

139. Id.
140. Id.
141. Bogus, supra note 50, at 47 (quoting DAVID KROGH, SMOKING: THE ARTIFICIAL PASSION 93-94 (1991)).
142. Jerry E. Bishop & Milo Geyelin, Researchers Show How Smoking Causes Cancer, WALL ST. J., Oct. 18, 1996, at B1. As proof that the cigarette manufacturers had knowledge of their product’s deleterious effects, the State of Florida included a 1958 memorandum in an amendment to its Medicaid suit. The Florida Times-Union reported as follows:

According to the April 23, 1958, memo, J.R. Lincoln, a Philip Morris research executive, demanded the removal of benzopyrene from cigarettes, and went on to suggest a publicity campaign to offset a health scare, protect profits and shield the industry from liability lawsuits.

“BENZOPYRENE MUST GO,” said Lincoln’s confidential memo. “We must do this not because we think it is harmful but simply because those who are in a better position to know than ourselves suspect it may be harmful.”
between smoking and lung cancer, industry attorneys state that "[t]he study ... is just one of a number of factors that future juries will have to consider when assessing fault in pending tobacco suits. Other factors ... include whether plaintiffs were aware of the risks of smoking and chose to light up anyway."\(^{143}\)

Despite these known hazards, there are forty-six million smokers in the United States and four hundred thousand smoking-related deaths each year.\(^{144}\) The perils of smoking can be recapitulated as follows:

We know that smoking causes about one-third of all cancer in the United States, including ninety percent of all lung cancer; that smokers have far greater risks of dying of heart disease than do nonsmokers; that smoking is the primary cause of chronic obstructive lung diseases such as chronic bronchitis and emphysema; that a mother's smoking may be worse for a fetus than cocaine use; and that every day 1,000 Americans die as a result of smoking.\(^{145}\)

Historically, the plaintiffs have been unable to prove to a jury that the tobacco cartel possessed knowledge of the forgoing. On March 21, 1997, this task became a whole lot easier.

In an extension of its previous five-state settlement, Liggett settled "with the attorneys general from 22 states suing to recover health care costs attributable to smoking."\(^{146}\) As part of this settlement, Liggett released the following statement: "... [w]e at Liggett know and acknowledge that ... cigarette smoking causes health problems, including lung cancer, heart and vascular disease, and emphysema. We at Liggett also know and acknowledge that ... nicotine is addictive. Liggett acknowledges that the tobacco industry markets to 'youth,' which means those under 18 years of age."\(^{147}\)

The "deal" requires the cigarette producer to pay twenty-five percent of its pretax income over twenty-five years to the states

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143. Bishop & Geyelin, supra note 142, at B1 (quoting William S. Ohlemeyer, a defense lawyer at the Kansas City, Missouri firm Shook, Hardy & Bacon, which represents several tobacco companies).

144. Farley, supra note 52, at 47.


147. Id. at 29-32.
and "to finance public-service advertisements warning about the health dangers of smoking. In addition, Liggett agreed to turn over to the courts a batch of company documents chronicling sensitive legal discussions Liggett has had with the other four major U.S. tobacco companies . . . ."  

Philip Morris, R.J. Reynolds, Lorillard, and Brown & Williamson attempted to block the dissemination of "any privileged or confidential information," but the temporary restraining order issued by a state court in North Carolina was disregarded by the attorneys general, who shipped the information to courtrooms around the nation.  

The attorneys general averred that "the judges hearing their various lawsuits [should] decide what could and could not lawfully be made public."  

In the convoluted legal battle between the tobacco industry, the states, and the nation's forty-six million smokers, there is only one certitude: "CIGARETTE SMOKING IS HAZARDOUS TO YOUR HEALTH!" Stay tuned . . . .

148. Id. at 29.  
149. Id.  
150. Id.
COWBOYS, CAMELS, AND COMMERCIAL SPEECH: 
IS THE TOBACCO INDUSTRY'S COMMODIFICATION OF 
CHILDHOOD PROTECTED BY THE FIRST AMENDMENT?

Kathleen J. Lester*

The use of tobacco products by children creates unique legal and ethical problems. Tobacco, while causing loss of potential and loss of life, is a legal product for adults. The age restriction currently placed on the sale of tobacco products to prevent their use by children, however, does not appear to be effective. More and more children are beginning to use cigarettes and smokeless tobacco. The failure of current legal methods raises the question of whether Americans should seek a solution for this public health problem using additional and stricter legal remedies.

The Food and Drug Administration (FDA) answered this question affirmatively. In the most recent step toward preventing the use of tobacco products by children, the FDA promulgated regulations restricting the manner and locations in which tobacco companies could advertise their products. These regulations are directed at decreasing the number of young people using cigarettes and smokeless tobacco. The FDA's attempt to prevent future tobacco users has sparked much debate over the constitutionality of these commercial speech regulations.

Relying upon legal solutions for public health problems, such as tobacco use by children, has great implications for one of the most fundamental aspects of American society — individual rights. By definition, public health looks at society as a whole working to increase the health of all rather than focusing on individual problems. Often in the quest for improving the public's health, individual rights are sacrificed, such as in the case of required vaccinations.¹ For such encroachments to be

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¹ Jacobson v. Massachusetts, 197 U.S. 11 (1905) (holding that the police powers of States permitted them to require vaccinations in the interest of public health).
accepted, Americans must believe that the benefit from such intrusions is great. While the absence of diseases such as smallpox, polio, and measles is directly correlated with the use of vaccines, it is less clear that the restriction of advertisements will directly reduce the use of tobacco products by children. These restrictions directly infringe upon the tobacco industry's ability to advertise its product as it believes best. The restrictions also prevent adults from viewing advertisements they may believe are helpful in making their decisions of whether to use tobacco products and, if so, what products to use.

Permitting such restrictions, even without the establishment of a causal link, may be acceptable if viewed as one of few remaining alternatives. The traditional means to which society has turned to restrict the use of tobacco products by children, such as age restrictions, educational programs, and counter-advertisements have not worked according to the recent data. Thus, the FDA advertising regulations appear to be yet another attempt to decrease use by children, while not completely abridging the rights of adults who smoke "by choice" through more restrictive means such as complete bans on advertising or use of tobacco products. Therefore, it seems likely that if Americans view the need to decrease the use of tobacco products among children as a valid public health goal, the encroachment on individual rights of some people will be inevitable.

In addition, it is possible that inaction could be viewed as renouncing a societal duty to protect children. While such a duty has not been recognized through common or constitutional law, the state lawsuits currently focusing on reimbursing Medicaid costs for the treatment of tobacco-related illnesses could establish a precedent that at least would make tobacco companies liable for injuries caused by the proper use of their products.

2. It is debatable whether most adults smoke by choice or because they are addicted to the product, especially in light of evidence that most adults started smoking during adolescence. See infra Part II.

3. See DeShaney v. Winnebago County Dep't of Social Servs., 489 U.S. 189 (1989) (holding that a state child welfare agency did not have a constitutional duty to protect a young child from an abusive father even though it had evidence such abuse was occurring).

Similarly, one could imagine inventive plaintiffs' attorneys trying to craft causes of action based on the government's failure to regulate nicotine use by children who are unable to make rational judgments. Thus, areas of the law could be recast to reflect societal outrage for the harms caused by tobacco use if the government fails to address the problem adequately.

The smoking epidemic among children also raises ethical concerns. First, Americans and the courts have recognized that children are different than adults. Their ability to make autonomous choices is limited because of their underdeveloped cognitive skills. For example, children are prevented from consenting to medical procedures and treatments and can be prevented from viewing specific types of entertainment. As bioethicists Tom Beauchamp and James Childress point out, "[i]ntervention in the life of a substantially nonautonomous dependent became and remains the most widely accepted model of justified paternalism. That is, the paradigmatic form of justified paternalism starts with incompetent children in need of parental supervision . . . ."

Other philosophers have recognized the need for paternalism in specific instances, even if they did not recognize it as true paternalism. John Stuart Mill argued that individuals who are ignorant of significant risks may be justifiably prevented from acting in a manner to ensure that the individual acts only with full knowledge of the consequences of such actions. Thus, at the very least there seems to be both legal and philosophical support for reducing the autonomy of children in order to protect them from less than fully realized decisionmaking.

Protecting children will necessarily entail infringing to some

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5. See infra Part II.C.
7. See generally Action for Children's Television v. FCC, 58 F.3d 654 (D.C. Cir. 1995) (validating a statute that would limit a minor's ability to view programs).
9. Id. at 277.
10. Like many of the arguments made in regard to regulating the use of tobacco, similar positions could be considered in relation to adults who are addicted to tobacco products or deceived by clever advertisements. One difference remains, however. Adults can choose to view news reports or to improve their own understanding about the dangers of tobacco use through adult level cognitive processes. This distinction would not, however, completely foreclose arguments that adults should receive at least some level of protection.
extent upon the autonomy of adults. At the crux of the debate surrounding the use of tobacco products by children is the desire to protect young people from deceptive influences and the ingrained belief in the ability of the individual to make her own decisions and control her destiny. The regulations infringe upon both the tobacco industry’s ability to freely advertise and an adult’s right to be swayed by these advertisements. Some argue that restrictions on advertisements could lead America down a slippery slope toward the eventual erosion of First Amendment protection. The problem with this argument is that the regulations do not prevent the distribution of information that is valuable to a consumer, including the continued ability to use and view images in adult publications. Second, advertisements are already restricted by the amount of money spent by an industry to advertise and the editorial decisions of some publications. In addition, tobacco product advertising is already severely restricted as compared with other industries.\textsuperscript{11} Thus, the question turns on whether the increased restrictions are viewed as curbing the autonomy of the tobacco industry and adults more than necessary to achieve the goal of decreasing the amount of tobacco use by children.

Both the tobacco industry and the FDA are looking to the judiciary to sort out this dilemma raised by the regulations. The tobacco industry position stresses that the regulations prohibit the free exercise of First Amendment rights, while the FDA argues that the advertisement restrictions focus on commercial speech, which deserves less than full First Amendment protection, and are narrowly tailored to directly advance the government’s interest in decreasing the use of tobacco products by children. Relegating this issue to the judiciary, however, will not prevent the nation as a whole from having to establish a normative preference regarding the use of tobacco products by children. Because of the inevitable problems of doctrinal indeterminacy, neither the language of the First Amendment nor the institution of judicial review can resolve the current controversy. Neither the judiciary nor the Constitution can serve as surrogate decisionmakers in creating cultural norms; they can only reflect these norms once established.

\textsuperscript{11} The most obvious restriction is the required warning labels on packages and advertisements.
This paper examines the First Amendment issues surrounding the new FDA regulations. Part I summarizes the FDA "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." Part II reviews the public health data surrounding the use of tobacco, its health effects, and the influence image-oriented advertising has on young people. Part III provides a summary of First Amendment commercial speech doctrine and a brief analysis of the FDA regulations under this doctrine. While strong arguments made within the doctrine would seem to lead to the conclusion that the regulations should be upheld, recent decisions and baseline problems leave the doctrine unsettled. Part IV examines the analytical framework of the First Amendment and demonstrates that even if clear doctrine existed, constitutional analysis generally is too indeterminate to serve as a useful framework for decisionmaking.

I. THE FOOD AND DRUG ADMINISTRATION ADVERTISING REGULATIONS

While the industry has been focusing on increasing its market through inventive advertising and promotional campaigns, the federal government has dealt with the public health problems caused by tobacco use in a piecemeal fashion.

Since the release of the 1964 Surgeon General's report linking smoking to some forms of cancer, the federal government has played a small but noticeable role in regulating the tobacco industry. In 1965, Congress passed the Cigarette Labeling and Advertising Act of 1965, which required package warning labels to tell consumers: "Caution: Cigarette Smoking May Be Hazardous to Your Health."\(^{12}\) The Act did not require cigarette advertisements to carry similar labels.\(^{13}\) With tobacco companies free to use whatever type of media they wanted to promote their products, the Federal Communications Commission ruled in 1967 that the Fairness Doctrine applied to cigarette advertising.\(^{14}\) Thus, radio and television stations broadcasting such ad-

\(^{13}\) Id.
\(^{14}\) Centers for Disease Control & Prevention, Selected Actions of the U.S. Government Regarding the Regulation of Tobacco Sales, Marketing, and Use (ex-
vertisements were required to donate air time for anti-smoking messages.\textsuperscript{15} Two years later, Congress prohibited cigarette advertising on television and radio in the Public Health Cigarette Smoking Act of 1969.\textsuperscript{16} It also required stronger warnings on packages: "Warning: The Surgeon General Has Determined that Cigarette Smoking Is Dangerous to Your Health."\textsuperscript{17} However, it also preempted state and local governments from regulating or banning cigarette advertising or promotion.\textsuperscript{18} Thus, by 1971, cigarette advertising had ended its run on radio and television.\textsuperscript{19} However, this ban also ended the Fairness Doctrine anti-smoking advertisements because the doctrine required counterspeech for only radio and television advertising.\textsuperscript{20} During the 1970s legislation regulating hazardous and toxic substances was passed, but these bills specifically excluded tobacco and tobacco products.\textsuperscript{21} In 1984, Congress expanded the specificity of the Surgeon General's warnings to require four rotating warnings: (1) smoking causes lung cancer, heart disease and may complicate pregnancy; (2) quitting smoking now greatly reduces serious risks to your health; (3) smoking by pregnant women may result in fetal injury, premature birth, and low birth weight; and (4) cigarette smoke contains carbon monoxide.\textsuperscript{22} These warnings rotate on cigarette packages and advertisements.\textsuperscript{23}

\begin{footnotesize}
\begin{enumerate}
\item<http://www.cdc.gov/nccdphp/osb/regulate.html>.
\item Id.
\item Id.
\item Id.
\item Id.
\item Id.
\item It is possible that the reason the tobacco industry did not defeat the ban on radio and television advertising is because of its desire to end the anti-smoking campaigns. During the first three years of the implementation of the Fairness Doctrine, the percentage of smokers declined seven percent from 1967 to 1970. The adolescent smoking rate declined during this period as well. It was the first time since the 1930s that such a decline was recorded. The effectiveness challenged the tobacco industry to increase its market share. Food and Drug Administration, \textit{Executive Summary: The Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents} §§ 77-78 (Aug. 1996) <http://www.lawpublish.com/fdarule.html>.
\item Centers for Disease Control & Prevention, \textit{supra} note 14, at ¶ 20.
\item Id.
\end{enumerate}
\end{footnotesize}
Two years later, Congress instituted three rotating warnings for smokeless tobacco packages and advertisements: (1) this product may cause mouth cancer; (2) this product may cause gum disease and tooth loss; and (3) this product is not a safe alternative to cigarettes. Among other things, it also prohibited advertising smokeless tobacco products on radio and televisions.

The most recent announcement came in the form of the FDA's anti-smoking initiative regulating tobacco sales, distribution, and marketing to children in 1995. That same year, the federal government through the Department of Justice settled with Philip Morris to remove tobacco advertisements in sport stadiums from the line of sight of television cameras.

These events demonstrate that the federal government has seen a need to increase its role in regulating tobacco industry marketing as more epidemiological data solidified the link between the use of tobacco products and negative health outcomes. The government's intervention can be justified by market analysis and paternalism. Informational failures and externalities have distorted the market, requiring the government to act in a way that corrects these distortions. The government has also

25. Id.
28. Although it is possible that no public health problem exists because the market provides Americans with the level of smoking they desire, the evidence of market distortion resulting from imperfect information and cognitive imperfections requires government intervention. See infra Part III.A.1. Arguments that the government has been too lenient in dealing with the tobacco industry by primarily restricting advertising rather than use may indicate a lack of seriousness on the part of the government to deal with the issue. This lack of seriousness may be indirect evidence that Americans are happy with the health costs associated with smoking, because they are willing to pay those costs in order to enjoy the other aspects associated with tobacco use. Of course, lack of a serious response by government could also be evidence that a special interest group, the tobacco industry, prevailed with the government and that because of the free rider problem the
voiced a strong paternalistic desire to protect children from the harms of tobacco products. This intervention and desire to protect children has culminated in the current FDA regulations restricting the advertising and marketing of tobacco products to children.

Following in the tradition of government attempts to restructure the market, in August 1996, the FDA published its final rules with regard to the sale, distribution, and marketing of cigarettes and smokeless tobacco products to children and adolescents. These rules were heralded by Donna Shalala, the Secretary of Heath and Human Services, as "the most important public health initiative in a generation. It ranks with everything from polio to penicillin. I mean, this is huge in terms of its impact." After considering the more than seven hundred thousand comments, David Kessler, Commissioner of Food and Drugs, called the regulations "the right public health strategy." The goal of the agency is to reduce the amount of teenage smoking in the United States by half during the next seven years. The regulations attempt to do this by (1) limiting children's and adolescents' access to cigarettes and smokeless tobacco and (2) diminishing the appeal of tobacco advertising to young people.

majority of Americans who are not happy with the health costs of tobacco use are paralyzed and do not act. Thus, it is not clear which way the ineffectiveness of government action in the past cuts.

29. Many argue that the government has been too lenient with the tobacco industry and has not placed enough restrictions upon them. While there are valid arguments for this point of view, it is not necessary to discuss here whether the government has actually been as effective as possible at restoring the market. The fact that the government, even with the pressure of the tobacco industry, has acted to impose some regulations on the industry indicates that the market is far from perfect. Thus, the FDA's regulations are merely an extension of this expressed need to intervene.


31. Id.

32. Id.

33. In its executive summary, the FDA states that the agency will also send letters discussing the benefits of a national notification campaign to educate young people about the risks of tobacco use to the six tobacco companies whose sales to young people are "significant." Food & Drug Administration, supra note 20, at ¶ 81.
A. Limiting Access

Although selling cigarettes to minors is already illegal in all states and the District of Columbia, the regulations make such transactions to those under eighteen years old a federal offense and limit the manner in which cigarettes and smokeless tobacco may be sold. First, retailers must verify the age of purchasers by checking identification cards that include both the purchaser’s photo and date of birth. Second, sales of cigarette or smokeless tobacco products that contain less than twenty cigarettes or amounts of smokeless tobacco less than that in a standard package are prohibited. Third, the regulations ban the use of vending machine sales except in adult locations, where a retailer or operator can ensure than no one under the age of eighteen can enter. Fourth, the regulations also ban self-service displays of tobacco products with some limited exceptions. Fifth, while mail order sales may continue, redemption of coupons through the mail will not be allowed. Finally, free samples of cigarettes and smokeless tobacco are also prohibited.

B. Limiting Advertising

The more controversial part of the regulations deals with limiting the manner in which cigarettes and smokeless tobacco products can be advertised and promoted. First, billboard and other outdoor advertisements are prohibited within one thousand feet of schools and public playgrounds. Second, cigarette and

36. 21 C.F.R. §§ 897.14, 897.16 (1996). “Kiddie packs” have been offered to children and adolescents because they are small, inexpensive, and easy to conceal. They are primarily a problem in countries other than the United States, but have recently begun to appear in this market. Food & Drug Administration, supra note 20, at ¶ 28-29.
37. 21 C.F.R. § 897.16 (1996).
38. 21 C.F.R. § 897.14 (1996). Self-service displays make it easier for children and adolescents to obtain tobacco products and decrease involvement of the sales clerk. They are also likely targets for shoplifters. Food & Drug Administration, supra note 20, at ¶ 37.
40. Id.
41. 21 C.F.R. § 897.32(c) (1996).
smokeless tobacco advertisements may only be in black-and-white, text-only formats, unless the advertisement appears in an adult publication. Adult publications are those whose total readership is made up of eighty five percent or more people over the age of eighteen or are read by two million or less people who are under eighteen years old. According to this definition, *Time* and *Newsweek* can retain color advertisements, while *Rolling Stone* and *Sports Illustrated* would be limited to text-only, black-and-white advertisements. Third, non-tobacco promotions, such as T-shirts, hats, posters, etc., that are identified with tobacco products cannot be sold or distributed. Finally, tobacco companies may only sponsor events, entries, and teams under the corporation’s name. It may not sponsor such sporting or cultural events using the brand name, logo, colors, or anything else associated with a brand. This prohibition includes a ban on the sponsorship of race cars or teams.

### C. Justification

The FDA justifies these limitations on access and advertising formats based on the epidemiological data detailing the increased use of tobacco products by children and adolescents, the significant health problems and costs associated with the use of tobacco products, the addictive nature of tobacco products, and the special vulnerability of children and adolescents. Even though the goals of the agency may be pure, the regulations must overcome two judicial hurdles. First, the FDA must establish that it has jurisdiction over tobacco products. Second, the advertising regulations must not violate the commercial speech doctrine of the First Amendment. While the first is an interest-

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42. These black-and-white, text-only advertisements are often referred to as tombstone advertising.  
44. Food & Drug Administration, *supra* note 20, at ¶ 67.  
46. 21 C.F.R. § 897.34(c) (1996).  
47. *Id.*  
49. *See infra* Part II.  
ing legal question, it is beyond the scope of this article.\textsuperscript{51} The latter raises questions which strike at the heart of our democratic ideals.

\section*{II. THE SMOKING EPIDEMIC}

In promulgating these regulations, the FDA paid a great deal of attention to the scientific data generated during the last fifty years detailing the health impacts related to the use of tobacco products. While the evidence linking the use of tobacco products to negative health outcomes is clear and considered to demonstrate causation of disease in some cases, such as lung cancer, the link between advertisements and use by children is not as definitive.

Cigarette smoking is the most preventable cause of death in the United States.\textsuperscript{52} Each year more than four hundred Americans die prematurely from tobacco-related illnesses,\textsuperscript{53} such as cancer, pulmonary disease, and chronic heart disease.\textsuperscript{54} The Centers for Disease Control and Prevention (CDC) estimates that each cigarette reduces a smoker’s life by seven minutes.\textsuperscript{55} Thus, smoking one pack a day (approximately twenty cigarettes) shortens an individual’s life by more than one month each year. Six million years of potential life are lost because of these premature deaths.\textsuperscript{56} The Office of Technology Assessment estimated that smoking-related disability and premature deaths in 1990 cost Americans $68 billion or about $2.59 per cigarette pack.\textsuperscript{57}

\begin{itemize}
\item \textsuperscript{51} For a detailed analysis of the FDA’s position on the jurisdictional question see \textit{FOOD & DRUG ADMINISTRATION, NICOTINE IN CIGARETTES AND SMOKE-LESS TOBACCO PRODUCTS ARE NICOTINE DELIVERY DEVICES UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.} (1995).
\item \textsuperscript{52} Thomas D. MacKenzie et al., \textit{The Human Costs of Tobacco Use}, 330 NEW ENG. J. MED. 975 (1994).
\item \textsuperscript{53} Centers for Disease Control and Prevention, \textit{Cigarette Smoking — Attributable Mortality and Years of Productive Life Lost — United States, 1990}, 42 MORBIDITY AND MORTALITY WKLY. REP. 645 (1993).
\item \textsuperscript{54} \textit{CENTERS FOR DISEASE CONTROL AND PREVENTION, DEP’T OF HEALTH AND HUMAN SERVS. PUB. NO.} (CDC) 89-8411, \textit{REDUCING THE HEALTH CONSEQUENCES OF SMOKING: 25 YEARS OF PROGRESS. A REPORT OF THE SURGEON GENERAL} (1989).
\item \textsuperscript{55} Dennis L. Breo, \textit{Kicking Butts — AMA, Joe Camel, and the “Black-Flag” War on Tobacco}, 270 JAMA 1978 (1993).
\item \textsuperscript{56} \textit{Hearing on Preventive Health: An Ounce of Prevention Saves a Pound of Cure Smoking-Related Deaths and Financial Costs: Office of Technology Assessment Estimates for 1990 Before the Senate Special Comm. on Aging} 2-4 (1993) (statement of Roger Herdman, Maria Hewitt, and Mary Laschober).
\item \textsuperscript{57} The figure breaks down to: $20.8 billion in direct health costs, $6.9
A. Pediatric Prevalence

Most smokers begin using tobacco at an early age. Of those adults who currently smoke on a daily basis, eighty-nine percent tried their first cigarette before they were eighteen years old. Thus, children who begin smoking today will most likely remain hooked for the rest of their lives. While the prevalence rate of smokers has been steadily declining from 42.2 percent in 1965 (one year after the release of the 1964 Surgeon General’s report drawing a causal link between cigarette smoking and cancer) to 25.5 percent in 1990, the prevalence of smoking remained unchanged among youths between 1980 and 1993. CDC reported that cigarette smoking increased among teens to 34.8 percent in 1995. The rates among African-American male teens has almost doubled between 1991 and 1995 from 14.1 percent to 27.8 percent. These children make up ninety percent of all new smokers. It has been estimated that three thousand young people become daily smokers each day. Between 1970 and 1985, there has been a ten-fold increase in the number of older teens using smokeless tobacco. The CDC estimates that unless smoking rates among teenagers are cut immediately, more than billion in lost productivity from smoking-related disabilities, and $40.3 billion in lost productivity from smoking-related premature deaths. It is possible to argue that the cost to society is offset by the fact that smokers die before they begin collecting societal benefits, such as social security benefits. This argument, however, discounts the non-economic value of human life also lost.

59. See generally Food & Drug Administration, supra note 20.
60. Breo, supra note 55.
61. In 1993, 29.9 percent of high school seniors were reported to have smoked within the last thirty days before the survey, while nineteen percent reported themselves as daily smokers. Institutes of Medicine, Growing Up Tobacco Free 8 (National Academy Press 1994) [hereinafter IOM].
five million children who are currently living will die prematurely from their adolescent decision to smoke. 66 Seventy percent of smokers twelve to seventeen years old already regret their decision to smoke with sixty six percent expressing their desire to quit. 67 It appears unlikely that former Surgeon General C. Everett Koop's call for "a smoke-free society by the year 2000" 68 will be answered.

B. Acceptance, Accessibility, and Advertising

The fact that selling tobacco products to minors is illegal in all states and the District of Columbia 69 makes the epidemiological data even more unsettling. Potentially, at least three reasons seem to account for the rise in youth smoking rates — acceptance, accessibility, and advertising. First, researchers report that peer disapproval of cigarette smoking has diminished during the past several years. According to a University of Michigan study, many young people do not view smoking cigarettes as dangerous. 70 The denial of the health consequences of smoking seems to be fed by the ease with which young people can obtain tobacco products. The University of Michigan study also reported that seventy six percent of eighth-graders and more than ninety percent of tenth graders say that they can obtain these products rather easily. These numbers have been constant during the past four years. 71 Another CDC report on teen smoking announced that more than seventy five percent of underage high school students could obtain cigarettes without showing proof of age. 72

69. See Centers for Disease Control & Prevention, supra note 34.
70. In one study, less than one-half of eighth-graders believed that there is a "great risk" to smoking a pack or more a day; less than two-thirds of twelfth-graders agree with their younger classmates. Centers for Disease Control & Prevention, Cigarette Smoking Among American Teens Rises Again in 1995 (Dec. 11, 1995) <http://www.cdc.gov/nccdphp/osh/ythmtf95.html>.
71. Id.
It also stated that fifty seven percent of ninth to twelfth graders usually obtained cigarettes through a store, vending machine, or by having another individual purchase the cigarettes for them.\textsuperscript{73} It has been estimated that nearly one billion packs of cigarettes are sold to children each year.\textsuperscript{74} With the decreasing number of adult smokers, children have become "the lifeblood of the tobacco industry."\textsuperscript{75}

The tobacco industry denies this growing dependence on the youth market, claiming that its advertising dollars are spent trying to encourage current smokers to switch brands or to maintain brand loyalty.\textsuperscript{76} In 1991, the tobacco industry as a whole spent more than $4.6 billion to advertise and promote their products.\textsuperscript{77} This number breaks down to more than $12.6 million per day, $8,750 per minute.\textsuperscript{78} The Institute of Medicine Committee on Preventing Nicotine Addiction in Children and Youths reported that "[t]he population of the United States is exposed to this massive array of pro-tobacco messages everyday. Inevitably, these messages 'promote' tobacco use to children and youths as well as adults, and to impressionable nonusers of tobacco products as well as users."\textsuperscript{79}

\textbf{C. Courting Children}

With the shrinking percentage of adult smokers in the United States, tobacco companies appear to be marketing to the only growing demographic group — children. While the industry denies the connection between their advertisements and the cultivation of young smokers,\textsuperscript{80} several studies suggest, indirectly at least, some link between the increase in teen smoking and the types of advertisements promoting the products. The strongest

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\textsuperscript{73} Id.  
\textsuperscript{75} Id.  
\textsuperscript{76} For a summary of the pro-industry arguments, see generally 61 Fed. Reg. 44,396 (1996).  
\textsuperscript{77} \textit{FEDERAL TRADE COMMISSION, REPORT TO CONGRESS FOR 1991 PURSUANT TO THE FEDERAL CIGARETTE LABELING AND ADVERTISING ACT} 5 (1994).  
\textsuperscript{78} Id.  
\textsuperscript{79} IOM, supra note 61, at 11.  
\textsuperscript{80} See supra note 76.
link seems to have been found by DiFranza and colleagues who reported that Camel cigarettes increased the brand's market share through the "smooth character" advertising campaign, which introduced Old Joe, the cartoon camel resembling James Bond and Don Johnson from "Miami Vice" in the late 1980s. In 1986, only 2.7 percent of seventeen to twenty-four year olds preferred Camel cigarettes. By the end of the third year of the Old Joe marketing campaign, the proportion of those under eighteen who smoked Camels climbed from 0.5 percent to 32 percent. Not only did the campaign increase cigarette sales, but it also increased the recognition of (and perhaps acceptance of smoking) Camel cigarettes. DiFranza and his colleagues analyzed the recognition, recall, appeal, and brand preferences among teen-age smokers in light of the Joe Camel campaign and found that children were more likely to recognize the cartoon and recall the advertisements than adults. Children also found Joe Camel more appealing concluding that the advertisements were "cool" or "interesting." Thirty-five percent of the children "wanted to be friends with him." One adolescent stated, "Camel's cartoons are for the younger kids. Joe camel's a cool person — a model." Joe Camel has become such an American icon that thirty percent of three year olds and ninety one percent of six year olds recognize Joe Camel as a symbol of smoking. While no definitive causal link exists between recognition and use, this study at the very least demonstrates the influence the advertisements have on children.

Other studies have described advertising's psychological appeal to children. The image-oriented tobacco advertisements, like those featuring the cartoon camel, encourage acceptance of smoking as a social norm in young children (those less than eleven years old) who are too immature to understand the purpose and nature of advertising. The advertisements instill in these chil-

82. Id.
83. Id.
84. Id.
85. Id.
86. IOM, supra note 61, at 117.
87. P.M. Fischer et al., Brand Logo Recognition by Children Aged 3 to 6 Years, 266 JAMA 3145 (1991).
children a positive image of smoking, and thus, plant the seeds for future use. 88 One psychologist posits that children's patterns of behavior, values, and thinking are shaped by modeling influences, including advertisements. 89 Through modeling, children learn what normative values are accepted. 90 Tobacco advertisements model the "virtues" of smoking to children inculcating the belief that smoking is socially acceptable before they can truly evaluate the health hazards of tobacco use.

Adolescents are particularly influenced by advertisements because of developmental changes. During adolescence, children mature physically, experience cultural pressures to "grow up," and begin to establish their values and views of themselves. 91 These changes create tension and insecurity within the teenager. Advertisements which convey independence, a smooth passage into adulthood, and success and acceptance in social situations may play on the teen's insecurities leading them to associate their ability to achieve their goals with the use of the products advertised, including cigarettes. 92 Other psychologists believe that intentions to act are formed by a person's attitude toward the act and others' normative beliefs about the act. 93 Thus, advertising directed at adolescents fosters a positive attitude toward smoking. Similar to its effects on young children, these advertisements may also establish a set of normative beliefs that accept the use of tobacco. 94 Cigarette advertisements promoting


89. IOM, supra note 61, at 118.
90. Id.
91. Id. at 106.
92. Id.
93. Id.
94. Id. at 118.
the achievement of independence, self-confidence, and peer acceptance through the act of smoking cigarettes are likely to sway teens toward the use of cigarettes before they can fully understand the potential health consequences of their decisions.

At least one study attempted to evaluate the correlation between the amount of money spent on advertising and the brand preferences of adolescents. In 1993, $75 million was spent advertising Marlboro and 60.0 percent of adolescents preferred the brand as opposed to only 23.5 percent of adults who preferred it. 95 Camel came in a distant second having spent $43 million and garnishing a 13.3 percent brand preference among adolescents, but only 3.9 percent among adults. 96 As one anti-tobacco spokesperson put it, "Adults respond to claims of low tar and nicotine, whereas kids respond to the Marlboro man." 97 Thus, even if tobacco companies are taken at their word that these advertisements and promotions are not directed at young people, the reality of the relationship offers less support for their claims.

Although these studies are persuasive, no conclusive scientific evidence exists clearly demonstrating a link between advertisements promoting these values and use of the products by young people. Even so, these studies, when coupled with the shrinking adult market and advertising practices of the tobacco industry, enhance the perception that the industry is indeed marketing to children.

D. Marketing Magic

Advertising for tobacco products extends beyond the more traditional media outlets, such as newspapers, magazines, and billboards. 98 The industry has devised several ways in which to convey its messages to potential users, including promotional...

96. Id.
98. Advertising expenditures for newspapers have dropped to 1.0 percent of marketing expenditures in 1991 reaching an all time low from a 1980 high of 24.5 percent. Expenditures on magazine ads have also fallen from 21.4 percent in 1980 to 6.0 percent in 1991. Billboards account for 3.8 percent of total advertising and promotion expenditures. IOM, supra note 61, at 111; see also Garner, supra note 74.
allowances to encourage retailers to stock cigarettes in prominent locations, point-of-sale advertising showcasing specific brands, distribution of free samples in public places, and direct mail promotions. One of the most popular and attractive strategies to teens is value-added promotions and specialty items. The industry spends forty percent of its total marketing expenditures on this strategy alone. By collecting Camel Coupons or Marlboro Miles, teens, often smokers and non-smokers, save to “purchase” T-shirts, caps, calendars, and other products. These items carry the logo or brand name deeper into the conscious and semi-conscious reality of teens. Not only do these promotional techniques encourage young people to enter the world of Camel or Marlboro, but they also provide the tobacco industry with a way to advertise without the federal labeling requirements. The impact of promotional sales has not been extensively studied, and thus, conclusions about the impact of these methods cannot be considered conclusive.

Another popular way in which the tobacco industry reaches consumers, especially teens, is through sponsoring sporting events and public entertainment. In adopting this marketing strategy, the industry fulfills two goals. First, these events provide tobacco companies with the ability to appear on television without violating federal law, which prohibits television advertising of tobacco products. During the 1989 Marlboro Grand Prix, the brand name was mentioned eleven times and the logo was shown 5,922 times. Thus, during the ninety-three minute broadcast, the brand received forty-six minutes of exposure, eighteen minutes of which were “clear, in-focus air time” that would approximately be worth more than $1 million. Thus, although the industry denies that it sponsors events to circumvent the television ban on cigarette advertising, the reality is

99. IOM, supra note 61, at 108.
100. Id. at 110.
102. Id.
that the sponsorship provides tobacco companies with valuable advertising time to reach millions of viewers. Second, DiFranza and colleagues suggest viewing the sponsorship of sports as a way for the tobacco industry to maintain its hold on young boys.\textsuperscript{104} Internal tobacco industry documents confirm that "[t]he single most commonly voiced reason for quitting among [boys] who had done so . . . was sports."\textsuperscript{105} Sponsoring events link the tobacco products and the event in the minds of these boys. Rather than view tobacco products as making sports not possible because of the health effects, these associations plant the idea that sports and tobacco products naturally go together. Sponsorship of events coupled with specialty items assures tobacco companies that their brands will be recognized by children and adolescents. The correlation between such events and the subsequent use of sponsoring products has not been definitively evaluated, however. In fact, some studies suggest that many of the sporting events most tied to tobacco products draw the smallest audience among children.\textsuperscript{106}

\textbf{E. Voluntary Violations}

The industry denies any connection between its marketing strategy and the use of tobacco products by children and adolescents. In 1965, the tobacco industry adopted a voluntary code that included language discouraging advertisements that appeal to young people, advertisements containing health representations and distributions of promotional items to young people.\textsuperscript{107} For all of its presumed good intentions, the code has failed to work. For example, one provision states that "[c]igarette advertising shall not depict as a smoker any person participating in, or obviously having just participated in, physical activity requiring stamina or athletic conditioning beyond that of normal

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104. DiFranza, \textit{supra} note 86.
105. \textit{Id.}
106. The FDA cites to studies showing that auto racing is watched sixty four million times a year by young people less than eighteen years old. Food & Drug Administration, \textit{supra} note 20, at ¶ 74. But see IOM, \textit{supra} note 61, at 113. Of 354 sporting events broadcast in 1992, only seven percent of the audience consisted of children. \textit{Id.}
107. IOM, \textit{supra} note 61, at 129.
\end{flushright}
recreation.\textsuperscript{108} While it is plausible that Newport's beach volleyball advertisements may not violate the text of the code, it is hard to imagine how the Marlboro advertisements featuring adventure-seeking enthusiasts or the kayakers in Kool advertisements are permitted. Some advertising agency groups have proposed new voluntary industry codes to regulate advertising and marketing to minors; however, not all advertising firms endorse the idea.\textsuperscript{109} Even if a voluntary code would be acceptable to all parties, it is unclear whether it would be held sacred in today's commercial markets. The recent demise of the sixty year-old Code of Good Conduct of the distillers' lobby\textsuperscript{110} suggests that voluntary codes, even those that have been followed, are vulnerable to fears of shrinking markets — fears that are real for the tobacco industry.

III. THE FIRST AMENDMENT AND COMMERCIAL SPEECH DOCTRINE

The scientific data regarding the health effects of smoking and the inability of children to process such messages rationally form the foundation of the FDA regulations. However, in light of the uncertainty surrounding some of the evidence, the regulations might be evaluated better in frameworks other than that offered by science. Reliance upon only scientific research would result in a bias toward scientific acceptance, which could result either in adoption or rejection of the regulations because of scientific uncertainty. Such a system also could not evaluate the potential infringement upon individual rights that would likely result. Presumably, judicial doctrine would be a favorable model by which to evaluate the regulations because it could balance the rights of individuals against the need to protect public health in a principled manner.

Both the tobacco industry and the FDA have focused their analysis of the regulations on the judicial commercial speech doctrine. The tobacco and advertising industries filed suit in

\textsuperscript{108} Id. at 5.
North Carolina District Court to prevent the agency from regulating the sale and advertising of tobacco products, claiming, among other things, that the regulations violate the First Amendment. The announcement of the regulations in the Federal Register was accompanied by a detailed doctrinal analysis justifying the validity of the regulations under the First Amendment. It is not clear that using judicial doctrine is an appropriate substitute for resolving policy debates, however, because of the unsettled doctrine and the indeterminacy inherent in constitutional analysis.

A. The Philosophy of the First Amendment

The Supreme Court has divided speech into two categories — high value and low value. In doing so, it has made normative value judgments about what type of speech should be protected. Primarily, three traditions of free speech philosophy have shaped the way in which the Court has categorized speech — promoting the marketplace of ideas; promoting self-governance; and promoting self-fulfillment and autonomy. Of these three, the most influential in relation to commercial speech is the marketplace of ideas and self-fulfillment. Understanding these traditional frameworks will provide some guidance as to why the Supreme Court currently views commercial speech as worth protecting.

1. Marketplace of Ideas

111. Coyne Beahm, Inc. v. FDA, 958 F. Supp. 1060 (M.D.N.C. 1997). The district court held that while the FDA has authority to regulate tobacco products, it does not have the authority to restrict the promotion and advertising of these products. The court did not reach the First Amendment issue. Although the jurisdictional issue seems to have dwarfed that of the First Amendment, further consideration of the constitutionality of the regulations is still warranted because a different analysis could be made on appeal or Congress could simply change the jurisdictional scope of the FDA by amending the agency's enabling statute.


113. The primary difference between high value and low value speech is the type of judicial review that applies to each category. GEOFFREY R. STONE ET AL., CONSTITUTIONAL LAW 1086 (1996). Courts subject high value speech, which includes subversive advocacy, hostile provocation, and confidential information to heightened scrutiny. Id. Restrictions on low value speech, which includes fighting words, hate speech, false speech, offensive speech, obscenity, and commercial speech, receive less strenuous review. Id.

114. Id. at 1078-86.
In a capitalist society priding itself in allowing the market to dictate prices and quantities, it is little wonder that the idea of the First Amendment functioning to allow individuals to choose ideas in a market dominates the theory of free speech. Oliver Wendell Holmes extolled the virtues of such a theory:

When men have realized that time has upset many fighting faiths, they may come to believe even more than they believe the very foundations of their own conduct that the ultimate good desired is better reached by free trade of ideas — that the best test of truth is the power of the thought to get itself accepted in the competition of the market, and that truth is the only ground upon which their wishes safely can be carried out.\(^\text{115}\)

Holmes' statement echoes that of John Stuart Mill:

[T]he peculiar evil of silencing the expression of an opinion is that it is robbing the human race, posterity as well as the existing generation — those who dissent from the opinion, still more than those who hold it. If the opinion is right, they are deprived of the opportunity of exchanging error for truth; if wrong, they lose, what is almost as great a benefit, the clearer perception and livelier impression of truth produced by its collision with error . . . . We can never be sure that the opinion we are endeavoring to stifle is a false opinion; and if we were sure, stifling it would be an evil still.\(^\text{116}\)

Thus, the marketplace of ideas theory envisions an America in which ideas are traded back and forth like commodities. Those that are truthful, it is assumed, will rise in value and dominate the discourse. Thus, the marketplace will weed out the false ideas in favor of the "truth." While Mill and Holmes placed great faith that the truth would rise above the chaos of ideas, a practical version of this theory holds that while true ideas can win out, so can those that are untrue or bad. The risk of accepting untrue or bad ideas is the price Americans pay for having the opportunity to have free and open discourse.\(^\text{117}\) Thus, the market

\(^{115}\) Abrams v. United States, 250 U.S. 616, 630 (1919) (Holmes, J., dissenting).


\(^{117}\) Market analysis does not accept that some ideas are inherently truthful while others are inherently untrue or bad. The ideas that rise to the top are those most preferred by the members of society. However, such a system must recognize
does not always produce truth or the best ideas.

The fact that bad ideas can defeat truthful ones in the marketplace of ideas is evidenced by the occurrence of market failures in economic markets. As economists have noted, any market is subject to failures in which the market does not work as it should because of transaction costs or externalities that prevent individuals' preferences from being expressed accurately. In the realm of tobacco use, for example, imperfect information causes the marketplace of ideas to fail to work efficiently. First, children and adolescents are bombarded by flashy, glamorous images of confident, self-assured smokers enjoying life. Because of the inability of most children to research the health effects of their decisions, they seem less likely to tune into the vague Surgeon General's warnings or the latest scientific studies proclaiming causal links between tobacco use and health problems than the glamorous advertisements, as evidenced by recent studies. The existence of more speech promised under the First Amendment does not address the informational problem with regard to children. While adults may suffer from similar gullibility or faulty reasoning, society has chosen to respect the individual autonomous choices of adults. With regard to children, society accepts paternalistic justifications for imposing restrictions upon minors. Thus, the lack of information, coupled with the lack of the sophistication to understand and comprehend the health consequences of smoking, distorts the market, resulting in less than perfect decision making for which the First Amendment cannot correct.

Second, children and adolescents are unable to accurately judge the truthfulness of cigarette and smokeless tobacco advertising because of the problem of cognitive imperfections. This phenomenon occurs when an individual is confronted by conflicting attitudes and behaviors that establish "an intolerable dis-

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118. See Centers for Disease Control & Prevention, supra note 72.

119. While some might argue that it is the role of parents to protect children from making the "wrong" decisions, contemporary society is full of examples, such as mandatory school attendance and mandatory vaccinations, which impose the government's risk calculus on young people and require their parents to comply except in extenuating circumstances.
sonance that the individual resolves by systematically discounting evidence relating to the veracity of one of the two thoughts. In young people, cognitive development is often connected with the image of one's self. Thus, they view the cigarette and smokeless tobacco product advertisements as promising them independence, happiness, and health. The views presented in the advertisements are sharply contrasted by the epidemiological and medical data documenting the harmful effects of using tobacco. Because children and adolescents want to live the life depicted in the advertisements, they discount the warnings of the medical establishment. Thus, they are unable to make choices based on a rational understanding of the risks involved.

These distortions of the market cause it to fail. Thus, under economic theory, when a market fails the government should step in to fix the problem. Often when the market failure involves information failures, the government's role is to disseminate information freely among all consumers. In theory, government counter-speech promoting anti-tobacco messages would resolve the lack of information problem; however, it would do little to impact the problem of cognitive dissonance because the information would remain at odds with the images resulting in the cognitive dilemma children (and many adults) already face.

The solution of counter-speech fails for another reason as well. Even if children and adolescents were able to internalize the mixed messages of the advertisements and anti-tobacco campaigns, it is doubtful the latter messages would be able to enter the marketplace of ideas. Although the percentage of smokers between 1967 and 1970, when the Fairness Doctrine required the airing of anti-tobacco advertisements on radio and television stations, fell seven percent, the inclusion of such messages in the marketplace is rare. Studies have indicated that publications accepting tobacco advertising run fewer articles about the dangers of tobacco use than those publications who refuse to accept

121. IOM, supra note 61, at 118-19.
123. Food & Drug Administration, supra note 20.
tobacco advertising.\textsuperscript{124} One study concluded that the relationship between coverage of the hazards of smoking and the acceptance of tobacco advertising was that writers submitting articles with an anti-tobacco message "have been told repeatedly by editors to stay away from the subject of tobacco. Information on the relationship of smoking to health has been edited out of several pieces submitted."\textsuperscript{125} Magazines not accepting cigarette advertising frequently ran articles on the health effects of smoking.\textsuperscript{126} Coupled with this chill on health stories related to smoking is the problem of combating the Madison Avenue campaigns that promote cigarettes and smokeless tobacco at a cost exceeding $4 billion yearly.\textsuperscript{127} Even if the government promoted anti-tobacco messages and disseminated the medical data widely, it would not be able to compete with the marketing budgets of the tobacco industry.\textsuperscript{128} Children and adolescents would still be primarily bombarded by the glamorous images with only a few public service announcement-type counter-ads appearing in between the tobacco industry's domination of the market.

In addition to the information failure, the government could also justify regulating this market because externalities create another type of market failure. Market failures may also occur because of externalities, which are instances where an

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\textsuperscript{126} Id. These magazines included: GOOD HOUSEKEEPING, SCIENCE DIGEST, SCIENCE, READER'S DIGEST, CONSUMER REPORTS, THE NEW YORKER, and WASHINGTON MONTHLY. Id.
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\textsuperscript{127} FEDERAL TRADE COMMISSION, supra note 77.
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\textsuperscript{128} While it is true that the government is the most powerful speaker in America, it does not follow that because of this position it could effectively counter the powerful advertising imagery of the tobacco industry. The tobacco industry focuses intensely on advertising its products, while the government must divide its resources among an enormous variety of expenses. Even if it could budget for advertising expenses focused on an anti-tobacco message, it may not do so because the tobacco industry as a special interest group could take advantage of the silent majority, paralyzed by the free rider problem, and lobby to prevent such expenditures. Under either scenario, it does not seem practical to believe that the government could launch as strong a counter-campaign as the tobacco industry's current advertising bombardment.
\end{footnotesize}
individual's actions impose costs on others. The most common externality problems arise from pollution situations, such as driving a car without a pollution control device. It is possible to argue that externalities associated with tobacco use could also lead to market failures. Negative externalities associated with smoking, such as increased health costs, enable the tobacco industry to avoid internalizing all of the cost of its products. Society, most often through Medicare/Medicaid expenditures and loss of productivity, bears the burden of the negative health consequences of using tobacco products. There are also the positive externalities that young people gain from believing the advertisements, such as increased security and confidence. These benefits, however, may wear off quickly as the addictive nature of nicotine establishes the child as a smoker. While adult smoking may create similar externalities, the difference comes from the age of the smoker. Based on current societal values, minors, who may not understand the consequences of their actions, deserve the protection of the government, while adults deserve the preservation of their autonomy.

Thus, the marketplace of ideas theory calls for little to no regulation of speech, but it does not take account of the possibility of market failures which in turn distort the market and keep it from functioning properly. The market failures argument, however, is as unsatisfying as the marketplace of ideas argument and does not provide further guidance as to whether there should be government regulation. Market distortion analysis assumes a natural baseline from which the existence of distortions may be determined. Because baselines are simply a function of the normative preferences of the person conducting the analysis, decisions based upon them simply reflect such preferences. They are not value neutral. Thus, the market distortion argument favoring government regulation is unappealing because it simply promotes one set of values over another set as determined by the baseline on which the analysis is grounded.

129. See Stiglitz, supra note 122, at 75.
130. Several states are now suing tobacco companies to try to recoup some of these expenses. See Hansen, supra note 4.
131. Of course, an argument based upon both informational failures and externalities could be constructed to prohibit all tobacco advertising. While such an argument may be valid, it is not the focus of this paper.
Therefore, neither the marketplace of ideas theory for protecting speech, because it fails to adequately address the problems associated with tobacco advertising and use, nor regulation justification, based upon the theory of market failure analysis, provide the neutral decisionmaking framework for which some would hope.

2. Self-Fulfillment and Autonomy

Under this broad theory of the First Amendment, speech is protected because it enables the individual to exercise her autonomy in a manner that permits self-actualization. The tobacco industry argues that restricting advertising and promotions denies individuals the opportunity to make autonomous decisions about smoking. The caveat, of course, is that the individual is capable of making autonomous decisions. Most children, and some adolescents, cannot make the rational choice to begin smoking because of the lack of information, cognitive dissonance, and most importantly their immature cognitive processes. In addition, the addictive nature of the nicotine in tobacco makes the continuation of smoking the fulfillment of the addict's need rather than an autonomous decision. Therefore, while autonomy argues for less regulation in advertising, the claim that children are capable of making fully rational, autonomous decisions is not supported by the manner in which society views children. The regulations, which do restrict the autonomy of the tobacco industry and adults, focus on advertising venues and methods

132. STONE, supra note 113, at 1084.
133. See supra note 76.
134. It is commonly accepted that children are not capable of autonomous decision-making. In the area of informed consent, for example, children assent to research, but their parents consent for them. This distinction likely arises from the immature cognitive processes of children. See Protection of Human Subjects, 45 C.F.R. § 46 (1997).
135. While similar arguments can be presented to oppose the use of tobacco products by adults, the distinction this author is drawing between children and adults is to further emphasize the point that children, even more so than adults whom society believes capable of rational decision-making, need protective help from the government in areas where parents are unable to control the strong influences on children. Other areas where the government or the private sector has stepped in to help parents enable their children to develop their thought processes before they are bombarded by influential messages include movie and television ratings, and especially the development of the V-chip.
particularly influential to children. Even so, the concerns of those encroached upon should not be ignored or lightly dismissed, especially since the scientific evidence linking tobacco product use to tobacco industry promotions has not solidified the relationship entirely.

These theories of the First Amendment fail to provide a satisfactory view of what types of speech should be protected under it. Many people instinctively believe in full First Amendment protection for some speech, but less for other types. The Supreme Court seems not to have latched too strongly onto one or another of these theories either. In failing to provide a principle on which to decide issues involving the protection of speech, it has created a confusing and inconsistent doctrine.

B. Commercial Speech Doctrine

Not until 1975 did the Supreme Court recognize First Amendment protection for commercial speech.136 In fact, the Court held more than thirty years earlier that commercial speech fell outside of First Amendment protection entirely.137 In Bigelow, however, the Court reassessed its view stating in dictum that the "relationship of speech to the marketplace of products or of services does not make it valueless in the marketplace of ideas."138 One year later, the Court invalidated a Virginia statute prohibiting pharmacists from advertising drug prices.139 In doing so, Justice Blackmun's majority opinion defined commercial speech as "expression related solely to the economic interests of the speaker and its audience"140 and granted a measure of First

138. Bigelow, 421 U.S. at 826.
140. Id. at 762. The definition of commercial speech as offered by the Court has been examined by several commentators. Some have suggested more elaborate definitions. Commercial speech is "(1) speech that refers to a specific brand name product or service, (2) made by a speaker with a financial interest in the sale of the advertised product or service, in the sale of a competing product or service, or in the distribution of the speech, (3) that does not advertise an activity itself protected by the first amendment." Comment, First Amendment Protection for Commercial Advertising: The New Constitutional Doctrine, 44 U. CHI. L. REV. 205, 236 (1976). See generally Ross D. Petty, Advertising and the First Amendment: A Practical Test for Distinguishing Commercial Speech from Fully Protected Speech, 12
Amendment protection. While the "idea" of "I will sell you the X prescription drug at the Y price"\textsuperscript{141} gained protection, the Court did not provide it with absolute protection, suggesting that "time, place, and manner restriction[s]" were permissible.\textsuperscript{142} Even with these initial recognitions of the possible value of commercial speech, the Court seemed reluctant to provide it with too much protection:

Because of the special character of commercial speech and the relative novelty of First Amendment protection for such speech, we act with caution in confronting First Amendment challenges to economic legislation that serves legitimate regulatory interests. Our decisions dealing with more traditional First Amendment problems do not extend automatically to this yet unchartered area.\textsuperscript{143}

Not until 1980 did the Court offer a test to determine whether the First Amendment had been violated in relation to commercial speech. In \textit{Central Hudson Gas v. Public Service Commission}\textsuperscript{144} the Court invalidated a prohibition on utility company advertisements promoting the use of electricity. In doing so, the Court applied a four-part test:

[First], we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. [Second], we ask whether the asserted governmental interest is substantial. [Third], if both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest. [Fourth], if the government interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive.\textsuperscript{145}

\textsuperscript{141} Virginia Pharmacy, 425 U.S. at 761.
\textsuperscript{142} Id. at 770-71.
\textsuperscript{143} Friedman v. Rogers, 440 U.S. 1, 10 (1979) (upholding a Texas statute prohibiting the practice of optometry under a trade name).
\textsuperscript{144} 447 U.S. 557 (1980).
\textsuperscript{145} Id. at 566.
In *Metromedia, Inc. v. San Diego*\(^{146}\) the Court upheld a San Diego ordinance prohibiting outdoor advertising display signs with respect to commercial speech. In applying the *Central Hudson* test, the majority found that the activity was lawful and not misleading.\(^{147}\) More importantly, it held that the ordinance directly advanced the government's interest in promoting traffic safety and the city's aesthetic interests.\(^{148}\) The Court seemed to be deferring to the government more than it had in cases involving high-value speech.

The trend of judicial deference continued to grow until reaching its peak in *Posadas De Puerto Rico Associates v. Tourism Co.*\(^{149}\) Upholding a Puerto Rico statute permitting certain types of gambling, but prohibiting the advertisement of it on the island, Justice Rehnquist writing for the majority found that "it is up to the legislature to decide whether or not such a 'counter-speech' policy would be as effective in reducing demand for casino gambling as a restriction on advertising"\(^{150}\) and that "the greater power to completely ban casino gambling necessarily includes the lesser power to ban advertising of casino gambling."\(^{151}\) This line of reasoning led many to conclude that the Court would look favorably upon most government regulations on commercial speech.

Subsequent cases continued to apply the *Central Hudson* test, but with some modifications that also suggested judicial deference to the state. The most significant adjustment came in *Board of Trustees v. Fox*.\(^{152}\) While the Court still applied the four-prong test in upholding a university regulation prohibiting a "Tupperware" party in a student's dormitory room, it read the fourth prong as requiring less than the least restrictive means, but more than a simple rational basis analysis.

What our decisions require is a "fit 'between the legislature's ends and the means chosen to accomplish those ends' — a fit that is not necessarily perfect, but reasonable; that represents not neces-

147. *Id.*
148. *Id.*
149. 478 U.S. 328 (1986).
150. *Id.* at 344.
151. *Id.* at 345-46.
sarily the single best disposition but 'one whose scope is in proportion to the interest served; that employs not necessarily the least restrictive means but . . . a means narrowly tailored to achieve the desired objective.  

Because it requires less than the rigorous standard set out in *Central Hudson*, *Fox* allows the state greater discretion in restricting commercial speech by requiring only intermediate scrutiny.

While the Court's decision in *Rubin v. Coors Brewing Co.* foreshadows the pendulum swing toward more judicial scrutiny of governmental commercial speech restrictions, it reaffirmed the use of intermediate scrutiny. In invalidating a statute prohibiting the listing of the alcohol content of beer on labels, the Court found that the government failed to demonstrate that the restriction directly and materially advanced the state's interest in preventing strength wars. The scheme was "irrational" because it permitted the use of the term "malt liquor," which describes the alcohol content of some beers, while prohibiting truthful, nonmisleading labeling for other beers. The Court focused on the impact the restriction would have on the consumer's ability to obtain truthful, nonmisleading information.

**C. Churning Doctrine**

In its most recent commercial speech decision, the Court appears to continue its consideration of the informational value of the commercial speech being restricted, but has also left the doctrine of commercial speech in disarray. A plurality in *44 Liquormart, Inc. v. Rhode Island* invalidated Rhode Island statutes prohibiting the advertising of liquor prices, finding that they banned truthful, nonmisleading speech. Although eight members of the Court apply the *Central Hudson* test, only four do so in accordance with previous doctrinal analysis.

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153. *Id.* at 480.


155. *Id.*

156. *Id.*


158. In his concurrence, Justice Thomas calls for the Court to abandon the *Central Hudson* test. *Id.* at 1516 (Thomas, J., concurring).

159. These include Justices O'Connor, Rehnquist, Scalia, and Breyer.
The remaining justices indicate a preference for a stronger *Central Hudson* test for cases involving truthful, nonmisleading speech that has informational value for consumers. Thus, there seems to be no consensus on what modified version of the *Central Hudson* test will be applied in future decisions.

Stevens' focus on the informational value of speech leads him to call for two levels of review depending upon its value to consumers; this aspect of his opinion, however, did not win a majority. In reviewing commercial speech that has particular informational value, such as availability, price, and content, the Court would rigorously review the government's restriction.

[Bans] against truthful, nonmisleading commercial speech rest solely on the offensive assumption that the public will respond "irrationally" to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. Deceptive or misleading speech, aggressive promotion of products, or governmentally required disclosure speech, on the other hand, are subject to a less rigorous review. This analysis rejecting paternalism is consistent with Justice Powell's majority opinion in *Central Hudson*. "Commercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information." Thus, even though only a minority of justices joined Stevens in his bifurcation of commercial speech, their reasoning is consistent with the dicta of previous cases and could be influential in future commercial speech cases.

Another important aspect of *Liquormart* is the Court's attention to *Posadas*. Under the deferential review established in *Posadas*, it would appear that the Rhode Island statute would have survived judicial review. Justices Stevens, Kennedy, Thomas, Ginsburg, O'Connor, Rehnquist, Souter, and Breyer basically overrule *Posadas* without directly saying so. Stevens, joined by Kennedy, Thomas, and Ginsburg, states that "on reflection, we are now persuaded that *Posadas* erroneously performed the First

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160. These are Justices Stevens, Kennedy, Souter, and Ginsburg.
161. *Liquormart*, 116 S. Ct. at 1508 (citation omitted).
Amendment analysis." O'Connor, in whose concurrence Souter, Breyer, and the author of the Posadas opinion, Rehnquist, join, echoes Stevens' unwillingness to accept the Posadas reasoning, but in more cryptic terms. "[W]e decline to accept at face value the proffered justification for the State's regulation, but examined carefully the relationship between the asserted goal and the speech restriction used to reach that goal." Therefore, while the plurality seems unable to decide upon a single modified Central Hudson test or the level of review for commercial speech of varying informational value, it seems clear that the judicial deference to government as promoted in Posadas has ended.

In light of the Liquormart decision, the Court vacated and remanded decisions granting summary judgment in two Baltimore cases also dealing with commercial speech restrictions. In Anheuser-Busch, Inc. v. Schmoke (Anheuser I), the Fourth Circuit upheld a city ordinance prohibiting billboard advertisements for alcoholic beverages in areas where children go to school and play. In the companion case, Penn Advertising v. Schmoke, the city enacted an ordinance banning billboard advertisements for cigarettes in areas children frequent. On remand, the Fourth Circuit concluded that "44 Liquormart does not require us to change our decision" upholding the ordinances. "In contrast to Rhode Island's desire to enforce adult temperance through an artificial budgetary constraint, Baltimore's interest is to protect children who are not yet independently able to assess the value of the message presented." Because of the similar focus on children and cigarette advertisements, these cases provide insight into how courts might view the FDA tobacco advertising regulations. The Baltimore ordinances, like the FDA regulations, focus on decreasing the use

163. Liquormart, 116 S. Ct. at 1511.
164. Id. at 1522.
168. Anheuser II, 101 F.3d at 329.
of illegal substances — alcohol and cigarettes — by minors. The Central Hudson prong upon which the case turns is the fit between the government's interest in "promoting the welfare and temperance of minors" and means by which they hope to achieve their goal — the restriction of advertising alcohol and tobacco products. In view of the dis-census surrounding this prong of the Central Hudson test in Liquormart, the court of appeals interprets the decision narrowly. The court does not adhere to Stevens' bifurcated analysis finding that the fit between the restriction on advertising and the city's interest in protecting children is tight enough to withstand First Amendment analysis. If the Fourth Circuit reasoning stands, it seems likely that the regulations would also be upheld.

E. Case Comparisons

The commercial speech Central Hudson test is subject to the baseline problem, however. The problem is that the person conducting an analysis makes specific undisclosed assumptions that influence the manner in which the outcome is determined. The following analysis discusses some of the strongest arguments supporting the regulations. These arguments, however, can easily be countered by changing the underlying assumptions or the level of generality at which the argument is made. Although, as the subsequent analysis demonstrates, the regulations could be supported within the judicial framework, its indeterminacy makes it difficult to rely upon the doctrine as a method of reliable decisionmaking.

1. The Central Hudson Test

169. Id. at 327. The other prongs of the Central Hudson test were not the focus of the Fourth Circuit's opinion.

170. Under Marks v. United States, 430 U.S. 188 (1977), when a fragmented Court decides a case and no single rationale explaining the result enjoys the assent of five Justices, "the holding of the Court may be viewed as that position taken by those members who concurred in the judgments on the narrowest grounds." Id. at 193. Thus, the court of appeals viewed Liquormart as narrowly holding that a state action to keep prices high in order to accomplish a professed goal of decreasing consumption is too broad a burden upon the speech.
Although it is unclear what modified version of the Central Hudson test will be applied in future cases, it seems certain that some form will in fact remain an integral part of any commercial speech analysis.

a. Lawful and Nonmisleading

The first prong of the Central Hudson test limits the government’s power to regulate speech that is lawful and nonmisleading. Although tobacco kills more than 400,000 Americans each year, it is legal to sell and advertise tobacco products. It is, however, illegal throughout America to sell tobacco products to minors. Advertisements directed at children specifically would not meet this requirement, and thus, not pass the threshold to permit such speech to receive First Amendment protection. Because of the difficulty in actually proving that the tobacco industry targets children, however, it is unlikely that the Court will view the practice of advertising tobacco products as unlawful. Neither the city nor the industry in the Baltimore cases disputed the legality of the advertisements for the purchase and consumption of these products to adults. Therefore, it is likely that the Court would take a broader view and accept the practice of advertising in which the industry is engaged as lawful, and thus require that the speech be either misleading or require the regulation to adhere to the other prongs of the Central Hudson test for the regulations to be upheld.

It also is unlikely that the Court would find the advertisements to be misleading. First, the State has a high burden of proof to establish deception. “Puffery” or exaggerated claims do not meet this burden. Thus, advertisements that do not actually mislead consumers in a literal manner would be entitled to some First Amendment protection. Second, the claims made in advertisements often defy the categories of “truth” or “falsehood.” It is difficult to determine whether an advertisement portraying a cartoon character riding in a convertible seeming to enjoy life

while smoking a cigarette is "true" or "false." It appears unlikely that the government could establish that such an advertisement is misleading since the advertisements thwart attempts to apply this traditional dichotomous standard. Therefore, it seems almost certain that tobacco advertising and promotions will clear this threshold.

b. Substantial Government Interest

Once the threshold requirement that the speech concerns a lawful activity and is not misleading is met, the government may only regulate the speech if it demonstrates a substantial government interest that is directly advanced by the regulation and "not more extensive than necessary." The purpose of the FDA regulations is "to decrease young people's use of tobacco products by ensuring that the restrictions on access are not undermined by the product appeal that advertising for these products creates for young people." It is difficult to imagine how the government's interest in protecting the health and welfare of children and adolescents could be viewed as anything but substantial. In City of Cincinnati v. Discovery Network, Inc., the Court found that the government's interest in maintaining safety and aesthetics was substantial. Therefore, it seems unlikely that it would not view protecting the health, welfare, and safety of children as substantial. The tobacco industry is equally unlikely to challenge the substantial nature of the government's interest in protecting children. Thus, if the interest is substantial, the Court must next determine if the regulation directly advances that interest.

c. Directly Advances Interest

The third prong of Central Hudson requires that the regulations directly achieve the government's goal. In Edenfield v. Fane, the Court explained that a regulation must further the

government's interest "in a direct and material way." 179

[The] burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree . . . . Without this requirement, a State could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression. 180

In Edenfield, the Court held that a Florida ban on in-person solicitations by certified public accountants was unconstitutional because the board presented no evidence demonstrating that the restriction would directly advance its goal of preventing fraud or compromise the independence of the advisory board. 181 Similarly, the Court in Rubin v. Coors Brewing Co. 182 held that the government's interest in preventing "strength wars" (increasing alcohol content of beer to increase sales) did not "directly and materially advance its asserted interest because of the overall irrationality of the Government's regulatory scheme" 183 and based on the lower court's findings that the government failed to present any "credible evidence" supporting its position. 184 Unlike the government in Edenfield and Coors, the FDA has evidence tentatively linking advertising to use. 185 The Court would likely accept the evidence since it previously recognized the impact of advertising on use in Central Hudson when it found a link between the state's interest in energy conservation and the prohibition on advertisements of electricity. "There is an immediate connection between advertising and demand for electricity.

179. Id. at 767.
180. Id. at 770-71.
181. Id.
183. Coors, 514 U.S. at 542.
184. Id. at 543.
185. The FDA has amassed a great deal of scientific evidence trying to establish the link between advertisements and use by children. While this evidence suffers from the weakness discussed in Part II, it goes far beyond the lack of evidence that defeated restrictions on commercial speech in the past.

It is also arguable that because the scientific data has not established a definitive causal link, the agency, as designated by the legislature to deal with such issues, should be left to deal with this imponderable circumstance because it has the expertise that the judiciary lacks to decide such a question.
Central Hudson would not contest the advertising ban unless it believed that promotion would increase its sales.\footnote{186} A similar conclusion follows from the tobacco industry's challenge to the regulations. It would not challenge the regulations if the advertisement restrictions did not threaten to decrease sales. However, because of the uncertainty of the link between advertising and use by children, it is possible to argue that the means of prohibiting specific types of advertisements does not directly advance the government's interest in decreasing the use of tobacco products by children. Yet, because of its statements in \textit{Central Hudson} acknowledging the link between advertisements and use of products in general, it seems likely that the Court would find that the regulations on tobacco advertising directly advance the government's goal of decreasing the use of tobacco products among young people.

d. \textit{Narrowly Drawn}

The final prong of the \textit{Central Hudson} test requires the Court to examine the fit between the end the government wants to achieve and the means by which it decides to meet the goal. It may be the most difficult to evaluate because of the need to ascertain the relationship between the tobacco advertisements and use by children. In \textit{Fox}, Justice Scalia's majority opinion redefined this prong to require that the means be "narrowly tailored to achieve the desired objective."\footnote{187} This requirement is less than the least restrictive means, but more than complete deference to the government.\footnote{188} In \textit{Discovery Network}, the Court further explained that "if there are numerous and obviously less burdensome alternatives to the restriction on commercial speech, [they] are certainly a relevant consideration in determining whether the 'fit' between ends and means is reasonable."\footnote{189}

The Court held in \textit{Discovery Network} that a city ordinance prohibiting the distribution of commercial handbills, but not "noncommercial" material, such as newspapers, on public property was not a reasonable fit because the distinction between

\footnotesize{
188. \textit{Id.}
}
commercial and noncommercial materials did not relate to the city's goals of safety and aesthetics. In the regulations, the FDA distinguishes between adult and non-adult publications prohibiting color, image-oriented advertisements in only non-adult publications. It defines adult publications as those whose total readership is made up of 85 percent or more people over the age of eighteen or are read by two million or less people who are under eighteen years old. The FDA's asserted goal is to prevent young people from using tobacco products. Unlike the restriction in Discovery Network, the FDA regulations distinguish commercial speech in a manner that would at least seem to be directly related to decreasing the use of tobacco products by young people. The goal is achieved by preventing advertisements that are particularly attractive to children from appearing in publications they frequently read. The regulations also prohibit advertisements on billboards near schools and playgrounds, the distribution of promotional items that are arguably primarily used by children, and the sponsorship of sporting events frequently watched by children on television. Thus, similar to those restricting color, image-oriented advertisements in print media, these regulations also seem to be targeted at preventing children from being enticed to use tobacco products because of flashy ads. Therefore, the regulations would likely survive a challenge in light of Discovery Network.

Recent circuit cases support this assessment as well. The Fourth Circuit in the Baltimore cases found regulations of billboard advertisements of alcohol and tobacco, similar to those proposed by the FDA, to be narrowly tailored to the city's interest.

Baltimore's interest is to protect children who are not yet independently able to assess the value of the message presented. This decision thus conforms to the Supreme Court's repeated recognition that children deserve special solicitude in the First Amendment balance because they lack the ability to assess and analyze fully the information present through commercial media.

190. Id. at 424.
192. Id.
194. Schmoke, 101 F.3d at 329.
Thus, like the billboards in the Baltimore cases, advertisements that attract children because of their images and colors or the sheer magnitude of these advertisements that bombard children daily should be restricted to protect children who are unlikely to understand objectively the dangers of the tobacco use promoted by these glossy images. Thus, unlike the distinction drawn in *Discovery Network*, the FDA regulations are narrowly tailored to the government's desire to decrease the prevalence of tobacco product use among young people and should be upheld based upon reasoning similar to that used by the Fourth Circuit in the Baltimore cases.

The problem with reaching this conclusion, however, is that the scientific evidence cited by the FDA in support of the link between advertising and use of tobacco products by children and the definition of advertising techniques that attract children are less than dispositive. Thus, in order for the Court to reach the conclusion that the regulations are in fact narrowly drawn, it must either defer to the legislature, which in light of *Liquormart’s* questioning of *Posadas* seems unpopular, or it must evaluate the evidence itself, which clearly falls outside of its realm of institutional competence. Thus, the doctrinal pathway seems to offer little guidance as to what the Court should do with regard to the regulations.

Opponents of the regulations are also troubled by the fact that the regulations are not the least restrictive way for the FDA to achieve its goal. In *Metromedia*, the Court upheld an ordinance prohibiting the use of outdoor advertising display signs even though there were less restrictive measures the city could have used to achieve its goals because the ban was "perhaps the only effective approach." While selling tobacco to minors is already illegal throughout the country and intense educational campaigns explaining the dangers of tobacco use exist, the prevalence of smoking among young people is rising. The regulations, while not as intrusive as a ban, could be viewed as perhaps one of the few potentially effective approaches to curbing the use of these products by minors. However, it is not clear that greater enforcement of existing laws or better targeted educa-

196. *See supra* part II.A.
tional campaigns would not be more effective. In addition, while a complete ban on the use of tobacco products might encroach upon individual autonomy, it would address the issue of use by children without subordinating constitutional rights to public health concerns based on uncertain data. Once again, the doctrine does not provide clear guidance to help determine which policy should be applied.

Even analogizing to these cases is problematic after *Liquormart* because it is unclear how this prong will be viewed because of the Court's divided decision. It is unclear whether the traditional *Central Hudson* or a stricter analysis will prevail. Regardless of this uncertainty, however, all eight Justices who applied the *Central Hudson* test failed to find that Rhode Island established a reasonable fit between its desire to promote temperance and its ban on advertising the price of liquor. 197

The availability of less burdensome alternatives to reach the stated goal signals that the fit between the legislature's ends and the means chosen to accomplish those ends may be too imprecise to withstand First Amendment scrutiny. If alternative channels permit communication of the restricted speech, the regulation is more likely to be considered reasonable. 198

These alternatives included taxation, limiting amounts purchased, and educational campaigns. 199 The alternatives of taxation, limiting amounts purchased, and educational campaigns are in effect now with regards to tobacco use by minors. The increasing prevalence of use among children would seem to indicate that they are not sufficient to achieve the FDA's goal. It is also possible that some of the FDA regulations could be viewed as not narrowly tailored. For example, arguments could be made suggesting that the definition of adult publications excludes too many publications that are focused toward young adults rather than children, and thus, the regulation should be invalidated. The prohibitions on the sale or distribution of non-tobacco promotions will turn on whether these items are primarily obtained by young people. In view of the FDA's evidentiary findings and the Court's previous experience of invalidating restrictions based on little or no evidence, it seems likely that these regulations

198. Id. at 1521 (citations omitted).
199. Id. at 1510, 1521.
will be upheld because of the fact-finding process and its results. The sponsorship of events, entries, or teams, on the other hand, might raise some evidentiary problems. Of the 354 sporting events broadcast in 1992, only seven percent of the audience were children and teens, but other studies have demonstrated that young people associate smoking with sporting events. Thus, it is unclear that the FDA has compiled sufficient evidence to support its claims regarding this regulation. However, the tobacco industry’s voice would not be completely silenced. It could still advertise in non-adult publications using text-only, black-and-white advertisements. It could still use color, image-oriented advertisements in adult publications. It could still use billboards that are not near schools and playgrounds. It would still be able to sponsor sporting events in the company’s name. The only complete ban would be on promotional items, which could be considered a valid time, place, and manner restriction. Therefore, depending upon the strictness of the test as eventually clarified by the Court, it seems likely that most, if not all, of the FDA advertising regulations will be viewed as “narrowly tailored to achieve the desired objective.”

e. Informational Value

If Justice Stevens’ bifurcated approach based upon the informational value of the speech prevails, it is equally unclear whether the regulations would withstand his stricter criteria. The regulations at one level do not prohibit consumers from obtaining information necessary to make rational choices about the product. The decision in *Liquormart* stressed that the ban on alcohol content appearing on labels blocked consumers from obtaining valuable and necessary information. Similarly, the Court in *Coors* invalidated a restriction on advertising the content of alcohol. The FDA regulations do not ban any information fundamental to consumers attempting to make an informed choice. Informational price, availability, and content (tar level) are still permitted even in non-adult publications through the use of tombstone advertisements. The regulations at another

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200. IOM, supra note 61, at 113.
201. See infra Part III.E.2.
202. Tombstone advertisements are the black-and-white, text-only print advertisements described in the regulations.
level, however, do prohibit the information contained in the images from being conveyed. Neither Liquormart nor Coors addresses the issue of images. Thus, it is unclear if they, like political cartoons, could be viewed as providing information necessary to the consumer. Because of the instability of the doctrine, it is unclear if the regulations inhibit the free flow of information about the product, and thus it is difficult to determine whether they are a valid means of regulating commercial speech using the framework of the commercial speech doctrine.

f. Conclusion

It is likely that these advertisements would meet the threshold requirement of being lawful and nonmisleading. The government's interest in regulating these advertisements would also likely be considered substantial. However, it is unclear based upon doctrinal uncertainties that these regulations directly advance the government's interest or are narrowly tailored to achieve the FDA's goal. Therefore, reliance upon a judicial doctrine does not resolve the difficulty of making normative choices about tobacco policy.

2. Time, Place, and Manner Restrictions

If, however, the tobacco-related advertisements would be considered protected speech, it is still possible for the FDA to regulate them. Under the doctrine of time, place, and manner, the government can regulate speech in a content-neutral manner. In Ward v. Rock Against Racism, the Supreme Court established the standard by which time, place, and manner restrictions should be reviewed.

[T]he government may impose reasonable restrictions on the time, place, or manner of protected speech, provided restrictions "are (1) justified without reference to the content of the regulated speech, that they are (2) narrowly tailored to serve a significant governmental interest, and that they (3) leave open ample alternative channels for communication of the information."

204. Id. at 791 (quoting Clark v. Community for Creative Non-Violence, 468 U.S. 288, 293 (1984) (numbering added)). The similarities between the commercial speech doctrine test and the time, place, and manner standard have been recognized.
Thus, if the FDA regulations are content-neutral and simply restrict the time, place, and manner in which tobacco companies can advertise, they would not violate the First Amendment. The difficulty with relying upon this doctrine for justification of encroaching upon individual rights is that any restriction can be viewed as simply regulating the time, place, and manner of the speech depending upon the baseline assumption with which this analysis begins.

a. Content Neutrality

First, the government’s purpose must be unrelated to the message that the speech conveys. A regulation that serves purposes unrelated to the content of expression is deemed neutral, even if it has an incidental effect on some speakers or messages but not others. In *Discovery Network*, the Court held that the city ordinance prohibiting the distribution of only commercial handbills was not content neutral because it distinguished between the commercial or non-commercial content of the speech. While the regulations restricting tobacco advertising are arguably content-based because, like the ordinance in *Discovery Network*, they distinguish between the pro-tobacco and anti-tobacco content of speech, at a higher level of generality the regulations do not prevent all pro-tobacco speech, but rather limit only the time, place, and manner in which advertising may appear so that children do not view these advertisements. The industry may freely convey its messages in forums not limited by the regulations. Viewed in this manner, the regulations do not prohibit the advertisements because the government disagrees.
with the pro-tobacco message, but merely limits how this message can be conveyed. The problem with this prong resides in the fact that the outcome of determining content neutrality depends upon the characterization of the regulations. When attempting to conduct evaluations of content neutrality, courts look to whether the speech is protected, whether the regulations prohibit the conveyance of a message that the government disfavors, and whether the speech poses a special danger. The doctrine, however, does not provide a neutral framework by which to make such determinations. Such decisions, rather, seem to be based upon the normative value preferences of judges.

The government’s regulations prohibiting pro-tobacco advertisements focusing on children may be valid if the advertisements are directed at children, even if they are content based. For speech to receive First Amendment protection, it must meet the threshold requirement of being lawful.208 If it does not meet this requirement, restrictions upon it would not have to be content-neutral because it would not be protected by the First Amendment. Because the use of tobacco by minors is prohibited, advertisements targeted at young people encourage them to engage in illegal activity. They, therefore, do not warrant constitutional protection. Arguments based upon the premise that the regulations unconstitutionally burden speech directed to children209 are therefore invalid because the speech would not qualify as protected. Advertisements to young people encouraging them to smoke would not meet this threshold requirement, and thus, not be protected under the First Amendment. Therefore, if held not to be protected speech, tobacco product advertisements could be regulated regardless of the content neutrality of the restrictions.

If, however, the First Amendment provides some protection for the advertisements, then the regulations must not prohibit the industry from conveying its message because the government disagrees with it generally.210 While it could be argued that the

209. The tobacco industry, however, denies that the advertisements are directed at young people. See supra part II.B. for discussion of studies demonstrating that the current advertisements for tobacco-related products may influence children to begin using these products.
FDA's focus on tobacco advertising is content-based because the agency has adopted an anti-tobacco stance that disagrees with the pro-smoking message of these advertisements, this view proves too much. The restrictions may be classified as not focusing on the message itself, but rather on the way in which it is conveyed. The tobacco industry may communicate its message, but is simply restricted as to the time, place, and manner in which it is delivered. In *Greyned v. City of Rockford*, the Supreme Court upheld restrictions on noise near a school while classes were in session, and thus, prevented protestors from picketing the school when most people were there. Like the restrictions in *Greyned*, the FDA regulations still permit the message to be conveyed, even if it is not in a way that the industry favors. For example, the regulations permit tobacco companies to place "tombstone" advertisements in publications directed at children or on billboards not near schools. The industry can continue to sponsor events, but may do so only in a manner that promotes a company rather than a brand. The prohibition on promotional items, such as t-shirts, caps, and lighters, do not prevent the tobacco industry from encouraging adults to smoke particular brands, but rather prohibits one manner by which such loyalty can be cultivated. Thus, the content of the advertisement, assuming the tobacco companies are truthful in their assertion that the advertisements focus on creating brand loyalty or providing information about the product, such as tar levels and price, can still be conveyed; it is only the manner and place in which it can be disseminated that are being restricted. However, the prohibition on the use of product names and effective advertising techniques could be viewed as a regulation of the message if that part of the message is delivered in a way similar to the expression associated in wearing armbands. Therefore, it is unclear whether the regulations are unrelated to the message and are a valid restriction upon speech.

In addition, the Supreme Court has permitted the government to single out types of speech through regulations if the speech

211. 408 U.S. 104 (1972).
212. Tinker v. Des Moines Sch. Dist., 393 U.S. 503 (1969) (holding that wearing armbands in protest of the Vietnam War was protected expression under the First Amendment).
poses a danger relevant to the reasons why commercial speech receives less First Amendment protection. "When the basis for the content discrimination consists entirely of the very reason the entire class of speech at issue is prescribable, no significant danger of idea or viewpoint discrimination exists." Following this argument, the risk to the health of children that the use of tobacco products creates is a danger which would permit the government to regulate speech associated with this activity because it relates to the Supreme Court's belief that commercial speech deserves less protection because some economic legislation is necessary and desirable. The regulations arguably promote the economic decision to prohibit children to buy cigarettes by restricting advertisements that because of their location or design are particularly influential to children. Therefore, no danger to speech exists, and the regulations do not discriminate because the regulations relate to the reason commercial speech is considered low value speech. However, as noted in Part IV, it is unclear whether commercial speech ought to be treated as low value speech. Thus, in light of the shifting doctrine, this argument is not completely satisfying.

b. Narrowly Tailored to Serve a Significant Government Interest

If the restriction is content neutral, it must be narrowly tailored to serve a significant government interest. Like its interpretation of the Central Hudson prong, the Supreme Court requires only that the means are no broader than necessary. As discussed in regards to the Central Hudson test, the government's interest in protecting the health of children is substantial. While it is likely the substantial government interest will go unchallenged, it may prove more difficult to determine if the regulations are narrowly tailored to promote this interest.

"[T]he requirement of narrow tailoring is satisfied 'so long as

217. See supra part III.E.1.b.
the . . . regulation promotes a substantial government interest that would be achieved less effectively absent the regulation.\textsuperscript{218} Thus, the FDA would have to establish that the advertisements do influence children to use tobacco products and that placing restrictions upon them would decrease tobacco use by young people. In \textit{Edge}, the Court, in upholding regulations prohibiting lottery advertisements on radio and television, found that a connection between advertising and demand could further the government's interest in preventing gambling.\textsuperscript{219}

If there is an immediate connection between advertising and demand, and the federal regulation decreases advertising, it stands to reason that the policy of decreasing demand for gambling is correspondingly advanced. Accordingly, the Government may be said to advance its purpose by substantially reducing lottery advertising, even where it is not wholly eradicated.\textsuperscript{220}

Like the restriction in \textit{Edge}, the FDA regulations are supported by the common sense notion, as well as some less than satisfactory scientific evidence, that industries advertise to increase sales. It is difficult to believe that the tobacco industry would spend millions of dollars to create and market images such as Joe Camel that appeal to children if these advertising images did not increase demand and use of their products.\textsuperscript{221} Following this economic logic, removing advertisements targeted at children, whether by design or by venue, will reduce demand among children. With the decrease in use by children, the government's interest in decreasing the use of tobacco products by young people to enhance their health status would be achieved. It is also important to note that the Court in \textit{Edge} did not require that all advertisements about the lottery, which entered the state through Virginia publications and stations, be stopped.\textsuperscript{222} The restrictions still directly advanced the government's interest even

\begin{verbatim}
\textsuperscript{218} Ward, 491 U.S. at 798 (quoting United States v. Albertini, 472 U.S. 675, 689 (1985)).
\textsuperscript{220} Id.
\textsuperscript{221} While it is arguable that the tobacco industry advertises to obtain the largest share of the available market, this explanation for the large sums spent on advertising does not seem complete. Since economic players not only try to obtain the largest share of their market, but also look to increasing their market to increase their profits as well, focusing only on the current market is myopic.
\textsuperscript{222} Edge, 509 U.S. at 434.
\end{verbatim}
if they only blocked advertisements originating in North Carolina.\(^{223}\) Thus, while there are other ways in which children may be encouraged to use tobacco products, such as parental use, seeing advertisements in adult publications, or viewing the use of tobacco products in television programs and movies, the government can legitimately focus on one aspect of the problem before working on the problems in other areas. The FDA regulations focus on the placement of advertisements promoting tobacco use in areas or venues in which children are likely to view them and on the manner in which the information is conveyed that is particularly attractive to young people.\(^{224}\) Therefore, the regulations are narrowly tailored to serve the government’s interest in decreasing the use of tobacco by young people.

The Court has also demonstrated that it would accept what otherwise might be considered overly restrictive encroachments upon speech when previous attempts to further a state interest have failed. In *Madsen v. Women’s Health Center, Inc.*,\(^{225}\) a thirty-six-foot buffer zone around an abortion clinic was upheld because the original injunction which tried to protect patients from anti-abortion protestors failed. The Court stated that “some deference must be given to the state court’s familiarity with the facts and the background of the dispute.”\(^{226}\) A similar argument for the FDA regulations can be made. Previous tobacco policy, such as warning labels, age restrictions on sales, and educational programs, have not worked to curb the use of tobacco among young people. In fact, the levels of young people smoking continue to rise.\(^{227}\) Thus, based on the Court’s previous decisions in *Edge* and *Madsen*, it seems likely that the regulations are narrowly tailored to decrease the use of tobacco-related products by young people.

\(^{223}\) Id. at 432, 434.

\(^{224}\) While it is possible to argue that the FDA regulations that focus on adult-only publications define these publications too broadly or that the actual viewership of sporting events by children is too low to make either restriction directly advance the government’s interest, the general disagreement turns on imponderables or questions of evidence that the agency is arguably better equipped to evaluate and resolve than the courts. However, such deference, in light of *Liquormart* seems no longer to be valid.

\(^{225}\) 512 U.S. 753 (1994).

\(^{226}\) Id. at 769-70.

c. Ample Alternative Channels

The final aspect of the time, place, and manner criteria requires that there are ample alternative channels by which the restricted speech can be conveyed. The Court has upheld city restrictions on traditionally protected speech because the restrictions permitted “ample alternative channels of communication.” In Frisby v. Shultz, the Court held that a city ordinance prohibiting protests focusing on and occurring in front of local residences was constitutional because the restriction left protestors alternatives including the freedom to march, hand out flyers, protest at other locations, or go door-to-door. The FDA regulations like the ordinance in Frisby provides the tobacco industry a multitude of channels through which they can continue to promote their products. For example, advertisements on billboards not located near schools or playgrounds would not be prohibited, nor would advertisements using images and color in adult publications. They may still sponsor events so long as they do so in the name of the company. The regulations only prohibit advertisements that attract children because of the manner or location in which the message is conveyed. Thus, the FDA regulations provide ample alternative channels for the tobacco industry to advertise its products.

d. Conclusion

It seems likely that even if the regulations are found to restrict protected speech under the Central Hudson test, they could be constitutional time, place, and manner restrictions, and thus, valid under First Amendment doctrine. The doctrine, however, is subject to the same problems of indeterminacy plaguing that of commercial speech. It is simply not clear that the regulations are content neutral. Counter-arguments underscoring the uncertainty of the data could create difficulties in assessing the fit between the restrictions and the FDA’s goal of reducing tobacco use by children. Similarly, while there seem to be ample alternatives according to some views, others could argue that the regulations

230. Id.
prevent the most effective means of conveying the message for which there are not alternatives. The outcomes seem not to turn on the application of impartial law, but on the assumptions made by judges. Thus, the doctrine, even if it were clear, is not an effective decisionmaking framework.

IV. ISSUE OF INDETERMINACY

Although it seems likely that even under the churning doctrine of commercial speech the FDA regulations will not violate the First Amendment, the analysis depends on the baseline chosen to evaluate how First Amendment protection should be structured. It is not at all clear that the Supreme Court should select one philosophical normative value over another, and thus, the Court’s decision will be based not upon judicial principles; rather, the decision will be an expression of political will. Since it is not clear that such decisions should be made by a court rather than an agency or legislature, the issue of indeterminacy destabilizes whatever comfort the doctrine attempted to provide. Thus, the dilemma of whether to regulate tobacco product advertisements cannot be solved by turning to First Amendment doctrine or principled decisionmaking. America must choose between encroaching on the tobacco industry’s desire to advertise according to its current practices and a perceived need on the part of public health officials to protect children from the influence of potentially deceptive advertisements using another method of decisionmaking. While it is unclear how such a choice should be made, the promulgation of the FDA regulations requires that the decision be reached.

A. Philosophical Spheres

The issue of indeterminacy centers around what the First Amendment protects. The Supreme Court’s commercial speech decisions seem to rest on the idea that the informational value of commercial speech promotes consumer autonomy and that a “consumer’s interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day’s most urgent political debate.”231 In reaching this con-

clusion, the Court tacitly assumes that the First Amendment rests on the theory of the marketplace of ideas. By providing less protection for commercial speech, however, the Court expresses a normative preference for political discourse. Although two levels of protection exist, the Court seems to view First Amendment doctrine as requiring less stringent review for commercial speech restrictions.

Providing protection to economic as well as political speech troubles some theorists. Public health scholar Dan Beauchamp argues that the Court is wrong in “giving very powerful economic interests the mantle of First Amendment rights.” His arguments seem to follow a strict interpretation of Meiklejohn’s explanations of the First Amendment. If one accepts this rather narrow view of the First Amendment as a provision posed to protect political parley, then the First Amendment should not protect commercial speech unrelated to the political/policy arena. If this assessment is correct, then restrictions on advertisements aimed at consumers of economic products would not raise constitutional issues.

The problem with Beauchamp’s narrow interpretation of the First Amendment is that it does not accurately account for the Court’s current evaluations. The Court maintains the distinction between high-value political speech and low-value commercial speech. Contrary to Beauchamp’s concern, First Amendment doctrine seems to maintain at least some distinction between the spheres. While advertisements, the epitome of commercial speech, warrant some protection from government regulation, their value seems to be less important to American values because it is given less than the strict protection available for political speech.

In reality, however, this distinction between the spheres of commercial and political speech is unstable. To accept the theory of two spheres governing the First Amendment requires one to assume that the political sphere centers on issues not related to those dealt with in the commercial sphere and vice versa. However, as the Court itself realized in Virginia Pharmacy, “consumer[s’] interest[s] in the free flow of commercial information” may

232. See supra Part III.A.1.
trump their interest in political debate. Thus, the spheres may not be as hierarchical and distinct as Beauchamp suggests. No better example of the fading of borders between the political and commercial world exists than that of current presidential political campaigns. As media consultants and pollsters massage messages and package presidents, the line defining political discourse becomes blurred as the political message meshes into commercial discourse. The candidates sell the images of new mornings in America or criminals running amuck. Thus, rather than run on the party platforms, candidates sell thirty-second soundbite images of themselves trying to convince the voters to "buy" these images for the next term. The merging of these spheres may signal a move toward a new paradigmatic view of the basic societal values and First Amendment.

B. Paradigm Shift

The traditional grounding of First Amendment thought rose out of the Enlightenment's belief in the autonomous individual. "On the eve of the twenty-first century [when] America's marketplace of ideas has largely become a junkyard of commodity ideology," are such principles relevant? Perhaps they are not. While the philosophy of the Enlightenment drew clear distinctions between the individual and government from which the distinctions between the commercial and political grows, postmodern America is plagued or blessed, depending upon one's view, with the indeterminacy of deconstruction. Thus, the distinctions previously believed to be clear and straightforward are no longer independent or obvious. The overlap between commercial speech and political speech exemplifies how the former barriers are crumbling. Some have argued that such indeterminacy

234. Virginia Pharmacy, 425 U.S. at 763.
236. A group supporting George Bush's bid for the presidency ran what may be the most controversial advertisement attacking Michael Dukakis' stand on crime. These ads featured the story of Willie Horton's parole.
may be indicative of paradigm shifts in the way Americans conduct the "science" of law.\footnote{Girardeau A. Spann, \textit{Deconstructing the Legislative Veto}, 68 MINN. L. REV. 473, 542 (1984). "Old" paradigms of scientific thought were plagued by indeterminacy before paradigm shifts occurred. "Traditional legal analysis is a 'normal science,' and deconstruction may well be the harbinger of a 'deviant science' that will shortly replace it." \textit{Id.} (citing THOMAS S. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (1962)).} The indeterminacy may also lead to a more subtle, but none the less important, change in the way we view our national discourse. The current shift in the realm of First Amendment protection seems to be a way from a society emphasizing the political self toward one centered around the consumer self. Thus, to maintain relevance for society, First Amendment doctrine will have to take account of the new paradigm. When Watson and Crick reordered the way in which biology and medicine viewed the human body with the discovery of the structure of deoxyribonucleic acid (DNA), the shift troubled many and created new legal and ethical issues. Similarly, a culture shift from granting primary protection for political speech to one in which commercial speech is viewed as equally valuable, if not more so, also leads to new dilemmas. The controversy surrounding the FDA advertising regulations demonstrates such tensions.

Although it has not occurred yet, the movement toward such a shift may be indicated by the Court's new desire in \textit{Liquormart} to provide commercial speech with more protection. The shift to a consumer-centered world will likely alter the concept of the marketplace of ideas. Some scholars believe the shift already has occurred. Ronald K. L. Collins and David M. Skover argue that ideas "foster[ing] rational decisions by the citizen" are being squeezed out by "commercial images that encourage fantasized decisions by the consumer . . . . [T]alking about and consuming commodities are now among our most significant 'political' acts."\footnote{Collins & Skover, \textit{supra} note 237, at 698, 724.} In such a marketplace, reality changes: "image is all . . . truth is irrelevant . . . there is no right to know . . . [and] we are as we consume."\footnote{\textit{Id.} at 736-41.} The exchange of ideas no longer drives the marketplace; rather, consumers seeking to obtain the product-images conveyed through advertising dominate the agenda. Advertisements no longer provide simple information to indi-
individuals making rational choices; rather, they sell life-styles and images,\textsuperscript{241} fusing the product, image, and consumer into one. “Only select values are traded in advertising’s exchanges, however. Life is pictured as a Land of Oz but without the Wicked Witch.”\textsuperscript{242} Ideas no longer serve the function envisioned by the framers of the constitution or the ideals of the Enlightenment which inspired them. The world of consumption as envisioned likely conjures up horrific images for many people; however, the Madison Avenue campaigns of today can be found in those images. While the shift may not have completely occurred, it is not difficult to imagine how it might.

If a paradigm shift occurs, society could also afford commercial speech even less than it currently provides by equating it with conduct. The First Amendment does not protect conduct, only speech. In \textit{Cox v. Louisiana},\textsuperscript{243} the Supreme Court held that expression when mixed with conduct would be regulated since the state may regulate an individual’s conduct.\textsuperscript{244} If the images dominate and the impact of advertising becomes more important than the information conveyed, the Court could view the advertisements as a type of conduct rather than speech leaving it unprotected by the First Amendment. While similar arguments are made by some feminists in relation to pornography, they have not been generally adopted by the courts.\textsuperscript{245} Thus, a paradigm shift toward obtaining product-images rather than information could actually decrease the amount of First Amendment protection commercial speech receives.

If society shifts to such a culture, should the First Amendment shift with it, and if so, in which direction? If consumers dominate and value image-advertisements more than political discourse and information of the ideal marketplace, does the theory of the First Amendment expand to protect those images as well or contract and offer less protection? It is difficult to answer these

\textsuperscript{241} Id. at 709.
\textsuperscript{242} Id. at 710.
\textsuperscript{243} 379 U.S. 559 (1965) (Cox II).
\textsuperscript{244} Id.
\textsuperscript{245} Feminists argue that pornography is a type of conduct/behavior rather than speech. Because it involves the conduct of dehumanizing and exploiting women, they argue that it should be regulated in accordance with the State’s power to restrict conduct and that no First Amendment issue is involved. \textit{See generally Stone et al., supra} note 113, at 1317-22.
questions until the shift has ultimately been made.

The tobacco advertisements and promotions of today bombard- ing children, adolescents, and adults do not stray far from this world of image-based consumption. The Court’s confused decision in Liquormart may be a move to adapt First Amendment commercial speech doctrine to the consumer-center paradigm. While Posadas provided commercial speech with what seemed to be little more than rational basis review, the Court’s holding in Liquormart may be a move toward a doctrine that provides commercial speech with more protection.

Although at first glance it may appear that the Liquormart decision is consistent with traditional First Amendment doctrine because it seems to err on the side of protecting speech, and thus, produces more speech, such an analysis fails to take into account the unique aspects of advertising. Assuming that advertising generally provides consumers with truthful, nonmisleading information, such as the alcohol content with which the Court concerned itself in Liquormart, advertisers may directly or indirectly attempt to influence reporters and editors to alter the content of “news” stories. Studies have found an inverse correlation between the number of stories about the health effects of tobacco use and the number of tobacco advertisements accepted by magazines. If counter-speech in the form of news reports and informational articles are suppressed to keep advertisers happy, then there is clearly a market failure that would require government intervention to correct the market distortion. While in one sense prohibiting or regulating advertisements of tobacco products may limit the expression of certain ideas or images and decrease the amount of speech from advertisers, it may actually increase the overall amount of speech of informational substance. The desire for intervention depends upon which paradigm of the First Amendment is accepted. If the “old” paradigm of the marketplace of ideas being an exchange of information to help individuals make rational decisions is assumed, restricting some commercial speech would be beneficial. If, however, one accepted the “new” paradigm of a consumer-based, image-advertising marketplace, then restrictions would be bad because they func-

tion to decrease the amount of image-advertisements available. In the end the decision of whether to regulate advertising will depend on subjective preferences rather than principled decision-making.

Because we cannot rest our choice of a First Amendment theory on principled reasoning, the validity of the FDA regulations rests then on subjective decision-making inherent in our view of the proper role of the First Amendment. While most can agree on the general principle of protecting free speech and avoiding paternalistic rules and regulations, the specific application of these principles is fraught with normative value judgments. Based on our view of the First Amendment, we can attempt to decide whether the regulations promote more speech or curtail the amount of speech. As discussed earlier, however, this decision turns on what type of societal paradigm we subjectively select as a baseline. It is also plausible to argue that the regulations should be upheld on the basis that the legislature and the FDA are more institutionally competent to decide such imponderables, and therefore, the Court should defer to their decisions. This conclusion, of course, resembles the Court's approach in Posadas, from which it distanced itself in Liquormart. We are left, it seems, with a choice between normative values. The uncertainty in the scientific data linking cigarette smoking to a myriad of diseases and health problems, which take a huge toll in both dollars and more importantly human life each year, does not provide decisionmakers with strong support for their conclusions to either permit the regulations or abandon them. This uncertainty combined with the indeterminacy involved in First Amendment analysis prevents society from addressing the legal and ethical issues raised by the data with a clean, understandable framework.

V. CONCLUSION

The use of tobacco in America and the health consequences associated with it led to the most recent government intervention into the market dominated by the tobacco industry. Many have looked to the First Amendment and commercial speech doctrine to help determine if the regulations are acceptable. The FDA's new regulations attempt to decrease the use of tobacco products by children. While justifications for these regulations could be found in market analysis and paternalistic concerns about
children's health, no analytical framework exists to provide Americans with clear directions as to the need or legality of the restrictions. Reliance upon the scientific evidence may lead some to permit the regulations focusing on decreasing the use of tobacco products, and thus, prevent addiction, illness, and death. This evidence, however, is an unsatisfactory foundation on which to rest complete justification for the regulations because no causal link between advertisements or advertising techniques and use by children has been established. An analysis of current commercial speech doctrine seems to suggest that such regulations would be valid; however, recent Supreme Court decisions have made this area of law less than lucid. Similarly, an examination of the theoretical foundations of First Amendment doctrine provides little guidance for making this decision because of the indeterminacy and the realization that subjective preferences will ultimately be the basis upon which any decisions are made.

Although these limitations may seem overwhelming, they do not permit policymakers to shrink from the decision facing them. On the contrary, a realization of these inadequacies of the analytical methods should encourage the beginning of an open and honest debate about the true validity and necessity of the regulations. It is quite possible that such a debate will lead to the development of a new framework under which similar issues can be addressed in the future.
CASTANO v. AMERICAN TOBACCO CO.: CLASS TREATMENT OF MASS TORTS IS GOING UP IN SMOKE

By Robert T. Krebs

I. INTRODUCTION

Mass manufactured products are a hallmark of socio-economic life in the twentieth century and promise to be as significant in the next century as companies move towards global standardization and technological production. Inextricably connected to this mass production is steadily increasing consumer consumption of mass produced goods. This relationship creates a social environment whereby tortious conduct by a manufacturer or a defect in the product can generate a substantial number of complaints of personal injury.

The proliferation of mass produced and mass marketed consumer goods and the complaints of injuries resulting therefrom have brought an “accelerating avalanche” of mass tort suits in federal courts. These mass tort claims are problematic to the federal judiciary because they result in the filing of many suits which litigate the same issues surrounding similar facts. The multiplicity of suits produces high litigation costs, long delays in the resolution of all of the claims and, as such, they affect not only the litigants, but other users of the court system. When these claims are left to traditional two party adjudication, “it is


2. Mass torts or mass toxic torts involve injuries or harm which occur in many different places at different times. They should be distinguished from mass disaster litigation which involves numerous injuries arising from a single event. See MANUAL FOR COMPLEX LITIGATION § 33.2 (3d ed. 1993), which discusses the fundamental differences between the two types of litigation in the context of the federal judiciary.

3. See [Judge] Alvin B. Rubin, Mass Torts and Litigation Disasters, 20 GA. L. REV. 429 (1986) (suggesting the traditional two party system is not adequate for the adjudication of mass injury and mass catastrophe cases in part because of the tremendous economic and social costs which result).
evident the proper functioning of the courts and the fair and efficient administration of justice for other litigants . . . are inevitably delayed inordinately by the clogging of the court system by mass tort actions tried individually . . . .

Prominent examples of mass produced products which have generated mass torts include asbestos-containing items, Agent Orange, the Dalkon Shield contraceptive device, Bendectin, DES, silicone breast implants, defective heart valves, penile prostheses, HIV infected blood products, tampons, and automobiles.

One method federal district courts can utilize to cope with this deluge of personal injury lawsuits is to certify a class-action lawsuit of the individual litigants under Federal Rule of Civil Procedure 23. In 1995, the United States District Court for the Eastern District of Louisiana certified perhaps the largest mass tort class action ever in federal court in Castano v. American Tobacco Corp. The class, which potentially numbered over 90 million, complained certain manufacturers of cigarettes injured them by reason of addiction to the nicotine contained within their products.

The Castano class was short-lived because it was decertified by the Fifth Circuit Court of Appeals on an interlocutory appeal. The decertification of Castano joins a recent growing trend in the federal judiciary to reject class treatment of mass tort claims. Thus, Castano is significant not only for its role in

4. In re A. H. Robins Co., 880 F.2d at 726.
10. Id. at 736.
the continuing saga of unsuccessful attacks on the tobacco industry, but also for its place in the increasing predilection of federal courts against use of the class action device in the context of mass torts. Each decertification order or denial of class treatment threatens to burden the judicial system with a mass of individual suits.

Section II of this casenote briefly reviews the history of tobacco litigation and the events which led to the Castano class action, including class certification. Section III reviews the decertification order of the circuit court and places the decision within the growing trend away from class actions. Section IV examines the court’s reasons for denying class treatment of mass torts and notes the judicially created restriction to class certification under Rule 23. Section V briefly concludes with the observation that mass products and mass injuries are not likely to decrease in the future, and Castano suggests there is a need for a better way to effectively handle mass tort litigation in the judicial system.

II. BACKGROUND

A. Origins of a Mass Tort

To understand the impact of Castano, it is necessary to briefly review the state of tobacco litigation prior to its class certification. An estimated 434,000 Americans die from smoking related illnesses each year. Approximately fifty million Americans are regular smokers, seventy-percent of whom became addicted before reaching the age of eighteen. Epidemiological studies link cigarette smoking to health problems such as cardiovascular disease, pulmonary disease, stroke, sudden death, heart attack, vascular disease, aortic aneurysm and cancers of the lung,

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12. A complete historical analysis of tobacco litigation is beyond the scope of this note. For a comprehensive overview of tobacco litigation, including statistical information related to smoking, see Irene Scharf, Breathe Deeply: The Tort of Smokers' Battery, 32 HOUS. L. REV. 615 (1995). See generally, Torts and Personal Injury: Tobacco Liability Pathfinder, 1996 WL 466262, available in WESTLAW, WLN Database (listing cases, statutes, law review articles, news articles and Internet sites regarding tobacco litigation).


15. Id. at 623.
mouth, pharynx, larynx, esophagus, stomach, pancreas, uterine cervix, kidney, ureter and bladder.\textsuperscript{16} The smoking statistics are staggering, yet before \textit{Castano}, plaintiffs were unsuccessful in almost every one of the over four hundred lawsuits filed against the tobacco companies in the previous forty years.\textsuperscript{17} Commentators cite claims of unforeseeable risk, lack of a direct causal link between smoking and cancers, comment i to section 402 of the Restatement (Second) of Torts, successful assertion of the assumption of the risk defense, and preemption as barriers to recovery against cigarette manufacturers.\textsuperscript{18}

Before the 1964 United States Surgeon General’s Report which declared cigarettes cause cancer,\textsuperscript{19} cigarette manufacturers successfully claimed they could not be liable for unknowable dangers associated with smoking.\textsuperscript{20} Even after the Report, the tobacco companies claimed there was a lack of a direct causal link between smoking and cancers.\textsuperscript{21} Indeed, the medical conclusions that linked smoking to health problems rested largely on epidemiological and toxicological proof.\textsuperscript{22} In other words, scientific

\textsuperscript{16} Carl E. Bartecchi et al., \textit{The Human Costs of Tobacco Use}, 330 NEW ENG. J. MED. 907 (1994).

\textsuperscript{17} Philip J. Hilts, \textit{Lawsuits Against Tobacco Companies May Be Consolidated}, N.Y. TIMES, Nov. 6, 1994, § 1 at 42; see also Jennifer Warren, \textit{Class-Action Suit Targets Top Tobacco Companies}, L.A. TIMES, Mar. 31, 1994, at A1 (“Since the 1950’s more than 320 health-related lawsuits have been filed against tobacco companies. Most . . . have been dismissed, and all but one of those that made it to trial were won by the tobacco industry.”).

\textsuperscript{18} See, e.g., Scharf, \textit{supra} note 12.

\textsuperscript{19} Id. at 696 n.41.

\textsuperscript{20} Id. at 696 n.40 (citing Lartigue v. R.J. Reynolds Tobacco Co., 317 F.2d 19 (5th Cir.), cert. denied, 375 U.S. 865 (1963) (stating that to hold cigarette manufacturers liable would make them insurers against unknowable risks)).


As late as 1986 . . . a Tobacco Institute publication stated that “eminent scientists believe that questions relating to smoking and health are unresolved.” These statements raise doubts in the minds of the public and their government representatives over a scientific debate that has been settled for nearly 30 years — namely, that cigarettes cause lethal diseases in humans.


\textsuperscript{22} See, e.g., Bartecchi, \textit{supra} note 16, at 907-12 (summarizing a comprehensive list of epidemiological statistics of smoking-related illnesses).
evidence could only show that smokers were statistically more likely to have adverse health consequences, leaving plaintiffs with the burden of showing causation. In direct juxtaposition to the assertion of the lack of scientific proof, cigarette manufacturers have successfully defended suits by affirmatively alleging the plaintiffs willingly assumed a known risk of danger by smoking. "We are not legally responsible," counsel for Philip Morris recently stated, "because the plaintiff chose to smoke and continued smoking knowing that smoking was a recognized risk factor for disease."

Further, in 1965, the American Law Institute codified the standards for strict products liability of sellers in section 402A of the Restatement (Second) of Torts. Instead of providing a cause of action to impose liability upon tobacco companies, however, the Restatement's own comment i insulated them by declaring "good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful." Thus, in juris-

23. This may change since very recent scientific discoveries claim to have directly linked smoking to cancer cells. See, e.g., Jerry E. Bishop & Milo Geyelin, Researchers Show How Smoking Causes Cancer, WALL ST. J., Oct. 18, 1996, at B1; David Stout, Direct Link Found Between Smoking and Lung Cancer, N.Y. TIMES, Oct. 18, 1996, at A1.


26. RESTATEMENT (SECOND) OF TORTS § 402A (1965). Entitled, "Special Liability of Seller of Product for Physical Harm to User or Consumer," the text provides:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
(a) the seller is engaged in the business of selling such a product, and
(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
(2) The rule stated in Subsection (1) applies although
(a) the seller has exercised all possible care in the preparation and sale of his product, and
(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Id.

27. Id. § 402A cmt. i. Comment i provides in part:
The rule stated in this Section applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer. Many products cannot possibly be made entirely safe for all consumption, and any food or drug necessarily involves some risk of harm, if only from over-consumption. The article sold must be dangerous to an extent beyond that which
dictions which adopted section 402A, plaintiffs have been defeated by the language of comment i while trying to prove tobacco products are defective and unreasonably dangerous. In addition, consumer awareness of the dangers associated with smoking, coupled with over thirty years of federally required warnings affixed to cigarette packages and advertisements has stilted products liability claims. This combination has led to the conclusion that tobacco products are not defective because they are not "dangerous to an extent beyond that which would be contemplated by an ordinary consumer who purchases them with ordinary knowledge common to the community as to their characteristics."

One of the final ways in which tobacco companies have averted liability is through the preemptive effect of the Federal Cigarette Labeling and Advertising Act upon state tort claims. The Supreme Court considered this preemption issue in Cipollone v.

would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics. Good whiskey is not unreasonably dangerous merely because it will make some people drunk, and is especially dangerous to alcoholics; but bad whiskey, containing a dangerous amount of fusel oil, is unreasonably dangerous. Good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful; but tobacco containing something like marijuana may be unreasonably dangerous. Good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful, but bad tobacco, contaminated with poisonous fish oil, is unreasonably danger-


29. See supra notes 24-25 and accompanying text.
31. Scharf, supra note 12, at 634.
32. RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (1965). See e.g., Roydson v. R.J. Reynolds Tobacco Co., 849 F.2d 230, 236 (6th Cir. 1988) ("[T]obacco has been used for over 400 years and . . . its characteristics have also been fully explored. Knowledge that cigarette smoking is harmful is widespread and can be considered part of the common knowledge of the community.").
The plaintiff alleged failure to warn, breach of express warranty, fraudulent misrepresentation and conspiracy. A sharply divided court issued a plurality opinion through Justice Stevens. The Court found the Act preempted any failure-to-warn claims after 1969 to the extent they relied on a state law requirement or prohibition with respect to advertising or promotion, but not any claim based on testing or research practices or other action unrelated to advertising or promotion. However, the plaintiff’s theories of fraud or misrepresentation, express warranty and conspiracy were not preempted. Beyond the preemption of failure-to-warn claims, perhaps the greatest effect of the Cipollone case was the transaction costs involved: the plaintiff’s attorneys spent over two million dollars, the defendants spent nearly fifty million dollars and the plaintiff “won” $400,000.

These factors comprise the unfavorable progeny of tobacco plaintiffs, but several key events provided the possibility of new evidence and new theories of liability. Specifically, the plaintiffs’ attorneys for Castano cited several key events which provided the impetus behind the lawsuit. On February 25, 1994, FDA Commissioner David A. Kessler announced that the FDA was investigating allegations that the tobacco industry manipulated

35. Id.
36. Id.
37. Id. at 524.
38. Id. at 529.
39. Id. at 525.
40. Id. at 531.
41. For a discussion of possible legal theories left after Cipollone, see Thomas C. Galligan, Jr., Product Liability — Cigarettes and Cipollone: What’s Left? What’s Gone?, 53 LA. L. REV. 713 (1993). The author suggests negligence, manufacturing defect, design defect, intentional tort (battery), and implied warranty of merchantability are still viable alternatives.
43. For a look into the events surrounding the Castano lawsuit through the perspective of the plaintiffs' attorneys, see Elizabeth J. Cabraser, The Road Not Taken: Thoughts on the Fifth Circuit’s Decertification of the Castano Class, A.L.I., Aug. 14, 1996. This admittedly biased article was written by one of the plaintiffs’ attorneys and traces the life of the Castano suit to date.
the levels of nicotine to create and sustain addiction to cigarettes. Second, ABC News reported on Day One that manufacturers boost the nicotine level of their products by adding a tobacco flavoring which spiked their cigarettes with nicotine to sustain smokers' addictions.

The allegations unraveled further when industry whistleblowers publicly made claims about the tobacco industry's knowledge of nicotine. A former chief scientist in charge of nicotine research at Philip Morris described at congressional hearings his observations of how a rat hooked to a pump repeatedly pressed a lever to get a steady flow of nicotine. The hearings on nicotine addiction also uncovered documents which confirmed industry knowledge and manipulation. For example, in one, another senior scientist for Philip Morris wrote, "Think of the cigarette pack as a storage container for the day's supply of nicotine."

These events created a whole new approach to tobacco litigation, because the issue was no longer one of free will, given the alleged manipulative acts of the cigarette companies who apparently had full knowledge of the addictive qualities of nicotine. Addiction was a risk the industry had not warned about and smokers may not have freely assumed the risks of becoming addicted. Further, since eighty-five percent of new smokers become addicted as teenagers, there is a claim that the industry consciously directed promotions and advertising to get them hooked before they could understand the risks of smoking.

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45. Id. ABC later publicly apologized for certain claims represented on the show, but staunchly defended their report that nicotine was controlled to addict smokers. Id.


47. See, e.g., U.S. Congress Seeks Tobacco Documents, WALL ST. J. EUR., May 11, 1994 at 8.


50. Weiser, supra note 44, at W15.

51. Scharf, supra note 12, at 635.

52. Geyelin, supra note 46, at B1. See generally Scharf, supra note 12, at 635-60 (providing a comprehensive overview of the role of advertising directed at children and young adults).
Despite these recent discoveries, the tobacco manufacturers still publicly deny nicotine is addictive. Further, the tobacco industry asserts nicotine is, at worst, a psychoactive drug, which, once in the bloodstream, affects the brain. They compare it to other psychoactive drugs like black licorice, caffeine and chocolate, and contend it is no more addictive because it is not intoxicating like heroin, alcohol or cocaine.

This "stark juxtaposition" of the tobacco company documents demonstrating knowledge of the addictive qualities in the tobacco industry and the conscious manipulation of levels of nicotine against the continuous affirmative denials by the tobacco company executives engendered the Castano action.

B. The Certification of the Castano Class

On February 17, 1995, the United States District Court for the Eastern District of Louisiana granted the plaintiffs’ Motion for Class Certification, in part to decide certain core issues. The class was defined as all nicotine-dependent persons in the United States and its territories, the estates, representatives and administrators of these persons, and their heirs or survivors.

The court defined nicotine-dependent persons as all cigarette smokers who have been diagnosed by a medical practitioner as nicotine dependent and all regular cigarette smokers who have been advised by a medical practitioner that smoking has had or will have adverse health consequences and have not quit.

55. Id.
58. Id. at 549. The complete class definition included:
   (a) All nicotine dependent persons in the United States, its territories and possessions and the Commonwealth of Puerto Rico who have purchased and smoked cigarettes manufactured by the Tobacco Companies;
   (b) the estates, representatives, and administrators of these nicotine dependent cigarette smokers; and
   (c) the spouses, children, relatives and "significant others" of these nicotine dependent cigarette smokers as their heirs or survivors.
Id. (footnote omitted).
59. Id. at 549, 559. The complete definition the court adopted stated:
1. All cigarette smokers who have been diagnosed by a medical practitioner as nicotine-dependent.
The plaintiffs alleged that the defendant tobacco companies fraudulently failed to inform smokers of nicotine's addictive qualities despite actual knowledge, and that they manipulated the nicotine content of cigarettes with the intent and purpose of sustaining addiction to cigarettes. The plaintiffs asserted numerous theories of liability including fraud, negligent misrepresentation, intentional infliction of emotional distress, negligence, negligent infliction of emotional distress, violation of consumer protection statutes, breach of express warranty, breach of implied warranty, and strict products liability. They sought economic damages, including restitution and refunds for amounts paid to purchase cigarettes, damages for emotional distress, punitive damages and disgorgement of any profits made from the sale of cigarettes to class members. They also wanted the establishment of a medical monitoring fund to monitor the health of the plaintiffs and to reimburse class members for medical expenses caused by the defendants' conduct. The plaintiffs also sought attorneys' fees in regard to violation of consumer protection statutes. The plaintiffs did not seek recovery of personal injury damages in the form of physical pain or suffering.

Judge Jones found that the general requirements of numerosity, commonality, typicality and adequacy or representation required by Federal Rule of Civil Procedure 23(a) to

3. All regular cigarette smokers who were or have been advised by a medical practitioner that smoking has had or will have adverse health consequences who thereafter do not or have not quit smoking.

Id. (quoting AMERICAN PSYCHIATRIC ASSOCIATION'S DIAGNOSTICS AND STATISTICAL MANUAL OF MENTAL DISORDERS (3d ed.).)


61. Id. at 548.

62. Id.

63. Id. Economic damages claimed included money spent on cigarettes, medical counseling, nicotine patches, the cost of smoking cessation clinics and other money spent in order to attempt to quit smoking. See, e.g., Warren, supra note 17, at A1; Weiser, supra note 44, at W18.

64. Castano, 160 F.R.D. at 548. The court rejected the request for class certification for medical monitoring under the Federal Rules of Civil Procedure 23(b)(2). Id. at 552. The plaintiffs did not appeal the ruling.

65. Id. at 548.

66. Id.

67. Federal Rule of Civil Procedure 23(a) provides:
maintain a class action were easily satisfied. In making this determination, the court remarked that its role, as ruled by the Supreme Court, was merely to determine whether the requirements of Rule 23 are met. It was not to base its decision upon whether the plaintiffs had stated a cause of action or upon the likelihood plaintiffs could prevail on the merits of the claim.

The plaintiffs firmly established the numerosity requirement by demonstrating over fifty million persons are presently and formerly "nicotine-dependent." Joinder of these claims, noted the court, was not just impracticable, but impossible. Second, the plaintiffs satisfied the commonality requirement since the key issues concerning the class were "whether defendants fraudulently failed to inform plaintiffs nicotine was addictive and/or manipulated the level of nicotine in cigarettes so as to control their addictive nature." The class fulfilled the typicality requirement because the claims and legal theories of the class representatives, two current smokers and a widow of a former smoker, would be similar to those of the proposed class members. Finally, the competence, expertise and financial resources of the attorneys purporting to represent the class met the adequacy of the representation requirement.

Finding the plaintiffs met the requirements of Rule 23(a), the court certified the class under Rule 23(b) as to the core issues

(a) Prerequisites to a Class Action. One or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fully and adequately protect the interests of the class.

(b) Class Actions Maintainable. An action may be maintained as a class action if the prerequisites of subdivision (a) are satisfied, and in addition:

69. Id. at 549 (quoting Eisen v. Carlisle & Jacquelin, 417 U.S. 156, 177-78 (1974)).
70. Id.
71. Id. at 550.
73. Id.
74. Id. at 551.
75. Id.
76. The applicable portion of Rule 23 provides:
of liability because they predominated any individual questions and because class treatment was superior to other methods of adjudication. The core issues of law included the claims of fraud, breach of express or implied warranty, intentional tort, negligence, strict liability, consumer protection and punitive damages. The common factual issues included whether the defendants (1) knew cigarette smoking was addictive, (2) failed to inform cigarette smokers of the danger of addiction, and (3) manipulated nicotine to sustain addiction.

The court found the common issues of law and fact predominated over individual issues because they would necessarily constitute a significant part of every case alleging similar conduct by the defendants. The court then addressed two challenges to a finding of predominance made by the defendants. First, the defendants claimed individual reliance as to claims of fraud would swamp the court and defeat predominance. The court dismissed this challenge noting first, an inference of reliance may be available in consumer class actions and second, determining issues of reliance at this point would be an impermissible prejudgment of the plaintiffs' claim. Second, the defendants asserted that the standards for determining each plaintiff's cause of action would vary from state to state destroying predominance of class issues and causing jury confusion. The court rejected this challenge for two reasons. The first ra-

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FED. R. CIV. P. 23(b)(3).

78. Id. at 556.
79. Id. at 558.
80. Id. at 553.
81. Id.
82. Castano, 160 F.R.D. at 553.
83. Id. (citing Mirking v. Wasserman, 858 P.2d 568, 574 (Cal. 1993)).
84. Id. (citing Eisen v. Carlisle & Jacquelin, 417 U.S. 156, 177-78 (1974)).
85. Id. at 554.
tionale was that issues of fraud, breach of warranty, negligence, intentional tort and strict liability do not vary so much from state to state as to defeat predominance. Second, the choice of law issue was not fully briefed by the parties and Rule 23(c)(4)(B) allows the court to subdivide the class into subclasses when appropriate.

As to superiority, the court recognized the class action was sui generis, it was unlike a toxic tort exposure case such as the asbestos cases and unlike a case involving a claim for physical injuries from a product such as occurred with the Dalkon Shield. Moreover, the uniqueness of the claim must cause the court to look forward and invent knowing "[t]he purpose of class actions is to conserve the resources of both the courts and the parties by permitting an issue potentially affecting every [class member] to be litigated in an economical fashion." The court acknowledged that manageability of the class action, a factor which Rule 23 offers as guidance to determine superiority, could prove to be difficult. But any such difficulties would "pale in comparison to the specter of thousands, if not millions, of similar trials of liability proceeding in thousands of courtrooms around the nation."

Using Rule 23(c)(4)(A), the court thus determined certain core issues were properly certifiable under Rule 23(b)(3). Certification of these issues, the court noted, would substantially move this unique and far-reaching litigation toward an end and also promote judicial economy and efficiency. The court denied certification as to issues of causation, injury, reliance, compensa-

86. Id. (citing In re School Asbestos Litig., 104 F.R.D. 422, 434 (E.D. Pa. 1984)).
87. Id.
88. Rule 23(c)(4) provides: "When appropriate (A) an action may be brought or maintained as a class action with respect to particular issues, or (B) a class may be divided into subclasses and each subclass treated as a class, and the provisions of this rule shall then be construed and applied accordingly." FED. R. CIV. P. 23(b)(3).
90. Id.
91. Id.
92. Id. (quoting Jenkins v. Raymark Indus., Inc., 782 F.2d 468, 471 (5th Cir. 1986) (quoting General Tel. Co. of S.W. v. Falcon, 457 U.S. 147, 155 (1982))).
93. Id. at 555.
94. Id. at 555-56.
95. See supra note 88.
97. Id.
tory damages or the applicability of affirmative defenses. Further, pursuant to Rule 23(c)(1), the certification of the core liability issues was conditional. The court reserved the right to revisit the propriety of certification if individual issues predominated, the class became unmanageable or if a better alternative for resolution of the claims were found.

Shortly after certification was granted to the core issues of liability, Judge Jones granted defendants' motion for interlocutory appeal of the certification. The court noted a substantial difference of opinion in the circuit courts whether class actions are appropriate for use with mass torts. Though the court believed it had faithfully adhered to the jurisprudence of the Fifth Circuit, it nonetheless granted the motion partly based upon the split of opinion in the circuit courts.

III. THE FIFTH CIRCUIT'S DECERTIFICATION OF CASTANO

The Fifth Circuit began its analysis by noting a district court must conduct its own rigorous analysis of the Rule 23 prerequisites before certifying a class, but commenting that the district court enjoys broad discretion within the framework of the rule. The court then found the district court abused its discretion by making two significant errors in its analysis. First, it failed to consider how variations in state law affect the requirements of predominance and superiority needed to maintain a class action under Rule 23(b)(3). Second, the court's predominance inquiry did not include a consideration of how a trial on the merits would be conducted. Though the court

98. Id.
99. The provision states: "As soon as practicable after the commencement of an action brought as a class action, the court shall determine by order whether it is to be so maintained. An order under this subdivision may be conditional, and may be altered or amended before the decision on the merits." FED. R. CIV. P. 23(c)(1).
100. Castano, 160 F.R.D. at 559.
101. Id.
103. Id. at 116.
104. Id.
106. Id.
107. Id.
108. See supra note 76.
109. Castano, 84 F.3d at 740.
noted that each of these "defects" alone mandated reversal, the "immaturity" of the tort demanded dismissal of the class complaint because it would render class treatment an inferior method of adjudication.110

The court first addressed how the variations in state law might affect predominance.111 The review of state law, stated the court, in this multi-district class action must be extensive.112 A district court must discuss in a "meaningful way" how the court would deal with variations in state law because in a multi-state class action, variations in state law may swamp any common issues and defeat predominance.113 The court declared it an abuse of discretion for the district court to rely on other cases to demonstrate that variations in state law could be reconciled114 because a court must know which law will apply before making a predominance determination when there may be differences in state law.115 The court cited In re School Asbestos to demonstrate the type of extensive analysis which it believed a court is required to undergo before certifying a class under Rule 23(b)(3).116 The novelty of the plaintiffs' claim with its "multiple jurisdiction, millions of plaintiffs, eight defendants, and over fifty years of alleged wrongful conduct" led the court to insist upon a more complete inquiry into the manageability of the class action.117 Furthermore, the court later found the complexity of the choice of law inquiry makes individual trials more attractive and ipso facto renders class treatment an inferior method of adjudicating the claims.118

The next error the Fifth Circuit found was a failure to consid-

110. Id.
111. Id. at 742.
112. Id. at 743.
113. Id. at 741.
115. Castano, 84 F.3d at 741.
116. Id. at 742. (citing In re School Asbestos, 789 F.2d 996, 1010 (3d Cir.), cert. denied, 479 U.S. 852, and cert. denied, 479 U.S. 915 (1986)).
117. Id. at 744.
118. Id. at 750.
er how the plaintiffs' addiction claims would be tried, individually or on a class basis. The root of this error, according to the court, was the district court's misinterpretation of Eisen v. Carlisle & Jacquelin and Miller v. Mackey International. The district court believed it could not go past the pleadings for the certification decision. But the court determined going past the pleadings was necessary, as a district court must understand the claims, defenses, relevant facts and applicable substantive law in order to make a meaningful determination for certification issues. The premise of the Fifth Circuit's rationale was the court's need for knowledge of how addiction-as-injury cases would actually be tried to know whether the common issues would compose a significant portion of the individual trials. Furthermore, the court noted the correct reading of Rule 23 was that the cause of action, as a whole, must satisfy the predominance requirement of Rule 23(b)(3). Thus, Rule 23(c)(4) is a "housekeeping rule" which only allows courts to sever the common issues for trial, otherwise the predominance requirement would be "eviscerated." The Fifth Circuit also held that the class must be decertified because it independently failed the superiority requirement of 23(b)(3). The court noted class certification magnifies and strengthens the number of unmeritorious claims. Citing the results of an empirical study, the court suggested that aggregation of claims in a class makes it more likely that a defendant will be found liable and results in significantly higher damage awards. The court further expressed its distaste for large class actions by commenting, "[i]n addition to skewing trial out-

119. Id. at 744.
120. Eisen v. Carlisle & Jacquelin, 417 U.S. 156, 177-78 (1974); Miller v. Mackey Int'l, 452 F.2d 424 (5th Cir. 1971); see supra notes 69-70 and accompanying text.
121. Castano, 84 F.3d at 744. These decisions held it was improper for a court to base the propriety of certification upon an inquiry into the merits of the case. Id.
122. Id. at 744.
123. Id. at 745.
124. Id. at 745 n.21.
125. See supra note 88.
126. Castano, 84 F.3d at 745 n.21.
127. Id. at 746.
128. Id.
129. Id. (citing Kenneth S. Bordens & Irwin A. Horowitz, Mass Tort Civil Litigation: The Impact of Procedural Changes on Jury Decisions, 73 JUDICATURE 22 (1989)).
comes, class certification creates an insurmountable pressure on defendants to settle, whereas, individual trials would not.\textsuperscript{130} Thus, the all or nothing verdict of a class action presented too high of a risk and forced defendants into "judicial blackmail" settlements and, for the Fifth Circuit, defeated superiority.\textsuperscript{131}

The court also held that a mass tort cannot be properly certified without a prior track record of trials from which the district court can draw the information necessary to determine whether class treatment meets the requirement of Rule 23(b)(3).\textsuperscript{132} Thus, according to the court's rationale, class treatment can be found superior only if individual adjudication has proved inferior for resolution of a particular mass tort. Otherwise, such an "immature tort" presents a higher than normal risk that the class action may not be superior to individual adjudication.\textsuperscript{133} The court also commented that in the context of an immature tort, any savings in judicial resources is speculative because there is no certainty that refusal to certify a class will lead to millions of individual trials.\textsuperscript{134} "Not every mass tort is asbestos," the court remarked, "and not every mass tort will result in the same judicial crisis."\textsuperscript{135} Only after the courts have more experience with this type of case, only after it "matures," can a court certify issues in a way that preserves judicial resources.\textsuperscript{136}

The Fifth Circuit also found one of the most compelling rationale for finding superiority in a class action, the existence of a negative value suit, was missing in this case.\textsuperscript{137} The court, apparently without considering the merits of the claims, found reason to believe individual suits are feasible because individual damage claims are high and punitive damages are available in most states.\textsuperscript{138} Also, expense would not turn it into a negative value suit because consumer protection statutes may allow recovery of attorneys' fees.\textsuperscript{139} The court proceeded to state that this

\textsuperscript{130} Id.
\textsuperscript{131} Castano, 84 F.3d at 746.
\textsuperscript{132} Id. at 747.
\textsuperscript{133} Id.
\textsuperscript{134} Id.
\textsuperscript{135} Id.
\textsuperscript{136} Id. at 749.
\textsuperscript{137} Castano, 84 F.3d at 749.
\textsuperscript{138} Id. at 748.
\textsuperscript{139} Id.
"belief" that an individual plaintiff can net a large award in an individual trial in a case "such as this one" led it to be persuaded by Judge Posner's analysis of superiority in a recent case decided in the Seventh Circuit.  

For this consensus or maturing of judgment the district judge proposes to substitute a single trial before a single jury. One jury will hold the fate of an industry in the palm of its hand. That kind of thing can happen in our system of civil justice. But it need not be tolerated when the alternative exists of submitting an issue to multiple juries constituting in the aggregate a much larger and more diverse sample of decision-makers. That would not be a feasible option if the stakes to each class member were too slight to repay the cost of suit. But this is not the case. Each plaintiff if successful is apt to receive a judgment in the millions. With the aggregate stakes in the tens or hundreds of millions of dollars, or even in the billions, it is not a waste of judicial resources to conduct more than one trial, before more than six jurors, to determine whether an industry is to follow the asbestos manufacturers into Chapter 11.  

The court ended its analysis by affirmatively declaring that individual trials are superior and "the collective wisdom of individual juries is necessary before this court commits the fate of an entire industry, indeed, the fate of a class of millions, to a single jury."  

IV. ANALYSIS OF THE FIFTH CIRCUIT'S DECISION  

"Quite obviously," Judge Jones aptly stated when he granted the defendants' motion for interlocutory appeal, "this is a developing area of law over which there is a substantial ground for a difference of opinion." The Fifth Circuit's decision, however, joins the increasing number of decisions denying class treatment to mass tort claims in the federal court system. The differ-
ence of opinion among the courts suggests judicial uncertainty and uneasiness for handling mass torts in aggregate form. Some of the rationale which the court used to support its decision reflects this uncertainty and uneasiness. Further, the decision imposes a standard of strict scrutiny and restrictiveness to the construction of Federal Rule of Civil Procedure 23.

The Fifth Circuit's decision declares that a rigorous inquiry into state law is necessary in a multi-district class action to prove individual issues will not predominate common class issues,\textsuperscript{145} thus making it a prerequisite to Rule 23 analysis. To be sure, differences in state law are a key feature in a system of federalism and each state grants its citizens a unique set of rights and responsibilities.\textsuperscript{146} Further, choice of law analysis is required by the \textit{Erie} Doctrine\textsuperscript{147} and is important to preserve the substantive rights of the parties in a multi-district mass tort class action.\textsuperscript{148} Ultimately, the analysis prevents a jury from being instructed by "a kind of Esperanto instruction, merging . . . [legal] standards of the 50 states and the District of Columbia."\textsuperscript{149} Thus, the choice of analysis is necessary, but it need not be an impediment to class certification and an efficient resolution of the substantial number of claims.

Variation in the legal rules is not great, and once a state-by-state survey is completed, judges will find a relatively small number of conflicts and an equally small number of approaches to choice of law.\textsuperscript{150} Cases have demonstrated variations among substantive laws of the states are not so disparate as to justify hindering the use of class actions to resolve mass tort claims.\textsuperscript{151}

\textsuperscript{145} Id. at 743; see also \textit{In re Rhone-Poullenc Rorer, Inc.}, 51 F.3d 1293, 1300-02 (7th Cir. 1995); \textit{Walsh v. Ford Motor Co.}, 807 F.2d 1000, 1017 (D.C. Cir. 1986), cert. denied, 482 U.S. 915 (1987) (holding nationwide class action movants must creditably demonstrate through an extensive analysis of state law variances that class certification does not present insuperable obstacles).


\textsuperscript{147} \textit{Erie R.R. v. Tompkins}, 304 U.S. 64 (1938).

\textsuperscript{148} Kramer, \textit{supra} note 146, at 578.

\textsuperscript{149} \textit{Rhone-Poullenc}, 51 F.3d at 1300.

\textsuperscript{150} Kramer, \textit{supra} note 146, at 583; see also \textit{Mullenix, supra} note 5, at 785.

As the court noted in *School Asbestos*:

At first blush, this aspect of the litigation would seemingly prevent nationwide class certification. First, there is a substantial duplication among the various jurisdictions as to the applicable law. For example, as to negligence, 51 jurisdictions are in virtual agreement in that they apply the Restatement (Second) of Torts § 388. As to strict liability, the basic test is Restatement (Second) of Torts § 402(A) that one who sells a product in a defective condition unreasonably dangerous to the user is liable. Forty-seven jurisdictions have adopted strict liability theories and all of them start with the concept of a defective product. In addition, plaintiffs have represented that they will direct discovery and trial briefs to meet the most stringent tests of liability. Finally, as the need arises, subclasses can be created to account for variances pursuant to Rule 23(c)(4).\(^{152}\)

Thus, states emulate each other’s legal formulations and substantive rules.\(^{153}\) Claims can be grouped and the task of resolving the conflicts completed in an efficient manner which saves resources for everyone.\(^{154}\) As one commentator noted, “It may not be fun, but it is far from impossible.”\(^{155}\)

The Fifth Circuit erected a monumental barrier to class certification under Rule 23(b)(3)\(^{156}\) by requiring prior judicial experience with a mass tort before a court can determine if the predominance requirement is met.\(^{157}\) Otherwise, the court noted, the class action would degenerate into innumerable separate trials because the court may later find that individual issues predominated the litigation.\(^{158}\) Following the basic theme of the court’s reasoning, it seems the court is suggesting numerous trials expending judicial resources in the federal courts are a necessary prerequisite before a court can consider the economies of class certification. Certainly former mass tort cases, such as asbestos, leads the court to its concern that mass tort class actions may result in large judicial inefficiencies,\(^{159}\) but as the

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153. Id.; see also Kramer, supra note 146, at 583.
154. Kramer, supra note 146, at 583.
155. Id. at 582.
156. See FED. R. CIV. P. 23(b)(3).
158. Id. at 745.
court itself noted, "Not every mass tort is asbestos..." Experience is definitely valuable, but there are other alternatives to gaining experience such as the use of mini trials or test cases, rather than dismissing any possibility of aggregate treatment of mass tort claims which lack a trial history. Determination of the liability issues in one suit may represent a substantial savings in time and resources, especially in Castano where the entire case turned on whether the defendants knew of the addictive qualities of nicotine and purposely manipulated the quantity in cigarettes to sustain addiction. Even if the action thereafter "degenerates" into a series of individual damage suits, "the result nevertheless works an improvement over the situation in which the same separate suits require adjudication on liability using the same evidence over and over again." Moreover, the resolution of some of these issues in the defendants' favor may end the litigation entirely.

Even if the district court had prior experience with "addiction as injury" claims, the Fifth Circuit decision, following the Seventh Circuit's lead in Rhone-Poulenc, disfavors "manufacturing" predominance by using Rule 23(c)(4) to try certain key common issues. The court converts Rule 23(c)(4) into a "housekeeping" provision which can only be used to sever certain common issues, if the entire case meets the requirements of Rule 23(b)(3).

This reading of Rule 23(c)(4) is inapposite to case law and the general understanding of the rule itself. For example, the
Fifth Circuit decision in *Jenkins v. Raymark Industries*\(^{169}\) certified a class solely for the determination of the viability of the state of the art defense.\(^{170}\) At least one recent district court decision has recognized this interpretation of Rule 23(c)(4) as an anomaly, stating, "[Rule 23(c)(4) is] a highly efficient way to preserve both judicial economy and the rights of the parties in the case . . . . [T]he effect of . . . [this interpretation] takes away one of the sharpest instruments available to trial courts managing mass tort litigation."\(^{171}\)

The decision of the Fifth Circuit also demonstrates the court's uneasiness with finding class treatment to individual adjudication when the tort is "immature."\(^{172}\) "Mature mass torts" are those where there has been full and complete discovery, multiple jury verdicts, and a persistent vitality in the plaintiff's contentions.\(^{173}\) When the tort has reached maturity, "little or no new evidence will be developed, significant appellate review of any novel legal issues has been concluded, and at least one full cycle of trial strategies has been exhausted."\(^{174}\) Though it is to be conceded experience with claims will assist with their prompt resolution, the court imported the requirement of maturity into Rule 23 analysis. The problem with this approach was fiercely noted by one of the plaintiffs' attorneys in the *Castano* case:

[Bly judicial amendment, the Rule's criteria are upended: a multiplicity of individual actions — in which the plaintiffs prevail — is now proclaimed a prerequisite for class treatment. Thus, plaintiffs must now first create the very problem the Supreme Court has said Rule 23 was enacted to avoid: multiple suits, piecemeal and inconsistent adjudication, and the very cost and delay that has demonstrably, in the case of asbestos litigation, caused plaintiffs to die without vindication and defendants to go bankrupt under a seemingly endless stream of claims.

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section (c)(4)')(citing 1 NEWBURG ON CLASS ACTIONS, §4.20 at 310 (2d ed. 1985)).

169. Jenkins v. Raymark Indus., Inc., 782 F.2d 468 (5th Cir. 1986); see also Agent Orange, 818 F.2d 145 (2d Cir. 1987) (certifying the availability of the military contractor's defense for class treatment.)

170. Id. at 470.


Furthermore, the importance of maturity, as the concept developed in legal commentary, centered around the propriety of large class action settlements. The proposition is that only at the mature stage can a large number of similar disputes be consolidated into groups of similar cases to facilitate settlement en masse. Yet, the court cites the likelihood of settlement, of "judicial blackmail," as one of the reasons class treatment is inferior. It is circular reasoning to require maturity before a mass tort can be certified, and then to shun class treatment because class actions tend to settle.

To be sure, the cost and risks of going to trial induces settlement or other dispositions short of trial in over ninety-five percent of all civil claims, mass tort or otherwise. Thus, even if it were practicable to try all individual disputes involved in a mass tort in individual trials, it would be neither desirable nor necessary. Class treatment can resolve common issues and possibly end the litigation if they are resolved in favor of the defendant. If the common issues are resolved in favor of the plaintiffs, the strength may prompt a settlement, which would help to end the litigation. In either event, the end result will be a substantial savings for the litigants, the courts and others needing access to the court system for resolution of their claims.

The Fifth Circuit also imported economic rationale from Judge Posner's opinion in *Rhone-Poulenc* to support its conclusion that class treatment was not a superior method of adjudicating this burgeoning mass tort. The court commented that since this class was not a negative-value suit, it lacked one the most compelling reasons to grant class certification. The court observed it had "reason to believe" individual suits were feasible because individual claims were high and punitive damages were available in most states. The court's observation raises two
concerns. First, how can a court measure the feasibility of individual claims without considering the merits of the claim? This practice of considering the merits of the claims while determining the applicability of class treatment under Rule 23 was expressly forbidden by the Supreme Court, as the court itself noted. Second, the court's conclusion is debatable since the Supreme Court has held each member of a class brought in a multi-district action based on diversity must individually meet the jurisdictional amount of $50,000.

The court also endorsed a lengthy quote from Rhone-Poulenc expressing the concern that a “single jury will hold the fate of an entire industry in the palm of its hand.” Followed to its logical conclusion, this economic justification would deny class treatment for all class actions whenever there was potential liability of any magnitude. Judge Rovner, dissenting in the Rhone-Poulenc decision, felt this rationale “was at odds with [Rule] 23 itself” and was a “rationale for amending the rule, not for avoiding its application in the first place.” At least one recent decision has declined to follow this “application of economic justice to the Federal Rules of Civil Procedure.” Furthermore, this reasoning demonstrates a profound mistrust in the jury system.

V. CONCLUSION

The Fourth Circuit presented what is perhaps the most comprehensive discussion of the propriety of class treatment of mass torts in a case in In re A.H. Robins Co. when it decided to affirm class certification of the Dalkon Shield case. The court noted that after Rule 23 was approved, the early view was that it should be given a liberal rather than a restrictive interpretation and, if there was an error to be made, let it be in favor of

185. Castano, 84 F.3d at 744.
187. 84 F.3d at 748 (citing Rhone-Poulenc, 51 F.3d at 1300).
188. Rhone-Poulenc, 51 F.3d 1293, 1308 (Rovner, J., dissenting).
189. Id.
191. See id. at 460 n.4.
192. 880 F.2d 709, 725-38 (4th Cir. 1989).
the class action. The court further noted:

[D]espite the clear mandate in the first Section of the Rules that such Rules "[should] be construed to secure the just, speedy and inexpensive determination of every action" some courts decided to depart from this liberal construction of Rule 23 and to adopt a standard of construction o[n] the basis of the standard of strict scrutiny.

The Fourth Circuit however, felt courts were taking a "fresh look" at the value of Rule 23 class actions in the context of mass torts because economies of time, effort, and expense advised against narrow application of the rule.

Unfortunately, the Fourth Circuit was wrong. The Fifth Circuit decision in Castano joins an ever-growing list of decisions which have denied class treatment to mass torts. Castano evidences a return to a very restrictive reading of the requirements of Rule 23 certification.

Mass torts impose a tremendous burden on the courts and result in tremendous public and private costs when endless trials consider the same issues in repeated court action. When adjudicated individually, everyone pays. As the Robins court noted:

The public is crying out for better solutions to mass tort litigation than separate, redundant trials in thousands of related cases. Why should hundreds, or even thousands, of trials take place in which the same issue of a defendant’s liability is litigated over and over again? Why should some plaintiffs recover compensatory and punitive damages, while other plaintiffs in other trials recover much less, or nothing at all, even though the issues of liability and causation are the same? Why should a defendant be put to the expense of parading the same witnesses on the stand in hundreds of different trials to demonstrate over and over again the same evidence that its product was correctly designed and engineered? Is it fair that defendants are exposed to multiple punitive damage claims?

193. Id. at 729 (citing cases).
194. See FED. R. CIV. P. 1.
195. A.H. Robins, 880 F.2d at 729.
196. Id. at 731.
197. See supra note 144.
198. See supra notes 3-5 and accompanying text.
199. A.H. Robins, 880 F.2d at 726-27 (quoting Panzer & Patton, Utilizing the Class Action Device in Mass Tort Litigation, 21 TORT & INS. L.J. 560, 561 (1986)).
Mass torts will continue to play a prominent role in future litigation. Technological and computerized mass production promises to produce even larger quantities of goods with less human interaction in their manufacture. Inevitably the immense quantity of goods will create increased opportunities of exposure to personal injuries; inevitably lawsuits seeking redress for these injuries will multiply. In an influential article, Professor Arthur Miller wrote:

It is important in understanding the class action debate to realize that the "big case" phenomenon transcends the class action. The "big case" is an inevitable byproduct of the mass character of contemporary American society and the complexity of today's substantive regulations. It is a problem that would confront us whether or not [R]ule 23 existed. Indeed, it is becoming increasingly obvious that the traditional notion of civil litigation as merely bilateral private dispute resolution is outmoded.

For now, the use of Rule 23 class actions is one method courts have to manage the difficulties associated with mass torts. The Fifth Circuit's decision and its progeny suggest the need for rethinking how large claims should be resolved or perhaps the need for an amendment to Rule 23 to address the unique problems presented by the resolution of mass torts. In the meantime, it seems undeniable that the use of class treatment is a more desirable, if not superior, method to resolving mass tort litigation, either partially or completely, when faced with the alternative of adjudicating each issue repeatedly in numerous individual trials.