Federal Regulation of Tobacco Products and Products That Treat Tobacco Dependence: Are the Playing Fields Level?

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I. INTRODUCTION

Company A is thinking about launching a traditional tobacco product, perhaps a cigarette or a smokeless tobacco confection, with a new ingredient, ingredient level, or ingredient mix that in the past has never been sold. Company B contemplates putting on the market an innovative medication, medical device, or dietary supplement intended to help consumers to free themselves from physical dependence on tobacco products. Company C ponders the possibility of introducing a smoking product whose novelty derives from express or implied marketing claims that the product will decrease or perhaps even eliminate physical dependence on tobacco, or reduce other risks associated with smoking. What factors will each firm take into account in making the initial decision whether or not to go ahead with the new product, in preparing the product for market, in producing the product, in promoting the product, and in reacting to postmarketing events that might affect the product’s fate?

The forces of the marketplace will weigh heavily on each firm’s decisionmaking process. Companies A, B, and C must calculate how they can best position their products vis-à-vis those of their competitors. This will motivate them to reduce costs, improve efficiency in production and distribution, lessen risks associated with their products, and make them more attractive to consumers. Thus, the marketplace itself may be viewed as a playing field on which companies producing similar goods compete for the consumer dollar. Ideally, this type of competition will provide the public with the best products at the cheapest possible price.

Unbridled competition, however, has not always accomplished this goal. Manufacturers and sellers have resorted at times to a variety of unfair trade practices that give them competitive advantages which others in the same field are unable to overcome, and which ultimately impose social costs, in the form of higher prices or lower-quality products. Moreover, a lack of information occasionally has caused consumers to make decisions, in purchasing and using the product, that cause preventable economic and physical harms to themselves or others. Such imperfections in the operation of the free market theoretically have justified, and at times have provoked, government intervention.

One form this intervention has taken is the recognition of legal remedies for use by competitors who have suffered losses as a result of unfair business practices, and by consumers and third parties who have incurred injury, illness, or financial disadvantage attributable to a product. Such recourse may originate in statutory enactments on the

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federal or state levels, as well as common-law remedies created by the courts. The threat of legal liability is intended to act as a deterrent against conduct that might produce unwarranted economic or physical harm. In making the numerous pre- and post-marketing decisions associated with a new product, firms such as our hypothetical Companies A, B, and C, if they are prudent, will factor the risk of liability into account when they make decisions at all stages of the life of a product.

Additionally, there is another type of public intervention with which manufacturers have to reckon. The government might decide that neither the market nor private lawsuits provide sufficient deterrence or create sufficient incentives. For example, not every consumer or user harmed by a product may be aware that he or she has suffered an injury or an illness, or that his or her injury or illness was caused by a product. A manufacturer aware of this lack of knowledge could expect a reduced level of exposure to liability, which in turn would reduce the manufacturer's incentive to avoid harm and would permit the manufacturer to lower prices, which in turn means that an increased number of units of an unduly risky product will be sold. Hence, more pervasive regulation might be necessary.

Policymakers hesitant to interfere directly with the functioning of the market might opt for indirect forms of regulation that would make it more costly for manufacturers to develop and sell their products, or would make it less easy for the public to consume them. The power to tax and the power to inform are obvious tools that government might use to decrease consumption of a product, as are regulations limiting the use of a product (such as restrictions on smoking). Conversely, the government might take steps to encourage manufacturers to develop products or encourage consumers to use them. Subsidies to producers might provide incentives for product development, while publicity and public education programs might stimulate consumption.

There also are direct forms that regulation might take, such as ground rules governing various parts of the production, marketing, and post-marketing processes, established either by statute or administrative rules promulgated by bodies to whom legislatures have delegated authority. Moreover, violations of these ground rules

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2 The common law provides remedies for competitors injured by such wrongful practices as the interference with contractual relations. See W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 125, at 978 (5th ed. 1984). It also provides a remedy in tort for consumers and others injured by defective, unreasonably dangerous products. See id. § 98, at 692.


6 See, e.g., 41 C.F.R. § 101-20.105-3(b) (1997) (prohibiting smoking in certain areas of federal buildings).


10 See, e.g., Consumer Product Safety Act, Pub. L. No. 92-573, 86 Stat. 1207 (1972) (codified as amended...
might result in the imposition of penalties, some of them quite severe.\textsuperscript{11} A less intrusive form of this kind of regulation might be a call for setting performance standards but leaving open to the affected parties how these goals will be met.\textsuperscript{12} Companies A, B, and C will have to pay close attention to both the framework and the details of government regulations that directly affect their operations.

This article will focus on direct government intervention as it might influence the decisions that Company A would make in marketing a new tobacco product, and that Companies B and C would make in marketing new products intended to help consumers stop using tobacco products or otherwise reduce smoking-related risks. The hidden hand of the marketplace will influence these three producers in exactly the same way. Likewise, the same liability rules will apply generally to them. Direct government regulation, however, tends to be more product-specific, and places different burdens on manufacturers and sellers of different products.\textsuperscript{13} It also tends to be more detailed and hence more intrusive than indirect efforts to influence the conduct of manufacturers.

The harmful effects of products containing tobacco have been known for some time.\textsuperscript{14} Therefore, one would expect that the government would place severe restrictions both on the sale of tobacco products and on the introduction of new or modified tobacco products that posed risks long associated with tobacco, and that less stringent restrictions would apply to products intended to reduce or counteract the damage caused to the public health by tobacco. Such a regulatory regime would seem to flow inevitably from a dispassionate, reasoned judgment about relative social costs and benefits associated with these classes of products. As this article will demonstrate, however, public policy affecting tobacco products does not seem to reflect this kind of calculation.\textsuperscript{15}

The regulation of medications such as those under consideration by Company B falls within a statutory framework that dates back to 1938, when Congress enacted the Federal Food, Drug, and Cosmetic Act (FDCA),\textsuperscript{16} subjecting drugs to a comprehensive system of regulation, and to subsequent amendments adopting detailed regulatory schemes for medical devices\textsuperscript{17} and dietary supplements.\textsuperscript{18} On other hand, trad
tional smoking products such as Company A’s new cigarette have for the most part managed to escape direct government regulation, although the days of this near-total immunity seem to be limited. Company C’s risk-reduction product falls somewhere in between the products under consideration by Companies A and B, inasmuch as it possesses characteristics of both. The regulatory burdens Company C might face are at this point somewhat uncertain.

In marketing their products, Companies A and B will not be competing with each other. Indeed, in a grotesque sense they are playing on the same side, because the development of new products that increase tobacco dependence increases the need and demand for new products that provide relief from tobacco dependence.

Both entities, however, will be competing with Company C, which seeks to promote a product that will appeal to tobacco users who might otherwise purchase Company A’s new tobacco product, or who might resort to Company B’s new treatment to reduce risks linked to the consumption of tobacco products.

This article will undertake a comparative analysis of the regulatory barriers facing the three hypothetical firms. It would seem reasonable to begin, in part II, with an analysis of the type of regulation Company B would have to surmount, so that it will be easier to delineate, in part III, the type of license Company A would have enjoyed (at least until recently), and the new type of regulation it might have to face today. This, in turn, will facilitate an exploration, in part IV, of the possible burdens facing Company C.

The purpose of this article is to facilitate a policy analysis of the implications of the discrepancies in the regulatory framework currently confronting innovation in the fields of tobacco and tobacco-dependence treatment products.

II. The Regulation of Tobacco-Dependence Treatment Products

A. In General

The first products marketed as aids to smoking cessation date back to the early


20 See infra part III (C). The days of the industry’s immunity from civil liability also may be numbered. For accounts of recent litigation that has begun to breach the wall of immunity, see Carrick Mollenkamp et al., The People v. Big Tobacco: How the States Took on the Cigarette Giants (1998); Peter Pringle, Cornered: Big Tobacco at the Bar of Justice (1998).

21 Indeed, the development of a reduced-risk cigarette by Company C might have significant product-liability implications for Company A. It might present plaintiffs seeking damages from Company A for smoking-related harm the opportunity to develop proof that Company A’s product was defective because at the time of its marketing there was a feasible, reasonably safe alternative design for cigarettes, and if such a design had been adopted, plaintiff would not have suffered harm. See Restatement of Torts: Products Liability § 2(b) (Proposed Final Draft Apr. 1, 1997).
part of the twentieth century and contained herbs, spices, or chemicals that sought to make the taste of tobacco unpleasant.\textsuperscript{22} Recognition of the addictive properties of nicotine led to experimentation with nicotine-replacement therapies that first were administered intravenously, and that sought to wean smokers from their dependence on nicotine by providing them with reduced amounts of the substance.\textsuperscript{23}

In 1984, for the first time the Food and Drug Administration (FDA) approved a replacement therapy in the form of a gum that released nicotine when chewed properly.\textsuperscript{24} In 1991 and 1992, the agency precleared four patches that released nicotine through the skin into the bloodstream.\textsuperscript{25} More recently, FDA approved a nicotine nasal spray and a vapor inhaler,\textsuperscript{26} and authorized the marketing of an antidepressant, bupropion hydrochloride, for prescription-only use in the treatment of nicotine dependence.\textsuperscript{27} Moreover, the agency permitted the over-the-counter sales of both the gum and the patch.\textsuperscript{28} Several homeopathic medications also are available to consumers wishing to escape dependence on nicotine.\textsuperscript{29} In addition, some aids to smoking cessation have taken the form of medical devices\textsuperscript{30} and dietary supplements.\textsuperscript{31}

B. Tobacco-Dependence Treatment Products as “Drugs”

1. The Statutory Definition of “Drug”

The first step in determining what regulatory mechanisms the federal government might use to regulate marketing of a new tobacco-dependence treatment product involves fitting the product into a statutory definition. The most obvious location for a substance or combination of substances intended to help an individual to stop smoking would be the category of drug.


\textsuperscript{24} See id. at 471-79; see also Tamara Nordenberg, Which Nicotine Replacement Product Appeals to You?, FDA CONSUMER, Nov.-Dec. 1997, at 22, 23.


\textsuperscript{25} See id. at 88.
\textsuperscript{26} See Nordenberg, supra note 24, at 22.
\textsuperscript{28} See Nordenberg, supra note 24, at 22, 23.
\textsuperscript{29} They include a cigarette-cessation tablet and a gum containing six homeopathic medicines. See Cigarrest, About the Formula (visited May 1, 1998) <http://www.cigarrest.com/formula.htm>.
\textsuperscript{30} One device is a receptacle for a pack of cigarettes. It generates, by a process of squeezing, tiny holes in the filters of each cigarette. The holes are designed to let air mix with the smoke from the cigarette, and produce a cooling effect that is claimed to condense and trap nicotine and other toxins. See Why Phaseout Works (visited May 1, 1998) <http://members.aol.com/freshairii/works2.html>. Another is an artificial cigarette with a cartridge that releases a flavor simulating the sensation of inhaling from a cigarette. It is meant to replicate smoking by occupying the hands of the consumer and releasing a mint-like flavor into the mouth and lungs. See E-Z Quit Smokeless Artificial Cigarette System (visited May 1, 1998) <http://www.quitsmoking.com/ezquit.htm>.
\textsuperscript{31} See Henningfield, supra note 24, at 90; see also Metacalm -S, The Natural Way to Become Smoke Free (visited May 1, 1998) <http://www.metabolic.com/metas.htm> (information about dietary supplement intended to help smokers manage the nervousness and craving that accompany nicotine withdrawal, and to provide vitamins, minerals, amino acids, and herbs that help body normalize metabolic pathways affected by smoking).
Tobacco-dependence treatment products might fall within the definition of “drug” under the FDCA in one of two ways. The nicotine in tobacco has been shown to cause physical dependence on, or even addiction to, tobacco products. Such addiction or dependence could be considered a disease. A product intended by its manufacturer to cure or mitigate a disease is by definition a “drug” under the statute.

Alternatively, addiction or physical dependence may be viewed as conditions affecting the functioning of the body of the afflicted individual. A product intended by its manufacturer to lessen or eliminate addiction or dependence thereby also would affect a bodily function, and hence would come within a second prong of the “drug” definition.

2. The Consequences of Being Classified as a Drug

A manufacturer whose product comes within the statutory category of “drug” becomes subject to the various strictures of the FDCA, which is administered and enforced by FDA. Of most significance is the fact that the manufacturer must avoid committing an act prohibited by law, such as the adulteration or misbranding of the drug, or the refusal, under certain circumstances, to permit FDA inspectors to enter the manufacturer’s place of business. FDA has broad discretion in deciding whether or not to seek legal action against someone who has allegedly committed a prohibited act. If the agency initiates an enforcement proceeding, penalties that a court may impose include seizure of the product, an injunction, and even a fine or imprisonment. FDA also may use the threat of enforcement to negotiate a voluntary recall of products already on the market, and may generate publicity that might be adverse to

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31 See generally The Health Consequences of Smoking — Nicotine Addiction, supra note 23; see also Henningfield, supra note 24, at 80.
33 See 21 U.S.C. § 321(g)(1)(A) (“[t]he term ‘drug’ means ... articles intended for use in the ... cure, mitigation, [or] treatment of disease in man ...”).
34 See 60 Fed. Reg. at 41,468.
35 See 21 U.S.C. § 321(g)(1)(C) (“[t]he term ‘drug’ means ... articles ... intended to affect ... any function of the body of man ...”). A third definitional alternative, being listed in one of several named pharmaceutical compendia (id. § 321 (g)(1)(A)), might also apply. For a discussion of the difficulties that might arise from the use of this subsection, see infra notes 178-80 and accompanying text.
37 See 21 U.S.C. § 331(a). For specifics on what constitutes the adulteration of a drug, see id. § 351.
38 See id. § 331(a). For specifics on what constitutes the misbranding of a drug, see id. § 352.
39 See id. § 331(f).
40 See Heckler v. Chaney, 470 U.S. 821, 831 (1985) (“an agency’s decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency’s absolute discretion”).
42 See id. § 332.
43 See id. § 333. For a good summary of the most recent developments in the use of the Act’s criminal sanctions, see Federal Food and Drug Act Violations, supra note 42, at 660-62.
a manufacturer’s interests.\textsuperscript{47}

Falling into the statutory category of drugs has one immediate implication for a manufacturer who has never before engaged in the production of this type of product, namely the necessity of registering with FDA.\textsuperscript{48}

3. Tobacco-Dependence Treatment Products as New Drugs

The FDCA divides the universe of drugs into new drugs and products that do not fall within the category of new drugs.\textsuperscript{49} By definition a “new drug” is a drug “the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . .”\textsuperscript{50} FDA has taken the view that general recognition of safety and efficacy on the part of qualified experts must be based on scientific evidence, rather than personal experience or anecdotes,\textsuperscript{51} a position that has been upheld by the U.S. Supreme Court.\textsuperscript{52}

A new smoking-cessation product probably would not have generated sufficient scientific data on which qualified experts might base a recognition of safety and efficacy. Hence, in all likelihood it would fall within the definition of, and would be subject to regulation as, a new drug.

4. New Drug Approval Process

a. General Requirements

A product deemed to be a new drug may not be introduced into interstate commerce unless FDA has precleared it, and marketing of an unapproved new drug is a prohibited act under the law.\textsuperscript{53} The process of preclearance places a considerable burden on the company or individual seeking to place the drug on the market. Similar to any other new drug, a tobacco-dependence treatment product may not be marketed in interstate commerce before FDA has made a determination that it is both safe and effective under the approved conditions of its use.\textsuperscript{54}

The process that an applicant for FDA approval must follow is rigorous, expensive, and time-consuming,\textsuperscript{55} which has given rise to criticism that it has kept useful medicines, and cosmetics 55, 70-72 (R. Brady, R. Cooper & R. Silverman eds. 1997) [hereinafter fundamentals].

\textsuperscript{47} See 21 U.S.C. § 375.

\textsuperscript{48} See id. § 360(b) (providing that new producers of drugs must provide FDA with their names and addresses).

\textsuperscript{49} A product falling into the latter category might be called “not a new drug” or an “old drug.” Today a drug not considered a new drug would be subject to regulation under the Over-the-Counter Drug Review and would be called an over-the-counter drug. See part (II) (B) (8) infra.

\textsuperscript{50} 21 U.S.C. § 321(p)(1). A second category of new drugs includes drugs whose safety and efficacy has been recognized as a result of investigations, but which have not been used to a material extent or for a material time under the conditions prescribed, recommended, or suggested in the labeling. Id. § 321(p)(2).

\textsuperscript{51} See 21 C.F.R. § 312.2(b)(3) (1997).


\textsuperscript{53} See 21 U.S.C. § 331(d).

\textsuperscript{54} The relevant statutory provision is found at 21 U.S.C. § 355, which sets out in detail the procedures that must be followed and the standards that must be applied before a new drug may be marketed legally. On new drug development generally, see U.S. Food & Drug Admin., from Test-Tube to Patient: New Drug Development in the United States — An FDA Consumer Special Report (2d ed. Jan. 1995).

new medications off the market, to the detriment of patients who could be helped by them.\textsuperscript{56}

An applicant, called the sponsor, may begin animal testing on a new drug without FDA’s permission.\textsuperscript{57} The purpose of these tests is to see whether the drug has the desired effect, to find a toxic level for the drug, to estimate what the safe level in humans might be, and to determine how the drug is metabolized and excreted in animals.\textsuperscript{58}

If animal tests indicate that the drug has promise, the sponsor next submits to FDA a "Notice of Claimed Investigational Exemption," which informs the agency about the composition of the new drug, its source, and how it is made. The notice also must contain the results of all the animal tests.\textsuperscript{59} FDA has thirty days to review the submission. If the agency does not disapprove, the investigational new drug exemption (IND) takes effect and testing on humans may begin.\textsuperscript{60}

Clinical trials involve three phases: tests on healthy volunteers to determine drug metabolism and excretion, and also to calculate the potential of the drug to produce adverse effects in humans; tests on small groups of patients to determine the drug’s efficacy, and also to see whether there are any adverse effects within the dosage range required to produce therapeutic results; and tests on larger groups of patients to observe the safety and efficacy of the drug within its environment of use.\textsuperscript{61}

If the sponsor of the new medication believes that it has passed muster, it will file a new drug application (NDA) with FDA.\textsuperscript{62} The NDA must contain all safety and efficacy data gathered during the clinical tests, which may amount to as many as fifteen volumes of material.\textsuperscript{63} This process has become even more costly as a result of statutory amendments imposing user fees on NDA applicants.\textsuperscript{64}

Under the law, FDA has 180 days to review and either approve or reject an NDA.\textsuperscript{65} As a practical matter, the agency generally takes longer, although it has been steadily reducing the average time required to process NDAs.\textsuperscript{66}

FDA’s statutory responsibility is to determine whether the data submitted by the sponsor establishes that the drug is “safe for use under the conditions prescribed,


\textsuperscript{57} See 21 C.F.R. § 312.2(b)(3).

\textsuperscript{58} See id. § 312.23(a)(8).

\textsuperscript{59} See id. pt. 56. If the sponsor plans to conduct clinical trials in an institution, such as a hospital, she must also obtain the approval of the institutional review board within the institution. See Geoffrey M. Levitt, James N. Czaban & Andrea S. Paterson, \textit{Human Drug Regulation}, in \textit{2 Fundamentals of Law and Regulation: An In-Depth Look at Therapeutic Products} 159, 165 (D. Adams, R. Cooper & J. Kahan eds. 1997) [hereinafter 2 \textit{Fundamentals}].

\textsuperscript{60} See 21 C.F.R. § 312.40.

\textsuperscript{61} See id. § 312.21.

\textsuperscript{62} See 21 U.S.C. § 355(b); 21 C.F.R. § 314.50.


\textsuperscript{65} See 21 U.S.C. § 355(c)(1).

recommended, or suggested in the proposed labeling thereof," and that there is "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.”

The statute nowhere defines the critical term “safe” as it applies to new drugs. In practice, FDA has determined that drug safety is a relative concept, to be assessed in light of the potential risks that accompany the use of any drug, and the agency will weigh those risks against the benefits to be gained by consumers for whom the product is prescribed. Thus, if a tobacco-dependence treatment product introduces nicotine into the human body, the agency must consider the potential risks involved. They may derive from the addictive effects of nicotine, or from other effects that have been associated with the product. The agency must assess these risks against the advantages to be derived from the use of the drug. There is no statutory requirement that safety be supported by any specific amount of evidence.

The efficacy requirement tests whether a new drug accomplishes what it is meant to do. The statutory language directs the agency to refuse to approve an NDA if "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.” Thus, it is the sponsor of the new drug who determines the intended effect of the medication, and it is FDA's responsibility to determine whether the evidence submitted by the sponsor establishes that the drug will have its intended effect.

In the case of tobacco-dependence treatment products meant to break the consumer's addiction to nicotine, FDA would have to determine how long a user of the drug would need to have refrained from smoking before the medication is judged to be effective.

A more troublesome issue arises with respect to tobacco-dependence treatments that promise less than total withdrawal from the use of cigarettes or other tobacco products. FDA has not yet approved any indications other than smoking cessation. Whether the agency lawfully may disapprove an NDA containing substantial evidence that the drug under review can provide, for example, relief of nicotine-withdrawal symptoms or a mere reduction in the craving for nicotine is open to question.

Efficacy must be demonstrated by "substantial evidence,” which the statute defines as evidence of well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the ef-

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68 See id.
69 See HUTT & MERRILL, supra note 63, at 522-24 (citing Hearings Before a Subcomm. of the House Comm. on Government Operations, 88th Cong., 2d Sess. (1964)).
71 In a regulation assessing, inter alia, the effectiveness of nonprescription smoking-deterrent medications, FDA took the position that the smoking status of subjects taking the product on a trial basis should be evaluated at the end of four months to determine efficacy. See Smoking Deterrent Products for Over-the-Counter Human Use, 58 Fed. Reg. 31,236, 31,238 (June 1, 1993).
72 See Henningfield, supra note 24, at 86. Moreover, the agency has rejected smoking reduction as a criterion for assessing the efficacy of nonprescription drugs. See infra note 108 and accompanying text.
73 A legal ground the agency might assert for disapproval is that "based on a fair evaluation of all material facts, [the proposed] labeling is false or misleading." 21 U.S.C. § 355(d)(7). FDA would have to ground such an assertion on the conviction that any indication other than smoking cessation would be of no real benefit to tobacco users, and, therefore, that labeling a drug for this use would deceive consumers.
fectiveness of the drug involved, on the basis of which it could fairly and responsibly concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recom-

mended, or suggested in the labeling or proposed labeling thereof. 74

Because of the use of the term “investigations” in the plural, FDA generally required that the sponsor present evidence of more than one study establishing a new drug’s efficacy. 75 The FDA Modernization Act of 1997 (FDAMA), however, has lessened this burden by giving FDA discretion to determine that data from one adequate and well-controlled clinical investigation, plus confirmatory evidence, might amount to substantial evidence of efficacy. 76

The “new drug” approval process enables FDA to pass judgment not only upon the safety and efficacy of the product in question, but also on the proposed labeling. A finding that the labeling is “false or misleading in any particular” will justify a refusal to approve an NDA. 77

b. “Fast-Track” Requirements

A phenomenon known as the “AIDS Revolution,” brought about by pressure from HIV-infected individuals, AIDS sufferers, and their supporters, has produced a number of dramatic changes in the process by which FDA approves new drugs intended for use in the treatment of the AIDS Syndrome. 78 These modifications, developed administratively by FDA, inter alia, shortened the time necessary for the approval of NDAs by changing the standard by which efficacy is measured. Normally, the objective criterion used to test the effectiveness of a drug intended to treat a life-threatening disease is survival, what is known as a clinical endpoint. In place of this clinical endpoint, FDA has permitted the use of surrogate endpoints, such as improvements in negative conditions known to be linked with a disease, to determine efficacy. 79 The agency subsequently took steps to apply these new rules to drugs intended to treat other serious or life-threatening diseases. 80

FDAMA in effect ratified what the agency FDA had done and permits the agency to use so-called “fast-track” procedures for any new drug intended to treat a serious or life-threatening condition and shown to have the potential to meet unmet medical needs for such a condition. 81 A new drug found by FDA to meet these two criteria may be approved if the agency concludes that it “has an effect on a clinical endpoint or on

74 Id. § 355(d)(7).
81 Pub. L. No. 105-115, § 112, 111 Stat. at 2309 (codified at 21 U.S.C. § 356). The terms “serious or life-threatening” would seem to encompass grave conditions, such as nicotine addiction, that do not have an immediate adverse effect but can lead to deadly consequences over the long term.
a surrogate endpoint that is reasonably likely to predict clinical benefit.\textsuperscript{82}

A new smoking-cessation product might qualify for these abbreviated procedures if tobacco dependence qualifies as a serious or life-threatening condition, and if the drug offers reasonable hope of achieving results not produced by medicines already on the market. In addition, the sponsor would have to convince FDA that there is an available surrogate endpoint that might be used to test the drug’s effectiveness.

5. Post-Approval Obligations

FDA preclearance for safety and efficacy does not terminate the legal obligations of the holder of an NDA. The latter has a continuing duty to maintain the basis on which the agency granted its approval. If at any point FDA has reason to believe that the available data no longer support the conclusion that a new drug is safe for its intended use and that there is substantial evidence of efficacy, the agency may terminate the approval,\textsuperscript{83} which means that the product must be withdrawn from the market.

In addition, the FDCA requires that the holder of an approved NDA maintain such records and make such reports to FDA as the agency may mandate.\textsuperscript{84} FDA regulations require that the NDA holder provide the agency with prompt reports of any adverse reactions associated with the drug.\textsuperscript{85}

A new drug that qualifies for the new fast-track procedures under FDAMA may be subject to additional postapproval requirements, such as the conducting of studies to validate the surrogate endpoint or otherwise confirm the drug’s effect on the clinical endpoint.\textsuperscript{86}

6. Changes in an Approved New Drug

Once FDA has approved an NDA, the sponsor legally may market the drug in conformity with the conditions detailed in the document. If the sponsor wishes to make minor alterations in the composition or labeling of the product or in the manufacturing process, he must obtain preclearance from the agency through the mechanism of a supplement to the approved NDA.\textsuperscript{87} If, on the other hand, the sponsor wishes to add a new indication to those already listed in an approved NDA, he would have to submit the results of tests that support the indication and obtain FDA approval for the new use to which he seeks to put the drug.\textsuperscript{88}

7. Regulation of Drug Distribution

a. In General

The FDCA gives FDA no general authority to regulate the distribution of new drugs that the agency has precleared for introduction into interstate commerce. The agency did make one notable effort to impose distribution controls on methadone,

\textsuperscript{82} Id. (codified at 21 U.S.C. § 356(b)(1)).
\textsuperscript{83} See 21 U.S.C. § 355(e).
\textsuperscript{84} See id. § 355(k).
\textsuperscript{85} 21 C.F.R. § 314.80.
\textsuperscript{87} See Levitt, Czaban & Paterson, supra note 59, at 176-78.
\textsuperscript{88} See 21 C.F.R. § 314.54.
which had been approved for use as an analgesic and an antitussive agent, shipments of which the agency wanted to limit to approved maintenance treatment programs and approved hospital pharmacies; but the courts held that this initiative fell beyond FDA’s statutory mandate. Hence, once the agency has approved an NDA, it may not place restrictions on how the product is made available to consumers.

b. Distribution Limitations Under the Controlled Substances Act

Although the FDCA does not expressly permit the imposition of distribution controls on new drugs, Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, also known as the Controlled Substances Act (CSA), permits the Drug Enforcement Administration (DEA), acting in consultation with FDA, to place dispensation limits on drugs found to have a potential for abuse. Thus, if a tobacco-dependence treatment medication contains nicotine, an addictive substance, and the nature of the product combined with the probable circumstances of its consumption present a likelihood of abuse, DEA and FDA might consider listing it under the CSA.

c. Limitation to Sale by Prescription Only

FDA approval, however, may be conditioned on one very significant limitation, which provides that a drug may be sold only by prescriptions written by authorized health-care providers. As a practical matter, this limitation derives from the agency’s authority to regulate the labeling of drugs. On a finding that the drug cannot be administered safely without the intervention of a physician, FDA may require that the label of the product bear the statement “Caution: Federal law prohibits dispensing without prescription.” Such a finding may derive from the fact that the drug is habit-forming, that the approved NDA includes a determination that the administration of the drug requires the supervision of a licensed practitioner, or that because of the drug’s toxicity, method of its use, or collateral measures necessary to its use it is not safe except under the supervision of a licensed practitioner. In actual practice, the most common method FDA uses to restrict a new drug to prescription sale only is by including that limitation as a condition of the drug’s approved NDA.

The legal standards for classifying a product as a new drug (that the drug is not generally recognized as safe and effective) and for limiting a drug to prescription sale only (that the drug cannot safely be used except under the supervision of a licensed practitioner) are not identical. Therefore, an approved new drug need not be placed on prescription-only status, but may, if FDA so determines, be safe enough for over-the-counter (OTC) sales. Hence, the agency might switch to OTC status a new drug that previously had been limited to prescription-only status (as it has already done for

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90 FDA, however, may approve NDAs for new drugs on which manufacturers have placed voluntary controls on distribution. See Hutt & Merrill, supra note 63, at 635.
92 The criteria for listing are spelled out in 21 U.S.C. § 811.
93 See id. § 353(b)(4) (FDCA § 503(b)(4)).
94 See id. § 353(b)(1)(A) (FDCA § 503(b)(1)(A)).
95 See id. § 353(b)(1)(C) (FDCA § 503(b)(1)(C)).
96 See id. § 353(b)(1)(B) (FDCA § 503(b)(1)(B)).
97 For discussion of so-called “OTC switches,” see Peter Barton Hutt, Framework for Future Decisions on Transferring Drugs from Prescription to Nonprescription Status, 37 Food Drug Cosm. L.J. 427 (1982); Kaplan et al., Over-the-Counter Drugs, in 2 FUNDAMENTALS, supra note 59, at 233, 238-41.
two tobacco-dependence treatment products)\(^98\) or it might approve an NDA without requiring that the new drug be sold by prescription only.

8. Regulation of Over-the-Counter Drugs

Until the 1970s, all but a handful of OTC drugs had come on the market without any FDA preclearance. The controlling assumption was that they were generally recognized as safe, and hence not new drugs. The 1962 Amendments to the FDCA\(^99\) had added the requirement that new drug status include a determination that a medication was not generally recognized as effective,\(^100\) and for the first time required a finding of efficacy before a new drug could be approved by the agency.\(^101\) The amendments also directed FDA to apply the new rules to drugs already on the market;\(^102\) because OTC medicines number in the hundreds of thousands, this promised to be a formidable task.\(^103\)

In response, beginning in 1971, FDA undertook a massive study of all OTC drugs. What came to be known as the OTC Review was an innovative undertaking that utilized panels of independent experts to review all the active ingredients found in OTC drugs and all the claims made for these ingredients.\(^104\) The panels recommended to the agency which of these ingredients were generally recognized as safe and which claims were not misleading. FDA then decided which of these recommendations to accept, and used administrative rulemaking to promulgate regulations with the force of law. These regulations would, in effect, state what active ingredients could be used and what labeling claims could be made in OTC drugs. Nonprescription medicines with unapproved active ingredients or unapproved labeling claims could be removed from the market.\(^105\)

One of the expert panels considered tobacco-dependence treatment OTC drugs, and concluded in 1985 that no active ingredient found in them had been demonstrated to be generally recognized as safe and effective for use as an OTC smoking-cessation medicine.\(^106\) FDA accepted the panel’s finding in a final regulation published in 1993.\(^107\) The agency agreed with the panel that the only claim appropriate for an OTC smoking deterrent was smoking cessation, and refused to include smoking reduction as a standard for efficacy.\(^108\)

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\(^{98}\) See supra note 28 and accompanying text.


\(^{100}\) 21 U.S.C. § 321(p) (FDCA § 201(p)).

\(^{101}\) Id. § 355(d) (FDCA § 505(d)).

\(^{102}\) Pub. L. No. 87-781, § 107(c), 76 Stat. at 788. For a concise summary of these provisions, see Note, Drug Efficacy and the 1962 Drug Amendments, 60 Geo. L.J. 185, 195 (1971).

\(^{103}\) At this time, FDA estimated that between 100,000 and 500,000 separate OTC products were on the market. See FDA Formally Proposes Extensive Review of Non-Prescription Drugs’ Effectiveness, WALL ST. J., Jan. 5, 1972, at 4.


\(^{105}\) For general descriptions of the OTC Review, see Charles C. Ames & Steven C. McCracken, Framing Regulatory Standards to Avoid Formal Adjudication: The FDA As a Case Study, 64 CAL. L. REV. 14 (1976); Note, FDA’s Over-the-Counter Drug Review: Expedient Enforcement by Rulemaking, 11 MICH. J.L. REFORM 142 (1977).


\(^{107}\) See Smoking Deterrent Drug Products for Over-the-Counter Human Use, 58 Fed. Reg. 31,236 (June 1, 1993).

\(^{108}\) See id. at 31,238.
9. Regulation of the Promotion of Drugs

a. In General

A company planning to market a new medicine intended to combat tobacco dependence must consider not only the legal hurdles it would have to vault in order to gain approval by FDA, but also the restrictions the law places on the promotion of drug products.

There are two approaches FDA may take to limit how companies may stimulate sales of their products. The first is to use its authority over drug labeling, and to interpret as broadly as possible the definition of the term “labeling.” The second is to resort to authority Congress granted for the specific purpose of regulating advertisements.

b. Restrictions on Labeling

The statute defines “labeling” as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”109 FDA has interpreted the term as including such items as brochures, booklets, letters, literature, sound recordings, and motion pictures.110 To be regulated as labeling, written or graphic matter that is not on the drug product, its container, or its wrapper must accompany the drug. The term “accompany” has been given a meaning expansive enough to encompass instances in which the material, although shipped separately, shared both the origin and destination of the drug.111

FDA has used this authority to prevent manufacturers from promoting physicians unapproved uses of a drug.112 Thus, if Company B already marketed a drug that had been approved for purposes other than combating tobacco dependence but there was some evidence, anecdotal or otherwise, that the drug might be useful in helping people to stop smoking, the Company could not publicize the latter use through the product’s labeling, as broadly defined by FDA.

FDAMA has eased this restriction by permitting manufacturers to engage in the limited distribution of written information about unapproved uses of a drug, and by setting out ground rules for such distribution.113

c. Prescription-Drug Advertising

At one time manufacturers promoted prescription drugs only to the medical profession, mainly through advertisements in medical journals.114 Congress clearly had this kind of promotion in mind when it gave FDA authority to enforce requirements that every advertisement and “other descriptive printed matter issued . . . by the manufacturer” and intended to promote the sale of prescriptions drugs carry, inter alia, a “brief summary relating to side effects, contraindications, and effectiveness.”115 FDA

109 21 U.S.C. § 321(m) (FDCA § 201(m)).
110 For a long illustrative list, see 21 C.F.R. § 202.1(1)(2).
111 See Jeffrey N. Gibbs & Judith E. Beach, Adulteration and Misbranding of Drugs, in 2 FUNDAMENTALS, supra note 59, at 205, 215.
115 21 U.S.C. § 352(n) (FDCA § 502(n)).
Regulations fleshing out this legal authority explain that the statute permits the agency to take action against advertisements that are false, misleading, or lacking in fair balance. In the 1980s, pharmaceutical companies began to advertise directly to consumers in magazines and newspapers. At first FDA secured a voluntary moratorium on such promotions, to determine how they might be regulated under the agency's existing authority. The moratorium lasted only for a few years. When direct-to-consumer advertising resumed, FDA took the position that the statutory requirements did not apply if an advertisement mentioned only the name of the product or only the symptom or symptoms for which the product might be useful. This resulted in some rather mystifying television advertisements that sought either to impress a trade name on consumers without telling them what the product was intended to treat, or to stress symptoms along with the suggestion that consumers detecting them should consult their physicians.

This was an unsatisfactory state of affairs, so in 1997 FDA changed its position and published guidelines that sanctioned the use of both the name of a drug and its indications of use, as long as the advertisement provided information about major risks associated with the drug and adequate provision for the dissemination of full information about side effects, contraindications, and effectiveness.

d. Nonprescription Drug Advertising

In 1938, Congress gave the Federal Trade Commission (FTC) the authority to regulate the advertising of all drug products. In the 1962 Amendments to the FDCA, Congress opted to shift to FDA legal responsibility for regulating prescription drug advertising. The FTC, however, retained its authority over OTC drug advertising. Therefore, the manufacturer of nonprescription medications is subject to the requirements of the Federal Trade Commission Act, which prohibits advertising that is deceptive and contains specific provisions sanctioning drug advertisements that are misleading in any material respect. FTC considers as deceptive any claim for which the advertiser has no reasonable substantiation when the claim is made.

118 See FOOD & DRUG ADMIN., POLICY STATEMENT: VOLUNTARY MORATORIUM ON DIRECT-TO-CONSUMER ADVERTISING (1983).
120 See generally FOOD & DRUG ADMIN., DIV. OF DRUG MARKETING, ADVERTISING AND COMMUNICATION, CURRENT ISSUES AND PROCEDURES (1994).
122 See Draft Guidance for Industry: Consumer-Directed Broadcast Advertisements, 62 Fed. Reg. 43,171 (Aug. 12, 1997). Adequate provision might constitute furnishing an "800" number, an e-mail address, or the address of a Website on the Internet where consumers might obtain complete information about the product. Television advertisements already have begun to promote the sale of one of the prescription-only medications approved for the treatment of nicotine dependence, bupropion hydrochloride.
126 Id. §§ 52, 55. Section 55 specifically states that the failure to reveal material facts might amount to false advertising.
If FTC concludes that an advertising claim is deceptive, it has the authority to issue a so-called "cease-and-desist" order prohibiting further use of the claim.128 In addition, the Commission can compel future advertising to correct any misimpressions created by the deceptive advertisement.129

Because FTC regulates the advertising of OTC drugs and FDA regulates the labeling of these products, it has been necessary for the agencies to coordinate their efforts.130

10. Regulation of Homeopathic Drugs

Homeopathic medical treatment derives from the theory that certain diseases or conditions can be cured or ameliorated by giving patients small doses of substances or agents that would produce in healthy persons the symptoms displayed by patients.131 Homeopathic drugs are prepared from natural sources such as plants, and are diluted with diluents such as water or alcohol.

The FDCA recognizes articles listed in the Homeopathic Pharmacopoeia as drugs.132 In addition, homeopathic remedies intended for use in the treatment or cure of disease have been held to fall within the statutory definition of drugs.133

FDA’s position on homeopathic medications appears to be that they are subject to all statutory requirements and regulations governing drugs, but that the agency will enforce the law selectively, in accordance with published guidelines spelling out the conditions under which homeopathic drugs may be marketed.134 FDA, therefore, could take regulatory action against homeopathic medicines intended for the treatment of nicotine dependence.

C. Tobacco-Dependence Treatment Products as Medical Devices

If Company B’s product takes the form of an instrument or contrivance intended to free users from tobacco dependence, it would fall within the statutory definition of “medical device,” which encompasses an “instrument, . . . contrivance, . . . or similar article . . . intended for use in the cure, mitigation, [or] treatment . . . of disease . . . or intended to affect the structure or any function of the body.”135 As such it would be subject to a range of regulatory controls having their origin in the Medical Device Amendments of 1976.136

128 See 16 C.F.R. §§ 2.31-2.34.
132 21 U.S.C. § 321(g)(1)(A) (FDCA § 201(g)(1)(A)).
134 See Kaplan et al., supra note 97, at 242-45.
135 21 U.S.C. § 321(h) (FDCA § 201(h)). Such a device would qualify as treating a disease or affecting a bodily function for the same reasons that a substance intended to serve the same purposes would qualify as a drug. See part II (B) (1) supra.
The statutory scheme calls first for the classification of the device according to the degree of risk it poses. The FDCA imposes general controls on Class I devices,\(^\text{137}\) permits the imposition of special controls (including performance standards) on Class II devices,\(^\text{138}\) and mandates premarket approval for Class III devices.\(^\text{139}\)

Class I controls might result in the imposition of requirements for recordkeeping and reporting,\(^\text{140}\) and premarket notification.\(^\text{141}\) The FDCA gives FDA discretion to engage in rulemaking for the purpose of developing performance standards for Class II devices to provide reasonable assurances of safety and efficacy.\(^\text{142}\) The FDCA requires premarket approval for Class III devices,\(^\text{143}\) but FDA has permitted many new devices to enter the market only after the agency has been notified of the pending commercial introduction of the product.\(^\text{144}\)

A medical device that delivered reduced amounts of nicotine into the human body probably would be regulated as a drug-device combination, which means that FDA would have discretion to choose among the regulatory tools it possesses to regulate new drugs and devices.\(^\text{145}\)

D. Tobacco-Dependence Treatment Products as Dietary Supplements

1. In General

Suppose that Company B wants to market a vitamin, mineral, or herbal product intended to supplement the human diet and at the same time help consumers combat tobacco dependence. Under the statutory definitions in the FDCA, such a product clearly would fall within the categories of "food"\(^\text{146}\) and "dietary supplement."\(^\text{147}\) To market this product, what regulatory obstacles would Company B have to surmount?

2. Dietary Supplements Making Disease-Related Claims

The definition of "drug" embraces "articles intended for use in the ... cure, mitigation, [or] treatment ... of disease,"\(^\text{148}\) but excludes foods or dietary supplements that comply with certain specific requirements governing disease-related claims.\(^\text{149}\)

\(^{137}\) 21 U.S.C. § 360c(a)(1)(A) (FDCA § 513(a)(1)(A)). The Act provides that Class I status is justified when general controls are adequate to provide reasonable assurances of safety and efficacy, or, if not, the device is not intended for a use that would have substantial importance in preventing impairment of human health and does not carry with it an unreasonable risk of illness or injury. Id.

\(^{138}\) Id. § 360c(a)(1)(B) (FDCA § 513(a)(1)(B)). The Act indicates that Class II status will rest on a finding that general controls are insufficient to provide reasonable assurances of the safety and efficacy of the device. Id.

\(^{139}\) Id. § 360c(a)(1)(C) (FDCA § 513(a)(1)(C)). The statutory standard for a Class III device is that neither general nor special controls would be adequate to provide reasonable assurances of safety and efficacy, and the device is intended for a use that would have substantial importance in preventing the impairment of human health, or it created a potential undue risk of injury or illness. Id.

\(^{140}\) Id. § 360i (FDCA § 519).

\(^{141}\) Id. § 360j (FDCA § 510(k)).

\(^{142}\) Id. § 360d (FDCA § 514).

\(^{143}\) Id. § 360e (FDCA § 515).

\(^{144}\) See Howard M. Holstein & Edward C. Wilson, Developments in Medical Device Regulation, in 2 FUNDAMENTALS 257, 265-67.

\(^{145}\) See part III (C) (4) infra for a more detailed discussion of these tools.

\(^{146}\) See 21 U.S.C. § 321(f) (FDCA § 201(f)).

\(^{147}\) See id. § 321(ff) (FDCA § 201(ff)).

\(^{148}\) Id. § 321(g)(1)(B) (FDCA § 201(g)(1)(B)).

\(^{149}\) Id. § 321(g)(1) (FDCA § 201(g)(1)).
The special rules applicable to dietary supplements limit disease-related claims to statements claiming benefits related to classical nutrient-deficiency diseases only.\textsuperscript{150} The FDCA goes on to postulate that if such a claim is permitted, it must carry with it disclaimers that "This product is not intended to diagnose, treat, cure, or prevent any disease"\textsuperscript{151} and "A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases."\textsuperscript{152} Thus, it would seem that if dependence on or addiction to nicotine is considered a disease, and if the labeling of a dietary supplement claimed that the product was useful in providing relief for persons dependent on or addicted to tobacco products, it could be regulated as a drug, because its labeling did not comply with the rules that regulate disease-related claims.

3. Dietary Supplements Making "Structure-or-Function" Claims

If dependence or addiction is considered as a condition that affects the functioning of the human body, however, a tobacco-dependence treatment dietary supplement also might be viewed as affecting this function.\textsuperscript{153} This might bring the product within a special provision permitting dietary supplements to bear statements describing how they affect a bodily function.\textsuperscript{154} To make such a claim the manufacturer would have to be able to substantiate its truth,\textsuperscript{155} and would have to include a disclaimer that FDA has not evaluated the statement and that the supplement is not intended to treat or cure any disease.\textsuperscript{156}

III. THE REGULATION OF TOBACCO PRODUCTS

A. In General

Tobacco, which has created the need for smoking-cessation and other types of products designed to relieve dependence on the nicotine in tobacco, has been remarkably free of direct federal health regulation. Although Congress has enacted laws that govern the growing of tobacco and its packaging, that tax its sale, and that encourage restrictions on smoking,\textsuperscript{157} no legislation seeks specifically and directly to diminish or eliminate health risks found to be caused by the consumption of tobacco products.

It was not until 1996, when FDA asserted jurisdiction over cigarettes as both drugs and medical devices,\textsuperscript{158} that the tobacco industry had to confront the possibility

\textsuperscript{150} Id. § 343(r)(6)(A) (FDCA § 403(r)(6)(A)). On the statutory evolution of this section, see William R. Pendergast, Dietary Supplements, in 1 FUNDAMENTALS, supra note 46, at 257, 271-73, 261-62.
\textsuperscript{151} Id. § 343(r)(6) (FDCA § 403(r)(6)).
\textsuperscript{152} See supra notes 32-34 and accompanying text.
\textsuperscript{153} See supra notes 32-34 and accompanying text.
\textsuperscript{154} 21 U.S.C. § 343(r)(6)(A) (FDCA § 403(r)(6)(A)).
\textsuperscript{155} Id. § 343(r)(6)(C) (FDCA § 403(r)(6)(C)).
\textsuperscript{156} Id. § 343(r)(6)(B) (FDCA § 403(r)(6)(B)).
\textsuperscript{157} See supra notes 32-34 and accompanying text.
\textsuperscript{158} These laws are summarized and discussed in Susan H. Carchman, Should the FDA Regulate Nicotine-Containing Cigarettes? Has the Agency Established a Legal Basis, and If Not, Should Congress Grant It?, 51 FOOD & DRUG L.J. 85, 90-93 (1996).
of governmental controls at or near the level of those applicable to tobacco-dependence treatment products. Whether FDA has exceeded its legal authority in undertaking this initiative is an issue currently before the courts,\textsuperscript{159} so the fate of this new regulatory approach remains unclear. Adding to the uncertainty is current congressional consideration of comprehensive legislation that seeks to solve all aspects of the public-health problem resulting from the widespread use of cigarettes and other tobacco products.\textsuperscript{160}

This section of the article first will consider how tobacco products escaped regulation before 1996, then it will examine the implications of FDA's tobacco regulation.

B. Nonregulation of Tobacco Products Before 1996

1. In General

Although suspicions about the harmful effects of tobacco date back to the very beginnings of its widespread use,\textsuperscript{161} it was not until the 1930s that laboratory tests began to confirm what many had suspected: there was a demonstrable association between smoking and lung disease.\textsuperscript{162} Yet scientific uncertainties about the link between cigarettes and lung disease, the popularity of smoking as a cultural phenomenon in the United States, and the political power of the tobacco industry combined to discourage any meaningful action by the government. Moreover, the one statute that might have provided a tool to regulate consumer products containing tobacco turned out to be ill-suited to the task.

2. Tobacco and the FDCA

The drafters of the 1938 FDCA, building on the Pure Food and Drugs Act of 1906,\textsuperscript{163} might have established a regulatory framework for substances ingested into or applied to the surface of the human body for purposes of nutrition, taste or aroma, or for therapeutic or cosmetic purposes. So delineated, the scope of the Act would have included tobacco products.

Both statutes, however, limited coverage to "food,"\textsuperscript{164} "drug,"\textsuperscript{165} "cosmetic,"\textsuperscript{166}...
which were defined in ways that made it highly problematic to include substances inhaled into the body for purposes of taste and relaxation. The only conceivable opening for the regulation of tobacco products emerged in the category of drugs, which the FDCA defined as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease,” and “articles (other than food) intended to affect the structure or any function of the body.”

The need to establish “intent,” however, proved to be a stumbling block, as the courts ruled that the requisite intent was not that of the consumer, but that of the manufacturer. Hence, only when the government could prove that the manufacturer meant for his product to prevent a disease or affect a bodily function could enforcement action be taken in the case of a tobacco product. This occurred only twice in reported cases, when a manufacturer claimed that its cigarettes were useful in preventing a range of illnesses, and when a cigarette manufacturer made weight-reduction claims for his products. Moreover, in an earlier decision setting aside an order of FTC seeking to prohibit the claim that a cigarette was less irritating to the nose and throat, a court had held that the definition of “drug” in the FTC Act, which was identical to the definition in the FDCA, did not encompass a substance that was intended merely to come into contact with the senses and soothe them.

Indeed, FDA took the position that in the absence of such express claims, cigarettes could not be regulated as drugs. This interpretation withstood a judicial challenge in 1980, when a consumer group petitioned the agency to assert jurisdiction over cigarettes as both drugs and devices. In ASH v. Harris, the petitioners argued that a substance might qualify as a drug if consumers used it to affect the structure or any function of the body. The court agreed that consumer use might be used to establish the intent of a seller, but only if the near-exclusive use of the product was for the purpose of affecting the structure or function of the body; in such a case, FDA might infer the requisite statutory intent from the way virtually all consumers were using the product and from the manufacturer’s presumed knowledge of this level of use. Petitioners, however, had not introduced any evidence of consumer intent, and hence the court upheld FDA’s denial of the petition on the ground that it failed to establish that cigarettes were drugs.

poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles, except that such term shall not include soap”.

Id. § 321(h) (FDCA § 201(h)) (covering instruments, apparatus, and contrivances intended for uses such as would qualify an article as a “drug” under 21 U.S.C. §§ 321(g)(2), (3)).

Id. § 321(g)(1)(B) (FDCA § 201(g)(1)(B)).

Id. § 321(g)(1)(C) (FDCA § 201(g)(1)(C)).

See 1 JAMES T. O’REILLY, FOOD AND DRUG ADMINISTRATION § 13.03 (1979).

It is ironic that Jean Nicot, the Frenchman for whom nicotine was named, helped popularize the smoking of tobacco in the mid-sixteenth century by extolling its curative powers. See FRITCHLER, supra note 19, at 5-6; KLUGER, supra note 14, at 9.


In other words, a manufacturer, knowing that almost every consumer of his product was using it in a certain way, could be considered to intend such a use if he continued to market the product with knowledge of the way it was being used.
The statutory definition of "drug" presents a third possibility, inclusion in the *United States Pharmacopoeia*, the *Homeopathic Pharmacopoeia of the United States*, or the *National Formulary*. Nicotine is listed as a drug in the first of these compendia. Mere listing in a nongovernmental publication, however, has been held not to qualify a substance as a drug, because to do so would amount to an unlawful delegation of legislative authority to a private organization.

3. Tobacco and Other Consumer Safety Statutes

In the 1960s and 1970s, Congress enacted a number of bills intended to protect consumers from the risks of physical injury and illness. In several of these statutes, however, the drafters specifically excluded from coverage tobacco and tobacco products. Thus, in the Consumer Product Safety Act, which creates broad authority to ban hazardous products and set consumer product safety standards, the definition of "consumer product" specifies that tobacco and tobacco products are not covered. An amendment to the Hazardous Substances Labeling Act of 1960 exempted tobacco and tobacco products from the definition of "hazardous substances." The Controlled Substances Act of 1970 exempted tobacco from its definition of "controlled substance." Even statutes seeking to protect consumers' wallets and pocketbooks omitted tobacco products.

4. Tobacco and FTC

In 1938 Congress gave FTC explicit authority to combat "deceptive acts or practices in commerce." This language made it clear that FTC could take action against false advertising that deceived the consuming public. In addition, FTC received additional procedural weapons and sanctions to deal with deceptive advertisements for food, drugs, medical devices, and cosmetics, statutorily defined in language identical to that found in the FDCA.

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178 21 U.S.C. § 321(g)(1)(a) (FDCA § 201(g)(1)(a)).
179 See 1 USP Dispensing Information, Drug Information for the Health Care Practitioner 2138 (1997).
180 United States v. An Article of Drug . . . Ova II, 414 F. Supp. 660 (D.N.J. 1975), aff'd without opinion, 535 F.2d 1248 (3d Cir. 1976). The court went on to make a not-altogether persuasive attempt to salvage some permissible meaning out of § 321(g)(1)(A). The shakiness of this prong of the "drug" definition probably persuaded FDA not to rely on it, even as an alternative ground, when the agency finally decided to regulate nicotine as a drug. See infra part III (C) (2).
185 21 U.S.C. § 802(6). This creates an interesting anomaly. Despite the recognized addictiveness of cigarettes, they are exempted from regulation under the Controlled Substances Act; a tobacco-dependence treatment medication containing nicotine, however, conceivably might be regulated under the Act. See supra part II (B) (7) (b).
188 In 1931, the U.S. Supreme Court held that FTC could take action against false advertising only if it adversely affected competition. FTC v. Raladam, 283 U.S. 643, 649 (1931). The Wheeler-Lea Amendments subsequently made it clear that the Commission could protect the consuming public against deceptive advertisements. See Pub. L. No. 75-447, 52 Stat. at 111.
190 Id. §§ 321(f), (g)(1), (b), (i) (FDCA §§ 201(f), (g)(1), (b), (i)).
Thus, although the Commission could not use this latter authority to police the advertising of cigarettes, which were not considered drugs at the time, it could use its general authority against misleading promotion by the tobacco industry. In 1942, FTC issued its first complaint against a cigarette manufacturer for deceptive advertising, based on unsubstantiated health claims.191

It was not until 1964, however, after the Surgeon General issued a report noting the scientific verification of a causal link between smoking and lung cancer,192 that the Commission began an administrative proceeding to issue rules governing the advertising and labeling of cigarettes.193 At this point Congress intervened.

5. Tobacco and Congress

In 1965 Congress enacted the Federal Cigarette Labeling and Advertising Act,194 which declared as its purpose the creation of a comprehensive federal program to regulate the labeling and advertising of cigarettes as a response to the health risks posed by smoking.195 The new law mandated a health warning to appear on cigarette packages and advertising.196 It also provided that no other warning could be required on the packages or in the advertising of cigarettes.197 Finally, it directed FTC to report annually to Congress about the effectiveness of the required labeling and about current cigarette promotion practices,198 and FDA to make annual reports about the health consequences of smoking.199 The new law cut short FTC’s effort to require health warnings in advertising, and gave the industry a strong defense to assert in product-liability cases—the assumption of known risks by smokers.200

Four years later, Congress passed the Public Health Cigarette Smoking Act, which strengthened the warning label requirements and banned cigarette advertising on radio and television.201 Congress intervened in 1973 to include little cigars within the coverage of the 1969 Act,202 and yet again in 1986 with the passage of the Comprehensive Smokeless Tobacco Health Education Act, which placed similar restrictions on the labeling and advertising of smokeless tobacco.203

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191 See KUGER, supra note 14, at 130.
196 Id. § 1333(a).
197 Id. § 1334.
198 Id. § 1337(a).
199 Id. § 1337(b).
201 Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified at 15 U.S.C. §§ 1331-1340). This statute preempted an initiative of the Federal Communications Commission, which first required broadcasters to give equal time for antismoking commercials and then proposed to ban all television advertising for tobacco products. See KUGER, supra note 14, at 303-08, 327-28. The ban on television advertising also would put an end to the broadcast industry’s need to provide time for antismoking advertisements, which apparently were having some effect on smokers. See Robert A. Kegan & David Vogel, The Politics of Smoking Regulation: Canada, France, and the United States, in SMOKING POLICY: LAW, POLITICS, AND CULTURE, supra note 19, at 22, 35.
6. An Overview of Cigarette Regulation in 1996

On the eve of FDA's promulgation of new rules governing cigarettes, the labeling and electronic advertising of cigarettes and little cigars was subject to the requirements and limitations spelled out in the 1969 Act, while the 1986 Act covered smokeless tobacco. Moreover, if cigarette companies made labeling claims to the effect that their products might prevent disease or affect a bodily function, the rules relating to the marketing of new drugs might apply.

As long as a manufacturer complied with the 1969 and 1986 Acts, and refrained from making assertions that would bring his product within the definition of a drug, he could continue to market cigarettes, little cigars, or smokeless tobacco (or make alterations in their composition) without concern for the impact of federal regulation. This situation changed in the mid-1990s, when disclosures based on internal documents from the tobacco industry revealed that the companies had long been manipulating nicotine levels in their products. 204

C. Regulation of Tobacco Products After 1996

1. In General

On August 28, 1996, FDA promulgated a set of regulations that marked a sharp departure from the hands-off policy the agency traditionally had followed in matters involving cigarettes and other tobacco products. 205 The new approach classified nicotine as a drug 206 and cigarettes as medical devices. 207 As a consequence of this reclassification, the agency imposed distribution controls on the sale of cigarettes and smokeless tobacco to keep them away from children. 208 The rule also provided that the labels of cigarettes and smokeless tobacco products bear the established names of the products and a statement of intended use. 209

2. Nicotine as a Drug

The 1996 regulation took the position that nicotine affects the structure or function of the human body by causing not only addiction and other psychoactive effects, but also by controlling weight. 210 The more difficult legal hurdle for FDA to surmount, however, was to establish that the manufacturers of cigarettes and smokeless tobacco intended these effects. The regulation sought to do this by producing evidence that the addictive and other pharmacological effects of nicotine are so widely known, and the public's consumption of cigarettes to achieve these effects is so widespread,

204 The story is told in PHILIP J. HILTS, SMOKE SCREEN: THE TRUTH BEHIND THE TOBACCO INDUSTRY COVER-UP ch. 4 (1996); see also KLUGER, supra note 14, at 740-47. For an explanation by the FDA officials involved, see David A. Kessler et al., The Food and Drug Administration's Regulation of Tobacco Products, 335 NEW ENG. J. MED. 988 (1996).


207 See id. at 45,205-18.


209 See id. at 44,617.

that manufacturers must have intended to market them for these purposes. In addition, manufacturers actually and consciously design cigarettes and smokeless tobacco to provide consumers with a pharmacologically-active dose of nicotine.211

FDA confronted its own prior and oft-repeated insistence that cigarettes are definitionally not drugs by asserting that the agency had new evidence, unavailable in the past, to support the new position being taken.212

3. Cigarettes and Smokeless Tobacco Products as Medical Devices

If the new rules merely had classified nicotine as a drug and had gone no further, FDA’s authority to regulate cigarettes and smokeless tobacco products would have been somewhat restricted. Given the addictive quality of nicotine, the substance hardly could qualify as being generally recognized as safe by qualified experts, and therefore it would fall within the definition of “new drug.”213 Under this scenario, the agency’s only option, if it wished to take action, would be to remove the products from the market on the ground that they were unapproved new drugs, a radical move that would have enormous economic, political, and social implications.

Therefore, the agency chose a more flexible regulatory approach.214 The Medical Device Amendments of 1976 had given FDA a range of statutory mechanisms to deal with problems associated with the marketing of medical devices, and these went considerably beyond the agency’s authority to regulate drugs.215 The availability of these mechanisms persuaded FDA to place into the device category those components of cigarettes and smokeless tobacco that delivered nicotine into the human body, and to view cigarettes and smokeless tobacco together as combination “drug-device” products.

The statutory definition of “device” encompasses an “instrument, . . . contrivance . . . or similar article . . . intended to affect the structure or any function of the body.”216 Hence, those parts of a cigarette or smokeless tobacco that made possible the entry of nicotine into the human body would be “devices,” because they were intended to affect a bodily function.217

The device definition went on to exclude a contrivance that “achieve[d] its primary intended purpose through chemical action within . . . the body.”218 FDA took the position that the device components of cigarettes and smokeless tobacco did not achieve their primary intended purpose as a result of chemical action; it was nicotine, the drug component, that had a chemical effect.219

Because the FDCA expressly recognized the possibility of combination drug-device products,220 FDA put cigarettes and smokeless tobacco within that category, and

211 See id. at 44,632-48.
212 See id. at 44,650-53.
213 21 U.S.C. § 321(p) (FDCA § 201(p)).
214 See 61 Fed. Reg. at 44,404. FDA insisted, however that it “could have used its drug authorities to implement similar types of controls on cigarettes and smokeless tobacco as it is imposing under the somewhat more flexible device authorities.” Id.
215 On FDA’s authority to regulate medical devices, see generally Howard M. Holstein & Edward C. Wilson, Developments in Medical Device Regulation, in 2 FUNDAMENTALS, supra note 59, at 257.
216 21 U.S.C. § 321(h) (FDCA § 201(h)).
217 FDA established the requisite intent by using the same evidence and reasoning employed to support the conclusion that nicotine is a drug. See supra part II (B) (1).
218 21 U.S.C. § 321(h) (FDCA § 201(h)).
220 See 21 U.S.C. § 353(g)(1) (FDCA § 503(g)(1)); see also Nancy L. Buc & Kate C. Beardsley, Combination Products and Other Jurisdictional Conundrums, in 2 FUNDAMENTALS, supra note 59, at 251.
went on to assert that it had the authority to decide which of the regulatory mechanisms applicable to drugs and devices would be invoked in this particular set of regulations.\textsuperscript{221}

4. Restrictions on Sale and Distribution

The 1996 regulations classify cigarettes and smokeless tobacco as “restricted devices,” a category analogous to the prescription-only status applicable to certain drugs.\textsuperscript{222} The FDCA gives FDA authority to place restrictions on the sale, distribution, or use of a medical device “if, because of its potentiality for harmful effect or the collateral measures necessary to its use, [FDA] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.”\textsuperscript{223} If the agency makes such a finding, it may require that the device be sold or distributed by prescription only, or “upon such other conditions as [FDA] may prescribe.”\textsuperscript{224}

On the basis of its reading of this statutory language, FDA placed various restrictions on the advertising and promotion of cigarettes and smokeless tobacco, and access to these products by minors,\textsuperscript{225} and issued requirements that certain information appear on packages, cartons, and boxes containing tobacco products.\textsuperscript{226}

5. Labeling Requirements

Utilizing its authority to take action against devices whose labels did not bear their established name,\textsuperscript{227} FDA required that the name of the product appear on the labels of cigarettes and smokeless tobacco products, and listed eight specific names for those products, ranging from cigarettes and cigarette tobacco to plug chewing tobacco and snuff.\textsuperscript{228} In addition, the label would have to bear the following statement of intended use: “Nicotine Delivery Device for Persons 18 or Older.”\textsuperscript{229}

6. Judicial Review of FDA Regulations

The industry mounted a legal challenge to the 1996 regulations, and a year later a U.S. District Court in North Carolina upheld most of them.\textsuperscript{230} The court found FDA’s position (that a manufacturer’s representations were not the only source for determining whether a product was intended to affect a bodily function) to be a permissible interpretation of the FDCA;\textsuperscript{231} both the way a product foreseeably might be...

\textsuperscript{221} 61 Fed. Reg. at 44,649-50.
\textsuperscript{222} See supra part II (B) (7) (c).
\textsuperscript{223} 21 U.S.C. § 360j(e)(1) (FDCA § 520(e)(1)).
\textsuperscript{224} Id. § 360j(e)(1)(B) (FDCA § 520(e)(1)(B)).
\textsuperscript{226} Id. at 44,462-65.
\textsuperscript{227} 21 U.S.C. § 352(a) (FDCA § 502(a)).
\textsuperscript{228} 61 Fed. Reg. at 44,617.
\textsuperscript{229} Id. Authority for this requirement stems from 21 U.S.C. § 360j(e)(2), which provides that the label of a restricted device describe restrictions that have been placed on the device under 21 U.S.C. § 360j(1).
\textsuperscript{230} The latter section provided FDA with a legal basis for placing restrictions on the distribution of cigarettes and smokeless tobacco products. See supra part III (C) (4).
\textsuperscript{231} Coyne Beahm, Inc., 958 F. Supp. at 1060.
\textsuperscript{231} The court relied on Chevron, U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984), which held that where a statute is silent or ambiguous with respect to a particular issue, an interpretation by the agency charged with administering the statute must be upheld if it is based on a permissible construction of the statutory language.
used and the way consumers actually use it provide objective evidence from which a manufacturer's intended use might be inferred. The court concluded that FDA had made an adequate finding of intended use on the basis of foreseeability and actual consumer use.

The court, however, went on to state that evidence of a manufacturer's subjective intent — in this case internal industry documents tending to show that the manufacturers actually meant for their products to affect a bodily function — would not be relevant to establish intended use, because FDA's own regulations limited proof of intended use to evidence of objective intent (intent delineated by objective manifestations).

The one portion of the regulation invalidated by the court was the attempt to place restrictions on the promotion and advertising of tobacco products. The court refused to give the agency the authority to restrict "sale, distribution, or use" or to apply the broad readings FDA had assigned to the phrase "such other conditions." The agency's argument was that restrictions on promotion and advertising were "other conditions" it might lawfully place on the "sale" of restricted devices. The court insisted that the term "other conditions" had to be construed within its context, which permitted FDA to put restricted devices on prescription-only status and impose similar controls on the way the devices were distributed. In addition, the court noted that other parts of the FDCA gave FDA limited power to regulate the advertising of restricted devices and concluded from this that Congress did not intend to give the agency similar but unlimited authority under the section authorizing distribution controls. This holding obviated the need for the court to address the plaintiffs' argument that the restrictions placed by the regulations upon the advertising of cigarettes violated the tobacco companies' constitutionally protected right of free speech.

The restrictions on access to cigarettes and smokeless tobacco by children and adolescents, however, survived the court's scrutiny, because they could be found reasonably to fall within the term "other conditions." The court also upheld FDA's authority to require the labeling of cigarettes and smokeless tobacco to bear the product's established name and intended use, as required by the agency's regulations.

7. Further Action FDA Might Take Under the 1996 Regulations

FDA limited the thrust of its 1996 regulations to restrictions that would protect children and adolescents from the addictive power of certain tobacco products. The agency insisted, however, that cigarettes and smokeless tobacco could be subject to the restrictions.

233 The internal documents might have some relevance to the finding of foreseeability, because if a manufacturer intends for a product to be used in a certain way, he surely could anticipate it would be used in that way.
234 21 U.S.C. § 360j(e)(1) (FDCA § 520(e)(1)).
235 Id. § 360j(e)(1)(B) (FDCA § 520(e)(1)(B)).
236 See id. § 352(q)-(r) (FDCA § 502(q)-(r)).
238 For FDA's explanation why it focused on the protection of minors, see 61 Fed. Reg. at 44,398-99.
entire range of regulatory controls applicable to medical devices, and expressly left open the possibility of future actions, such as the invocation of provisions of the FDCA that include prohibitions on adulteration and misbranding; the imposition of certain requirements that govern labeling, recordkeeping and reporting, and premarket notification; and the insertion of cigarettes and smokeless tobacco products into one of three classes, which would trigger additional regulatory burdens.

Under the last of these options, FDA might classify cigarettes and smokeless tobacco products as Class II medical devices, and set performance standards for them. This might result in the imposition of onerous controls on manufacturers, but it also would place a considerable strain on the agency’s resources.

A Class II medical device is one for which general controls would not be sufficient to ensure safety and effectiveness. The specific controls that FDA is authorized to impose on Class II devices include performance standards, which are nowhere defined in the FDCA. The House report on the Medical Device Amendments of 1976 states a preference for result-oriented standards permitting manufacturers to use technological alternatives to achieve desired results, which suggests the setting of performance requirements, but the report adds that design-related standards also may be promulgated. The Senate report, on the other hand, indicates that “standards must relate to the safety or effectiveness (including reliability over time) of the device or other ‘performance’ characteristics.” The conference report sheds no further light on what Congress meant by performance standards.

Under a result-oriented reading of the term “performance standards,” FDA might specify the maximum amounts of particular ingredients a cigarette or smokeless tobacco product might deliver to the consumer, and leave it to manufacturers to design filters or other mechanisms to keep these ingredients at the designated level when absorbed into the body. This would seem to be a permissible reading of the statutory language.

The FDCA, moreover, may expressly permit performance standards that go beyond the designation of results; it states that standards may include “provisions respecting the . . . ingredients . . . of the device.” This opens the possibility of regulating what ingredients might, or might not, be used in cigarettes and smokeless tobacco products.

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239 See id. at 44,404.
241 Id. § 352 (FDCA § 502).
242 E.g., id. § 352(s) (FDCA §502(s)) (device misbranded if it is subject to a performance standard that requires specific labeling and it fails to bear such labeling).
243 Id. § 360I (FDCA § 519).
244 Id. § 360(k) (FDCA § 510(k)).
245 For a discussion of these burdens, see supra part II (C).
246 Cf. James T. O’Reilly, A Consistent Ethic of Safety Regulation: The Case for Improving Regulation of Tobacco Products, 3 ADMIN. L.J. 215, 234-35 (1989) (resource drain as reason why FDA has hesitated to do battle with powerful tobacco industry).
248 See id. § 360d (FDCA § 514).
Once a decision has been made to set performance standards, FDA would have to follow a number of procedural requirements in order to put a device into Class II. Having placed a device in Class II, the agency would have to follow an even more cumbersome set of procedures to finalize performance standards. The procedural barriers to be overcome in promulgating performance standards, even though they have been somewhat simplified, explain why FDA has finalized very few of them. Hence, reliance on performance standards to regulate cigarettes and smokeless tobacco products seems an unlikely regulatory option, at least under the statutory authority as it currently stands.

Another option would be for FDA to regulate cigarettes and smokeless tobacco products as Class III medical devices. The agency first would have to follow the same type of classification procedures as are required for Class II. Next, the agency would have to promulgate regulations requiring premarket approval. The manufacturers whose devices are covered by the regulation would then have to apply to FDA for premarket approval. The FDCA directs FDA to deny an application on a finding of insufficient evidence demonstrating a "reasonable assurance" of safety and efficacy.

Given the risks known to be associated with cigarettes and smokeless tobacco products, it is difficult to see how the agency could reasonably be assured of the safety of these products. Thus, regulating them as Class III medical devices would involve the same sort of inflexibility that would attach to regulating them as new drugs. This, plus the burdensome procedures FDA would have to follow, cut heavily against the Class III option.

FDA might use its existing authority to go beyond the 1996 regulations, a move that has been urged in a petition submitted to the agency by the American Lung Association and other interested groups. Such an initiative might classify other tobacco products, like full-length cigars, as drug-device combinations, and might seek to decrease the incidence of smoking and smoking-related diseases among the general population, rather than target only children and adolescents.

IV. THE REGULATION OF RISK-REDUCTION SMOKING OR SMOKELESS TOBACCO PRODUCTS

A. In General

An important unresolved issue the American Lung Association petition asked FDA to address is how the agency should regulate the manufacture and marketing of
cigarettes that expressly or impliedly purport to reduce risks associated with smoking. This would be the type of product the hypothetical Company C wants to sell. It would provide consumers with the taste and smell of a traditional smoking product, but at the same time it would contain reduced tar or nicotine levels, or other physical qualities, that would lessen the level of danger posed by other tobacco products. As such, the new item would share characteristics of the products Companies A and B want to introduce.

B. FDA’s Prior Responses to Risk-Reduction Cigarettes

The cigarette industry has had a long history of bringing to market smoking products with designs (such as filters) and content (such as lower tar levels) that apparently mitigated some of the adverse effects associated with smoking. FDA did not seek to classify such cigarettes as drugs, perhaps because the agency concluded that the claims made for them did not, with sufficient specificity, promise the prevention of disease.

In the late 1980s, the tobacco industry began to experiment with “smokeless” cigarettes that burned substances other than tobacco. At this point, an antismoking group petitioned FDA to regulate both these new products and all low-tar cigarettes as drugs, on the ground that they clearly were intended to prevent disease. The agency temporized, and the petition found itself relegated to the backburner when FDA began its initiative to regulate all cigarettes and smokeless tobacco products as drug-device combinations.

C. FDA’s Current Options Regarding Risk-Reduction Cigarettes

1. Risk-Reduction Cigarettes as Covered by the 1996 Regulations

If FDA decided to react to Company C’s planned introduction of a risk-reduction cigarette, the first issue to be confronted would be whether the new product fell within the scope of the 1996 regulations. If the cigarette contained no ingredient, such as nicotine, that might addict users, then Company C hardly could be found to have intended the product to affect a bodily function, and therefore it could not be swept into the category of a drug-device combination under the approach utilized to regulate cigarettes and smokeless tobacco. If the new product had lower levels of nicotine than ordinary cigarettes, the agency would have to determine how addictive the product might be, and whether the level of addiction was strong enough to warrant government intervention, under the parameters of the 1996 regulations, on behalf of smokers unable to free themselves from dependence on the product. In addition, FDA would have to establish that Company C intended that its product affect a bodily function. If Company C were new to the cigarette business, the agency would have a difficult burden to establish intent on the basis of foreseeability or actual consumer use.
A finding that the characteristics of Company C’s new cigarette were sufficiently close to those of traditional cigarettes to render them subject to the 1996 regulations would mean, at this point in time, only that certain requirements with respect to labeling and distribution would apply to the new product. These requirements, however, were designed to reduce risks associated with cigarettes and smokeless tobacco, and would seem ill-suited to a product whose unique characteristic was risk reduction.

2. Risk-Reduction Cigarettes Regulated as Disease-Treatment Products

Whether or not FDA could classify risk-reduction cigarettes as drug-device combinations subject to the 1996 regulations, the agency also might consider whether to treat them like any other tobacco-dependence treatment medication. Since the purpose of Company C’s new product would seem to be identical to that of the type of product Company B seeks to market, it would appear logical that both products be subject to the same kind and degree of regulation. Before regulating Company C’s product as a drug, however, FDA would have to determine whether it fell within the parameters of the “drug” definition.

A new smoking product marketed with the claim that it could free smokers from nicotine addiction would fall within the drug category for the same reasons that tobacco-dependence treatment medications are classified as drugs.\(^{270}\) It also might be considered a medical device designed to deliver whatever substance brought to fruition the claim that the product could free the user from tobacco dependence.\(^{271}\) Thus, FDA might treat Company C’s product as a drug-device combination.

But suppose Company C merely makes a claim that its new cigarette had low levels of tar and nicotine. FDA has never taken the position that this type of claim alone would justify classifying the product as a drug.\(^{272}\) Because the agency has never previously taken the position that such claims are not disease-related and therefore would not bring a product within the drug category, however, the agency might now ponder the possibility of regulating such products as drugs on the basis of the claim.

A conceptual hurdle that would confront the agency derives from the fact that a “low-tar-and-low-nicotine” claim might mean only that Company C’s new cigarettes are less risky than cigarettes with higher levels of tar and nicotine. The mere assertion that a product is less apt to cause harm than competing products may not be enough to bring the product within the ambit of the “drug” definition. Labeling milk as pasteurized might imply that the product was safer than nonpasteurized milk, but this would not make pasteurized milk a drug.\(^{273}\)

On the other hand, the claim might be interpreted to mean that Company C’s new product could help smokers free themselves from existing dependence on traditionally formulated smoking products. If Company C could foresee that this is how consumers would use the product, this might be enough to fit it within the “drug” defini-

\(^{270}\) See supra part II (B) (1).
\(^{271}\) See supra part III (C) (3).
\(^{272}\) See supra part IV (B).
\(^{273}\) In the 1950s, food labeling began to bear implied health-related claims to the effect that a particular product was low in fat or cholesterol. When FDA doubted the truth of the assertion, the agency took the position that such claims rendered the food misbranded. See Peter B. Hutt, Government Regulation of Health Claims in Food Labeling and Advertising, 41 Food Drug Cosm. L.J. 3, 27-34 (1986). FDA, however, could not take the same approach toward “low-tar-and-low-nicotine” cigarettes without first establishing jurisdiction over the products.
FDA might classify Company C’s product as a new drug because there would be no general recognition of its efficacy. The agency then could condition the marketing of the product upon the issuance of an approved NDA, just as it would require an NDA for Company B’s new tobacco-dependence treatment medication.

3. **Risk-Reduction Cigarettes Regulated as Devices**

An alternative approach FDA might consider is similar to that taken in the 1996 regulations. The agency might classify “low-tar-and-low-nicotine” cigarettes as drug-device combinations, and might utilize its administrative discretion in not calling for Company C to submit safety and effectiveness data as part of an NDA; instead, FDA might resort to the more flexible regulatory authority it has over medical devices to classify risk-reduction cigarettes as Class II medical devices and set performance standards for them.

Not to subject Company C to the full panoply of rules relating to new drugs would foster inconsistencies in the regulation of risk-reduction cigarettes and tobacco-dependence treatment products, which in turn would create economic disincentives for the development of the latter. On the other hand, to require manufacturers wanting to market low-tar-and-low-nicotine cigarettes to go through the new drug approval process would create economic disincentives for the development of such products. The setting of performance standards might be an appropriate middle ground.

V. **Conclusion**

The social problems attributable to tobacco require steps that will prevent addiction to nicotine by developing ways to discourage people from smoking (perhaps by a combination of “command-and-control” government intervention and public education), help those already addicted to break the chains that bind them, and deal with the issue of how to pay for the economic costs tobacco products have exacted on society.

This article has dealt with the government regulation of tobacco products, an initiative that seeks to prevent or reduce tobacco-related harm, and the government regulation of tobacco-dependence treatment products, an effort that seeks to reduce the social and economic costs of tobacco consumption. It has demonstrated that Company A, in bringing to market a new tobacco product, will face regulatory requirements that differ markedly from those imposed on Company B in its preparation for the introduction of a new product intended to treat tobacco dependence, and from those imposed on Company C, which seeks to market a risk-reduction tobacco product.

Company C is competing with Company A. It wants to offer smokers an alternative that would provide them with the satisfaction they derive from smoking but at a reduced level of risk. It would not seem reasonable to permit the playing field to tilt in favor of the more hazardous product. Indeed, the opposite would be more consistent with sound public health policy.

274 For a discussion of how foreseeability might establish intended use, see supra part III (C) (5).
275 For a discussion of tobacco-dependence treatment medications as new drugs, see supra part II (B) (3).
276 For a discussion of the new drug approval process, see supra part II (B) (4).
277 For a discussion of the difficulties that might arise from a decision to set performance standards, see supra part II (A) (7).
278 For elaboration of this point, see Henningfield, supra note 24, at 92.
Company C also is competing with Company B, in that it is appealing to smokers concerned with freeing themselves from dependence on nicotine, or otherwise lessening the dangers associated with smoking.\textsuperscript{279} Consumers use Company B's smoking-cessation product for the exact same reason they would use Company C's low-tar-and-low-nicotine cigarette, to reduce their intake of nicotine while still holding their addiction at bay. To force Company B to do clinical testing to support an indication of smoking cessation without requiring similar tests from Company C before it can market a cigarette to be marketed for the identical purpose makes little sense. Here, the playing field ought to be level.

The regulatory inconsistencies that have been described in this article might be dealt with in one of two ways. The first would be to amend the FDCA to clarify FDA's legal authority over tobacco products, and to address any problems peculiar to the regulation of tobacco-dependence treatment products. The so-called "global-settlement" legislation now before Congress includes statutory changes as one facet of a total package that addresses issues of civil liability for tobacco-related harm, the taxation and regulation of tobacco products, and the appropriation of funds for smoking-cessation programs.\textsuperscript{280} A second approach would be to utilize FDA's existing authority in a manner aimed at creatively and comprehensively achieving a broad goal of decreasing the incidence of smoking and smoking-related diseases among the general population in the most expeditious, effective way possible. Such an ambitious project would weigh heavily on FDA's limited resources. The agency already bears vast responsibilities for overseeing the integrity of the nation's supply of food and beauty products, and for ensuring the safety and effectiveness of drugs and medical devices. The 1996 regulations amounted to a modest step with a limited aim; going far beyond them might push FDA into deep, uncharted, turbulent waters that the agency might not be prepared to navigate.

Perhaps a more prudent course of action would be to concentrate on the more manageable task of how to regulate reduced-risk cigarettes under the current statutory framework, a project on which FDA could utilize its expertise and experience in the fields of drug and device regulation. Despite the procedural obstacles they trigger, the provisions of the FDCA dealing with Class II medical devices seem to offer the best chance of reducing the tilt on the playing field where manufacturers of reduced-risk tobacco products and tobacco-dependence medications compete.


\textsuperscript{280} Some of the bills that have been introduced in Congress to effectuate the settlement are cited in note 160, \textit{supra}. See also S. REP. No. 105-180, 105th Cong., 2d Sess. (1998) (report on S. 1415). On a motion to close off debate, S. 1415 failed to attract the requisite number (60) of votes. See 144 CONG. REC. S6479 (daily ed. June 17, 1998). For a provocative criticism of the proposed settlement, see Jon D. Hanson & Kyle D. Logue, \textit{The Costs of Cigarettes: The Economic Case for Ex Post Incentive-Based Regulation}, 107 YALE L.J. 1163 (1998).