



THE FOOD AND DRUG ADMINISTRATION AND THE PROPOSED REGULATION OF CIGARETTES

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**THE FOOD AND DRUG
ADMINISTRATION
AND THE PROPOSED REGULATION
OF CIGARETTES**

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W[INTER TERM 1995

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INTRODUCTION

Congress enacted the first federal food and drug law in 1906, and broadened the (Food and Drug Administration's responsibilities in the 1930s with an expansive definition of drugs that included substances intended by their makers to affect the structure or function of the body.'

Since the 1930s the Food and Drug Administration (FDA) has taken broad Jurisdiction over everyday products in an attempt to ensure public health. Despite that mission, the FDA in particular and the Federal government in general has done little to regulate the tobacco industry. Recently, however, the Commissioner of the FDA, Dr. David A. Kessler, raised the possibility of regulating the cigarette industry.² But is the simple regulation of cigarettes permitted by the Federal Food, Drug and Cosmetic Act of 1938, which grants the FDA jurisdiction over products? Given the unanimity of opinion on the hazards of cigarette smoking, the answer to this question is no, and yet the conclusion that cigarettes must be banned seems too radical to seriously imagine. As a result, the context in which the FDA has approached cigarette smoking should be analyzed.

Public health officials and other health advocates have long warned our society of the dangers of smoking.³ Tobacco is the major cause of

Schwartz, 'FDA Targets 'Nicotine-Delivery Systems': Kessler's Agency Belatedly Zeroes In On Drug In Cigarettes, WASH. POST, May 31, 1994, at A1.
2 Testimony to Chairman Henry Waxman's Subcommittee on Health and the Environment of the House Energy & Commerce Committee on March 25, 1994. See also Letter from FDA Commissioner Dr. David A. Kessler to the Chairman of the Coalition on Smoking OR Health (Feb. 25, 1994).

~ Tobacco products' hazards are recognized to exist beyond reasonable scientific dispute. O'Reilly, A Consistent Ethic of Safety Regulation: The Case for Improving Regulation of Tobacco products, 3 Admin. L.J. 215, 216 (1989). See also U.S. Department of Health and Human Services, THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION- A REPORT OF THE SURGEON GENERAL, at 1(1988) (highlighting that cigarettes and other forms of tobacco are addicting, [nicotine is the drug in tobacco that causes addiction, [and] the pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine.); Wynder, Tobacco and Health: A Review of the History and Suggestions for Public Health Policy, 103 PUB.

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American adult respiratory illness, including lung cancer, heart disease, and related problems.⁴ In fact, tobacco related illnesses are the United States's major avoidable health problem.⁵ In recent years, this message has resonated with the American public and widespread regulation of smoking has been enacted at the local level.⁶ Ordinances have been adopted all over the country which ban or restrict smoking in public places, such as restaurants and government offices. At the federal level, however, the story has been very different: In spite of its well-established risks, tobacco has been untouchable at the federal level, due to, among other things, the influence of the powerful tobacco lobby, the loyalties of congressional lawmakers from tobacco-producing states, and continued consumer demand for tobacco products.⁷

Generally, regulation is a systematic method of risk control which is used as an alternative to the tort system for situations in which excessive costs or minimal net benefits result from our slow and costly tort system.⁸

HEALTH REP. 8 (Jan./Feb. 1988) (discussing background of a 1950 study of the effects of tobacco that showed cigarette smoking plays an important part in the etiology of lung cancer,

~ O'Reilly, *supra* note 3, at 218. See also U.S. Surgeon General, THE HEALTH CONSEQUENCES OF SMOKING: CANCER AND CHRONIC LUNG DISEASE IN THE WORKPLACE- A REPORT OF THE SURGEON GENERAL 1, 7 (1985); Benowitz, Pharmacologic Aspects of Cigarette Smoking and Nicotine Addiction, 319 NEW ENG. J. MED. 1318(1988) (stating that cigarette smoking is major risk factor for heart disease, stroke, and several types of cancers); U.S. Department of Health and Human Services, BIBLIOGRAPHY ON SMOKING AND HEALTH (1987) (containing a comprehensive bibliography of data sources establishing the effects of tobacco use).

O'Reilly, *supra* note 3, at 218.

⁶ Clmons, Federal Control of Tobacco: A Smoldering Issue Heats Up, L.A. TIMES, March 25, 1992, at A5.

Id.

~ O'Reilly, *supra* note 3, at 217. Policies favoring the use of regulation may... be justified by the information defects affecting the ways in which consumers can avoid injury, or may be justified by the spillover costs which are paid by society as a whole when the product injures a consumer who then draws on public assistance or social insurance funds, instead of attributing all costs back to the product manufacturer who created the risks. *Id.*, at 253 n.39 (citing Breyer & Stewart, ADMINISTRATIVE LAW AND REGULATORY POLICY 14-20 (1985)). See also Pierce, Shapiro, & Verkuil, ADMINISTRATIVE LAW & PROCESSES 11(1985) (asserting that regulation may also be used to address market failure in an inefficient market); Walsh &

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With respect to tobacco, individual consumers who are Injured by the product's effects cannot force industry participants to change their products through deterrence in the form of individual tort litigation. Tort law offers the Injured tobacco user high costs of gathering information and virtually no chance of expecting deterrence of Injuries even if recovery could be obtained in tort.⁹ Regulation, on the other hand, has lower information costs and obvious deterrent effects, and, therefore, is much more appealing to the federal official concerned about the effects of cigarette smoking.¹⁰

Local REGULATION

As previously discussed, local regulation of smoking has been generally accepted in this country for some time. Given the obvious risks and irritation of second-hand smoking, local governments have sought to confine smoking to areas that are either ventilated, isolated, or, at the very least, clearly designated as smoking areas. Using the health of the general public as a motivation, local governments have used their broad police powers to limit smoking, but have not attempted to sanction tobacco producers, due to lack of jurisdiction and, more importantly, sufficient political power.

State REGULATION

Each state could, theoretically, adopt a system of regulation of cigarettes as long as it was consistent with the state and federal constitutions. Such an approach, though consistent with the U.S.

Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 *FOOD DRUG COSM. L.J.* 171(1986).

O'Reilly, *supra note 3*, at 217. *See also* Singer, *Cigarette Papers*, 10 *AMER. LAW.* 91, 93 (May 1988) (stating that the cost of one major case was \$1,750,000 for plaintiffs, with \$600,000 in expert witness costs).

¹⁰ Health officials blame smoking for an estimated 434,000 deaths annually. Chen, *In Shift, FDA Says It Could Classify Nicotine as a Drug*, *L.A. TIMES*, Feb. 26, 1994, at A1. *See* O'Reilly, *supra note 3*, at 244.

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Constitution's 10th Amendment,¹² would almost certainly have devastating effects in terms of transaction costs (especially those of enforcement) and on individuals who are addicted to the habit of smoking.¹³ One could certainly foresee the tyranny of the majority creating smoking and non-smoking states, as well as the temptation for tobacco industry to get even more financially involved in state legislative politics. It is clear, however, that such a program would be difficult to implement and the health benefits would be seriously uneven.

METHODS OF FEDERAL REGULATION

Jurisdiction over the tobacco industry can be gained by Congress through the Federal Commerce Power contained in U.S. CONST. Art. I, § 8.¹⁴ Because tobacco is a product produced in mass quantities by a relatively small number of states, almost all tobacco is shipped over state lines and, therefore, subject to regulation by Congress. Given that strong basis for jurisdiction, it is surprising that the federal legislature's restrictions on smoking have been so limited.¹⁵ The most well-known federal restriction to

¹² The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the People. U.S. CONST. Amend. X.

Reserving for the moment the question of nicotine addiction.

Congress has the power to regulate Commerce ... among the several states. U.S. CONST. Art. I, § 8

Though given the strength of the tobacco lobby, the 700,000 American jobs that are directly related to tobacco, the 46 million smoking American citizens, and the relative strength of tobacco state legislators, it may not be so surprising. See Quindlen, Smoking, Health, Congress and a Canny FDA Chief, CHIC. TRIBUNE, March 4, 1994, at 23. As a poignant example of the inability to regulate tobacco, compare the absence of FDA control over tobacco, which is related causally to premature deaths among one out of six persons who die each year, with the outright ban on cancer-causing agents in colorants, although such colorants may have less than a one-in-one-million lifetime additional cancer risk. Seligman, Don't Bet Against Cigarette Makers, Fortune, Aug. 17, 1987, at 70-71. See also *Public Citizen v. Young*, 831 F.2d 1108, 1111 (D.C. Cir. 1987), *cert den*, 108 S.Ct. 1470 (1988) (comparing effect of dyes with one-in-one-million risk of causing cancer to one-in-200,000 risk of average male smoker's developing cancer).

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date on cigarette smoking has been the ban on smoking on certain airline routes and the mandatory installation of smoke detectors in airplane lavatories.

The lack of federal regulation on cigarette smoking has certainly not been due to a shortage of possible methods of regulation at the disposal of the Executive branch.¹⁶ I will examine four of them: the Controlled Substances Act, the Federal Hazardous Substances Act, The Federal Food, Drug, and Cosmetic Act's Device Regulations, and the Federal Food, Drug, and Cosmetic Act's Drug Regulations.¹⁷

CONTROLLED SUBSTANCES ACT

One method of regulating tobacco would be to declare tobacco a controlled substance under the Controlled Substances Act (CSA). Given the 1988 Surgeon General's finding that tobacco is an addictive substance,¹⁸ this would seem proper and would bring cigarettes into the control of the Drug Enforcement Administration, rather than the FDA.¹⁹ However, the

In addition, Congress has been urged to allow the Public Health Service to have administrative authority over the tobacco industry, but it has not done so. H.R. REP. No.

449. 89th Cong., 1st Sess. 2-3. reprinted in 1965 U.S. CODE CONG. & ADMIN. NEWS 2350,

2357-58. A House subcommittee voted 9-5 on Nov. 18, 1987 not to delete the tobacco exemption in the Consumer Product Safety Act. 1987 CONG. Q. ALMANAC 356 (1987). As a relevant aside, House members were paid \$104,000 in speaking fees by the Tobacco institute in 1988. O'Reilly, *supra note 3*, at 253 n.40 (citing Sarasohn, Luring Legislators, LEGAL TIMES, June 5, 1989, at 4). This discussion is meant to highlight the difficulty of Kessler's current attempt to regulate cigarettes.

THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION- A REPORT OF THE SURGEON GENERAL, *supra note 3*. See also Schwartz, FDA Panel says Nicotine is Addictive, WASH. POST, Aug. 3, 1994, at A1 (FDA Panel unanimously voted that the amount of nicotine delivered by currently marketed cigarettes is likely to lead to addiction in the typical smoker); *Infra*, discussion of addiction, 12-14.

This approach has the other, perhaps fatal, drawback that the DEA is already vastly overburdened with the War on Drugs. O'Reilly, *supra note 3*, at 240.

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Congress has granted an explicit exemption to the cigarette industry from the CSA, so, without congressional action, such an approach is bound to fail.²⁰

FEDERAL HAZARDOUS SUBSTANCES ACT

Another regulatory approach would be to declare cigarettes as consisting of hazardous substances, as defined in the Federal Hazardous Substances Act (FHSA). Though it has been found by a past Commissioner and Assistant General Counsel of FDA that FHSA cannot be applied to tobacco without the consent of Congress,²¹ such an approach ignores the reality that some of the substances that are contained in tobacco may be considered hazardous substances as defined in section 2(g) of the Act.²² The unwillingness of FDA in 1972 to assume jurisdiction under the FHSA was based on the assumption that Congress's enactment of the Federal Cigarette Labeling and Advertising Act of 1965 and the Public Health Cigarette Smoking Act of 1970 demonstrated an intent not to include tobacco under FHSA.²³ While politically prudent, it can be argued that this interpretation was a violation of the FDA's duty to ensure public health. The adoption of subsequent legislation that governs a substance does not invalidate the

²⁰ I have consciously omitted several other pieces of legislation, such as the Consumer Product Safety Act and the Toxic Substances Control Act, which have explicit exemptions for tobacco. The problem of requiring further Congressional action is common across these pieces of legislation.

²¹ Hearings on S. 1454 Before the Consumer Subcomm., 92nd Cong., 2nd Sess. 242, 245 (1972) (statements by Dr. Charles C. Edwards, FDA Commissioner, and Peter Barton Hutt, Assistant General Counsel for Food, Drugs, and Consumer Product Safety Division of FDA).

²² *Id.*, at 245 (statement of Mr. Hutt).

²³ *Id.*, at 242 (statement of Dr. Edwards).

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ability of previous legislation to gain authority over such a substance, unless so explicitly stated.²⁴

Though not favored by history or the FDA, FHSA's approach is appealing given the traditional lack of control over both tobacco itself and the substances added to cigarettes (which were not known, even to the public health agencies, for many years). A little more than a decade ago, under pressure from public health advocates, tobacco companies agreed to supply the Department of Health and Human Services with a complete list of ingredients that was to be checked for safety (though the list was kept from the public to prevent the revelation of trade secrets).²⁵ Recognizing that this supposed guarantee of public health was doing little or nothing to curb the addition of hazardous substances, health advocates widely publicized the fact that cigarette smoke was found to contain acetone, ammonia, arsenic, benzene, carbon monoxide, and cyanide, which are all poisonous in sufficient amounts.²⁶

To further deflect public criticism, RJR Reynolds recently released a list of some 600 substances contained in or added to cigarettes.²⁷ Industry officials said the list proved that nothing added to tobacco products is

²⁴ assume that there is no explicit exemption for tobacco due to the lack of any citation in the hearing. It is, however, suggested by the Department of HEW that the legislative history of FHSA demonstrates a lack of contemplation of cigarettes. *Id.* at 240 (statement of Dr. Edwards). This point seems to me to be irrelevant because, in no way, does it matter what form these hazardous substances are in as long as they affect public health. It appears to me that such an approach is an excuse not to govern cigarettes, rather than a valid interpretation.

²⁵ Schwartz, 1981 Report on Tobacco is Released Nicotine Study Seems to Contradict Claims, WASH. POST, April 14, 1994, at A3. *See* Let Congress Break the Tobacco Habit. CHIC. TRIBUNE, July 5, 1994, at 14 (While tobacco companies complain of being overregulated, cigarettes themselves are largely unregulated. The only people who know what goes into them are the manufacturers.).

Monk, Nicotine Boosting Alleged: FDA Head Tells of Cigarette Plot, DETROIT FREE PRESS, June 22, 1994, at A1.

²⁷ Schwartz, *supra* note 25, at A3.

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unsafe. RJR had previously asked six outside toxicologists to review the substances. The panel reported that the substances are not hazardous to the consumer in the manner in which they are used nor are they hazardous in the amounts in which they are used.~ This finding is in direct conflict with the statement of former FDA Assistant General Counsel Hutt:

If cigarettes were placed under [FHSAJ... I think the [Commissioner] and I would agree that they would then fall within the definition of toxic in section 2(g) of the act, in that they would produce illness as a result of inhalation. The only determination we would then be in a position to make [under section 2(q) of the act] would be whether cigarettes would be required to be banned under the banned hazardous substances provision.... [T]here is no one who knows what a safe level of inhalation of cigarette smoke or components is. As a result, if the Congress did place cigarettes under the FHSA, we would have no alternative but to declare them banned hazardous substances and make them illegal~

Given the resistance of the FDA to apply the FHSA, it is unlikely that the FHSA, as currently constituted, provides a sufficient vehicle to regulate tobacco products. In addition to recognizing this reality, the public health community has noted the difficulty of demonstrating conclusively that obviously minuscule amounts of dangerous ingredients in tobacco are insufficient to take a product as popular as cigarettes off the market?~

FEDERAL FOOD, DRUG, AND COSMETIC ACT OF 1938

In 1972, FDA Commissioner Dr. Charles C. Edwards gave his Interpretation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) authority over cigarettes:

Cigarettes and other tobacco products would be drugs subject to the [FD&C Act] if medical claims are made for the product. *United States v. 46 Cartons... Fairfax Cigarettes*, 113 F.Supp. 336 (1952). We have on occasion proceeded against cigarettes recommended for use in controlling appetite or otherwise recommended as a weight reducing aid. *United States v. 354 Bulk Cartons... Trim Reducing Aid Cigarettes*, 178 F.Supp. 847(1959). However, cigarettes recommended for smoking pleasure are

²⁸ *Id.*

²⁹ Statement of Mr. Hutt, *supra note 21*, at 245 (emphasis added).

³⁰ See Schwartz, *supra note 25*, at A3.

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beyond the [FD&C Act]. In *Federal Trade Commission v. Liggett and Myers Tobacco Company*, 108 F.Supp. 573 (1952), it was held that cigarettes are not drugs within the meaning of the act unless a therapeutic purpose is claimed. Indeed, if cigarettes were to be classified as drugs, they would have to be removed from the market because they were safe for their intended use.

Until Dr. Kessler's statement to Congress 22 years later, this statement, for all practical purposes, remained the approach of the FDA.³²

On May 26, 1977, a coalition of anti-smoking groups led by an organization called Action on Smoking and Health (ASH) filed a citizen petition with the FDA requesting that the agency assert jurisdiction over cigarettes as a drug or device; that the FDA regulate cigarettes no less strictly than it did saccharin, and that the agency restrict the sale of cigarettes to pharmacies. ~ FDA Commissioner Donald Kennedy refused to assert such jurisdiction based on the same rationale as his predecessor Dr. Edwards had 5 years earlier. In response to the contention of the petitioners that cigarettes fall squarely within the statutory definition, ~ Kennedy responded:

The petitioners have presented no evidence that manufacturers or vendors of cigarettes represent that the cigarettes are intended to affect the structure or any function of the body of man... 21 U.S.C. 321 (g)(1)(XC). Statements by petitioners and citations in the petition that cigarettes are used by smokers to affect the structure or any functions of their bodies are not evidence of such intent by the manufacturers or vendors of cigarettes.. .?~

The D.C. Circuit Court picked up on the same theme, but with an important ~ Statement of Dr. Edwards. *supra note 21*, at 239 (emphasis added). See also *Action on Smoking and Health v. Califano*, Civ. No. 78-338 (D.C. Cir. 1979) (deferring to FDA Commissioner's interpretation that absent vendor's assertion of therapeutic claim, no jurisdiction would be applied).

³² Dr. Kessler, despite his apparent change of policy, still stated in his Feb. 25 1994 letter that: The FDA's fundamental position remains unchanged: Tobacco is not a food and is not a drug and as such has special regulatory protection. FDA Considers Classification of Nicotine as Drug, CHIC. TRIBUNE, Feb. 26, 1994, at 4.

³³ *Action on Smoking and Health v. Harris*, 655 F.2d 236 (DC Cir. 1980), reprinted in Hutt & Merrill, FOOD AND DRUG LAW 382 (2nd. ed, 1991).

~ *Id.*

~ *Id.* (citing Letter from FDA Commissioner Donald Kennedy to Action on Smoking and Health (Dec. 5, 1977)).

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qualification:

Unlike petitioners, we do not read these statements to mean either that the Commissioner will never consider evidence of consumer intent on this question... Rather, by failing to introduce any evidence of vendor's intent - whether based upon subjective vendor claims or objective evidence such as labeling, promotional material, and advertising - ASH placed itself in the position of having to meet the high standard established in cases where the statutory intent is derived from consumer use alone. Clearly, it is well established that the 'intended use' of a product, within the meaning of the Act, determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source. Whether evidence of consumer intent is a relevant source for these purposes depends upon whether such evidence is strong enough to justify an inference as to the vendor's intent. This requires a substantial showing... ~36

REGULATE THE CIGARETTE AS A DEVICE UNDER THE FD&C ACT

The FDA could possibly regulate a cigarette as a nicotine delivery system or more simply as a device, as defined in section 201(h) of the FD&C Act, which states, in pertinent part: [the term 'device' ... means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended ... to affect the structure or any function of the body of man or other animals.³⁷

Under section 513(a)(1)(C), cigarettes would certainly be categorized as a Class III device, which would require pre-market approval before cigarettes could be sold. The FD&C Act states, in relevant part:

CLASS III, PREMARKET APPROVAL. - A device which because -

(I) it cannot be classified as a class I device because insufficient information exists to determine what the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine what the specific controls ... would provide reasonable assurance of its safety and effectiveness, and... (II) presents a potential unreasonable risk of illness or injury, is to be subject, in accordance with section 515, to pre-market approval to provide reasonable assurance of its safety and effectiveness?⁸

~ *Id* (emphasis added).

~ **See, e.g., *United States v. 23... Articles***, 192 F.2d 308(2nd Cir. 1951) (describing the

application of § 201(h) to phonograph records intended to induce sleep), *reprinted in* Hutt &

Merrill, *supra note* 33, at 723.

~ FD&C Act, § 513(a)(1)(C).

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Though this language clearly would endanger the continued sale of cigarettes?⁹ the complexity of the process over and above that involved in declaring nicotine a drug would be substantial.⁷

As a matter of interest, it should be noted that many other forms of devices which deliver nicotine to consumers are already regulated by the FDA.⁴¹ To say that cigarettes are different is a legal fiction, if it is assumed that nicotine is intended to be addictive (as I will soon discuss).⁴²

REGULATE NICOTINE AS A DRUG UNDER THE FD&C ACT

The other alternative offered by the FD&C Act, and certainly the more promising in terms of regulating cigarettes, is to regulate nicotine as a drug.

Especially given the dictates of FD&C Act § 51.5(b)(2), which states The Secretary shall deny approval of an application for a device if ... the Secretary finds that ... there is a lack of showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended or suggested in the proposed labeling thereof...

⁴⁰ Dr. Kessler did raise the possibility of considering some cigarettes as "high technology nicotine delivery devices" in his March 25, 1994 testimony before Congress. Schwartz, Kessler Tells Committee FDA May Act to Regulate Tobacco Products' Content: Agency Wants Guidance from Congress, WASH. POST, March 26, 1994, at A3. See also Schwartz, *supra note 1*, at A1; Feb. 25, 1994 letter, *supra note 2*.

⁴¹ Hutt & Merrill, *supra note 33*, at 381 n.2. See, e.g. Regulatory Letter No. 87-HFN-312-06 from Director of the Office of Compliance in the FDA Center for Drugs and Biologics D.L. Michels to Director of Advanced Tobacco Products J.P. Ray (Feb. 9, 1987) (stating that "Favor Smokeless Cigarettes, a hollow paper tube with nicotine in the mouthpiece but containing no tobacco, was a drug because it was represented to deliver an amount of nicotine comparable to that of conventional cigarettes and to produce the same nervous system effects"); Hutt & Merrill, *supra note 33*, at 381 n.2. (stating that the FDA approved a New Drug Application for Nicorette, which is indicated as a temporary aid to the cigarette smoker seeking to give up his or her smoking habit...); Waldholz & Helyar. FDA Feels Heat on Smokeless Cigarette, WALL ST. J., Oct. 21, 1988, at B1 (stating a nicotine inhaler is a far more effective delivery mechanism for an addictive drug than a cigarette); Health Consequences of Smoking: Nicotine Addiction: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 100th Cong., 2d Sess., 163-64 (1988) (statement of Dr. John Slade) (stating that the nicotine inhaling device will be the most addictive form of nicotine ever devised). See also Editorial, N.Y. TIMES, Mar. 3, 1989, at A38 (stating that the withdrawal of RJR Nabisco's Premier smokeless cigarette had prevented the FDA from declaring whether the device would have been termed a drug delivery system.)

⁴² Proof of addiction destroys the foundation of the argument that cigarettes are different and leave[s] lobbying power as the sole determinant of differential

treatment. O'Reilly. *supra* note 3, at 223.

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The FD&C Act defines a drug, in pertinent part, as articles (other than food) intended to affect the structure of the body of man or other animals. FD&C Act § 201(g)(1)(C). To regulate cigarettes, therefore, the FDA must demonstrate two elements: first, that nicotine affects the structure of the body, which can be proved by evidence of its addictive quality; and, second, that cigarette manufacturers intend for the addictive quality to be an element of their product.

Anw'rs THE STRUCTURE OF THE BODY

In his February 25, 1994 letter to the chairman of an anti-smoking organization, FDA Commissioner Kessler stated that 77% of smokers desire to quit but cannot, primarily because of nicotine addiction.~ Since the 1988 study of nicotine addiction undertaken by the Surgeon General, such statements are uncontroversial.~ Addiction, as opposed to a habit, is, without question, an affect on the structure of the body, as contemplated in FD&C Act's section 201(g)(1)(C).

Despite the strong evidence of the addictive quality of nicotine, Kessler appointed a special FDA panel to study the issue of nicotine addiction. By not accepting the widespread view that nicotine was addictive and referring it to a panel, Kessler demonstrated a willingness to question all the evidence supporting the regulation of nicotine as a drug, a tactic which certainly would make it harder to dismiss the FDA's findings as a rush to judgment. When the panel reported back in August of 1994, the panel voted unanimously that the amount of nicotine delivered by current cigarettes [is!

⁴³Chen, *supra* note 10, at A1.

See THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION- A REPORT OF THE SURGEON GENERAL, *supra* note 3, at I.

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likely to lead to addiction In the typical smoker. ~ The findings of the panel were disputed by only the most adamant tobacco supporters but were hailed as definitive by organizations such as the American Medical Association. ~

Perhaps the most damaging information on the subject of addiction came from within the tobacco industry itself.⁴⁷ A 1963 document from British-American Tobacco Company ifies stated: Chronic intake of nicotine tends to restore the normal physiological functioning of the endocrine system. so that ever-increasing dose levels of nicotine are necessary to maintain the desired action. ~ Another 1963 memo, which was from Brown & Williamson's General Counsel Addison Yeaman, stated that We are, then, in the business of selling nicotine, an addictive drug effective in the release of stress mechanisms.⁴⁹ A supervisor of research at Phillip Morris in 1972 wrote: 'Think of the cigarette pack as a storage container for a day's supply of nicotine. Thing of the cigarette as a dispenser of a dose unit of nicotine. ~ In April of 1994, 2 former scientists for Philip Morris testified to a House panel that:

their studies on rats more than a decade ago indicated that nicotine was highly addictive. The laboratory was also working on [addictive] drugs that could give nicotine's kick without Its harmful cardiovascular effects. Phillip Morris kept the researchers from publishing the research and abruptly closed down their

~ Schwartz, *supra note 18*, at A1. The panel said that the 10-15 percent of smokers who smoke 5 cIgarettes or fewer a day do not appear to be addicted. Neal Benowitz of UCSF and David Sacha of the Paito Alto Center for Pulmonary Disease Prevention believe[dl that 5 mg of nicotine a day would not addict anyone. *Id.* Alice Young of Wayne State University pointed out that currently addicted smokers might increase their intake of cigarettes (and thereby receive a higher amount of tar) If the amount of nicotine in cigarettes were reduced. *Id.* 46 A Growing Tide Against Smoking: AIvIA Urges Tobacco Be Viewed as Addictive Drug. L.A. TIMES, June 8, 1994, at B4.

~ This chink in the armor of the tobacco industry has become a key factor behind the tobacco regulation movement's success.

48 FDA Chief Says Nicotine is Bolstered Genetic, Chemical 'Manipulation' of Tobacco by Companies Charged, BOS. GLOBE, June 22, 1994, at 1.

~ Schwartz, Internal Papers Fuel Tobacco Debate Cigarette Firms May Face Turning Point in Regulation, Litigation, WASH. POST. May 14, 1994. at A1.

50 Schwartz, *supra note 1*, at A1.

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lab in 1984.

The tobacco industry had long contended that smokers chose their habit freely; nicotine addiction, however, would eliminate that choice. Knowledge of that fact raised serious questions about the intent of the tobacco companies.

INTENDED TO AFFECT

The FDA has long recognized that nicotine in tobacco produces druglike effects, but that's not enough to give it jurisdiction;⁵² the second prong of the test of § 201(g)(1)(C) must also be fulfilled, especially given the benefit of the doubt that the FDA has traditionally given cigarette manufacturers.⁵⁸ As of this writing, Commissioner Kessler has not concluded whether cigarette makers intend to addict smokers to nicotine,⁵⁹ but he did state in his Feb. 25, 1994 letter that evidence brought to our attention is accumulating that suggests cigarette manufacturers may intend that their products contain nicotine... to achieve drug effects in some smokers. This evidence is exactly the kind of any other relevant source that the D.C. Circuit in *Action on Smoking and Health V. Hanis* claimed could show intent on the part of tobacco manufacturers to affect the structure of the body.

~ *Id.*

⁵² McGinley, *The Trials of Tobacco: What David Kessler Wants And How He'll Try to Get It*, WALL ST. J., June 23, 1994 at B1.

⁵⁸ Kessler wrote in his Feb. 25, 1994 letter that the FDA has traditionally given cigarette vendors the benefit of the doubt as to whether they intend cigarettes for this purpose, because some people smoke for other than the drug effect. Schwartz, *In Policy Shift, FDA is ready to Consider Regulating Tobacco*, WASH. POST, Feb. 26, 1994. at A4.

⁵⁹ McGinley. *supra note 52*, at B 1. In my opinion, however, It is unlikely that he will do so in the near future, as I will later discuss.

~ Schwartz, *supra note 49*, at A1.

⁵⁶ 655 F.2d 236 (DC Cir. 1980). Dr. Kessler has stated that, because tobacco companies manipulate and control the level of nicotine in their cigarettes, such evidence could be used as a kind of gauge of their intentions. McGinley, *supra note 52*, at B1.

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The evidence relating to Intent is, indeed, becoming quite substantial. Besides the addiction data that the industry held back from the public, Dr. Kessler suggested that the tobacco companies had experimented with high-nicotine tobacco plants, used ammonia to boost the impact of nicotine, and manipulated nicotine levels because of its addictive quality.⁵⁷ In his House Energy and Commerce subcommittee testimony, Commissioner Kessler stated that several tobacco companies had cultivated a specially-engineered high-nicotine yield tobacco plant, known as Y-1, at overseas locations.⁶ He further accused Brown & Williamson of formulating its cigarettes with a 10 percent portion of Y-1 leaves. In response, B&W admitted to having stored 3.5 million pounds of imported Y-1 leaves in a U.S. warehouse, despite representations to the FDA, only 2 months before, that it did not try to breed high-nicotine tobacco.

Dr. Kessler also asserted that FDA had evidence that many U.S. tobacco companies inserted ammonia into cigarettes in order to 'almost double' the amount of nicotine that gets into smokers' blood.⁶¹ The companies claimed that ammonia merely adds to the flavor or preserves the cigarettes.⁶² Kessler responded by stating that the findings lay to rest any notion that there is no manipulation and control of nicotine undertaken in the tobacco industry.⁶³

⁵⁷ Let Congress Break the Tobacco Habit, *supra note* 25, at 14.

⁶ Monk, *supra note* 26, at A1.

⁵⁹ *Id.*

⁵⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

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The tobacco industry conceded that they have the technology to

control nicotine during the manufacturing process, but that it is used only

to ensure the taste and to reduce levels of tar and other unhealthy materials.⁶⁷ The validity of such a claim was attacked openly by both Kessler and the Congress. Kessler testified that cigarette company scientists had done research that showed certain substances, including citric acid and spicy pepper extract, could act as [taste] substitutes for nicotine, giving the same characteristic burn in the throat.⁶⁵

U.S. Rep. Henry Waxman produced a 1981 study by researcher Alexander Spears, which indicated that companies have long manipulated the levels of nicotine in cigarettes. Industry officials have responded that their manipulation of nicotine, rather than being based on some sinister intent, has attempted to provide consistent products and conformity with

• federal truth-in-labeling requirements. ⁶⁷ With the advent of low-tar cigarettes, Spears testified to Waxman's House panel that nicotine has increased in direct relation to the decrease in tar.⁶⁶ But FDA researchers and Spears's own 1981 study, found that nicotine and tar levels [are] not directly related and that low-tar cigarettes provide] the highest yield of nicotine.⁶⁷ In direct contrast to his Congressional testimony, Spears wrote in the 1981 study that: Current research is directed toward increasing the **nicotine levels while maintaining or marginally reducing tar deliveries.**⁷⁰

⁶⁴ Let Congress Break the Tobacco Habit, *supra note 25*, at 14

⁶⁶ Schwartz, The Paradox: How Can Tobacco Ever Be Considered Safe? WASH. POST, May 31,

1994, at All.

⁶⁶ Schwartz, *supra note 25*, at A3.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

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In Dr. Kessler's words, such evidence of past and current manufacturing practices suggests that cigarette vendors intend the obvious-that many people buy cigarettes to satisfy their nicotine addiction.⁷¹ If FDA concludes that this is the case, the second prong of § 20 i(g)(I)(C) will be fulfilled and nicotine will be concerned a drug for the purposes of the Federal Food, Drug and Cosmetic Act of 1938.

DOEs 1113 FDA HAVE A DUTY TO B~w m DRUG NIco'rmE?

A few months after being confirmed as FDA Commissioner in 1990 David Kessler held a strategy meeting concerning tobacco. At that meeting, he recognized the difficulty of asserting Jurisdiction over the product, especially when some of the old hands stated simply It's a fool's mlssion.~ The majority present, however, stated they were willing to take a shot.⁷³ When the shot came in February of 1994, the defensive reaction of the tobacco companies was typified in the statement: I don't know what they could be talking about.⁷⁴ When Kessler testified before Congress in March of 1994, that shot landed and made a deep crater.

Kessler's approach was a well-calculated strategy. By writing to a leading anti-smoking activist in February of 1994, he put that community on notice that something was going to be done about smoking. But he might

have been **doing something else: preventing a new petition to FDA** requesting

that the agency declare cigarettes a drug and ban them. In 1980, the D.C. Circuit threw out a challenge to the FDA's decision not to regulate cigarettes

⁷¹ Schwartz, *supra note* 49, at Al.

⁷² Schwartz, *supm note* 1, at Al.

⁷³ *Id.*

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as a drug, due to a lack of evidence concerning the manufacturers intent;Th today, such information is much more plentiful, as I have described, and, in fact, it **seems quite possible that a reasonable trier of fact would conclude** that the tobacco industry, or at the very least parts of it, had the requisite intent. Such a ruling would probably force FDA to ban cigarettes and would force Congress, on the panic-stricken brink of a new age of prohibition, to produce new legislation regulating cigarettes .

In 1972, FDA Assistant General Counsel Peter Barton Hutt stated that Congressional legislation was necessary to provide jurisdiction over cigarettes; once jurisdiction was granted, cigarettes would have to be banned pursuant to the Federal Hazardous Substances Act. Though Dr. Kessler suggested in 1994 that he could foresee some type of regulation of cigarettes rather than an outright ban, it is clear from his careful testimony that he was aware that, if he concluded nicotine is a drug, he would arguably have the statutory duty to ban cigarettes.tm There are two possible ways Kessler could avoid banning cigarettes and simply regulate them: get a Congressional directive or creatively read the FD&C Act. For legitimacy reasons, the former is obviously much preferred to the latter.

~ *Id* (statement of Walker Merryman, Director of Communications for the Tobacco Institute). ⁷⁵ *Action on Smoking and Health v. Harris*, 655 F.2d 236 (DC Cir. 1980).

~ I think it is relatively uncontroversial to say that such times are not well-suited to complex policy decisions. It is quite likely, actually, that the backlash against the court's ruling would provide the smoking lobby to gain an outright exemption for tobacco.

Statement of Mr. Hutt, *supra note 21*, at 245.

~ See Quindien, *supra note 15*, at 23. See also Statement of Dr. Edwards, *supra note 21*, at 239 (if cigarettes were to be classified as drugs, they would have to be removed from the market because it would be impossible to prove they were safe for their intended use). U.S. Rep. Thomas Bliley Jr.'s spokesman stated that even though anti-tobacco forces insist they do not want to ban tobacco, 'if they get it under the FDA it would be a de facto ban.' Schwartz, *supra note 65*, at A1. U.S. Rep. Henry Waxman put it more bluntly: unless Congress acts, FDA is going to have only one option: ban cigarettes, since the FDA cannot approve a drug that is known to be unsafe. Chen, *supra note 10*, at A1.

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Through his testimony of March 25, 1994 and his letter of Feb. 25, 1994, Commissioner Kessler sent an implicit warning to the Congress: Act or FDA will. By demanding action, the Commissioner was able to shift attention away from the traditional bad guy (the cigarette) and put the focus on nicotine and the cigarette manufacturers. By threatening their livelihoods without actually taking any action, Kessler, in effect, dared the tobacco giants to either propose some system of reduced nicotine in cigarettes or seek an exemption from the Congress from the FD&C Act.

Both Mr. Hutt and Dr. Kessler were asking the federal legislature to take a stand on tobacco. In 1974, Mr. Hutt was stating, in effect, If you want FDA to have jurisdiction over cigarettes, we will ban them, unless Congress gives us some guidance. What Dr. Kessler is saying now is FDA will reluctantly declare nicotine a drug and will attempt to regulate it (though there is a small possibility we might have to ban it unless Congress gives us some guidance). The implied threat of the latter and the direct line of the former both have the same fundamental message to the Congress, take the lead on tobacco.~

By tempering his comments and stating that he could see simply regulating tobacco, Kessler may have been trying to avoid all-out war with the tobacco Industry, but, at the same time, he was recognizing a

fundamental truth: we cannot ban tobacco outright. Approximately 46 million Americans are smokers, and, of this number, we can estimate that

~ In U.S. Rep. Henry Waxman's words, Kessler's position will require us to do a lot of thinking and force Congress to figure out a more rational scheme for handling tobacco. Chen,supranote 10, atAl.

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40 to 42 million of them are addicted to nicotine.~ Regulating tobacco alone would have dramatic effects on society; banning tobacco would return us to the nightmare of Prohibition with predictably similar results.⁸⁷ For this reason, during the last Congressional session, U.S. Representatives Richard Durbin, Mike Synar, and Ron Wyden tried to attach an amendment to an agricultural bill that would have given FDA authority over cigarettes.~ It failed.

FDA Commissioner David Kessler has to make that threat of FDA action on cigarettes real again by turning up the rhetoric and forcing the Congress to react?6 If he doesn't or if he tries to regulate nicotine without Congressional support, it will be much more difficult for our society to break free of the nicotine habit?'

~ See Schwartz, *supra note* 18, at A1.

⁸¹ McGinley, *supra note* 52, at B1.

⁸² Clmons, *eta*), Quick House Vote Sought on Regulation of Tobacco- Congress: The Legislation would require the FDA to control the substance but prohibit the agency from banning cigarettes, LA. TIMES, June 14, 1994, at A12.

⁸³ Most likely with legislation similar to that proposed by Durbin, Synar, and Wyden. Perhaps addiction would have been more appropriate, given the latest revelations from the tobacco industry.