“That really bothered me when I heard that more nicotine was going in to make sure that people were hooked.”

— President Bill Clinton, March 19, 1994

The Tobacco Industry’s Use of Nicotine as a Drug
What Do the Recent Revelations Mean for Tobacco Control?

by Clifford E. Douglas

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Introduction

On February 28, 1994, *Day One*, a magazine show produced by ABC News, aired an expose on the tobacco industry’s manipulation of nicotine. The segment (and a follow-up segment which aired on March 7, 1994) resulted from a year-long investigation by Pulitzer Prize-winning journalist Walt Bogdanich, a *Day One* producer and former *Wall Street Journal* reporter, and associate producer Keith Summa. The imminent airing of the first segment on a Monday prompted the release the preceding Friday of a remarkable letter by Food and Drug Administration (FDA) Commissioner David Kessler, announcing that in light of the new evidence the FDA would consider regulating tobacco products as drugs.\(^1\) While the FDA reportedly had been interested for some time in pursuing regulatory action against tobacco products, the information obtained by *Day One* provided the “hook” the FDA felt it needed in order to proceed.\(^2\)

The evidence uncovered by *Day One* and assembled by FDA investigators illustrates publicly for the first time the extent to which the tobacco industry is capable of and does in fact manipulate the amount and even the presence of nicotine in cigarettes. Before these recent revelations, nicotine generally was perceived to be merely a natural part of the tobacco leaf and an inevitable component of any tobacco product. The potential implication of the new disclosures is substantial.

After four years of independently investigating the subject of nicotine manipulation, I pitched the story to ABC in the fall of 1992 and provided assistance during the investigation. The information and insights offered in this paper come, in part, from this experience. Offered here are background on the investigation’s major findings, a look at the broader context in which the *Day One* story fits and an examination of some of the policy implications it raises.

Background

*The presence of nicotine in tobacco products makes them addictive and is the reason many people smoke despite the evidence of the deadly effects of tobacco use.*

Nicotine appears naturally in tobacco and is absorbed into the body when tobacco is smoked, chewed or sniffed. Nicotine has always been perceived as an inevitable part of the tobacco leaf. “If you used tobacco, you ingested nicotine.”

The role of nicotine in tobacco products has been studied for years. In the early 1980’s, a scientific consensus developed that cigarettes are not just habit-forming but addictive in the same way that drugs such as cocaine and heroin are addictive. This research resulted in an entire report by the U.S. Surgeon General devoted to the addictive nature of tobacco products and the central role that nicotine plays in causing that addiction. The release of the 1988 Surgeon General’s report silenced any lingering, credible scientific debate about whether tobacco products are addictive and whether nicotine is the substance in tobacco products that makes them addictive. The latest Surgeon General’s report on children and tobacco, issued on February 24, 1994, confirmed that the nicotine in tobacco products is responsible for the rapid addiction of up to half of all children who experiment with tobacco.
Nicotine’s impact on tobacco usage and the resulting epidemic of tobacco-related disease was examined in an editorial in *The Lancet*:

“The core of the problem lies in the addictiveness of nicotine. It is nicotine that people cannot easily do without, not tobacco; it is nicotine dependence that slows the progress of existing programmes. As a drug delivery system the modern cigarette is a highly efficient device for getting nicotine to the brain, but by pharmaceutical standards it is also a very ‘dirty’ one, the nicotine being contaminated with nitrosamines and other carcinogens in the tar, as well as with carbon monoxide and other harmful gases.”

Cigarette smoke contains such chemicals as arsenic (poison), ammonia (toilet cleaner), carbon monoxide (car exhaust fumes), methane (swamp gas), acetone (nail polish remover) and formaldehyde (used to preserve dead bodies), among thousands of others, and would remain a serious health risk in the absence of nicotine. In other words, taking nicotine out of cigarettes would not make them safe. However, relatively few people would use nonaddictive tobacco products and thus few would subsequently face exposure to these other harmful chemicals. Furthermore, new smokers (mainly adolescents) would not become addicted in the first place.

*The FDA regulates nicotine when included in other products but has not regulated it in tobacco products.* [*Favor, a nicotine delivery system produced by Advanced Tobacco Products, was an exception to this rule. It was regulated by the FDA on the basis of its nicotine content.*]

Federal law gives the FDA regulatory authority over food, drugs and cosmetics. Certainly, tobacco products (cigarettes, chewing tobacco, snuff, etc.) are not considered foods under the law. Nor have they been considered as drugs, as defined by the FDA. To conclude that a product is a drug, the FDA has held that a the product must not only affect the structure and function of the body; in additon, the seller (manufacturer) must intend it to do so. Thus, the FDA has determined that cigarettes which are advertised and sold “for smoking pleasure only” are not drugs.

Even so, the FDA has long recognized nicotine as both an addictive and toxic substance. As a result, the FDA tightly regulates the sale and use of nicotine in all forms and in all products (i.e., nicotine gum or nicotine patches) except when sold for “pleasure” as part of a tobacco product. Until now, the FDA’s rationale for not regulating nicotine when sold as part of a tobacco product has been that there is inadequate evidence that nicotine in tobacco products is sold with the intent to have a pharmacologic effect on the body.

*The tobacco industry knows that nicotine is addictive.*

Internal tobacco industry documents made public during the trial in *Cipollone v. Liggettt* in the 1980’s demonstrate the industry’s understanding of the central role that nicotine plays in causing and sustaining addiction. For example, an internal report written in 1972 by William L. Dunn, Jr., a senior scientist with the Philip Morris Tobacco Company, says the following:
“As with eating and copulating, so it is with smoking. The physiological effect serves as the primary incentive; all other incentives are secondary. Without nicotine, the argument goes, there would be no smoking. Some strong evidence can be marshaled to support this argument: (1) No one has ever become a cigarette smoker by smoking cigarettes without nicotine. (2) Most of the physiological responses to inhaled smoke have been shown to be nicotine-related.

“Why then is there not a market for nicotine per se, to be eaten, sucked, drunk, injected, inserted or inhaled as a pure aerosol? The answer, and I feel quite strongly about this, is that the cigarette is in fact among the most awe-inspiring examples of the ingenuity of man....

“The cigarette should be conceived not as a product but as a package. The product is nicotine. The cigarette is but one of many package layers. There is the carton, which contains the pack, which contains the cigarette, which contains the smoke. The smoke is the final package. The smoker must strip off all these package layers to get to that which he seeks....

“Think of the cigarette pack as a storage container for a day’s supply of nicotine.... Think of the cigarette as a dispenser for a dose unit of nicotine.... Think of a puff of smoke as the vehicle of nicotine.... Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke.”

Moreover, it was not disclosed until March 1994 that Philip Morris Inc.’s own researchers prepared a paper in 1983 — five years before the Surgeon General’s landmark report on addiction — reporting that nicotine had been found to be highly addictive in rats. The report was peer reviewed and accepted for publication in a respected scientific publication, *Psychopharmacology*, but then withdrawn on the company’s orders. Subsequently, Philip Morris closed the researchers’ laboratory and destroyed evidence of their work.

In their defense, the major cigarette manufacturers have argued of late that their products contain less nicotine now than they did in the 1950’s. This appears to be false. In 1952, the FDA found that the tobacco from the five leading cigarette brands contained an average of 1.58 - 1.82 percent nicotine on a dry weight basis. This was less nicotine than the 1.5 - 2.5 percent nicotine reported for finished cigarettes by R.J. Reynolds Tobacco’s (RJR’s) chief executive James Johnston in a March 1994 letter to the FDA.

Despite the evidence of the addictive nature of tobacco and the tobacco industry’s awareness of the role of nicotine, neither Congress nor the FDA have yet altered their traditional hands-off approach to regulating tobacco. This may soon change, however, in light of the new evidence. The FDA is considering its options, and Congress is holding hearings and starting to address these issues.

**More on the Nature and Extent to Which Tobacco Manufacturers Manipulate Nicotine**

While it has been known for some time that tobacco manufacturers have some control over
nicotine, the new evidence shows that:

- Tobacco manufacturers have the capability to remove all or virtually all of the nicotine from their tobacco products using technology already in existence.

- They currently remove substantial quantities of the nicotine from tobacco, manipulate the extracted nicotine and then apply it to the final manufactured product in carefully controlled, precisely measured quantities. According to experts in the tobacco manufacturing process, leading cigarette brands contain a significant percentage of nicotine that was previously extracted from tobacco, manipulated and reapplied. A lawyer for RJR testified before Congress that approximately 70 percent of the nicotine contained in the company’s ill-fated nicotine delivery device, Premier (which some observers inaccurately dubbed a “smokeless cigarette”), consisted of separately added nicotine extract.
  - Tobacco manufacturers add substantial quantities of nicotine to their products that they have purchased from other sources, including firms which specialize in extracting and processing nicotine and other substances.

  In a nutshell, what this means is that while nicotine appears naturally in raw tobacco, it is no longer an unavoidable component of a cigarette product. Today, tobacco manufacturers consciously manipulate nicotine during the manufacturing process. They add nicotine to the processed tobacco and other contents of the manufactured product.

  While manufacturers have used a number of euphemisms to describe the role of nicotine, there is widespread agreement in the medical and scientific communities that its primary function is to make the product addictive.

*The Tobacco Reconstitution Process*

It has long been known that tobacco manufacturers prepare a substantial portion of the contents of their cigarettes through what is called the “reconstitution” process. What has not been known is the extent to which manufacturers could remove all or virtually all of the nicotine and the fact that in some cases the manufacturers are boosting the quantity of nicotine found in the reconstituted tobacco beyond the level which would otherwise be found there.

One reason why tobacco manufacturers use nicotine extracted from tobacco is that in its natural state, the nicotine in the tobacco leaf is distributed in uneven concentrations. By extracting the moisture from tobacco, including nicotine, manipulating it and spraying the extract evenly across the reconstituted tobacco sheet, manufacturers are able to control the precise amount of nicotine and provide a smoother, more consistent drug delivery per puff. This process also saves manufacturers money, in part because it enables them to use substantial amounts of reconstituted tobacco (consisting of tobacco leaf scraps and stems, dry tobacco dust, adhesive, reinforcing fibers, mineral ash modifiers, humectants and other inexpensive material) and less actual tobacco, which is the most
expensive part of the cigarette.

LTR Industries, a subsidiary of Kimberly-Clark Corporation, specializes in the tobacco reconstitution process and, as the company says, in helping tobacco companies control their nicotine. The LTR reconstitution process is used around the world. An LTR advertisement published in tobacco industry trade publications states:

“Nicotine levels are becoming a growing concern to the designers of modern cigarettes, particularly those with lower ‘tar’ deliveries. The Kimberly-Clark tobacco reconstitution process used by LTR INDUSTRIES permits adjustments of nicotine to your exact requirements. These adjustments will not affect the other important properties of customized reconstituted tobacco produced at LTR INDUSTRIES: low tar delivery, high filling power, high yield and the flexibility to convey organoleptic modifications. We can help you control your tobacco.” (Emphasis added.)

As noted in the chapter on nicotine delivery devices in Nicotine Addiction Principles and Management, fortification (i.e., the addition of nicotine) of the reconstituted tobacco sheet with nicotine is a routine part of the LTR process. The chapter states that: “The use of nicotine as an additive permits precise titration of the amount of this alkaloid in the finished product.” This process is also described in the tobacco industry’s own trade literature, which explains that LTR’s process enables manufacturers to triple or even quadruple the nicotine content of reconstituted tobacco, thus substantially increasing the level of nicotine contained in the final manufactured product. In addition, tobacco industry patents, cited by FDA Commissioner David Kessler in testimony before Congress, describe the manipulation of nicotine in tobacco products.

Another enterprise evidently specializing in the manipulation of nicotine and use of the drug as an additive is the Contraf Group. A recent advertisement run by Contraf in the international tobacco trade press says, “Don’t Do Everything Yourself! Let us do it More Efficiently!” Referring to itself as “The Niche Market Specialists,” the company lists among its areas of specialization one dealing with “Pure Nicotine and other special additives.”

Information Sources

The evidence of the extent to which tobacco manufacturers are able to extract nicotine and the extent to which they add nicotine purchased from outside suppliers comes from at least three sources.

1. Information concerning the tobacco reconstitution process is described in technical articles and industry publications.
2. Information uncovered in ABC’s Day One investigation documents the industry’s purchase of nicotine from outside suppliers, the importation of nicotine from abroad, the processes used for extracting and reapplying nicotine and the manner in which the industry has sought to avoid
public discussion of its use of nicotine extract.

3. A former RJR manager corroborated some of the key findings made by ABC, stating in a taped interview that the tobacco companies “put nicotine in the form of tobacco extract into a product to keep the consumer happy.” He elaborated by describing how manufacturers control the amount of tobacco extract added to reconstituted tobacco to achieve specific nicotine levels. ABC reported that this high-level source had firsthand knowledge of the use of nicotine in the manufacturing process which was previously unavailable to the public.

Also important is the tobacco industry’s inclusion of “tobacco extracts” as #552 of the 599 additives identified in a list released publicly by RJR on behalf of the six major American cigarette companies on April 12, 1994. The industry’s additives list defines tobacco extracts in a carefully worded way, stating that this additive “produce[s] no measurable increase in nicotine in cigarettes.” The industry consistently adopts a misleading approach to the issue, arguing that what matters is that there is no more nicotine included in the final product than would have been there naturally.

What actually matters is that in the modern manufacturing process, unlike forty years ago, the companies exercise complete discretion and absolute control over the presence and level of nicotine in their products. The use of nicotine in tobacco extract as an additive is one of the primary ways in which tobacco manufacturers exercise this control.

**What Policy Options Are Now Available?**

The new information about the tobacco industry’s nicotine manipulation yields several options. One focuses on the amount of nicotine in tobacco products. Given that the technology exists, it would be possible to order, at the state or federal levels, that nicotine in tobacco products be reduced to non-addictive levels or eliminated entirely. This is the most intriguing proposal because it presents the greatest opportunity for influencing consumption directly. An unresolved question is precisely how much nicotine is necessary for a product to be addictive. What is known is that it is a very small amount.

A second option focuses on potential regulations that restrict the advertising, marketing and manufacture of tobacco products which contain nicotine, such as those proposed in federal bill H.R. 2147 introduced in the 103rd Congress by Rep. Mike Synar (D-OK). The FDA controls what additives may be placed in products that it regulates. The agency also maintains control over the advertising and promotion of those products and, for some, restricts where and to whom the products can be sold. Applying similar rules to tobacco could foster meaningful restrictions that would make it more difficult for minors to purchase these products.

Another option would be for Congress to legislate differential tax rates on tobacco products based on their nicotine content, thus effectively making tobacco products with addictive levels of nicotine more expensive and thus less accessible to children and teenagers. This option would have to be considered quite carefully, since, as noted, even very small quantities of nicotine make a product addictive.
Who Can Change Tobacco Policy?

If the FDA determined that the new information is adequate to take jurisdiction over tobacco products as “drugs,” it could take a number of actions under its existing authority. While one might assume the FDA will have to assert jurisdiction in light of the new information, actually, the FDA has substantial discretion in whether to exert regulatory authority. In the late 1980’s, the FDA failed to act on a petition filed with the agency by health groups calling for regulation of RJR’s “Premier,” despite the knowledge that nicotine was intentionally added to the non-tobacco portion of the product. Now, however, the letter issued by the FDA’s Commissioner Kessler on February 25, 1994, and his subsequent testimony before Congress, signal that the agency is seriously rethinking its stance.

If the FDA nonetheless fails to take sufficient action, Congress could either give the FDA specific authority to act or could itself enact legislation governing the nicotine content of tobacco products, restricting tobacco marketing, etc. In addition, state agencies with regulatory authority similar to that of the FDA could act for their own particular states. Petitions similar to those filed with the FDA also were filed with a number of state food and drug agencies before the revelations regarding nicotine manipulation became public. No action has been taken on any of them. Health groups could now supplement these petitions with the new information or submit new petitions dealing specifically with the need to regulate nicotine in tobacco products.

Separate from the enactment of specific legislation, Congress and state bodies can play a role in further eliciting and publicizing the new information through their investigative authority and by holding hearings. Congressional committees have subpoena power to gather industry information, although they rarely exercise it. The Subcommittee on Health and the Environment of the House Energy and Commerce Committee held hearings on nicotine manipulation and related issues in March and April 1994. Further hearings in the House and Senate are anticipated.

Some Final Thoughts

*The Tobacco Industry’s Own View of the Story’s Potential Impact*

Health advocates’ predictions that the nicotine manipulation story may result in dramatic changes in the tobacco and health policy environment are echoed by the tobacco industry itself. In a $10 billion libel suit brought by Philip Morris against ABC in response to airing of the story, the tobacco company complained that the assertions made by *Day One*...

“... have precipitated and fueled a climate of public, media, regulatory and congressional reaction against the tobacco companies, including such plaintiff [Philip Morris U.S.A.], which threatens to embroil plaintiff in regulatory and congressional inquiries, heightens the prospect of regulatory or congressional action severely detrimental to plaintiff’s business, heightens the prospect of passage by Congress of major increases in tobacco taxes severely detrimental to plaintiff’s business, will tend to spawn additional litigation against plaintiff, undermines confidence in plaintiff’s products affecting sales, and have otherwise damaged plaintiff in the conduct of its trade and business.”

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While the cigarette maker’s allegations of libel will likely be rejected or even dropped by the company, the concerns voiced by Philip Morris may otherwise turn out to have a great deal of merit.

**Litigation Potential**

Knowledge of the tobacco manufacturers’ deliberate manipulation of nicotine has the potential to change dramatically the product liability scene as it affects smoker death lawsuits.

A number of state laws exempt the manufacturers of those products which are considered to be “inherently dangerous” from product liability. These laws have shielded tobacco manufacturers from liability in a number of cases involving tobacco-related deaths.

Since the new information makes clear that nicotine is not an inherent and unavoidable part of tobacco products, plaintiffs may now be able to argue that the laws precluding litigation involving inherently dangerous products should not shield tobacco manufacturers. Plaintiffs might argue that tobacco products are “inherently dangerous” only if their addictiveness is inherent. The news of industry manipulation suggests that this is not the case. Even if they want to quit, many smokers can’t because of their addiction. Hence they continue to be exposed to the numerous carcinogens and other toxins present in tobacco and tobacco smoke. If a plaintiff can demonstrate that he or she became addicted to tobacco products because of the deliberate manipulations of the manufacturer, the manufacturer’s defense would be severely weakened. This cutting-edge legal argument involving nicotine and addiction could thus provide plaintiffs with a tool to overcome some of the existing exemptions in state product liability laws.

The following additional legal arguments suggested by the Tobacco Products Liability Project may also thwart tobacco company defenses.

- “Many states hold manufacturers “strictly liable” only for those ‘unreasonably dangerous’ products for which a safer feasible alternative existed. This limitation, strongly supported by the tobacco industry, was generally supposed to protect it from strict liability. The new revelations suggest that the tobacco industry has known how to make safer cigarettes, but has deliberately made them more addictive to increase their market appeal.

- “Tobacco companies defend their products in court by arguing that the use of tobacco is a great American tradition, dating back to the Indians and the first settlers. But, since the Indians and the first settlers did not chemically remove nicotine from — and add nicotine to — their tobacco so as to maximize the customers’ addictions, the new revelations may make it harder for tobacco defendants to win juror sympathies.”*

  *In addition, inhalation was not a feature of using any traditional tobacco product. That only became possible on a large scale with the development of cigarette tobaccos in the mid to late 19th century, and these were commercial, not traditional, varieties from the very beginning.*

- “Deliberately manipulating nicotine levels to hook their customers, and keep them hooked, is
clearly an ‘intentional tort.’ Unlike negligent or even reckless behavior, intentionally tortious
behavior is likely to alienate both judges and jurors, producing punitive damage verdicts
which will be upheld on appeal.”

• “Civil RICO class actions by consumers seeking reimbursement of expenses for breaking their
addiction, or even perhaps for servicing their addiction, may now be possible. They may now
be seen as furthering a core function of the Racketeer Influenced and Corrupt Organizations
Act — to redress financial injuries caused by the behavior of drug cartels!”

A Useful Precedent

(D-IL) in testimony before his colleagues in the House of Representatives, “if it was revealed that
the corporation’s product contained a harmful ingredient that could be removed? It would remove
the dangerous additive.” A case in point, he said, is the Coca-Cola Company, which almost 100 years
ago voluntarily adopted a process to make sure that no cocaine remained in coca extract, a flavoring
agent, it uses in making Coca-Cola. At the time, there was increasing public concern about the
addictive effects of the drug. Noting the parallel between the cola product and cocaine on the one
hand, and tobacco products and nicotine on the other, Congressman Durbin declared that: “The
obvious, socially responsible act would be for tobacco companies to voluntarily remove this dangerous
ingredient from their products.”

About a decade after Coca-Cola had begun to ensure that there was no cocaine in its popular
product, Congress enacted the Harrison Narcotic Act which prohibited the non-prescription use of
cocaine. Even now, coca leaf is imported from South America and decocainized by a private firm at
a plant in Maywood, NJ for use as a non-addictive flavor extract in a variety of products. The impor-
tation of coca leaf is monitored by the U.S. Drug Enforcement Agency, while the decocainization
process and use of the coca extract is regulated by the FDA.

The example of Coca-Cola and the federally mandated removal of cocaine from over-the-
counter consumer products offers a useful precedent to any measures that might be implemented to
mandate removal of nicotine from tobacco products. Like cocaine, nicotine is addictive, is produced
naturally as part of a plant and can be removed.

If tobacco is required to be denicotinized, any such measure should also prohibit substitution
of nicotine with other known or potentially addictive substances.

Epilogue

What would a society free of almost all tobacco product-related nicotine addiction look like?
If the FDA and/or Congress mandate that tobacco manufacturers reduce the quantity of nicotine in
tobacco products to non-addictive levels, some addiction experts predict that perhaps 95 percent of
all smokers would successfully quit using tobacco in the long term. If we ignore for the moment, the
possibility that a black market in nicotine-containing tobacco products might emerge which could
influence the ultimate picture (although only in part), we can foresee 47 million of the 50 million
people (including children) who currently smoke cigarettes in the United States quitting. Thus, among other potential benefits:

- The number of cigarettes smoked in the United States each year would drop from roughly 500 billion to perhaps 25 billion.

- Since cigarette smoking is directly responsible for the premature deaths of approximately one of every four smokers, at least 10 million lives would be prolonged among smokers now living, and countless additional lives would be protected in the future.

- Tobacco-related health care and economic costs would almost disappear in the long term. (They now exceed $68 billion a year.)

- Sickness and death related to secondhand smoke would be virtually eliminated.

- Injury, death and property damage resulting from cigarette-caused fires would quickly become a historical curiosity.

- More than 40 non-tobacco-producing states would benefit economically if tobacco sales were eliminated or curtailed, according to a recent study by economists at the University of Michigan. Expenditures on tobacco would be redirected into sales of other goods and services. While there would be small losses in retail and wholesale trade and in state and local government employment, there would be substantial gains in the remainder of the economy.16

While such remarkable outcomes may boggle the mind, the possibility of accomplishing them has suddenly become real. The “outing” of the tobacco industry’s manipulation of nicotine to addict millions has strengthened and emboldened an already thriving movement to control tobacco, protect children and save lives. Advocates, health minded policy-makers and others can take heart that the years of the modern epidemic of tobacco-related death and illness are now numbered — at least in the United States.

References


2. As anchor Peter Jennings reported on ABC’s “World News Tonight,” February 25, 1994, “The U.S. government is considering a major frontal assault on the tobacco industry. The commissioner of the Food and Drug Administration said today that he is looking into whether cigarettes might be regulated as an addictive drug. Here is what’s changed. There is now evidence that cigarette manufacturers carefully manipulate the nicotine content of their product to assure each cigarette packs a certain punch.” (emphasis added)


Additional Suggested Reading


“Evidence brought to our attention is accumulating that suggests that cigarette manufacturers may intend that their products contain nicotine to satisfy an addiction on the part of some of their customers. The possible inference that cigarette vendors intend cigarettes to achieve drug effects in some smokers is based on mounting evidence we have received that: (1) the nicotine ingredient in cigarettes is a powerfully addictive agent and (2) cigarette vendors control the levels of nicotine that satisfy this addiction.”

— Dr. David Kessler (February 25, 1994, letter to Coalition on Smoking OR Health

“The public knows that cigarettes are harmful and many smokers desire to quit. Research has revealed that 77 percent of smokers desire to quit but cannot primarily because of nicotine addiction.”

— Dr. David Kessler (February 25, 1994, letter to Coalition on Smoking OR Health

“Although technology was developed years ago to remove nicotine from cigarettes and to control with precision the amount of nicotine in cigarettes, cigarettes are still marketed with levels of nicotine that are sufficient to produce and sustain addiction. In fact, it is our understanding that manufacturers commonly add nicotine to cigarettes to deliver specific amounts of nicotine”

— Dr. David Kessler (February 25, 1994, letter to Coalition on Smoking OR Health

“The National Cancer Institute strongly supports the position of the U.S. Food and Drug Administration that nicotine is a drug and that tobacco products — like all drug delivery systems — could come under the same strict regulatory controls as nicotine drug products used in the management and treatment of cigarette addiction.”


“Cigarettes and other tobacco products have not been previously regulated except under rare circumstances. In effect, cigarettes have been nearly totally exempt from federal regulations which govern virtually all other consumer products in the marketplace.”

— Samuel Broder, M.D., NCI Director (in NCI press release)

“Until now, cigarette manufacturers have been free to add virtually anything, in any quantity, to cigarettes and no regulatory mechanism existed which provided even minimal safeguards. Yet tobacco is the only consumer product on the market that when used as intended by the manufacturer, will kill 500,000 consumers this year.”

— Samuel Broder, M.D., NCI Director (in NCI press release)