

# MICROFILM DIVIDER

OMB/RECORDS MANAGEMENT DIVISION  
SFN 2053 (2/85) 5M



ROLL NUMBER

DESCRIPTION

1410

2007 HOUSE INDUSTRY, BUSINESS AND LABOR

HB 1410

## 2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1410

House Industry, Business and Labor Committee

Check here for Conference Committee

Hearing Date: 01-23-2007

Recorder Job Number: 1646

Committee Clerk Signature

*David M Thomas*

Minutes:

**Chairman Keiser opened the hearing on HB 1410. HB 1410 relates to the nicotine yield of cigarettes sold in the state.**

**Rep. Wrangham** introduced the bill.

**Rep. Wrangham:** There is a group of people who have been brainstorming on how to positively deal with the smoking issue. This is one of the ideas that came out of one of those sessions. This bill reduces the amount of nicotine allowed in cigarettes sold in North Dakota, incrementally over the next seven years. After August 1, 2015, the nicotine yield you have to be less than 1/100 of milligram calculated using the federal trade commission's method. This bill by reducing the addictive substance in cigarettes over a period of time is believed it will help smokers who want to quit, be able to quit. Penalizing and demoralizing smokers is not a good or successful way to promote smoking cessation. We are looking for a more positive way to do it. Reducing the additive substance will help those who want to quit, quit.

I don't have a lot of the scientific information that we need to move this bill forward, but hopefully we will all learn a lot and out of this bill will come some solutions. I know there is one gentlemen here to testify on this and can probably answer more questions for you.

**Rep. Ruby:** How do we direct the cigarette companies to reduce the nicotine?

**Rep. Wrangham:** With a law. HB 1410.

**Rep. Johnson:** When I read this, I thought about what a tremendous black market we would have in our state, have you thought about that?

**Rep. Wrangham:** Nothing is easy. There are pitfalls to most all solutions. We have to weigh the pros and cons.

**Rep. Amerman:** By 2008, not to exceed 1 milligram per cigarette, do you know what it is right now?

**Rep. Wrangham:** There are statistics available, I didn't keep a copy of what LC looked up. I believe 1.7 grams.

**Rick LaFleur,** Current President of the North Dakota Coin Machine Operators Assoc. and Member of the Coin and Tavern Association, spoke in support of the bill.

**LaFleur:** We are here today as a result of discussions that we have had trying to conclude how to eliminate the smoking issue. We think the smokers have really been singled out in this scenario as being portrayed in a negative light and we think that they are victims of more than one thing, but certainly nicotine manipulation. These articles that I am passing out to you today are just reference articles. *See attached.*

**Rep. Ruby:** Do you have statistics of how many people have increased in people who now are addicted within the same time frame?

**LaFleur:** I really don't know.

**Rep. Ruby:** During that time, if we don't have statistics that show that there was an increase, how will we know that it will be lower?

**LaFleur:** We don't. I'm going to be the first one to tell you.

**Rep. Nottestad:** Is this kind of legislation the first one?

**LaFleur:** The state of Massachusetts has wrestled with it, and I don't see that they have solved it.

**Rep. Nottestad:** Do you think the manufacturers will comply with this?

**LaFleur:** Probably not.

**Nicki Weissman, NDHA,** spoke in support of the bill.

**Weissman:** This bill is looking for an alternative for the smokers that are having a situation trying to quit. We all know the situation of smoking. We are looking for suggestions and alternatives.

**Rep. Nottestad:** Then will the retail sales in North Dakota be gone?

**Weissman:** You are probably correct.

**Rep. Clark:** Does this bill have a fiscal note?

**Weissman:** There is a possibility.

**Rep. Keiser:** You either smoke five times as much or you don't have as many.

**Opposition was allowed at this time.**

**David Remes,** see attached written testimony.

**Rep. Amerman:** The studies and so on that was in the handout for Mr. LaFleur, do you believe those studies are accurate?

**Remes:** I haven't studied them closely enough.

**Rep. Keiser:** Internet sales are beginning to grow in this sector, what is your knowledge and experience with internet sales and what impact would a law like this have potentially?

**Remes:** Internet sales have been a problem ever since they started because the internet retailers don't collect tax.

**Rep. Boe:** What is your knowledge on sales of cigarettes on reservations?

**Remes:** I think I may be the wrong person to ask about the legalisms of ND tax on reservations.

**The committee recessed and reconvened later that day.**

**Rep. Amerman:** I don't see how it is doable.

**Rep. Amerman moved a DO NOT PASS. Rep. Gruchalla seconded.**

**Rep. Keiser:** The discussion was that this was creating a black market and it's unenforceable and these are going to have the biggest impact on retail sales. You are going to have to smoke twice as much or four times as much, or you are not going to smoke.

**Rep. Ruby:** I just see it as a bill that will probably make retail sales completely disappear because the manufacturers are not going to have every brand of cigarette at the lower level.

**Rep. Gruchalla:** I do believe that the sales tax would not apply on reservations.

**Rep. Keiser:** I am sure it would not apply. I do not now. You would have everyone in Bismarck that smokes going to the casino to buy cigarettes.

**Roll Call Vote: 12 yes. 1no. 1 absent.**

Date: 1-23-07  
Roll Call Vote #: \_\_\_\_\_

2007 HOUSE STANDING COMMITTEE ROLL CALL VOTES  
BILL/RESOLUTION NO. HB 1410

House Industry Business & Labor Committee

Check here for Conference Committee

Legislative Council Amendment Number \_\_\_\_\_

Action Taken Do Not Pass

Motion Made By Rep Amerman Seconded By Rep Gruchalla

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser	X		Rep. Amerman	X	
Vice Chairman Johnson	X		Rep. Boe		X
Rep. Clark	X		Rep. Gruchalla	X	
Rep. Dietrich	X		Rep. Thorpe	X	
Rep. Dosch	X		Rep. Zaiser		
Rep. Kasper	X				
Rep. Nottestad	X				
Rep. Ruby	X				
Rep. Vigesaa	X				

Total Yes 12 No 1

Absent 1

Floor Assignment Rep. ~~Zaiser~~ Ruby

If the vote is on an amendment, briefly indicate intent:

**REPORT OF STANDING COMMITTEE**

**HB 1410: Industry, Business and Labor Committee (Rep. Keiser, Chairman)**  
recommends **DO NOT PASS** (12 YEAS, 1 NAY, 1 ABSENT AND NOT VOTING).  
HB 1410 was placed on the Eleventh order on the calendar.

2007 TESTIMONY

HB 1410

David Remes

January 23, 2007

**HB 1410 SHOULD BE REJECTED**

Beginning in 2008, HB 1410 would prohibit the sale in North Dakota of cigarettes whose FTC nicotine ratings exceed levels specified in the bill would allow. By 2015, only cigarettes whose smoke contains virtually no nicotine could be sold in the State. The bill should be rejected.

**HB 1410 could amount to ban a ban on legal cigarettes in North Dakota.** Previous efforts by cigarette manufacturers to market cigarettes with ultra-low nicotine ratings have been unsuccessful. Whether in the short term or as ultimately implemented, HB 1410 therefore could amount to a ban on legal cigarettes in North Dakota. Outlawing legal cigarettes would adversely affect State revenues. In calendar year 2005, North Dakota collected over \$19.5 million per year in cigarette excise tax revenues. In addition, outlawing legal cigarettes would cause financial hardship for cigarette retailers, shift legal sales to retailers in adjoining states and to Internet retailers, and create a black market in North Dakota.

**HB 1410 would conflict with federal law.** Congress has foreclosed a ban of tobacco products, choosing instead a distinct regulatory scheme focusing on labeling and advertising (under the FTC) and ingredient disclosure (under the U.S. Department of Health and Human Services). The chosen regulatory approach to nicotine content has been disclosure to the FTC under a long-standing voluntary agreement. Except for certain product disclosure requirements, federal courts have held that federal agencies and the states may not regulate cigarettes except as specifically authorized by federal law.

Thus, the Supreme Court has held that Congress has not authorized the FDA to regulate cigarettes, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 137 (2000), and has barred States from regulating cigarette advertising and promotion, *Lorillard v. Reilly*, 533 U.S. 525, 540-566 (2001). In *Brown & Williamson*, the Supreme Court concluded that Congress had not authorized the FDA to regulate cigarettes because the FDA would then have to ban cigarettes. The Court stated: "Congress, however, has foreclosed the removal of tobacco products from the market." *Id.* at 137. The Court explained:

Congress stopped well short of ordering a ban. Instead, it has generally regulated the labeling and advertisement of tobacco products, expressly providing that it is the policy of Congress that "commerce and the national economy may be . . . protected to the maximum extent consistent with" consumers "be[ing] adequately informed about any adverse health effects." 15 U.S.C. § 1331. Congress' decisions to regulate labeling and advertising and to adopt the express policy of protecting "commerce and the national economy . . . to the maximum extent" reveal its intent that tobacco products remain on the market. Indeed, the collective premise of these statutes is that cigarettes and smokeless tobacco will continue to be sold in the United States. A ban of tobacco products . . . would therefore plainly contradict congressional policy.

*Id.* at 138-39 (emphasis added). Federal courts have similarly concluded that applying state tort law that would have the effect of banning cigarettes would conflict with federal law. Thus, for example, courts have dismissed claims that cigarette manufactur-

ers should be liable for manufacturing and marketing an inherently-dangerous product because punishing manufacturers for continuing to market cigarettes would conflict with Congress's policy in favor of keeping cigarettes on the market. See, e.g., *Valle-Ortiz v. R.J. Reynolds Tobacco Co.*, 385 F. Supp.2d 126, 133 (D. P.R. 2005) (citing precedents).

**HB 1410 would violate the Commerce Clause.** "In order to prevent economic balkanization among the states, the dormant Commerce Clause prohibits certain state regulation even when Congress has failed to legislate on the subject." *Hampton Feedlot, Inc. v. Nixon*, 249 F.3d 814, 818 (8th Cir. 2001). A state law violates the Commerce Clause if it (1) discriminates in favor of local interests and against out-of-state interests, or (2) imposes on interstate commerce a burden that is "clearly excessive in relation to the putative local benefits." *U & I Sanitation v. City of Columbus*, 205 F.3d 1063, 1067-68 (8th Cir. 2000) (citation omitted). The second of these tests is known as the *Pike* balancing test.

HB 1410 would fail the *Pike* balancing test. On one side of the balance, the bill's burden on interstate commerce would be "far from trivial," 205 F.3d at 1072, because, to comply with the bill's requirements, cigarette manufactures must either (1) reformulate their cigarettes specifically for the North Dakota market, (2) reformulate their cigarettes for the national market to meet North Dakota's requirements, or (3) stop selling cigarettes in North Dakota. On the other side of the balance, any local benefit from the bill would be "illusory," 205 F.3d at 1070, because, as noted, experience indicates that smokers would simply shift legal sales to retailers in other states and Internet retailers and create a black market. At most, it is "sheer speculation" to say that the bill would advance its apparent purpose. *Id.*

\* \* \*

In short, HB 1410 would effectively ban legal cigarettes, eliminating North Dakota's excise tax revenues, conflict with Congress's purposes and objectives, and violate the Commerce Clause. For these reasons I would recommend a Do Not Pass on HB 1410.

#1

washingtonpost.com

## Nicotine Up Sharply In Many Cigarettes

Some Brands More Than 30% Stronger

By David Brown  
Washington Post Staff Writer  
Thursday, August 31, 2006; A01

The amount of nicotine in most cigarettes rose an average of almost 10 percent from 1998 to 2004, with brands most popular with young people and minorities registering the biggest increases and highest nicotine content, according to a new study.

Nicotine is highly addictive, and while no one has studied the effect of the increases on smokers, the higher levels theoretically could make new smokers more easily addicted and make it harder for established smokers to quit.

The trend was discovered by the Massachusetts Department of Public Health, which requires that tobacco companies measure the nicotine content of cigarettes each year and report the results.

As measured using a method that mimics actual smoking, the nicotine delivered per cigarette -- the "yield" -- rose 9.9 percent from 1998 to 2004 -- from 1.72 milligrams to 1.89. The total nicotine content increased an average of 16.6 percent in that period, and the amount of nicotine per gram of tobacco increased 11.3 percent.

The study, reported by the Boston Globe, found that 92 of 116 brands tested had higher nicotine yields in 2004 than in 1998, and 52 had increases of more than 10 percent.

Boxes of Doral lights, a low-tar brand made by R.J. Reynolds Tobacco Co., had the biggest increase in yield, 36 percent. Some of this may have been the result of an increase in the total amount of tobacco put in that brand's cigarettes, one expert said.

The nicotine in Marlboro products, preferred by two-thirds of high school smokers, increased 12 percent. Kool lights increased 30 percent. Two-thirds of African American smokers use menthol brands.

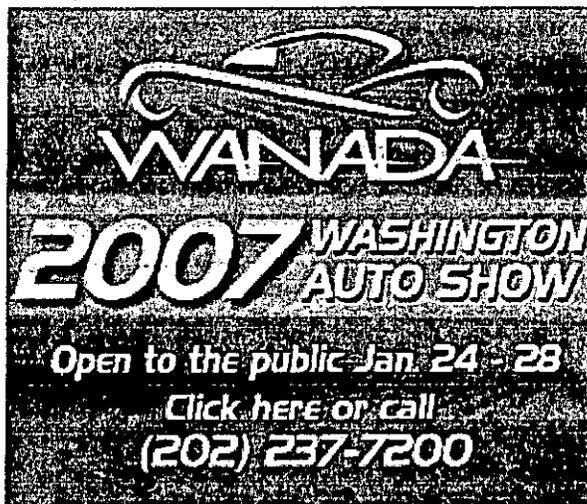
Not only did most brands have more nicotine in 2004, the number of brands with very high nicotine yields also rose.

In 1998, Newport 100s and unfiltered Camels were tied for highest nicotine yield at 2.9 milligrams. In 2004, Newport had risen to 3.2 milligrams, and five brands measured 3 milligrams or higher.

"The reports are stunning," said Matthew L. Myers, president of the Campaign for Tobacco-Free Kids. "What's critical is the consistency of the increase, which leads to the conclusion that it has to have been conscious and deliberate."

"People need to be aware of this," said Sally Fogerty, Massachusetts's associate commissioner for

Advertisement



community health. "If a person is trying to quit and is having a hard time, it's not just them. There is an increasing percentage of nicotine that they are ingesting, and that may make it more difficult."

The Centers for Disease Control and Prevention also focused on the potential behavioral consequences of the finding.

"We know nicotine is addictive, so if the amount of nicotine in cigarettes is increasing, it could make it even harder for the 70 percent of smokers who want to quit and the more than 40 percent who try to quit every year," Corinne Husten, acting director of the CDC's Office on Smoking and Health, said in an e-mail message.

No spokesman for a tobacco company would speak on the record about the Massachusetts findings yesterday.

One company official, speaking on the condition of anonymity, said that while the nicotine content measured by smoking machines can vary by up to 6 percent between individual cigarettes of the same brand, "we don't know" whether an entire brand's production could differ that much from year to year.

But in a 1,653-page opinion released two weeks ago in a landmark suit against the major tobacco companies by the federal government and several anti-smoking organizations, the judge found that cigarette makers adjusted nicotine levels with great care.

"Using the knowledge produced by that research, defendants have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction," wrote U.S. District Judge Gladys Kessler.

The ruling enjoined the companies from misinforming the public about tobacco's hazards. The companies are uncertain what that means and cited the ruling yesterday as the chief reason for their silence. Reynolds and Lorillard Tobacco Co. have also temporarily shut down their Web sites.

Reginald V. Fant, a clinical pharmacologist and nicotine expert at Pinney Associates, a consulting firm in Bethesda, said increasing nicotine content by 10 percent "would not be expected" to change how much a person smokes but could affect his ability to quit.

"We know that physiologically the changes in the nicotine receptors in the brain are related to the amount of nicotine consumed," he said.

Neal Benowitz, a physician and pharmacologist at the University of California at San Francisco, said, "I don't think we know what the consequences are for the population in terms of addictive behavior and how hard it is for people to quit."

Myers said the Massachusetts findings are evidence that tobacco products should be more strictly regulated.

"The only way the companies were able to secretly increase nicotine levels without anyone knowing about it is because no federal agency regulates tobacco products," he said.

© 2006 The Washington Post Company

**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH**

**CHANGE IN NICOTINE YIELDS 1998 - 2004**

**DATA SUBMITTED IN ACCORDANCE WITH MASSACHUSETTS  
GENERAL LAWS**

**CHAPTER 94: Section 307B, 105 CMR 660.000**

**Report produced by:**

**The Massachusetts Tobacco Control Program, Massachusetts Department of Public Health**

**Lois Keithly, Ph.D., Director; Doris Cullen, MA, Research Analyst; Thomas Land, Ph.D., Research Analyst**

---

**TABLE OF CONTENTS**

---

1. Summary
2. Background
3. Nicotine Yield Testing  
*Table 1-- Historical/MA Nicotine Yield Summary*
4. Nicotine Content of Whole Tobacco
5. Percent Filter Ventilation
6. Nicotine Yield Ratings  
*Table 2-- Nicotine Yield Ratings*
7. Appendix--Table Summary

---

## SUMMARY

---

Since 1997, cigarette manufacturers have delivered nicotine reporting information using testing methods established by the Massachusetts Department of Public Health (MDPH). Massachusetts General Law chapter 94 section 307B and Department of Public Health Regulations 105 CMR 660.000 mandate that cigarette companies report each year to the Department the nicotine yield ratings for all cigarette brands with a U.S. market share of greater than 1.5%.

### Nicotine Yield Testing

- For all brands tested in both 1998 and 2004 (N = 116), the total amount of nicotine delivered to the smoker has increased significantly: 1.72 mg in 1998 compared to 1.89 mg in 2004. These data were also evaluated by manufacturer. For each of the major manufacturers (i.e., Brown & Williamson, Lorillard, Phillip Morris, and RJ Reynolds), the increases in nicotine delivered were significant.
- Each manufacturer markets many brands of cigarettes and this data was analyzed by brand. Once again, the increases in nicotine delivered were significant. With the exception of Winston cigarettes, all brands that were tested in both 1998 and 2004 had significant increases in nicotine delivered to the smoker. This includes Basic, Camel, Doral, Kool, Marlboro, and Newport cigarettes.
- Cigarette brand families (e.g. Marlboro) with a U.S. market share of greater than 1.5% were required to submit nicotine yield information. In 2004, a total of 179 brands were tested from the four major cigarette manufacturers – Brown & Williamson (now owned by RJ Reynolds), Lorillard, Philip Morris, and RJ Reynolds.
- For over 30 years, nicotine yields have been reported from tests using smoking machines. The operation of the machine was an attempt to mimic the smoking behavior of a typical smoker. However, these historical methods have been found to be inadequate<sup>1,2</sup> because the machine's puff duration is too short, too little smoke is inhaled, and none of the filter ventilation holes is covered. The MDPH testing method better simulates the smoking behavior of the typical smoker under typical smoking conditions. Using the Massachusetts' method, the amount of smoke inhaled with each puff is increased and the amount of time between puffs is reduced. In addition, 50% of the cigarette filter is covered.
- Testing for nicotine yield using the MDPH method revealed levels that are more than twice as high as those found by the historical method. For the typical smoker, 'low yield' cigarettes in almost every case deliver moderate to high doses of nicotine. These levels are sufficient to cause and maintain heavy dependence. For all brands tested in both 1998 and 2004 (N = 116), the average from using the historical method was 0.90mg/cigarette while the average from the Massachusetts method was 1.89mg/cigarette.

### Nicotine Ranges

- Massachusetts has rated different brands of cigarettes based on the nicotine that a cigarette delivers under typical smoking conditions. The nicotine ratings range from high, moderate, low, or nicotine free. These ranges were created in order to allow smokers to compare nicotine levels among brands of cigarettes.
- Ninety-three percent of the cigarettes tested in 2004 fell into the highest nicotine range. This compares to 84% in 1998. Of 179 cigarette brands tested in 2004, 166 were rated as *high nicotine*. This includes 59 brands that the manufacturers label as 'light' cigarettes, 12 brands labeled as 'mild' or 'medium', and 14 labeled as 'ultra-light'. All remaining brands fell into the moderate range. Cigarettes with moderate and high yields can cause heavy dependence on nicotine.

### Nicotine Content of Whole Tobacco

- For all brands tested in both 1998 and 2004, there were no significant differences in the total nicotine content between 'full flavor,' 'medium,' 'mild,' 'light,' or 'ultra-light' cigarettes.
- Whether a cigarette is classified by the manufacturer as being 'full flavor,' 'medium,' 'mild,' 'light,' or 'ultra-light,' it is likely to contain similar amounts of nicotine in the unsmoked tobacco. Smokers who switch to 'lower yield' cigarettes to reduce their intake of nicotine are faced with similar levels of nicotine content.

### Percent Filter Ventilation

- For all brands tested in 2004, cigarettes ranged from 0% to 83% filter ventilation, emphasizing the extreme differences in cigarette design.
- When smokers place their lips and fingers over the vents, they keep outside air from diluting the smoke. As a result, they take in higher levels of tar and nicotine.
- Based on information provided by the manufacturers, there is a strong correlation between the percent of filter ventilation and total nicotine content for *ultra-light* cigarettes. When the nicotine content is low, there is relatively little filter ventilation. When it is high, there tends to be much more ventilation. Under typical smoking conditions, the amount of filter ventilation reduces the amount of nicotine delivered to the smoker. Despite lower nicotine content for some ultra-light cigarettes, these same cigarettes tend to have correspondingly low levels of filter ventilation. This means that a much higher proportion of the nicotine in the cigarette enters a smoker's lungs.

---

### **BACKGROUND**

---

M.G.L. Chapter 94, Section 307B requires tobacco manufacturers to file an annual report concerning nicotine yields with the Massachusetts Department of Public Health (MDPH) for each brand of tobacco product sold in the Commonwealth. This annual report provides nicotine yield ratings which accurately predict nicotine intake for typical consumers, based on standards established by MDPH.

The national standard for testing tar and nicotine in mainstream smoke by use of a smoking machine was developed over thirty years ago.<sup>3</sup> The nicotine yield ratings produced by this historical method were meant to serve as a relative measure of nicotine yield between cigarette brands.<sup>4</sup> They are not reliable measures of how much nicotine a smoker actually takes into their body under normal smoking conditions.

Cigarette design has undergone significant changes over the last 30 years. Technology has altered the manner in which tar and nicotine are delivered to the smoker, and the smoking practices of consumers have shifted accordingly. Since the introduction of 'low yield' cigarettes (i.e. light and ultra-light cigarettes) in the late 1970's, smokers have been found to compensate for lower levels of nicotine yield by smoking more frequently, by smoking more cigarettes, smoking more deeply, and increasing puff volume.<sup>5</sup> These changes in smoking behavior result in much higher relative nicotine levels being delivered to the body from lower yield cigarettes than what is calculated using the historical testing method.<sup>6</sup>

A recent report of the National Cancer Institute's Ad Hoc Committee of the President's Cancer Panel on the historical test method concluded that current ratings from this method provide little information for consumers who wish to know how much nicotine they actually take into their body when smoking.<sup>7</sup> MDPH testing standards, developed in 1997, draw heavily on that report and reflect current scientific knowledge about compensatory smoking behaviors and nicotine intake.

This report features the following information reported to Massachusetts for cigarette brands:

- ◆ total nicotine content (mg) of tobacco contained in the cigarette rod
- ◆ percent filter ventilation (the amount of air allowed to dilute the smoke)
- ◆ nicotine yield based on MDPH developed test
- ◆ nicotine classification based on MDPH developed classification
- ◆ pH levels for a selected subset of cigarette brands

## NICOTINE YIELD TESTING

### What Is Nicotine Yield?

- A cigarette does not deliver fixed amounts of tar and nicotine in the manner that a capsule delivers a fixed dose of medicine. In part, it is how a person smokes that determines the amount of tar and nicotine that is delivered from the cigarette into the body.
- Nicotine yield is a measure of the amount of nicotine in the smoke that a smoker inhales. It does not measure the amount of nicotine in a cigarette.
- The amount of nicotine which smokers inhale is based on how long and how deeply they breathe in with each puff (puff volume), the amount of time between puffs (puff interval), and the percent filter ventilation of the smoke they breathe (the amount of pure air which is drawn in through vent holes in the filter tip during smoking and allowed to mix with the smoke, lessening its concentration).

When compared to the historical method of testing cigarettes, the Massachusetts method better simulates the smoking behavior of the typical smoker under normal smoking conditions. The Massachusetts method increases the amount of smoke inhaled with each puff by the smoking machine, reduces the amount of time taken between puffs, and requires that 50% of the cigarette filter be covered.

### What Do Nicotine Yield Ratings Reflect?

- The historical method of measuring nicotine yield uses a smoking machine to simulate the way in which a smoker smokes. Nicotine yields and tar levels using the historical method are determined on the basis of the amount of smoke which is inhaled by the machine.
- Because nicotine yield is based on the way in which an individual smokes, ratings based on the historical method reflect what you take into your body only if you smoke a cigarette in exactly the same way as the testing machine.
- Ratings based on the historical method cannot accurately reflect the effects of vent blocking -- blocking ventilation holes in the filter. A typical smoker is likely to cover the vents placed around the filter, raising the levels of tar and nicotine which they inhale. The filter vents are left open when nicotine yields are measured using the historical method.
- The Massachusetts testing method was developed to reflect compensation techniques-- such as vent blocking, puffing more frequently, and inhaling more deeply. If smokers employ these compensation behaviors, they will inhale increased amounts of nicotine.

### What Were the Results of Massachusetts Nicotine Yield Testing?

- By adjusting parameters to more accurately reflect typical smoking conditions, 2004 Massachusetts testing for nicotine yield produced numbers that were about twice as high as those found using the historical method. The typical smoker receives much greater levels of nicotine than is suggested by historical methods ratings.

**Table 1: Nicotine yield from Massachusetts method compared to historical method**

<b>Cigarette Type<sup>1</sup></b>	<b>MA Method Nicotine Yield (mg/cigarette)<sup>2</sup></b>	<b>Historical Method Nicotine Yield (mg/cigarette)<sup>2</sup></b>	<b>% Difference<sup>3</sup></b>
Full (Regular)	2.16	1.09	98%
Medium / Mild	2.01	0.93	116%
Light	1.71	0.80	114%
Ultra-light	1.21	0.43	181%

Note: All data in Table 1 was supplied to the Massachusetts Department of Public Health (MDPH) by the cigarette manufacturers in compliance with M.G.L. Chapter 94, Section 307B. Tobacco manufacturers are required to file an annual report concerning nicotine yields with the MDPH for each brand of tobacco product sold in the Commonwealth. 1) In reporting information to MDPH, cigarette manufacturers classify cigarettes as Full Flavor, Medium or Mild, Light, or Ultra-Light. 2) Each year, manufacturers report nicotine yield in milligrams per cigarette from studies using both the Massachusetts and historical methods. 3) MA method yield divided by historical method yield.

- Compensation techniques used by smokers alter levels of nicotine received from 'light' or 'ultra-light' cigarettes to a much greater degree than with regular cigarettes. All cigarettes ('light', 'ultra-light', etc.) are based on nicotine yield ratings using the historical method, but 'low yield' cigarettes depend more heavily on design factors such as filter ventilation which are not accounted for by the historical testing method.
- For the typical smoker, 'low yield' cigarettes deliver moderate to high doses of nicotine. These levels are sufficient to cause and maintain heavy dependence. No brand tested produced nicotine yields of less than 0.5 mg per cigarette when smoked under typical smoking conditions.

---

## NICOTINE CONTENT OF WHOLE TOBACCO

---

### What Is Nicotine Content?

- The nicotine content of a cigarette is an important element in its design. Nicotine content is the amount of nicotine contained in the tobacco before it is burned and inhaled. A smoker extracts the nicotine contained within the tobacco by inhaling nicotine which is released into the smoke when the tobacco is burned.
- A cigarette with a higher nicotine content has a greater amount of nicotine, which may potentially be extracted by the smoker and inhaled during smoking.
- Consumers may believe that 'light' and 'ultra-light' cigarettes contain less nicotine than full flavor cigarettes. However, such classifications do not reflect the amount of nicotine in the cigarette-- they are based solely on ratings of nicotine yield using the historical method.

### Why Is Nicotine Content Important?

- Nicotine yield ratings from the historical method are based on the amount of nicotine 'inhaled' by a smoking machine. These data suggest that light cigarettes contain less nicotine than regular cigarettes. In reality, the difference in nicotine content across types is not statistically significant. Light and regular cigarettes offer similar amounts of nicotine to the smoker.
- Compensation techniques such as vent blocking or taking longer and deeper puffs on a cigarette are used by smokers as means of extracting a greater amount of nicotine. When a cigarette has a high level of nicotine content, the smoker may be able to extract high levels of nicotine even when smoking cigarettes labeled with lower nicotine yields.
- A cigarette classified as 'light' according to the amount of nicotine which a standard smoking machine will extract from it, will contain levels of nicotine similar to that of a regular cigarette.
- Smokers who switch to 'lower yield' cigarettes in order to reduce their intake of nicotine, can be faced with similar levels of nicotine content in the 'low yield' cigarettes. By simply smoking harder and longer on light and ultra-light cigarettes, smokers can achieve the same impact and the same level of nicotine as they did from 'higher' nicotine yield brands.

According to 2004 data, there were no statistically significant differences in the nicotine content of 'full flavor,' 'medium,' 'mild,' 'light,' or 'ultra-light' cigarettes.

Whether a cigarette is classified as 'full flavor,' 'medium,' 'mild,' 'light,' or 'ultra-light', it is likely to contain similar amounts of nicotine in the unsmoked tobacco.

---

## PERCENT FILTER VENTILATION

---

### What Is Vent Blocking?

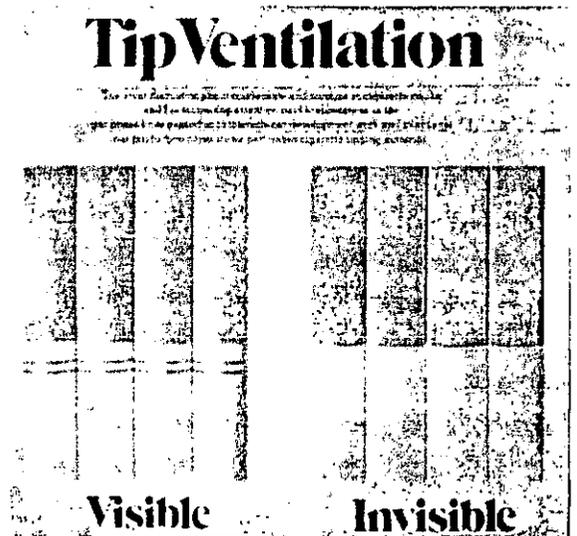
- Many cigarettes are made with tiny holes around the filter which allow air that has not been drawn through the end of the cigarette to mix with the tobacco smoke during smoking.
- When smokers place their mouth or fingers over the vents, they keep outside air from diluting the mixture and so take in higher levels of tar and nicotine.

### How Can a Smoker Tell If They Are Vent Blocking?

- It is difficult for smokers to know if they are covering up the vents. Many brands have vents that are so tiny they are invisible to the naked eye. Often the placement of the holes makes it difficult if not impossible for a smoker to smoke a cigarette without blocking some or all of the vents.
- Cigarettes are designed in such a way that normal smoking behaviors results in covering some or all of the filter vents. Thus, normal smoking behaviors result in heavier amounts of tar and nicotine delivered to a smoker.

### What Does Vent Blocking Mean for 'Light' and 'Ultra-light' Cigarettes?

- Filter vents are more often found in 'light' and 'ultra-light' cigarettes.
- The filter vents reduce the amount of nicotine and tar measured by the historical testing method, without reducing the amount of tar and nicotine in the cigarette.
- A smoker will likely block at least some of the filter vents on a 'light' or 'ultra-light' cigarette, breathing in more of the dangerous and addictive substances in the smoke.
- For cigarettes tested in 2004, filter ventilation ranged from 0% to 83%. This emphasizes the significant differences in cigarette design between brands of cigarettes.



---

## NICOTINE YIELD RATINGS

---

### Why Publish Nicotine Ranges?

- Because of the differences in individual smoking patterns, no number is truly representative of the amount of nicotine any smoker will receive from a cigarette. Therefore, Massachusetts has developed ranges which classify levels of nicotine relative to each other. These ranges are high (>1.2 mg), moderate (>0.2-1.2), low (.01-.2) or nicotine free (<.01).

Massachusetts is publishing the range of nicotine which a cigarette delivers under typical smoking conditions. All brands are classified as either *high*, *moderate*, *low*, or *nicotine free*. Since individual smoking behaviors vary, these ranges will allow smokers to compare nicotine levels among brands of cigarettes without suggesting specific amounts of nicotine delivered.

### What Do the Classifications Show?

**Of 179 cigarette brands tested, 166 were rated as *high*, including most of the 'light' cigarettes tested, and even some of the 'ultra-light' cigarettes tested.**

- Of the remaining 13 brands (7% of cigarettes tested), all were rated moderate by MDPH standards. This suggests that virtually all cigarettes on the marketplace today deliver moderate to high doses of nicotine sufficient to cause and maintain heavy dependence.
- Eighty-five (85)—or more than half of the all brands rated as high were classified as 'ultra-light,' 'light,' or 'medium.'
- No brand tested fell into the 'low' classification.

The results tests performed in accordance with MDPH regulations demonstrates the highly addictive potential of nearly all brands of cigarettes-- whether full flavor, 'light,' or 'ultra-light.' Brands rated as low in nicotine according to the historical method are shown to deliver significantly greater levels of nicotine and to be potentially more addictive than the ratings would suggest.

## Table 2-- Nicotine Yield Ratings

### HIGH (>1.2 mg)

BRAND <sup>1</sup>	SUB-BRAND <sup>2,3</sup>	BRAND	SUB-BRAND
Basic	085 FI FF HP *	Camel	085 FI LT HP MEN (TURKISH JADE)
Basic	085 FI FF HP MEN *	Camel	085 FI LT SP *
Basic	085 FI FF SP *	Camel	085 FI LT SP (SPECIAL) *
Basic	085 FI FF SP MEN *	Camel	100 FI FF HP (99's) *
Basic	085 FI LT HP *	Camel	100 FI FF HP (TURKISH GOLD)
Basic	085 FI LT SP *	Camel	100 FI FF HP MEN (TURKISH JADE)
Basic	085 FI LT SP MEN *	Camel	100 FI FF SP *
Basic	100 FI FF HP *	Camel	100 FI LT HP (99's) *
Basic	100 FI FF SP *	Camel	100 FI LT HP (SPECIAL) *
Basic	100 FI FF SP MEN *	Camel	100 FI LT HP MEN (TURKISH JADE)
Basic	100 FI LT HP *	Camel	100 FI LT SP *
Basic	100 FI LT SP *	Camel	100 FI UL HP *
Basic	100 FI LT SP MEN *	Doral	085 FI FF HP *
Basic	100 FI UL SP *	Doral	085 FI FF HP MEN *
Benson & Hedges	100 FI FF SP MEN *	Doral	085 FI FF SP *
Benson & Hedges	100 FI LT HP MEN	Doral	085 FI FF SP MEN *
Benson & Hedges	100 FI LT SP MEN *	Doral	085 FI LT HP *
Benson & Hedges	100 FI UL HP *	Doral	085 FI LT SP *
Camel	070 NF FF SP *	Doral	085 NF FF SP *
Camel	085 FI FF HP (RED KAMEL) *	Doral	100 FI FF HP *
Camel	085 FI FF HP *	Doral	100 FI FF HP MEN
Camel	085 FI FF HP (TURKISH GOLD)	Doral	100 FI FF SP *
Camel	085 FI FF HP (TURKISH ROYAL)	Doral	100 FI FF SP MEN *
Camel	085 FI FF HP (WIDES) *	Doral	100 FI LT HP *
Camel	085 FI FF HP MEN (TURKISH JADE)	Doral	100 FI LT SP *
Camel	085 FI FF HP MEN *	Doral	100 FI LT SP MEN *
Camel	085 FI FF SP (AEGEAN SPICE)	Doral	100 FI UL HP
Camel	085 FI FF SP (BACK ALLEY)	Doral	100 FI UL SP *
Camel	085 FI FF SP (BAYOU BLAST)	Kool	085 FI FF HP MEN *
Camel	085 FI FF SP (BEACH BREEZER)	Kool	085 FI FF SP MEN *
Camel	085 FI FF SP (DARK MINT)	Kool	085 FI LT HP MEN *
Camel	085 FI FF SP *	Kool	085 FI LT SP MEN *
Camel	085 FI FF SP (KAUAI KOLADA)	Kool	085 FI MD HP MEN (CARIBBEAN CHILL)
Camel	085 FI FF SP (MANDALAY LIME)	Kool	085 FI MD HP MEN (MIDNIGHT BERRY)
Camel	085 FI FF SP (MIDNIGHT MADNESS)	Kool	085 FI MD HP MEN *
Camel	085 FI FF SP (TWISTA LIME)	Kool	085 FI MD HP MEN (MINTRIQUE)
Camel	085 FI FF SP (WINTER TOFFEE)	Kool	085 FI MD HP MEN (MOCHA TABOO)
Camel	085 FI FF SP (WINTER MOCHA MINT)	Kool	085 FI MD SP MEN *
Camel	085 FI FF SP MEN (MANDARIN MINT)	Kool	085 FI UL SP MEN *
Camel	085 FI FF SP MEN (RARE)	Kool	100 FI FF HP MEN
Camel	085 FI FF TN (BASMA)	Kool	100 FI FF SP MEN
Camel	085 FI FF TN (CREMA)	Kool	100 FI LT SP MEN *
Camel	085 FI FF TN (IZMIR STINGER)	Kool	100 FI MD HP MEN *
Camel	085 FI FF TN (SAMSUM)	Kool	100 FI MD SP MEN *
Camel	085 FI FF TN (TWIST)	Kool	100 FI UL SP MEN *
Camel	085 FI LT HP *	Marlboro	085 FI FF HP *
Camel	085 FI LT HP (SPECIAL) *	Marlboro	085 FI FF HP MEN *
Camel	085 FI LT HP (WIDES) *	Marlboro	085 FI FF SP *
Camel	085 FI LT HP (RED KAMEL) *	Marlboro	085 FI FF SP MEN *
Camel	085 FI LT HP MEN *	Marlboro	085 FI LT HP *

BRAND	SUB-BRAND
Marlboro	085 FI LT HP MEN *
Marlboro	085 FI LT SP *
Marlboro	085 FI LT SP MEN *
Marlboro	085 FI MD HP *
Marlboro	085 FI MD SP *
Marlboro	085 FI UL HP *
Marlboro	100 FI FF HP *
Marlboro	100 FI FF HP MEN *
Marlboro	100 FI FF SP *
Marlboro	100 FI LT HP *
Marlboro	100 FI LT HP MEN *
Marlboro	100 FI LT SP *
Marlboro	100 FI LT SP MEN *
Marlboro	100 FI MD HP *
Marlboro	100 FI MD SP *
Marlboro	100 FI UL HP *
Maverick	100 FI FF HP
Maverick	100 FI FF HP MEN
Maverick	100 FI LT HP MEN
Max	120 FI FF SP
Merit	100 FI UL SP
More	120 FI FF SP MEN
Newport	085 FI FF HP MEN *
Newport	085 FI FF SP MEN *
Newport	085 FI FF SP MEN *
Newport	085 FI LT HP MEN *
Newport	085 FI LT SP MEN *
Newport	085 FI MD HP MEN
Newport	100 FI FF HP MEN *
Newport	100 FI FF SP MEN *
Newport	100 FI FF SP MEN *
Newport	100 FI LT HP *
Newport	100 FI LT HP MEN *

BRAND	SUB-BRAND
Newport	100 FI LT HP MEN *
Newport	100 FI LT SP MEN *
Newport	100 FI MD HP MEN
Newport	120 FI LT HP MEN *
Old Gold	085 FI FF SP
Old Gold	085 NF FF SP
Parliament	085 FI LT HP *
Parliament	085 FI LT HP MEN
Parliament	100 FI LT HP
Salem	085 FI FF HP MEN
Salem	085 FI FF SP MEN
Salem	085 FI LT HP MEN
Salem	085 FI LT SP MEN
Salem	100 FI LT HP MEN
Salem	100 FI UL HP
Virginia Slims	100 FI FF HP MEN
Virginia Slims	100 FI LT HP *
Virginia Slims	100 FI UL HP MEN
Winston	085 FI FF HP *
Winston	085 FI FF HP (S2)
Winston	085 FI FF HP (SELECT) *
Winston	085 FI FF SP *
Winston	085 FI LT HP
Winston	085 FI LT HP (SELECT) *
Winston	085 FI LT SP *
Winston	085 FI UL HP *
Winston	100 FI FF HP
Winston	100 FI FF HP (S200's)
Winston	100 FI FF SP *
Winston	100 FI LT HP *
Winston	100 FI LT HP (SELECT SLIM)
Winston	100 FI LT SP *
Winston	100 FI UL HP *

**Table 2 -- Nicotine Yield Ratings (cont.)**

**MODERATE (>.2-1.2)**

<b>BRAND</b>	<b>SUB-BRAND</b>	<b>BRAND</b>	<b>SUB-BRAND</b>
Basic	085 FI UL SP *		
Camel	085 FI UL HP *		
Camel	085 FI UL SP *		
Doral	085 FI LT HP MEN		
Doral	085 FI LT SP MEN *		
Doral	085 FI UL HP		
Doral	085 FI UL SP *		
Eclipse	085 FI UL HP		
Eclipse	085 FI UL HP MEN		
Merit	085 FI UL SP		
Salem	085 FI UL HP		
Winston	085 FI UL SP *		
Winston	100 FI UL SP *		

## Table 2 -- Nicotine Yield Ratings (cont.)

**LOW (>0-0.2)**

**None**

**None**

**NICOTINE FREE (=0.0)**

Note: All data Table 2 was supplied to Massachusetts Department of Public Health (MDPH) by the cigarette manufacturers in compliance with M.G.L. Chapter 94, Section 307B. Tobacco manufacturers are required to file an annual report concerning nicotine yields with the MDPH for each brand of tobacco product sold in the Commonwealth. 1) Brand information supplied by the manufacturer. 2) The sub-brand code includes information about the length of the cigarette in millimeters (070, 085, 100, or 120), whether the cigarette was filtered (FI) or unfiltered (NF), whether a cigarette was listed as full flavor (FF), light (LT), or ultra-light (UL), whether the cigarettes were sold in a hard pack (HP) or a soft pack (SP), whether the cigarettes were listed as mild or medium (MD), and whether the cigarettes contained menthol (MEN). In some cases, the above coding system was insufficient to distinguish brand/sub-brand combinations. In those cases, additional labeling information was added to the code in order to produce a unique list of brand/sub-brand combinations. 3) Sub-brands marked with asterisks (\*) have nicotine delivery values from both 1998 and 2004.

---

<sup>1</sup> Kozlowski LT, O'Connor RJ. Official cigarette tar tests are misleading: use a two-stage, compensating test. *Lancet* 2000;355:2159-61.

<sup>2</sup> Kozlowski LT, O'Connor RJ. Cigarette filter ventilation is a defective design because of misleading taste, bigger puffs, and blocked vents. *Tobacco Control*, 2002;11, 40-50.

<sup>3</sup> Pillsbury, Harold C., Jr. "Review of the Federal Trade Commission Method for Determining Cigarette Tar and Nicotine Yield," *The FTC Cigarette Test for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes (Monograph 7)*. Report of the NCI Expert Committee: U.S. Department of Health and Human Services, National Institutes of Health, 9.

<sup>4</sup> Peeler, C. Lee. "Cigarette Testing and the Federal Trade Commission: A Historical Overview," *The FTC Cigarette Test for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes (Monograph 7)*. Report of the NCI Expert Committee: U.S. Department of Health and Human Services, National Institutes of Health, 2.

<sup>5</sup> Zacny, James P. and Maxine L. Stitzer. "Human Smoking Patterns," *The FTC Cigarette Test for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes (Monograph 7)*. Report of the NCI Expert Committee: U.S. Department of Health and Human Services, National Institutes of Health, 154-55.

<sup>6</sup> Kozlowski, Lynn T. and Janine L. Pillitteri. "Compensation for Nicotine by Smokers of Lower Yield Cigarettes," *The FTC Cigarette Test for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes (Monograph 7)*. Report of the NCI Expert Committee: U.S. Department of Health and Human Services, National Institutes of Health, 168.

<sup>7</sup> Freeman, Harold P. *The FTC Cigarette Test for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes (Monograph 7)*. Report of the NCI Expert Committee: U.S. Department of Health and Human Services, National Institutes of Health, vi-viii.

U.S. Food and Drug Administration

SPEECH 03/25/1994

**Statement on Nicotine-Containing Cigarettes**  
**by**  
**David A. Kessler, M.D.**  
**Commissioner of Food and Drugs**  
**House Subcommittee on Health and the Environment**  
**March 25, 1994**

Mr. Chairman, the cigarette industry has attempted to frame the debate on smoking as the right of each American to choose. The question we must ask is whether smokers really have that choice.

Consider these facts:

- Two-thirds of adults who smoke say they wish they could quit.
- Seventeen million try to quit each year, but fewer than one out of ten succeed. For every smoker who quits, nine try and fail.
- Three out of four adult smokers say that they are addicted. By some estimates, as many as 74 to 90 percent are addicted.
- Eight out of ten smokers say they wish they had never started smoking.

Accumulating evidence suggests that cigarette manufacturers may intend this result -- that they may be controlling smokers' choice by controlling the levels of nicotine in their products in a manner that creates and sustains an addiction in the vast majority of smokers.

That is the issue I am here to address. Whether it is a choice by cigarette companies to maintain addictive levels of nicotine in their cigarettes, rather than a choice by consumers to continue smoking, that in the end is driving the demand for cigarettes in this country.

Although FDA has long recognized that the nicotine in tobacco produces drug-like effects, we never stepped in to regulate most tobacco products as drugs. One of the obstacles has been a legal one. A product is subject to regulation as a drug based primarily on its intended use. Generally, there must be an intent that the product be used either in relation to a disease or to affect the structure or function of the body. With certain exceptions, we have not had sufficient evidence of such intent with regard to nicotine in tobacco products. Most people assume that the nicotine in cigarettes is present solely because it is a natural and unavoidable component of tobacco.

Mr. Chairman, we now have cause to reconsider this historical view. The question now before us all is whether nicotine-containing cigarettes should be regulated as drugs. We seek guidance from the Congress on the public health and social issues that arise once the question is posed. This question arises today because of an accumulation of information in recent months and years. In my testimony today, I will describe some of that information.

The first body of information concerns the highly addictive nature of nicotine. The second body of information I will be talking about -- in some detail -- concerns the apparent ability of cigarette companies to control nicotine levels in cigarettes. We have information strongly suggesting that the amount of nicotine in a cigarette is there by design. Cigarette companies must answer the question: what is the real intent of this design?

## **I. NICOTINE IS A HIGHLY ADDICTIVE SUBSTANCE**

Let me turn then to my first point about the addictive nature of nicotine.

The nicotine delivered by tobacco products is highly addictive. This was carefully documented in the 1988 Surgeon General's report. You can find nicotine's addictive properties described in numerous scientific papers.

As with any addictive substance, some people can break their addiction to nicotine. But I doubt there is a person in this room who hasn't either gone to great pains to quit smoking, or watched a friend or relative struggle to extricate himself or herself from a dependence on cigarettes.

Remarkably, we see the grip of nicotine even among patients for whom the dangers of smoking could not be starker. After surgery for lung cancer, almost half of smokers resume smoking. Among smokers who suffer a heart attack, 38 percent resume smoking while they are still in the hospital. Even when a smoker has his or her larynx removed, 40 percent try smoking again.

When a smoker sleeps, blood levels of nicotine decrease significantly. But the smoker doesn't need to be an expert on the concept of nicotine blood levels to know full well what that means. More than one-third of smokers reach for their first cigarette within 10 minutes of awakening; nearly two-thirds smoke within the first half hour. Experts in the field tell us that smoking the first cigarette of the day within 30 minutes of waking is a meaningful measure of addiction.

I am struck especially by the statistics about our young people. A majority of adult smokers begin smoking as teenagers. Unfortunately, 70 percent of young people ages 12-18 who smoke say that they believe that they are already dependent on cigarettes. About 40 percent of high school seniors who smoke regularly have tried to quit and failed.

It is fair to argue that the decision to start smoking may be a matter of choice. But once they have started smoking regularly, most smokers are in effect deprived of the choice to stop smoking. Recall one of the statistics I recited earlier. Seventeen million Americans try to quit smoking each year. But more than 15,000,000 individuals are unable to exercise that choice because they cannot break their addiction to cigarettes. My concern is that the choice that they are making at a young age quickly becomes little or no choice at all and will be very difficult to undo for the rest of their lives.

Mr. Chairman, nicotine is recognized as an addictive substance by such major medical organizations as the Office of U.S. Surgeon General, the World Health Organization, the American Medical Association, the American Psychiatric Association, the American Psychological Association, the American Society of Addiction Medicine, and the Medical Research Council in the United Kingdom. All of these organizations acknowledge tobacco use as a form of drug dependence or addiction with severe adverse health consequences.

Definitions of an addictive substance may vary slightly, but they all embody some key criteria: first, compulsive use, often despite knowing the substance is harmful; second, a psychoactive effect -- that is, a direct chemical effect in the brain; third, what researchers call reinforcing behavior that conditions continued use. (Chart A) In addition, withdrawal symptoms occur with many drugs and occur in many cigarette smokers who try to quit. These are hallmarks of an addictive substance and nicotine meets them all.

When a smoker inhales, once absorbed in the bloodstream, nicotine is carried to the brain in only 7-9 seconds, setting off a biological chain reaction that is critical in establishing and reinforcing addiction.

Over the past few years, scientists have generated a tremendous amount of information on the similarities among different addictive substances. Some crucial information has come from the fact that, in a laboratory setting, animals will self-administer addictive substances. This self-administration may involve the animal pushing a lever or engaging in other actions to get repeated doses of the addictive substance. With very few exceptions, animals will self-administer those drugs that are considered highly addictive in humans, including morphine and cocaine, and will not self-administer those drugs that are not considered addictive.

Understanding that animals will self-administer addictive substances has fundamentally changed the way that scientists view addiction in humans. It has turned attention away from the concept of an "addictive personality" to a realization that addictive drugs share common chemical effects in the brain.

Despite the wide chemical diversity among different addictive substances, a property that most of them share is the ability to affect the regulation of a chemical called dopamine in parts of the brain that are important to emotion and motivation. It is now believed that it

is the effect of addictive substances on dopamine that is responsible for driving animals to self-administer these substances and for causing humans to develop addictions.

Regulation of dopamine, rewards the activity, and causes the animal or person to repeat the activity that produced that reward. The process by which the regulation of dopamine leads an animal or a human to repeat the behavior is known as "reinforcement." Drugs that have the ability to directly modify dopamine levels can produce powerfully ingrained addictive behavior."

One of the ways that researchers now test the addictive properties of drugs is to determine whether animals will self-administer that substance and then to determine whether the animals will stop self-administering if the chemical action of the substance is blocked by the simultaneous administration of another drug that prevents the first substance from acting in the brain. Data gathered over the past 15 years have documented that laboratory animals will voluntarily self-administer nicotine, that nicotine does stimulate the release of dopamine; and that laboratory animals will decrease self-administration of nicotine if the action of nicotine, or the release of dopamine, in the brain is blocked.

A number of top tobacco industry officials have stated that they do not believe that tobacco is addictive. They may tell you that smokers smoke for "pleasure," not to satisfy a nicotine craving. Experts tell us that their patients report that only a small minority of the cigarettes they smoke in a day are highly pleasurable. Experts believe that the remainder are smoked to primarily sustain nicotine blood levels and to avoid withdrawal symptoms.

The industry couches nicotine's effects in euphemisms such as "satisfaction" or "impact" or "strength." Listen to what they say in one company's patent:

It also has been generally recognized that the smoker's perception of the "strength" of the cigarette is directly related to the amount of nicotine contained in the cigarette smoke during each puff.

-patent no. 4,595,024 C1:33-36

But these terms only sidestep the fact that the companies are marketing a powerfully addictive agent. Despite the buzzwords used by industry, what smokers are addicted to is not "rich aroma" or "pleasure" or "satisfaction." What they are addicted to is nicotine, pure and simple, because of its psychoactive effects and its drug dependence qualities.

To smokers who know that they are addicted, to those who have buried a loved one who was addicted, it is simply no longer credible to deny the highly addictive nature of nicotine.

## II. CONTROLLING THE LEVEL OF NICOTINE IN CIGARETTES

My second point today involves a growing body of information about the control of nicotine levels exercised by the tobacco industry. Mr. Chairman, I do not have all the facts or all the answers today. The picture is still incomplete. But from a number of pieces of information, from a number of sources, a picture of tobacco company practices is beginning to emerge.

The public thinks of cigarettes as simply blended tobacco rolled in paper. But they are much more than that. Some of today's cigarettes may, in fact, qualify as high technology nicotine delivery systems that deliver nicotine in precisely calculated quantities -- quantities that are more than sufficient to create and to sustain addiction in the vast majority of individuals who smoke regularly.

But you don't have to take it from me. Consider how people in the tobacco industry itself view cigarettes.

Just take a moment to look at the excerpts from an internal memorandum written by a supervisor of research that circulated in the Philip Morris Company in 1972:

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 for nicotine. . . . Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke.

"Dispensers of smoke . . . which is a vehicle for delivering nicotine." This quote is a revealing self-portrait. Or listen to the words in one tobacco company patent: Medical research has established that nicotine is the active ingredient in tobacco. Small doses of nicotine provide the user with certain pleasurable effects resulting in the desire for additional doses.

-patent no. 4,676,259 C1:21-24

### **The Design of Cigarettes**

How does this industry design cigarettes?

The history of the tobacco industry is a story of how a product that may at one time have been a simple agricultural commodity appears to have become a nicotine delivery system. Prior to the 1940's, the waste products from cigarettes -- the stems, the scraps, and the dust -- were discarded. The tobacco industry had identified no use for these materials in the cigarette manufacturing process.

Then, in the 1940s and '50s, the industry created reconstituted tobacco from the previously unusable tobacco stems, scraps, and dust. This gave cigarette makers the

ability to reduce the cost of producing cigarettes by using fewer tobacco leaves and making up the difference by using reconstituted tobacco. While the motive appeared to be purely economic, the reconstitution process was nevertheless a critical development that started the industry down the path toward controlling and manipulating nicotine levels. The ability to control and manipulate nicotine levels becomes important in light of another key realization. Industry patents show that the industry recognized that nicotine is the active ingredient in tobacco smoke. It is what produces the psychoactive effects that lead smokers to crave cigarettes.

Numerous patents illustrate how the industry has been working to sustain the psychoactive effects of nicotine in cigarettes. These charts show samples from several categories of patents: eight patents to increase nicotine content by adding nicotine to the tobacco rod (Chart B); five patents to increase nicotine content by adding nicotine to filters, wrappers and other parts of the cigarette (Chart C); three patents that use advanced technology to manipulate the levels of nicotine in tobacco (Chart D); eight patents on extraction of nicotine from tobacco (Chart E); and nine patents to develop new chemical variants of nicotine (Chart F).

Patents not only describe a specific invention. They also speak to the industry's capabilities, to its research, and provide insight into what it may be attempting to achieve with its products.

It is prudent to keep in mind that patents do not necessarily tell us what processes are currently being used in manufacturing cigarettes. Nevertheless, the number and pattern of these patents leaves little doubt that the cigarette industry has developed enormously sophisticated methods for manipulating nicotine levels in cigarettes. Today, a cigarette company can add or subtract nicotine from tobacco. It can set nicotine levels. In many cigarettes today, the amount of nicotine present is a result of choice, not chance.

Let me show you the language in some of these patents. This is in the industry's own words.

Listen to what industry says it wants to be able to do with nicotine.

First, the industry wants precise control of the amount of nicotine in cigarettes to provide desired physiological effects:

Maintaining the nicotine content at a sufficiently high level to provide the desired physiological activity, taste, and odor...can thus be seen to be a significant problem in the tobacco art.

-patent no. 3,280,823 C1:43-48

Second, the industry wants to increase the amount of nicotine in some cigarettes.

...the perceived taste or strength of the cigarettes classified as having lower levels of "tar" and nicotine are progressively less than that of the cigarettes which are classified as approaching the characteristics of the "full flavor" cigarettes. It has been proposed to add nicotine and other flavorants to the cut filler of the lower "tar" cigarettes to enhance the taste, strength, and satisfaction of such cigarettes.

-patent no. 4,830,028 C1:40-47

This invention...concerns the problem of maintaining or increasing the nicotine content of the smoke whilst avoiding an undesirable level of particulate matter in the smoke....

-patent no. 3,861,400 C1:1-10

Now listen to what the industry says it can do, right now, at least for patent purposes, with the nicotine in cigarettes:

It can precisely manipulate nicotine levels in cigarettes:

This invention permits the release into tobacco smoke, in controlled amounts, of desirable flavorants, as well as the release, in controlled amounts and when desired, of nicotine into tobacco smoke.

-patent no. 3,280,823 C2:37-40

It is another object of the invention to provide an agent for the treatment of tobacco smoke whereby nicotine is easily released thereinto in controlled amounts.

-patent no. 3,584,630 C2:69-71

[I]t can be seen that the process...enables the manipulation of the nicotine content of tobacco material, such as cut leaf and reconstituted leaf, by removal of nicotine from a suitable nicotine tobacco source or by the addition of nicotine to a low nicotine tobacco material.

-patent no. 4,215,706 C3:61-66

...processed tobaccos can be manufactured under conditions suitable to provide products having various nicotine levels.

-patent no. 5,031,646 C5:63-65

Examples of suitable tobacco materials include...processed tobacco materials such as expanded tobaccos, processed tobacco stems, reconstituted tobacco materials or reconstituted tobacco materials having varying levels of endogenous and exogenous nicotine....

-patent no. 5,031,646 C5:21-27

...the present invention...is particularly useful for the maintenance of the proper amount of nicotine in tobacco smoke.

...previous efforts have been made to add nicotine to tobacco products wherein the nicotine level in the tobacco was undesirably low.

-patent no. 3,584,630 C2:5-15

It can precisely manipulate the rate at which the nicotine is delivered in the cigarette:

It is a further object of this invention to provide a cigarette which delivers a larger amount of nicotine in the first few puffs of the cigarette than in the last few puffs.

-patent no. 4,595,024 C2:23-26

It can transfer nicotine from one material to another at will:

Moreover, the process is useful for transferring naturally occurring nicotine from tobacco having a generally high nicotine content to a nicotine deficient tobacco, tobacco filler materials, or RL (reconstituted leaf) which are used in the production of cigarettes and other smoking products... [A] low nicotine tobacco ...can also be used as the nicotine donor...

-patent no. 4,215,706 C1:40-48

It is another object of this invention to provide a process for the migration of nicotine from one tobacco substrate (leaf material or reconstituted leaf) to a second tobacco substrate (leaf material, reconstituted leaf material or tobacco stems) or to a non-tobacco substrate.

-patent no. 5,018,540 C2:39-43

It can increase the amount of nicotine in cigarettes:

If desired, nicotine can be incorporated into the expansion solvents used to provide a volume expanded processed tobacco material having a high nicotine content.

-patent no. 5,031,646 C5:65-68

The present invention provides a nicotine-enhanced smoking device with a high nicotine release efficiency....Thus, the smoker is provided with more nicotine from the nicotine-enhanced device than from a similar smoking device which does not contain the nicotine solution or from a comparable cigarette.

-patent no. 4,676,259 C2:30-33, 53-56

The present invention is concerned with the application of additives, such as... physiologically active agents such as nicotine components to the smoking rod, in order to improve or help to improve the satisfaction provided to the smoker.

-patent no. 4,236,532 C1:35-40

It can add nicotine to any part of the cigarette:

The salts [nicotine levulinate] can be incorporated into the smoking article in a variety of places or sites. For example, the salt can be applied to the filler material, incorporated within some or all of the filler material, applied to the wrapper of the tobacco rod, applied within the glue line of the wrapper of the tobacco rod, applied within a region (e.g., a cavity)....

-patent no. 4,830,028 C5:59-65

It can use a variety of methods to add nicotine to tobacco:

...[T]he additive [nicotine levulinate] can be applied using syringes or techniques such as spraying, electrostatic deposition, impregnation, garniture injection, spray drying, inclusion and encapsulation technologies, and the like.

-patent no. 4,830,028 C6:-7

Let me describe in some detail how some of the technologies can be used to increase or control the nicotine level of tobacco.

The industry had to tackle a new problem beginning in the 1960s as public concern about the health consequences of smoking intensified. The industry began to market cigarettes it described as low yield. It faced a major challenge, however, because in the words of patent no. 4,830,028, "the perceived taste or strength of the cigarettes classified as having lower levels of 'tar' and nicotine are progressively less than that of the cigarettes which are classified as approaching the characteristics of the "full flavor" cigarettes."

The patent then describes a way to add nicotine to the "low yield" cigarettes. If nicotine alone is sprayed on a blend of tobacco, the patent states that the smoke that results will be unacceptably harsh or irritating to the user. So, instead of just spraying nicotine on the tobacco blend, the patent combines nicotine with another compound, an organic acid called levulinic acid, to form a salt that masks the irritating qualities of nicotine. (Chart G and H) The patent demonstrates that different percentages of the nicotine salt can be added to blends of tobacco to produce different nicotine concentrations. The control cigarette, the one without any added nicotine, contains 1.66 percent nicotine. Adding one percent nicotine salt results in a cigarette with 2.05 percent nicotine. As one increases the amount of

nicotine salt sprayed on the tobacco blend, the nicotine content of the tobacco increases.

In this process, great care is paid to the pH of the smoke because pH affects the bioavailability of nicotine -- that is, how much the body absorbs. The patent demonstrates the technology to increase nicotine content in tobacco by up to 76 percent.

U.S. patent no. 5,065,775 (Chart I) describes another technology that can control the nicotine content of tobacco filler. This involves a process for "modifying the alkaloid content of a tobacco material and, in particular, for providing a processed tobacco material having a controlled nicotine content." (C2:57-60) In the words of the patent "[t]he process of the present invention provides a skilled artisan with an efficient and effective method for changing the character of a tobacco material (e.g., rearranging components of a tobacco material or altering the chemical nature or composition of a tobacco material) in a controlled manner. That is, the process...can be employed in a way such that changes in the chemical composition of tobacco can be monitored as to occur to a desired degree." (C3:55-63)

The patent allows for the removal of selected substances from tobacco, and incorporating controlled amounts of substances into tobacco. Example 4 within this patent shows how a tobacco blend that starts off with a 2.3 percent nicotine content can end up with a 5.2 percent nicotine content. A highly concentrated nicotine solution is created by subjecting a tobacco blend to a series of chemical steps, including adding water, removing solids, increasing the pH, and mixing this substance with chlorofluorocarbon (CFC) 11 and then evaporating off that CFC 11. This concentrate is then added to water-washed tobacco to increase its nicotine content. This patent demonstrates the technology to increase the nicotine content in tobacco by more than 100 percent .

A third example of sophisticated technology involves the direct transfer of nicotine from one type of tobacco to another type of tobacco. (Chart J) U.S. patent no. 4,898,188 utilizes supercritical fluid extraction. In example 2 in the patent, liquid carbon dioxide is used to transfer nicotine from Burley cut tobacco filler to flue-cured cut tobacco. The flue-cured cut filler starts off with a nicotine content of 2.59 percent and ends up with a nicotine content of 4.83 percent. The Burley cut filler starts off with a nicotine content of 3.56 percent and ends with a nicotine content of 0.88 percent. This patent demonstrates that nicotine can be transferred in significant amounts from one type of tobacco filler to another.

Additional information about the ability to set nicotine content at varying levels comes from the following ad, headlined "More Nicotine or Less," which appeared in an international tobacco trade publication: (Chart K)

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.

In fact the process described in this advertisement can raise the level of nicotine beyond what is naturally found in tobacco materials, especially the stems and scraps. A 1985 tobacco journal article describing the LTR process states

Though standard reconstituted tobacco products contain 0.7 - 1.0 percent nicotine, LTR Industries offers the possibility of increasing the nicotine content of the final sheet to a maximum of 3.5 percent...

A dramatic increase in tobacco taste and smoke body is noted in the nicotine-fortified reconstituted tobacco.

All of this apparent technology for manipulating nicotine in tobacco products raises the question of how the industry determines how much nicotine should be in various products. More importantly, since the technology apparently exists to reduce nicotine in cigarettes to insignificant levels, why, one is led to ask, does the industry keep nicotine in cigarettes at all?

The tobacco industry would like you to believe that all it is doing is returning the nicotine that is removed during the process of producing reconstituted tobacco. It should be clear from what I have described thus far that the technology the industry may have available goes beyond such modest efforts.

The industry may also tell you that it is adjusting nicotine levels to be consistent with established "FTC yields" -- these are the amounts of tar, nicotine, and carbon monoxide that are measured for each cigarette product by smoking machines, and disclosed under a voluntary agreement with the Federal Trade Commission. In fact, the control of nicotine levels in cigarettes, dating back at least to patents granted in 1966 for adjusting nicotine levels, preceded the first rules adopted by the FTC on disclosing tar and nicotine yields. Moreover, there is nothing about the FTC yields that would require tobacco companies to increase nicotine in low tar cigarettes, as the industry patents suggest they do. There are no FTC restrictions on nicotine levels, and the FTC guidelines take into account crop variability by sampling completed cigarettes from 50 retail outlets across the country. Indeed, there is no FTC restriction that would prevent the industry from reducing nicotine below addicting levels or eliminating it altogether.

In fact, the technology reflected in the cigarette industry's patents appears to be intended to allow the industry to set the nicotine content of tobacco products at defined levels that have little to do with either the amount of nicotine that was removed during the processing of the tobacco, or with the simple goal of maintaining consistency with established FTC yields. The technology may exist to allow the industry to set nicotine levels wherever it want, or, in fact to remove nicotine entirely. With all the apparent advances in technology, why do the nicotine levels found in the vast majority of cigarettes remain at addictive levels?

Nicotine levels may be dictated in part by marketing strategies and demographics. A blatant example comes from information on the marketing of smokeless tobacco. There is evidence that smokeless tobacco products with lower amounts of nicotine are marketed as "starter" products for new users, and that advertising is used to encourage users to "graduate" to products with higher levels of nicotine. (Chart L) The evidence was developed in lawsuits brought against one manufacturer of smokeless tobacco.

The tobacco industry may tell you that nicotine is important in cigarettes solely for "flavor." There is a great deal of information that suggests otherwise. Some of the patents specifically distinguish nicotine from flavorants. An RJR book on flavoring tobacco, while listing around a thousand flavorants, fails to list nicotine as a flavoring agent. Even research scientists from the same company acknowledge that the nicotine in cigarettes provides pharmacological and psychological effects to smokers in addition to any mere sensory effects.

Moreover, the available information shows that the industry has gone to significant lengths to develop technologies to mask the flavor of increased levels in cigarettes. As I have already noted, the industry's own patents reveal that increasing nicotine in fact usually produces an unacceptably harsh and irritating product, and that the industry has had to take special steps to mask the flavor of increased nicotine in low tar cigarettes.

This should not come as a surprise. The Merck Index, the authoritative encyclopedia of chemicals, describes nicotine as having "an acrid, burning taste." Webster's 7th New Collegiate Dictionary defines acrid as "sharp and harsh or unpleasantly pungent in taste or odor; irritating, corrosive." In fact, U.S. patent 4,620,554 uses the word "hazardous" to describe the taste of nicotine.

What appears to be true is that smokers become accustomed to, and associate, the sensory impact of nicotine (burning in the throat) with the resulting psychoactive effects of nicotine, and thus look for those sensory signals in a cigarette; this is called "conditioned reinforcement."

Moreover, if nicotine is just another flavorant in tobacco, why not use a substitute

ingredient with comparable flavor, but without the addictive potential? For example, it has been repeatedly shown that substitute ingredients, such as hot pepper (capsaicin) and citric acid, have similar irritating sensory effects.

### **Similarities to the Pharmaceutical Industry**

Mr. Chairman, this kind of sophistication in setting levels of a physiologically active substance suggests that what we are seeing in the cigarette industry more and more resembles the actions of a pharmaceutical manufacturer. Besides controlling the amount of a physiologically active ingredient, there are a number of other similarities.

One similarity between the cigarette industry and the pharmaceutical industry is the focus on bioavailability. Bioavailability is the rate and extent that pharmacologically active substances get into the bloodstream. For example, the pH of tobacco smoke affects the bioavailability of nicotine. The tobacco industry has conducted research on the pH of smoke and has undertaken to control the pH in tobacco smoke. In patent examples, chemicals have been added to tobacco to affect the pH of tobacco smoke. The industry has even performed bioavailability and pharmacokinetic studies on conventional and novel cigarettes.

The cigarette industry has undertaken research to look at the specific activity of added versus naturally occurring nicotine. Additional research looked at the differences between spiking, spraying and blending compounds into cigarettes.

Development of an "express" cigarette, a shorter, faster burning cigarette with the same amount of tar and nicotine, has been reported in the lay press recently. This is another example of how cigarette companies appear to be controlling the amounts of nicotine to deliver set levels.

The cigarette industry has also undertaken a significant amount of research looking at the potential "beneficial" effects of nicotine. It has studied the effects of nicotine on anxiety, heart rate, electroencephalographs (EEG's), and behavioral performance tasks. Such research on the physiological effects of an active ingredient is a common part of pharmaceutical drug development.

Perhaps the most striking aspect of the research undertaken by the tobacco industry is its search for, and its patenting of, new nicotine-like chemicals that exhibit pharmacological properties which, in their own words, "are indicated for utility as potential psychotherapeutic agents." One patent describes nicotine-like chemicals which

exhibit tranquilizing and muscle-relaxing properties when administered to mammals. The nicotine analogs do not exhibit nicotine-like properties, such as tachycardia, hypertension, gastrointestinal effects, emesis in dogs, and the like.

Example XXIX in the patent

illustrates the pharmacological properties of nicotine analogs....

The tranquilizing effects of invention nicotine compounds are measured after intraperitoneal (IP) and intraventricular (IVC) administration in the form of hydrochloride salts.

Sedation is determined by measuring locomotion in an open field maze, and the response to noxious (air blast) stimuli. Body tone is estimated by handling rats and by the ability to hang from a rotating rod.

Tranquilization after intraventricular (IVC injection) is estimated from muscle weakness in all four limbs, body tone and general activity.

Chart M illustrates the results.

### **The Problem of the Low-yield Cigarette**

We, at the Food and Drug Administration, are concerned not only about the control over nicotine levels exercised by the cigarette industry, we are also concerned that the problems associated with nicotine are aggravated by significant limitations in consumer's ability to reduce their exposure to nicotine by selecting "low" nicotine cigarettes.

Most people who smoke low yield or "light" cigarettes believe that they are getting less nicotine and tar by smoking these cigarettes. For the last 25 years the American public has relied on FTC ratings of tar and nicotine in advertising to tell them what they will be consuming. The "FTC method" utilizes a machine that tests cigarettes in a process involving a two- second, 35 milliliter puff each minute until a predetermined butt length is reached.

Most people don't realize that low yield cigarettes, as determined by the FTC method, do not usually result in proportionally less nicotine being absorbed when compared to high yield cigarettes. Furthermore, there is little correlation between low yield FTC ratings and the total amount of nicotine in cigarettes.

It is a myth that people who smoke low nicotine cigarettes are necessarily going to get less nicotine than people who smoke high nicotine cigarettes. There are several reasons for this. One reason is that there are differences between the smoking habits of a machine and a human. The way in which a cigarette is smoked is probably the most important determinant of how much tar and nicotine is inhaled. Humans can compensate -- and do compensate -- when smoking low yield cigarettes, by altering puff volume, puff duration, inhalation frequency, depth of inhalation, and the

number of cigarettes smoked. As a result of these compensatory mechanisms, a low yield cigarette can actually result in a relatively high intake of nicotine.

Beyond the human compensatory mechanisms, several other factors under manufacturers' control contribute to a lowering of machine ratings. These factors include the positioning of ventilation holes, how fast the cigarette paper burns, and the length of the filter paper overwrap.

To understand how the position of ventilation holes in a cigarette can confound the FTC ratings, it is important to recognize that the main determinants of whether a cigarette has a high or low yield in machine testing are the cigarette's ventilation and burning characteristics. Most low yield cigarettes achieve their low ratings because of filter characteristics and also because the smoke is diluted with air. The air dilution is accomplished in part by placing ventilation holes in the filter. What scientists have demonstrated is that "although smoking machines which measure tar and nicotine do not occlude the perforations," 32-69 percent of low tar smokers have blocked the holes with their fingers or lips, resulting in larger nicotine yields. The ventilation holes are sometimes laser generated and can be hard for the smoker to see. Not all smokers are aware of the existence of these holes or that the smoker may be blocking them. (Chart N)

Two other factors that are under manufacturers' control can also confound the usefulness of the FTC ratings. The FTC method smokes a cigarette down to within 3 millimeters of the tipping paper overwrap. According to one study, "between 1967 and 1978, 18 brands of filter cigarettes underwent increases in overwrap width that reduced the amount of tobacco smoked in the cigarettes on the machine, even though the remaining tobacco is still smokeable." (Chart O) Another way that the FTC numbers can be confounded is by "increasing the rate at which cigarettes burn." A faster burning cigarette lowers the puff count. Manufacturers can increase the rate at which a cigarette burns by controlling the porosity of the cigarette paper. The machine takes a puff every minute, but humans can adjust their smoking rate.

Because of all these confounding factors we are concerned that consumers may assume that low yield cigarettes in fact deliver low tar and nicotine when in reality they do not.

### **Actual Nicotine Levels in Cigarettes**

To assess the levels of nicotine in cigarettes, we did two things. First, FDA laboratories measured the amount of nicotine actually in several types of cigarettes. We analyzed three varieties of one brand family of cigarettes; one that is regular, one that is low tar, and one that is ultra low. What surprised us was that the variety advertised as having the lowest yield in fact had the highest concentration of nicotine in the cigarette. (Chart P)

Second, we formally requested from our colleagues at the Federal Trade Commission summary information derived from their data base on the levels of nicotine in cigarettes. What we found was that since 1982 (the earliest year for which the computer data base is available), the sales weighted levels of FTC nicotine in cigarettes appear to increase. (Charts Q,R,S, and T) What was equally striking was that when we segmented sales into high tar, low tar, and ultra low tar cigarettes, the nicotine/tar ratio was higher in the ultra low tar group. (Chart U) We would not have expected to see these differences because high tar has usually been associated with high nicotine, low tar has usually been associated with low nicotine. It has often been said that tar and nicotine travel together in the cigarette smoke. The disparities in the nicotine/tar ratios among these varieties raise the question as to how this can occur.

### **III. FDA REGULATION OF NICOTINE IN CIGARETTES**

The next task facing the FDA is to determine whether nicotine-containing cigarettes are "drugs" within the meaning of the Federal Food, Drug, and Cosmetic Act.

Our inquiry is necessarily shaped by the definition of "drug" in the Act. It is a definition that focuses on "vendor intent." More specifically, it focuses primarily on whether the vendor intends the product to, "affect the structure or any function of the body."

Mr. Chairman, the evidence we have presented today suggests that cigarette manufacturers may intend that most smokers buy cigarettes to satisfy their nicotine addiction.

We do not yet have all the evidence necessary to establish cigarette manufacturers' intent. It should be clear, however, that in determining intent what cigarette manufacturers say can be less important than what they do. The fact that the technology may be available to reduce the nicotine to less than addictive levels is relevant in determining manufacturer intent.

It is important to note that the possibility of FDA exerting jurisdiction over cigarettes raises many broader public health and social issues for Congress to contemplate. There is the possibility that regulation of the nicotine in cigarettes as drugs would result in the removal of nicotine-containing cigarettes from the market, limiting the amount of nicotine in cigarettes to levels that are not addictive, or otherwise restricting access to them, unless the industry could show that nicotine containing cigarettes are safe and effective. If nicotine were removed, the nation would face a host of issues involving the withdrawal from addiction that would be experienced by millions of Americans who smoke.

There is, of course, the issue of black market cigarettes. With nicotine, as with other

powerfully addicting substances, a black market could develop.

In these issues, we seek guidance from Congress.

The one thing that I think is certain is that it is time for all of us -- for the FDA, for the Congress, for the American public -- to learn more about the way cigarettes are designed today and the results of the tobacco industry's own research on the addictive properties of nicotine.

Thank you.

####

[FDA HOME PAGE](#)

[BACK ISSUES](#)

*(Hypertext updated by jch 1998-MAY-22)*