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ROLL NUMBER

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2007 HOUSE HUMAN SERVICES

HCR 3060

2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HCR 3060

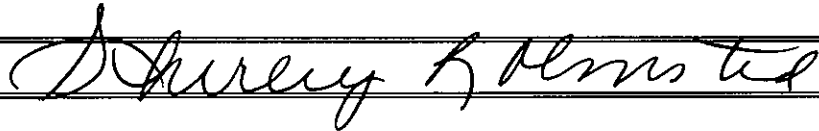
House Human Services Committee

☐ Check here for Conference Committee

Hearing Date: February 26, 2007

Recorder Job Number: 3839

Committee Clerk Signature



Minutes:

Chairman Price opened the hearing on HCR 3060 and the clerk read the title.

Representative Dwight Wrangham of District 8 came forward as a sponsor of HCR 3060.

See written testimony marked as Item #1.

Representative Porter said short of something happening on the federal level, if we do something just in North Dakota and somebody still wants and understands the charts on nicotine levels and cigarettes and they want to come in and bring a carton of cigarettes back from Minnesota, aren't we just basically setting ourselves up for failure from the retail side. If you look out to the reservations, they wouldn't have to come into compliance with anything like this. How do we make it a level playing field from the retail side?

Representative Wrangham said he was glad he brought that up. Those are some of the questions that we heard on HB 1410. Those are some of the answer that has to be researched. You bring up the federal level. I think that is a very good possibility that something will be done because everything has to start somewhere. Maybe a study here in North Dakota is where to start. Good things that have happened in the country have started here before so maybe this will be another one. I hope the study will find better answers for your questions.

Representative Conrad asked if the federal government had established a nicotine amount in cigarettes. Is there an amount that they can't go beyond or a minimum?

Representative Wrangham said he did not think that there was any regulation at this point. There have been many states who have been working on this very thing of testing and Massachusetts is one state that has done a lot of work as far as establishing a standardized method of testing cigarettes. There is a lot of information out there on this subject and I hope that these interim studies through gathering all this information and putting it together can come up with answers.

Representative Kaldor asked if we were to be successful and the study were done and we could find that in deed we could do this, limit the nicotine in cigarettes, if the state does take the responsibility on this do we also assume some kind of responsibility for giving the impression that cigarettes are safe.

Representative Wrangham said he could not make that connection but possibly he is not seeing something that you are.

Representative Kaldor said that where he was heading with this is that I don't know what the federal government does in terms of restricting the contents of a cigarette. I would be interested in finding that out and maybe your study will help us. One of the things that concerns me is that we know what cigarettes cause. We know their effect and if the state involves themselves in regulating the contents of a cigarette I am wondering if we give the impression of safety standards. In other words, certified by the State of North Dakota to be no more than .0008 nicotine means that you may not get addicted. I am just wondering if that possibility was considered when you were working on your other bill.

Representative Wrangham said no but doing nothing would be a much worse option.

Mr. Rick LaFleur from Devils Lake and current president of the North Dakota Coil Machine Operators Association and a member of the Coin and Tavern Association. We have been working very hard trying to come up with a concept that can be implemented to help solve the second hand smoke issues and the bar smoke issue. The bar smoke issue is one that we are most concerned with. We don't feel that prohibition works very well and there is always the opportunity to pass a law that would make tobacco sales illegal. The question comes up that how North Dakota can be an island on its own in establishing an amount of nicotine in cigarettes and still have the surrounding states still doing something different. It seems like an impossibility however just like Representative Wrangham had alluded to, everything has to start somewhere. There is no reason why we can't start right here in North Dakota and develop a collaborative effort that will take a look at what is happening with the manufacturing of cigarettes. Currently there really is no control over the manufacturing of cigarettes. I have handed out some documentation today. See attachment marked as Items 2, 3, & 4. One is a statement on nicotine containing cigarettes by Dr. David A. Kessler, Commissioner of Food and Drugs. The other one is the study done in the state of Massachusetts and was actually conducted by the Harvard Medical School. Page 2 of the opinions that are on the top are a recent article out of the Washington Post and they allude to the fact that in the past since 1998 to 2004 the level in nicotine in cigarettes has been spiked on an average 10% and as much as 30% in some brands. Not only did they conclude that, they also concluded that the manufacturing process by which the cigarettes are made are more efficient in delivering the amount of nicotine. I think that we could at least establish a baseline by which we could say for now until we understand what is going on, why wouldn't we freeze the levels of nicotine that is currently in cigarettes. We know that manipulation of nicotine is entirely possible and it is directly in those documents. There is scientific data showing how they have done it. We know

that has occurred in other areas of drug manufacturing even on the illegal side. It is somewhat of an idealistic approach, however our position is that if we can lower the level of nicotine in cigarettes whether it be in 10 years, 15 years, 20 years, or whatever it is. Whatever could be determined to be the very best possibility, we would then have people that would no longer be addicted to nicotine eventually if they were so inclined to start smoking and they wanted to quit, they could quit. Presently 70% of the population that smokes would like to quit. If they weren't addicted, that would make it much easier for them to quit. There are a lot of gaps in this bill and we will be the first ones to admit that. One of them is what about the person that is addicted and can't quit and then all of a sudden you are going to reduce the amount of nicotine. The fact of the matter is that maybe there is some nicotine replacement therapy that could be offered to them. There are some things that I think the study could obviously take a look at and help determine. This is not a resolution to outlaw the sale of tobacco. This is one that would get control of the addictive qualities of tobacco. One of the things that is different between the United States and Canada is that in Canada they list the ingredients right on the pack of cigarettes. This includes the amount of tar, the amount of nicotine and all things in it. We don't do that in this country and I think we should because the consumer just by buying an Ultra Light as you will find in the study is that it has more nicotine in some cases. I want to just speak briefly about the efforts of the Coin and Tavern Association. We have four things that we stand for. The number one thing is that we think that education is the very most component of getting control of smoking and we need to do that in school systems to the best of our ability. I am not an expert in any of these fields. We know that our educational system is one of the best in the nation and we need to put it to the very best use that we can. The second thing is that we believe in cessation assistance. We think that people who would like to quit should be assisted in that process. Many of the insurance companies, and we hear all

of these numbers like the twenty nine dollars that is collected in taxes against the two hundred and ninety million dollars that is in direct costs from the medical side and the insurance side but we find things that are somewhat like an oxymoron such as insurance companies that will not cover pharmaceutical prescriptions for nicotine replacement. That doesn't make sense when it costs more to insure a smoker and then on the other hand when you want to quit in many cases they can't. We should be helping these people quit. The third thing is to come up with a plan to try to get control of the problem. Increasing nicotine by 10 to 30 percent in the next ten years would only make that more difficult for us so the common sense approach for us would be for us to do something today that will at least not make this problem worse. We need a reform in health care and of course everyone needs to be a part of that process regardless of where you sit within the healthcare system. We need to make health care more affordable because there are so many people out there who cannot afford it whether they are smokers or nonsmokers. A lot of people think our group is pro smoking. I want to make this perfectly clear. We are not but we are pro smoker. With the number of people in the population that smoke and we all know family members, or doctors, or friends, or lawyers, or teachers and that doesn't make them bad people. They are victims and victims of nicotine manipulation and addiction. We need to be there for them. You can't just paint them in a corner and make them look bad. I have to say I am happier at the odds more recently have been more towards letting people think about what the causes of second hand smoke are rather than taking the smoker and making them look like they are holding the Saturday night special in their hand which they are not. They just can't quit as it is a very powerful addiction. Some might say there are other addictive components of cigarettes. That is probably true and this is what this study would do.

The study should contact Minnesota and make the next step to South Dakota and make the step beyond to Wisconsin and all the way to Washington. From a grass roots level we need to

say that we want to start to reduce the addictive qualities that cigarettes have. I know there are a lot of people here that would like speak so I want to abbreviate. I could go on forever but I am hoping for questions.

Representative Kaldor said that he and Mr. LaFleur had been on the opposite side of the fence for years on this issue and I respect your position. The Massachusetts study that you have given us is kind of interesting because it gets to the circumstance that smokers face when they are addicted to a substance like nicotine. You and I agree that it is a very addictive substance. In this study there is a little paragraph on the bottom of page 8 that gives me cause for thought. It has to do with the fact that smokers who switch to a 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. I assume that is true and if we put less nicotine in a cigarette it is more cigarettes to achieve the same affect. That doesn't sound like a very good policy from my standpoint. Maybe no nicotine would be an alternative. That sounds like that would actually be easier but I am not sure about the manufacturing process of cigarettes. Maybe nicotine is an inherent component. How do you respond to that? It sounds to me like you may be selling more cigarettes if we lower the nicotine based on this study.

Mr. LaFleur said he would guess that is what the study would take a look at. I think that as we would reduce the nicotine this is really not for the present standard. This would be for the people that are just starting to begin to smoke. Eventually as those levels would be lowered it would get less nicotine. I don't have the science on it and I don't pretend to have the science on it but I do know this. If we did increase the nicotine content by 10% to 30% over the last few years, why did we do that? Why has that happened? I guess because I think it has a

higher grab on the people who smoke. That is part of what the study also talks about in the manufacturing process and how they have become more efficient in delivering the nicotine itself. I think this is pretty much common sense. I agree that it would be nice to eliminate the nicotine but there are people who cannot quit smoking. Like you alluded to, do we have twice as many cigarettes? One of the things that possibly might be out there are nicotine replacements and there are different things out there. I don't know how we can fund it but there has got to be a way. When it comes down to eliminating second hand smoke in public places I do want to say this. Currently you can pretty much avoid second hand smoke if you choose. If we totally eliminate second hand smoke in all public places that is not the monument because people are still going to smoke. The important thing is where is the second hand smoke at? There are innocent people affected outside the public. I would like you to keep that in mind as you shift the burden of where it takes place. People have the right and business owners have the right. It is about how do we get control and how do we eliminate the impact on society. I have always said that we should always respect ourselves and everyone still has the same common goal. We need to get rid of the problem. We might not always agree as to how it takes place.

Representative Conrad asked if they did they do anything after the Massachusetts study.

Mr. LaFleur said he thought they continued to collect the data and it takes awhile to compile the data so I would imagine there has been a three year lag but that is my assumption. Again, this information is something that we have in the power of the internet. I took this right off the internet. People have asked if this is going to affect the amount of cigarettes that we sell. We do not sell cigarettes. We are not in that business. It took the president of R. J. Reynolds two days to respond to the failure of HB 1410. Obviously they must be very concerned about the wave of popularity of this kind of thing.

Chairman Price asked for further testimony in favor of this resolution. Hearing none she asked for opposition. Hearing none, the hearing was closed on HCR 3060.

2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HCR 3060

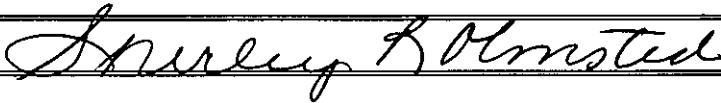
House Human Services Committee

☐ Check here for Conference Committee

Hearing Date: February 27, 2007

Recorder Job Number: 4015

Committee Clerk Signature



Minutes:

Chairman Price asked the committee to consider HCR 3060. This is the nicotine study and the amount of nicotine in the cigarettes. You had asked for information about the asthma study.

Representative Potter moved for a do not pass on HCR 3060.

Representative Hatlestad seconded the motion.

Chairman Price said that she had asked Sara, the intern to check with the legislative council on the wording on the bill if it is mandated as it is written. What did you find out?

Sara Dornfel said that no information is mandated in a study and this never happens. Even if you say "shall" it is not actually shall because they will change it. The only way you can mandate a study is to write it into the bill.

Chairman Price said we have a motion for a do not pass on HCR 3060. Is there any discussion? Hearing none, the clerk called the roll for a **do not pass on HCR 3060**.

Let the record show 11 yes, 0 no with 1 absent.

Representative Potter will carry this to the floor.

Date: 4/27
Roll Call Vote #: 1

2007 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. "Click here to type Bill/Resolution No."

House HUMAN SERVICES

HCR 3068

Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken

Do not Pass Consent Calendar

Motion Made By

Rep. Potter

Seconded By

Rep. Hatlestad

Representatives	Yes	No	Representatives	Yes	No
Clara Sue Price – Chairman	✓		Kari L Conrad	✓	
Vonnie Pietsch – Vice Chairman	✓		Lee Kaldor	✓	
Chuck Damschen	✓		Louise Potter	✓	
Patrick R. Hatlestad	✓		Jasper Schneider	✓	
Curt Hofstad	✓				
Todd Porter					
Gerry Uglem	✓				
Robin Weisz	✓				

Total

(Yes)

¹¹
"Click here to type Yes Vote"

No

⁰
"Click here to type No Vote"

Absent

Floor Assignment

Rep.

Potter

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

REPORT OF STANDING COMMITTEE (410)
February 27, 2007 4:09 p.m.

Module No: HR-37-4058
Carrier: Potter
Insert LC: . Title: .

REPORT OF STANDING COMMITTEE

HCR 3060: Human Services Committee (Rep. Price, Chairman) recommends DO NOT PASS and BE PLACED ON THE CONSENT CALENDAR (11 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING). HCR 3060 was placed on the Tenth order on the calendar.

2007 TESTIMONY

HCR 3060

Item # 1

Testimony of Representative Dwight Wrangham on HCR 3060

Chairman Price and members of the Human Services Committee

I am here to ask for your support of HCR 3060 which asks the Legislative Council to conduct an interim study on the feasibility and desirability of limiting the amount of nicotine in cigarettes sold in North Dakota.

Nicotine is the addictive substance in cigarettes. The amount of nicotine in each cigarette can and is being manipulated. Many people would like to quit smoking but the nicotine addiction is too strong. Nicotine addiction, is the biggest roadblock to improving health through smoking cessation. Attacking and demoralizing smokers, who cannot quit, is not an effective or compassionate approach. Reducing the addictive substance, nicotine, is a positive step and would result in smoking cessation and better health.

HB 1410, introduced earlier this session would have, over a period of years, gradually diminished the amount of nicotine allowed in cigarettes. There was very good discussion on the bill but more study than could be conducted in the short time we have during session is required. Debate on the bill and public input, after the bill failed, support the need for this study. I believe an interim study can find the answers to pertinent questions and move this sensible approach forward lowering the addiction level, helping people quit and improving health.

Thank you and please support this interim study resolution.

JAN 30, 2007

Item 2

Companies spike nicotine levels, but regulators sit on their hands

By Rick LaFleur

I find it more than interesting to see the House Industry, Business and Labor Committee hearing on HB 1410, which would lower the nicotine content in cigarettes, noticeably devoid of testimony from the health department or the district health units. They certainly must have a position on nicotine content. The concept of nicotine, the addictive substance in cigarettes, and its relationship to smoking deserves the attention of the health department and those who truly wish to come up with a long-term meaningful solution.

The elimination of smoking in all public places is simply not going to stand as the monument in this issue. Presently, nonsmokers are not subjected publicly to secondhand smoke

unless they enter a tavern where they know secondhand smoke is present, or a nursing home, hospital, truckers' lounge or motel room that allows smoking. Even if these last legal public refuges for smokers are eliminated, smokers are simply going to smoke somewhere else. Smoking and secondhand smoke will not go away.

We need a thoughtful and carefully crafted effort to be effective. Nicotine content of cigarettes has increased an average of 10 percent to as much as 30 percent from 1998 to 2004, (Change in Nicotine Yields 1998-2004 by Massachusetts Department of Health), as well as cigarette design, which also increases the effectiveness of the delivery of nicotine. Here we are over a decade later and have no policy on the spiking of

nicotine levels, the very substance that makes quitting a misery those who do not smoke cannot appreciate. Surely at the very least the state health department and the district health units should advocate the freezing of additional nicotine being put into the cigarette content.

Smokers are victims of nicotine manipulation and addiction. They are not bad people and the negative demeaning advertising has eclipsed their true needs, and that is long-term solutions. Hopefully HB1410 will have served as a platform to begin to get control of the addiction which apparently is a non-issue in the current smoking plans.

LaFleur is a Devils Lake, N.D., businessman. He is president of the N.D. Coin Machine Operators Association and a member of the Coin and Tavern Association.

FARGO FORUM JAN 30, 2007

THEIR OPINION

Harvard nicotine level report came to the wrong conclusions

By John R. Nelson

The recent report by Harvard University that concluded Philip Morris USA and other tobacco companies have deliberately increased the amount of nicotine that smokers get from cigarettes over the past seven years, if true, raises legitimate public and scientific concerns (Rick LaFleur column, Forum, Jan. 29).

News of this report has increased the volume of those voices that favor regulation of cigarettes by the federal Food and Drug Administration. Philip Morris USA continues to support the legislation introduced in 2005 to grant the FDA authority over the product including the regulation of tar and nicotine. Such authority would directly address the concerns raised in the Harvard report. It's a comprehensive bill, and currently Philip Morris

USA is the only major cigarette manufacturer that supports it.

Cigarettes are addictive and cause serious diseases. The nicotine in cigarette smoke is addictive and an important health issue. But the conclusion from the report, that there was a trend of more and more nicotine in cigarettes between 1997 and 2005, and that the cigarettes were designed to yield greater amounts year after year, is not true for Philip Morris USA. We recognize that is a strong statement. And we understand it is important for us to demonstrate why and in what ways this conclusion is not accurate.

Contrary to the implications of the report, we have not changed the design of our cigarettes with the intention of increasing nicotine yields in order to make the product more addictive. The Harvard report itself also found no upward trends in Marlboro

cigarettes for measures that the authors concluded were related to cigarette design and increased nicotine yield, including puffs per cigarette, nicotine content per cigarette or nicotine concentration in the tobacco rod.

In fact, the machine test data we submitted to the Massachusetts Department of Public Health shows that year-to-year variations in nicotine occur. These year-to-year variations occur as part of the normal processes of growing tobacco and manufacturing cigarettes, but the nicotine yields in Marlboro cigarettes were the same in 1997 as in 2006: 1.86 milligrams per cigarette. That's not a trend up or down.

We understand that many are skeptical of what we say and do, but our actions and the data are transparent.

Nelson is president of operations and technology

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.

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Item 3

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

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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^{1,2} 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.³ The nicotine yield ratings produced by this historical method were meant to serve as a relative measure of nicotine yield between cigarette brands.⁴ 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.⁵ 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.⁶

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.⁷ 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

Cigarette Type¹	MA Method Nicotine Yield (mg/cigarette)²	Historical Method Nicotine Yield (mg/cigarette)²	% Difference³
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?

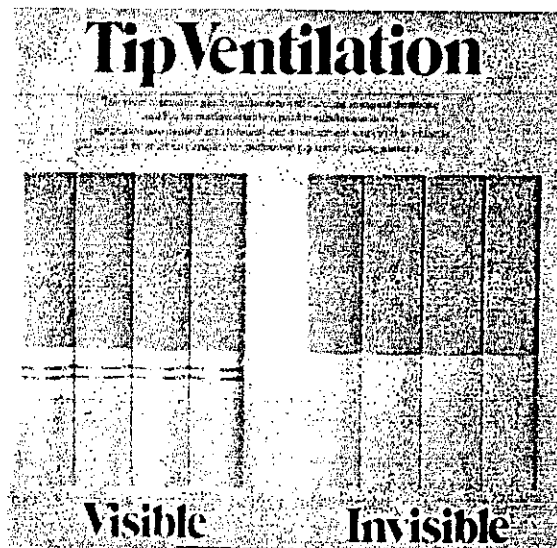
- Many cigarettes are made with tiny holes around the filter which allow air that has not been drawn through the end of the cigarette to mix with the tobacco smoke during smoking.
- When smokers place their mouth or fingers over the vents, they keep outside air from diluting the mixture and so take in 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 ¹	SUB-BRAND ^{2,3}	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	BRAND	SUB-BRAND
Marlboro	085 FI LT HP MEN *	Newport	100 FI LT HP MEN *
Marlboro	085 FI LT SP *	Newport	100 FI LT SP MEN *
Marlboro	085 FI LT SP MEN *	Newport	100 FI MD HP MEN
Marlboro	085 FI MD HP *	Newport	120 FI LT HP MEN *
Marlboro	085 FI MD SP *	Old Gold	085 FI FF SP
Marlboro	085 FI UL HP *	Old Gold	085 NF FF SP
Marlboro	100 FI FF HP *	Parliament	085 FI LT HP *
Marlboro	100 FI FF HP MEN *	Parliament	085 FI LT HP MEN
Marlboro	100 FI FF SP *	Parliament	100 FI LT HP
Marlboro	100 FI LT HP *	Salem	085 FI FF HP MEN
Marlboro	100 FI LT HP MEN *	Salem	085 FI FF SP MEN
Marlboro	100 FI LT SP *	Salem	085 FI LT HP MEN
Marlboro	100 FI LT SP MEN *	Salem	085 FI LT SP MEN
Marlboro	100 FI MD HP *	Salem	100 FI LT HP MEN
Marlboro	100 FI MD SP *	Salem	100 FI UL HP
Marlboro	100 FI UL HP *	Virginia Slims	100 FI FF HP MEN
Maverick	100 FI FF HP	Virginia Slims	100 FI LT HP *
Maverick	100 FI FF HP MEN	Virginia Slims	100 FI UL HP MEN
Maverick	100 FI LT HP MEN	Winston	085 FI FF HP *
Max	120 FI FF SP	Winston	085 FI FF HP (S2)
Merit	100 FI UL SP	Winston	085 FI FF HP (SELECT) *
More	120 FI FF SP MEN	Winston	085 FI FF SP *
Newport	085 FI FF HP MEN *	Winston	085 FI LT HP
Newport	085 FI FF SP MEN *	Winston	085 FI LT HP (SELECT) *
Newport	085 FI FF SP MEN *	Winston	085 FI LT SP *
Newport	085 FI LT HP MEN *	Winston	085 FI UL HP *
Newport	085 FI LT SP MEN *	Winston	100 FI FF HP
Newport	085 FI MD HP MEN	Winston	100 FI FF HP (S200's)
Newport	100 FI FF HP MEN *	Winston	100 FI FF SP *
Newport	100 FI FF SP MEN *	Winston	100 FI LT HP *
Newport	100 FI FF SP MEN *	Winston	100 FI LT HP (SELECT SLIM)
Newport	100 FI LT HP *	Winston	100 FI LT SP *
Newport	100 FI LT HP MEN *	Winston	100 FI UL HP *

Table 2 -- Nicotine Yield Ratings (cont.)

MODERATE (>.2-1.2)

BRAND	SUB-BRAND	BRAND	SUB-BRAND
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.

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

² 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.

³ 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.

⁴ 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.

⁵ 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.

⁶ 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.

⁷ 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.

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.

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(Hypertext updated by jch 1998-MAY-22)

North Dakota
2005 Fact Sheet



Asthma

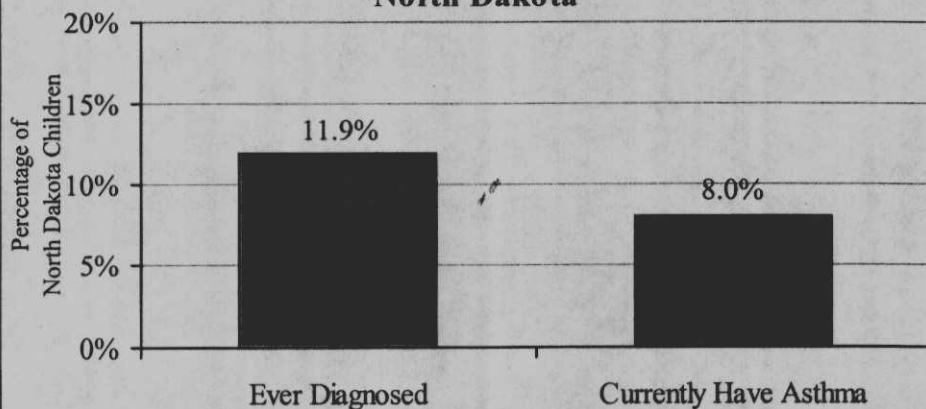
The Burden of Childhood Asthma

Asthma is a disease that affects the lungs. It is the most common long-term disease in children. Repeated episodes of wheezing, breathlessness, chest tightness, and nighttime or early morning coughing characterize the disease. Asthma can be controlled by knowing the warning signs of an episode, avoiding things that trigger an episode, and following the advice of a health-care provider.

Well-controlled asthma results in decreased symptoms such as wheezing or coughing. Sleep is more restful and there is less absenteeism from work or school. Participation in physical activity is not limited and visits to the hospital or emergency room are unlikely.

Twelve percent of the children in North Dakota have ever been diagnosed with asthma, and 8 percent currently have asthma. This equates to approximately 11,000 children who currently have asthma. (2004 BRFSS)

**Prevalence of Childhood Asthma
North Dakota**

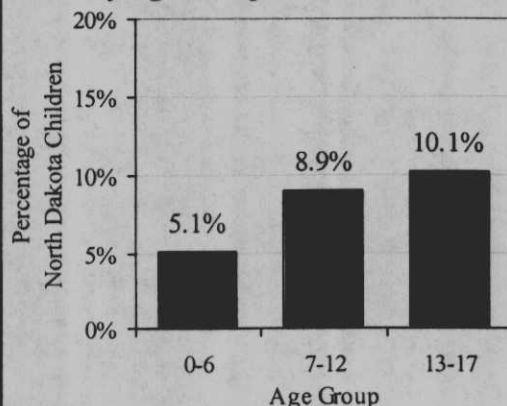


Age of Children with Asthma

Asthma is more common among teenagers than younger children.

The prevalence rate among teenagers is nearly twice as high as the rate for children ages birth through 6.

**Prevalence of Childhood Asthma
by Age Group - North Dakota**



Factors Related to Asthma

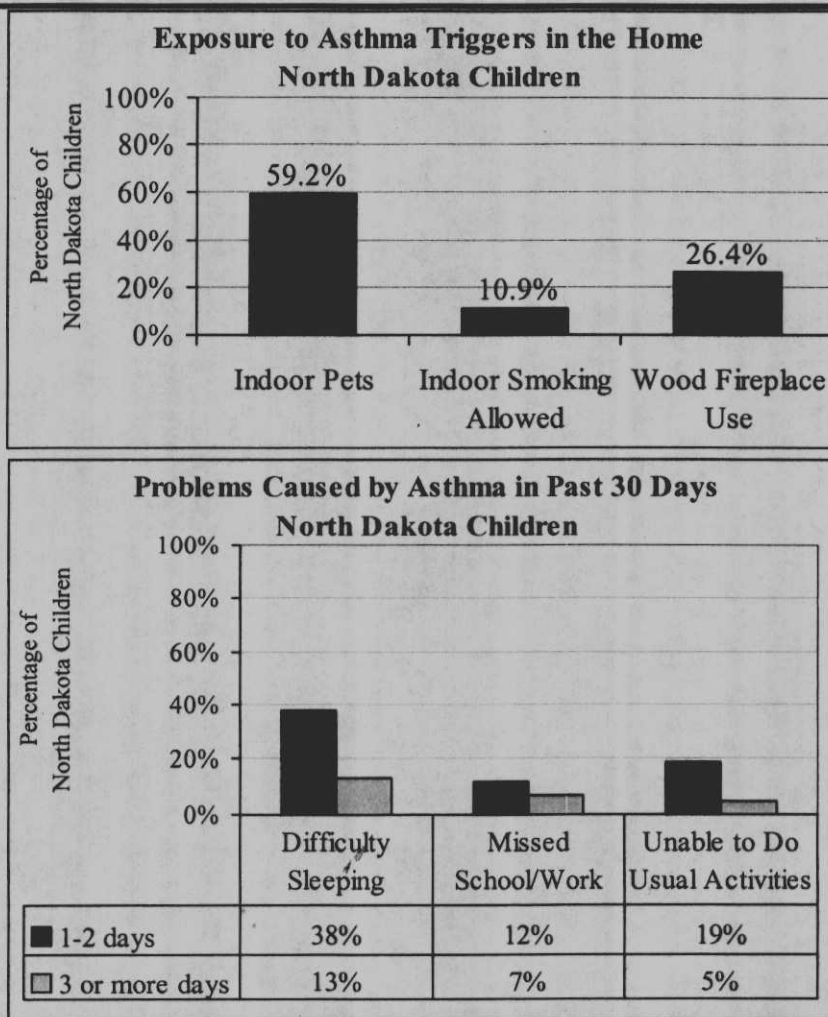
Asthma Triggers

Many children with asthma are exposed to triggers in the home such as pets, tobacco smoke and wood burning fireplaces. Other common triggers in the home include dust mites and mold.

Outdoor air triggers include pollen, cold air and weather (wind, rain, etc.). Food allergies and exercise also can trigger an asthma episode. The ways in which children react to asthma triggers vary. Some children react to only a few triggers, others to many.

Asthma Problems

Many children with asthma experience difficulty sleeping, miss days of school or work, and are unable to participate in their usual activities. This chart shows the percentage of children with asthma who experienced these problems and the number of days these problems occurred in the 30 days prior to responding to the 2004 BRFSS survey.



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*Improving Health for All
North Dakotans*

The North Dakota State Asthma Workgroup strives to improve the health of adults and children with asthma in North Dakota. This workgroup focuses on four areas; data and surveillance, treatment, education and collaboration.

Primary prevention of asthma focuses on:

- * Exposure to asthma triggers.
- * Indoor air quality.
- * Outdoor air quality.

Secondary prevention focuses on developing effective strategies to reduce the burden of asthma and on improving the quality of care provided by health-care systems.

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