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BEFORE THE
FEDERAL TRADE COMMISSION

COMMENTS OF PHILIP MORRIS INCORPORATED,
R.J. REYNOLDS TOBACCO COMPANY,
BROWN & WILLIAMSON TOBACCO CORPORATION,
AND LORILLARD TOBACCO COMPANY

ON THE PROPOSAL ENTITLED

FTC CIGARETTE TESTING METHODOLOGY
FTC FILE NO. P944509
REQUEST FOR PUBLIC COMMENT
(62 Fed. Reg. 48,158)

Pursuant to the Commission's request for public comment dated September 9, 1997, Philip Morris Incorporated, R.J. Reynolds Tobacco Company, Brown & Williamson Tobacco Corporation, and Lorillard Tobacco Company ("the manufacturers") submit these comments on the above-captioned proposal.

For more than 25 years, the manufacturers in cooperation with the Commission have tested their cigarettes according to the smoking-machine test method prescribed by the Commission and have disclosed the ratings produced by that testing in their advertising. Since 1987, when the Commission closed its own cigarette testing laboratory, the manufacturers have continued cigarette testing by the Tobacco Institute Testing Laboratory utilizing the method prescribed by, and subject to the oversight of, the Commission.

The Commission's current test method requires, in pertinent part, that cigarettes be tested by a routine analytical smoking machine according to a 60/35/2 puffing regimen (*i.e.*, every 60 seconds, a 35 milliliter puff of two seconds' duration is drawn by the machine). The "tar," nicotine and carbon monoxide (CO) yields for each brand style tested according

to the prescribed method are reported to the Commission.[1] The Commission reports those numbers to the public.[2] The manufacturers, by agreement with the Commission, include the "tar" and nicotine numbers in their advertising for each brand style.[3]

The Commission has proposed that the current test method be supplemented with a second test method requiring that cigarettes be tested by a routine analytical smoking machine according to a 30/55/2 puffing regimen (*i.e.*, every 30 seconds, a 55 milliliter puff of two seconds' duration would be drawn by the machine). The "tar" and nicotine numbers produced for each brand style by the two tests would be included in the advertising for each brand style, together with a legend indicating that an individual smoker's actual "tar" and nicotine intake depends on how a cigarette is smoked.

For the reasons discussed herein, the manufacturers are not convinced that changes in the Commission's current system for testing cigarettes and reporting "tar" and nicotine numbers in cigarette advertising are necessary or will serve the Commission's purpose. Notwithstanding that difference of opinion, the manufacturers are prepared to assist the Commission in its efforts to help strengthen consumer understanding of what the numbers produced by smoking machine tests do and do not signify. In particular --

- The manufacturers believe that the current test method should continue to be used. They are not convinced that it should be supplemented with a second test method.

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[1] The smoking machine measures the amount of "tar" and nicotine in the smoke from a cigarette that is captured on the pad of the machine when the cigarette is smoked according to the prescribed test method. The CO from the smoke is captured in a bag.

[2] *See, e.g.*, Federal Trade Commission Report on the Tar, Nicotine and Carbon Monoxide of the Smoke of 1,249 Varieties of Domestic Cigarettes for the Year 1995 (Jan. 15, 1998).

[3] *See* Letter to Federal Trade Commission from the manufacturers dated December 17, 1970.

- The manufacturers are prepared to include in their advertising, together with the "tar" and nicotine numbers, a legend stating that how much "tar" and nicotine a smoker gets depends on how intensely the cigarette is smoked.

- If the current test method is to be supplemented, the manufacturers believe that the additional test method proposed by the Commission is rational.

- The manufacturers should be permitted to use the "multiplier" they have proposed to produce close estimates of the ratings that such an additional test would produce, in lieu of having to test every cigarette twice.

- The manufacturers believe that the scientific evidence necessary to support a vent-blocking test parameter is lacking and that a test method incorporating such a parameter would not be justified.

Before addressing the specific questions posed by the Commission, several general comments are in order, all of which are developed in greater detail in the answers to the Commission's specific questions.

1. The manufacturers do not claim that lower-yield cigarettes are "safe" or are "safer" than higher-yield cigarettes. Every cigarette advertisement and every cigarette package includes one of four federally-mandated health warnings that are incompatible with the belief that *any* cigarette is "safe," or is "safer" than any *other* cigarette.

2. To the extent that proposed changes in the current FTC test method reflect a concern that the numbers produced by the current test method do not reflect actual smoker intake, such proposed changes rest on a misconception that routine analytical smoking machine tests are meant to predict, and are able to predict, actual smoker intake. As the Commission has long recognized, testing by routine analytical smoking machines -- the type of smoking machine used for standardized cigarette testing -- is not meant to predict actual smoker intake and is incapable of doing so.

Routine analytical smoking machines cannot smoke like people.[4] The amount of "tar" and nicotine that may be trapped on the Cambridge Filter *pad* of such a smoking machine from a puff on a cigarette taken by the smoking machine in accordance with a prescribed (and -- given the wide variation in smoking behavior -- necessarily arbitrary) puffing regimen cannot predict, and was never intended to predict, the amount of "tar" and nicotine that a smoker or any group of smokers will *inhale*. As the Commission has emphasized, no individual smoker smokes the same way all the time, and no two smokers smoke alike. Efforts to devise a standardized test method that will produce "tar" and nicotine ratings that predict actual intake for a particular smoker are therefore misconceived.

Like all other standardized smoking machine test methods of which the manufacturers are aware, the current FTC test method ranks brand styles by "tar" and nicotine yield.[5] Smokers are familiar with the ratings produced by the current test method, and continued use of the current test method assures historical continuity of the data. For those reasons, testing under the current FTC test method should continue. The available evidence indicates, moreover, that other standardized testing regimens, while producing different numbers, would not appreciably change the relative rankings of the

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[4] Routine analytical smoking machines of the type used for standardized cigarette testing are to be distinguished from "human-mimic" smoking machines. Some laboratories have built smoking machines that can replicate the "puffing profile" of an individual as measured on a single cigarette-smoking, or as an average profile for that individual over multiple smokings. The machines are not designed for, nor are they capable of, the high-output, multiple smokings conducted with the routine analytical smoking machines. While the human-mimic machines can produce different puff profiles, the smoke yields generated are no more representative of an "average" of the smoking population than those generated by the routine analytical smoking machines at a given set of puffing conditions.

[5] "The term 'brand style' means a variety of cigarettes distinguished by the tobacco used, tar and nicotine content, flavoring used, size of the cigarette, filtration on the cigarette, or packaging." Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1332(8).

brand styles tested.[6] It is unclear what purpose would be served by adopting a new test that simply substitutes new (arbitrary) ratings for the current (arbitrary) ratings while preserving the existing brand-style ranking.

3. To the extent that proposed changes in the current FTC test method reflect a concern that smokers *believe* that the numbers produced by the current test method represent actual smoker intake, better means are available to correct any such perceived misimpression. The most effective way is to communicate to smokers what the numbers produced by the test do and do not signify. The legend set forth in Attachment B to the Commission's request for public comment ("How much tar and nicotine you get from a cigarette depends on how intensely you smoke it.") encapsulates both messages that the Commission apparently seeks to convey -- (1) the "tar" and nicotine smokers may get from a cigarette is not a fixed value, and (2) how much "tar" and nicotine smokers will get from a cigarette depends on how the cigarette is smoked. There is no need to use dual ratings to communicate those messages symbolically. Attempting to do so could create other problems, for dual ratings may perpetuate misunderstanding about what routine analytical smoking machine yield ratings signify. More broadly speaking, the effects of the Commission's proposed dual-rating system on consumer perception and behavior are unknown. Extensive consumer research would be required, at a minimum, to determine what those effects would be.

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[6] As discussed in Appendix A, in connection with the nicotine testing required by the Massachusetts Department of Public Health, this appears to be the case even with respect to testing requirements utilizing partial vent-blocking.

It seems plausible that supplementing the current FTC test method with the proposed upper-tier test method would be viewed by smokers as providing more accurate, or more precise, information about their actual intake of "tar" and nicotine. Smokers may, indeed, conclude that the "high" and "low" end points produced by the proposed two-tier test bracket the range of "likely" smoker intake -- a message the Commission's question 1b suggests it intends the dual ratings to convey. In fact, the "high" and "low" end points of "likely" intake of "most smokers" for each of the hundreds of cigarette brand styles on the market have *not* been established, and it may not be possible to develop a test to predict individual smoker intake that could be used to establish such end points. Moreover, even if such a predictive test could be developed, it would have to be validated; and such a test, once developed and validated, would require smoker testing on a significant scale -- not in laboratory settings, but in real-world settings -- to establish "high" and "low" end points of "likely" intake for "most smokers" for each of the hundreds of brand styles on the market. In the absence of such testing, there would be no scientific basis for viewing the end points as bracketing "likely" smoker intake for any brand style.

4. To the extent that proposed changes in the current FTC test method reflect a concern that the current method does not reflect "compensatory" smoking behavior, such proposed changes, again, rest on a misconception that routine analytical smoking machine tests are meant to predict, and are able to predict, actual smoker intake. As discussed in detail below, such proposed changes also rest on a view of the extent of "compensatory" smoking behavior -- in particular the extent of the behavior called "vent blocking" -- that lacks the degree of scientific support needed to justify a vent-blocking test parameter.

Moreover, as discussed in Appendix A, even taking into account the factors that render the data crude and imprecise, the incorporation of a partial vent-blocking parameter in nicotine-testing requirements recently prescribed by the Massachusetts Department of Public Health did not appreciably alter the relative ranking of cigarettes produced by the current FTC test method for the cigarettes that were tested pursuant to those requirements. In addition, the partial vent-blocking parameter generally did not, in combination with the other parameters prescribed by Massachusetts, produce nicotine yield ratings higher than those produced by the Commission's proposed upper-tier test.[7]

5. Finally, although we are not convinced that the current FTC test method should be supplemented with an additional test, if the Commission should determine that an additional test is warranted, the Commission should permit the use of the "multiplier" proposed by the manufacturers to produce estimates of the ratings that the additional test

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[7] We urge the Commission to discourage (and, if possible, prevent) individual states from imposing their own cigarette testing and reporting requirements on manufacturers. To date, Massachusetts has already required the manufacturers to submit nicotine yield data for samples of cigarettes sold in Massachusetts, pursuant to testing requirements prescribed by the Massachusetts Department of Public Health that differ significantly from the current and proposed FTC test methods. The Texas Department of Health has also issued proposed rules requiring the manufacturers to submit nicotine yield data for samples of cigarettes sold in Texas, pursuant to requirements similar to those prescribed by Massachusetts. In addition, as detailed in Appendix B, as of February 4, 1998, bills were pending in at least eight other states (Delaware, Illinois, Indiana, Iowa, Maine, Michigan, New Jersey and New York) that would similarly require the manufacturers to submit nicotine yield data for cigarettes sold in those states, under testing requirements to be prescribed by the health department in each state.

Such state testing and reporting requirements compete directly with the testing and reporting required by the Commission. To the extent that a state's testing requirements are different from the Commission's, testing and reporting pursuant to the state's requirements are bound to further confuse consumers, who will be presented with different yield ratings from multiple sources for the same products. We urge the Commission to take the necessary steps to ensure that consumers receive a uniform set of yield ratings for cigarettes pursuant to a single set of testing requirements.

would produce, rather than require that the manufacturers and others test all cigarette brand styles twice.[8/]

I. CIGARETTE TESTING METHODOLOGY

1. The Proposed New Testing Methodology

a. What effect, if any, are the dual ratings that would be provided by the Commission's proposed two-tier test method likely to have on consumers' purchases of cigarettes and/or their smoking behavior? Will this information affect smoking intensity, brand choice, and/or the decision whether to quit smoking, and if so, how?

The manufacturers do not know how the dual ratings produced by the Commission's proposed two-tier test would be perceived, and therefore cannot predict how they might affect consumer behavior. Extensive consumer research would be needed, at a minimum, to determine the likely effects of the proposed dual-rating system on consumer behavior. It seems likely that, at least initially, the dual ratings would generate consumer confusion. Beyond that, one can only speculate about the effects of the proposed dual ratings on consumer behavior.

Under the current testing system, each cigarette brand style has a single set of "tar" and nicotine ratings that clearly distinguish it from all other brand styles with different "tar" and nicotine ratings. By contrast, the dual ratings produced by the proposed two-tier test would produce, for each brand style, *two* sets of "tar" and nicotine ratings -- one produced by the current FTC test method, and another produced by the proposed second test. As a result, the ratings for each brand style would overlap with the ratings for other brand styles.

[8/] Some of the scientific studies cited in these comments were funded by cigarette manufacturers. The manufacturers believe that any study should be evaluated on its scientific merits rather than on the basis of its funding sources.

This overlap would complicate the system. Several possible effects on consumers can be imagined.

First, some smokers of "less flavorful" lower-yield brand styles might be prompted to switch to "more flavorful" higher-yield brand styles in the belief that smoking the lower-yield brand style involves a pointless sacrifice of flavor. Smokers may interpret the rating system this way because they would be convinced that they are not getting less "tar" and nicotine when they smoke, and yet they are smoking less-flavorful cigarettes. *Second*, some smokers, who wish to avoid receiving the higher amounts of "tar" and nicotine from their current brand styles that are implied by the higher numbers, may be prompted to switch to lower-yield brand styles. *Third*, some smokers may change the way they smoke their current brand styles -- smoking them either less intensely or more intensely -- prompted by the reminder that the yield from a particular cigarette can vary depending on how the cigarette is smoked. *Fourth*, some smokers, perhaps the overwhelming majority, may not pay any attention to the dual ratings -- either because they do not care or because the new system is so confusing that it makes any attempt to use the added information pointless.

Other possible effects of the dual ratings undoubtedly could be imagined. Without extensive consumer research, it is impossible to know what consumer perception or the effects on consumer behavior would be. One thing, however, is certain: If the Commission's goal is to ensure that smokers understand that the "tar" and nicotine they may get from a cigarette is not a fixed value, and that how much "tar" and nicotine they will get depends on how the cigarette is smoked, those two messages can be communicated clearly

and easily by means of the legend set forth in Attachment B, without resorting to a potentially confusing system of dual "tar" and nicotine ratings.

b. If the proposal for testing all cigarettes under the same two sets of parameters is adopted, and if the parameters incorporated in the Commission's test method are intended to produce yields covering the range likely to be experienced by most smokers, are the proposed parameters appropriate? Why or why not? If not, what parameters would be more appropriate and why?

1. The "range" of actual smoker intake for particular cigarette brand styles has not been established.

The "range" of "likely" intake of "tar" and nicotine by "most smokers" for particular cigarette brand styles has not been established. As discussed above, a predictive test that could be used to establish such a range of actual smoker intake does not exist; such a test may not be possible to develop; assuming that such a test could be developed, it would then need to be validated; and, if such a test could be developed and validated, establishing the range of "likely" smoker intake for each of the hundreds of cigarette brand styles on the market would be a significant undertaking. Without extensive human testing, it could not be said definitively that the particular end points produced by the proposed two-tier test (or any two-tier test) would bracket the amount of "tar" and nicotine "likely" to be inhaled by "most smokers" of any particular brand style, or would bracket the range of "likely" intake for different brand styles with equal precision.

In the absence of such testing, all that can be said with confidence about the proposed two-tier test is that the "high" and "low" yield end points will be lower for lower-yield brand styles than for higher-yield brand styles, and higher for higher-yield brand styles than for lower-yield brand styles. That is, the proposed two-tier test would continue to serve the function of ranking brand styles according to routine analytical smoking machine

yields. The two-tier system would supplement the current rating for each brand style with a second, higher rating, but -- as reported to the Commission by the manufacturers in their submission of June 23, 1997[9] -- the ranking produced by the current FTC test would be preserved.

But data do not exist to support the conclusion that the end points produced by the two-tier system for any particular brand style will bracket the actual amount of "tar" and nicotine "likely" to be inhaled by most smokers of that brand style. To the extent that the proposed two-tier test suggests *actual* human intake ranges to smokers -- and it seems inevitable that it would -- the addition of the upper-tier number could be misleading to consumers.

2. Reliance on smoking machine yields as surrogates for smoker intake is misconceived.

The danger in characterizing the proposed two-tier test as a surrogate for smoker intake at the "low" and "high" end points is that the tests would be legitimized as predictors of smoking behavior and smoke intake. But, as the Commission has repeatedly emphasized, routine analytical smoking machine tests are incapable of predicting smoker behavior or intake.

Routine analytical smoking machines cannot predict intake for any individual or group of individuals. Such a smoking machine can capture "tar" and nicotine from a cigarette on the *pad* inserted in the machine, but the amount of "tar" and nicotine captured

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[9] Philipp, C., St. Charles, K., Norman, V., Whidby, J., Garman, J., Lewis, L., Borgerding, M., *An Experiment to Determine the General Relationship Between Cigarette Smoke Yields Using an Alternative Puffing Regimen (55/30/2) and the Standard FTC Method*, compiled by Borgerding, M., Bodnar, J., Willard, B., R.J. Reynolds Tobacco Company, Winston-Salem, N.C. (June 23, 1997).

on the machine's *pad* cannot be equated with the amount of "tar" and nicotine that any individual smoker draws into his or her *mouth*, and the amount of "tar" and nicotine that any individual smoker draws into his or her *mouth* cannot be equated with the amount of "tar" and nicotine that he or she *inhales* and does not *exhale*.

The purpose of routine analytical smoking machine testing, the Commission explained, "is not to determine the amount of tar and nicotine inhaled by any human smoker, but rather to determine the amount of tar and nicotine generated when a cigarette is smoked by a [smoking] machine in accordance with the prescribed method."[10/] Explaining the Commission's long-held view, the Associate Director of the Advertising Practices Division has stated:

> From the outset, the [FTC] testing was intended to obtain uniform, standardized data about the tar and nicotine yield of mainstream cigarette smoke, *not* to replicate actual human smoking. The Commission recognized that individual smoking behavior was just that -- too individual to gauge what a hypothetical 'average' smoker would get from any particular cigarette.[11/]

From the beginning, the Commission stressed that no testing method could predict actual deliveries to individual smokers. In announcing on August 1, 1967, the completion of trial tests by its laboratory, the Commission made its position clear:

> No test can precisely duplicate conditions of actual human smoking and, within fairly wide limits, no one method can be said to be either 'right' or 'wrong.' The Commission considers it most important that the test results

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[10/] FTC To Begin Cigarette Testing, FTC News Release, Aug. 1, 1967.

[11/] Peeler, C., "Cigarette Testing and the Federal Trade Commission: A Historical Overview," in U.S. Department of Health and Human Services, *Smoking and Tobacco Control, The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes, Report of the NCI Expert Committee* 2 (1996).

> be based on a reasonable standardized method . . . that is readily understandable.[12]

The Commission's characterization of its proposed two-tier test as an attempt to bracket "likely" intake by "most smokers" for a particular brand style appears to reflect a recognition that smoking machines cannot predict the "average" yield to the "average" smoker. Reliance on smoking machines to produce "low" and "high" *end points* for each brand style is similarly misconceived, however, because it still depends on smoking machines to predict "average" intake at the "low" and "high" end points of "likely" human intake (*i.e.*, it depends on the machines to predict that "most smokers" are unlikely to experience yields outside of the range bracketed by the end points).

The Commission has long recognized that a standardized testing method that replicates actual average human smoking is not possible because human smoking conditions affecting intake are simply too variable and are beyond the ability of a simple machine method to mimic:

> No two human smokers smoke in the same way. No individual smoker always smokes in the same fashion. The speed at which one smokes varies both among smokers, and usually also varies with the same individual under different circumstances even within the same day. Some take long puffs (or draws); some take short puffs. That variation affects the tar and nicotine quantity in the smoke generated.
>
> Even with the same type of cigarette, individual smokers take a different number of puffs per cigarette depending upon the circumstances. When concentrating, or talking, the number of puffs is usually less. When listening, or required to listen to another person talking, the number of puffs per cigarette, as well as the duration of each puff, usually increases. Smoking rates while reading a book may differ from smoking rates while

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[12] FTC To Begin Cigarette Testing, FTC News Release, Aug. 1, 1967.

> viewing a television program. The number of puffs and puff duration (as well as butt length) will vary according to emotional state.[13]

The Commission also recognized other basic differences between individual smokers:

> Some smokers customarily put their cigarettes down in an ashtray where they burn between puffs; other smokers constantly hold cigarettes in their mouths; others hold them between their fingers.[14]

The Commission has further noted:

> The Cambridge Filter Method does not and cannot measure these many variations in human smoking habits. It does not measure tar or nicotine in the smoke generated while the cigarette is not being puffed. It does not measure all of the tar and nicotine in any cigarette, but only that in the smoke drawn in the standardized machine smoking according to the prescribed method. *Thus, the purpose of testing is not to determine the amount of tar and nicotine inhaled by any human smoker, but rather to determine the amount of tar and nicotine generated when a cigarette is smoked by machine in accordance with the prescribed method.*[15]

Given the range and variability of individual smoking behavior, the Commission concluded that a testing method purportedly based on some spurious notion of "average" smoker behavior could actually *mislead* the public:

> [T]he testing method should not be considered defective because it does not rely on 'averages.' There are too many variables as to both smokers and smoking conditions for any average to be meaningful. Test results phrased in terms of an 'average' smoker could be misleading to the public, because a smoker has no way of knowing how closely his smoking habits conform to those of the purportedly 'average' smoker.[16]

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[13] *Id.*

[14] *Id.*

[15] *Id.* (emphasis added).

[16] *Id.*

The Commission's choice of testing methods, therefore, expressly took into account the risk that it would be misleading and inappropriate to speak of an "average" smoker:

> It should be emphasized that the Cambridge Filter Method itself did not purport to duplicate an 'average' smoker. Rather, it was an amalgam of many choices -- some of them arbitrary. For example, the temperature and humidity specified in that Method were not determined by reference to the 'average' temperature or the 'average' humidity at which people smoke cigarettes. There is no human smoker who smokes, and no cigarette that is smoked, under conditions that precisely duplicate either the Cambridge Filter Method in its original form or as modified by the Commission [prior to its adoption]. Thus, to reiterate, the uniform method determined by the Commission has as its purpose measurement of the tar and nicotine generated by cigarettes when smoked according to that procedure.[17]

As Dr. Michael Borgerding, a Master Chemist at R.J. Reynolds Tobacco Company, stated in a 1997 article, routine analytical smoking machines "cannot replicate actual human smoking behavior. These smoking machines are designed to take uniformly shaped puffs of a precisely set volume and duration . . . at a constant frequency."[18] Adding an upper tier to the FTC test method would ensure only that a smoking machine will take uniformly shaped puffs at *another* arbitrary constant puff volume, puff duration, and interpuff interval.

Smoking machines also cannot replicate human behavior because they cannot replicate the complicated process of smoke inhalation and exhalation. For example, smokers typically do not inhale all of the smoke that they draw from the cigarette. A smoker draws mainstream smoke into his or her mouth by puffing on the lit cigarette. The design of the cigarette, including tobacco types, weight, filtration and ventilation, along with

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[17] *Id.*

[18] Borgerding, M., "The FTC Method in 1997 -- What Alternative Smoking Condition(s) Does the Future Hold?" *Recent Adv. Tob. Sci.* 23:75, 136 (1997). In the quoted passage, "ISO" stands for the International Organization for Standardization.

the size, shape and duration of the puff, determine the amount of the smoke that a smoker takes into his or her mouth in any particular puff. After drawing a puff, but before inhaling, a smoker may mix the smoke with air in his or her mouth, and during the mixing, some of the smoke can escape into the air of the room. Indeed, smokers who do not inhale at all allow all of the smoke to escape into the room air.

No smoke similarly escapes from the smoking machine.[19] Moreover, unlike a smoker, a smoking machine does not exhale before (or after) inhaling. Thus, even if a smoking machine *pad* captured the same amount of "tar" and nicotine as the amount received in the *mouth* of a smoker from a particular puff, that amount may not be the same as the amount of "tar" and nicotine inhaled and not exhaled by the smoker.

Dr. L.T. Kozlowski, who has published a number of articles discussing the FTC testing method, has reiterated the Commission's 1967 position that any testing method designed to produce standard yield figures necessarily has significant limitations:

> Even if a valid or accurate estimate of average smoking behavior is attainable, it does not follow that it would be sufficiently reliable or precise to give many smokers information about their own idiosyncratic tar and nicotine yields from a given brand. The ideal average smoker may always be an inadequate stand-in for individual smokers; an average tells you about the behavior of other members of the population to the extent that the other members of the population cluster in close proximity to the average. . . . *The variability of human smoking behavior is large enough that standard yields do not, on their own, provide a good indication of actual yields to individual smokers.*[20]

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[19] *E.g.*, Bentrovato, B., *et al.*, "Variations in Tar, Nicotine And Carbon Monoxide Deliveries Obtained by Smokers of The Same Brand," *CORESTA Report of The Joint Meeting of The Smoke And Technology Groups,* App. VII (1995).

[20] Kozlowski, L., "Physical Indicators of Actual Tar and Nicotine Yields of Cigarettes," *in* Grabowski, J. & Bell, C. (eds.), *Measurement in The Analysis And Treatment of Smoking Behavior*, NIDA Research Monograph 48, 50-61, 52 (1983) (emphasis added).

Recent research confirms that human smoking behavior is not constant from puff to puff as the smoker smokes a cigarette, from cigarette to cigarette for a particular smoker, or from smoker to smoker. In a 1995 study, Reeves and Dixon reported that a person's smoking behavior varies puff by puff while smoking a single cigarette, due to changes in tobacco rod filtration efficiency during smoking.[21] Zacny and Stitzer have stated that "[i]nitially, smokers take larger and longer puffs from the cigarette, but as they smoke down the rod, the puffs get shorter and smaller. Interpuff intervals [*i.e.*, the interval between the end of one puff and the beginning of another puff] are shortest at the beginning of the cigarette and longest near the end of the cigarette."[22]

The variability of smoking behaviors among individuals is illustrated in a recent study by Bentrovato and colleagues, who in 1995 reported results from their study of smoke yields obtained by 13 Canadian smokers, each smoking the same commercial king size filtered brand.[23] All of the smokers in the study had been smoking this same brand for at least 3 years. Smoking topography (the pattern of a smoker's puffing behavior -- *i.e.*,

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[21] Reeves, N. & Dixon, M., "The Measurement of Human Smoking Behaviour And The Influence of Mainstream Smoke Deliveries on Changes in Behavioural Parameters," *CORESTA Report of the Joint Meeting of the Smoke & Technology Groups, Presentation No. ST19* (1995).

[22] Zacny, J. & Stitzer, M., "Human Smoking Patterns," in U.S. Department of Health And Human Services, *Smoking and Tobacco Control, The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes, Report of the NCI Expert Committee* 151, 153 (1996). *Accord* U.S. Department of Health and Human Services, *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General*, 155 (1988) ("during the smoking of a single cigarette, the duration of each puff tends to decrease and/or the time between each puff (interpuff interval) tends to increase").

[23] Bentrovato, B., *et al.*, "Variations in Tar, Nicotine And Carbon Monoxide Deliveries Obtained by Smokers of The Same Brand," *CORESTA Report of The Joint Meeting of The Smoke And Technology Groups*, App. VII (1995).

puff volume, duration, and shape) was measured for each smoker on four consecutive days. An average topography for each smoker as well as a population average were then calculated. The study noted wide variations in average smoking behavior among individuals.[24]

3. The proposed two-tier test uses parameters that are within the range of reported human puffing behavior.

As the Commission has stated, "within fairly wide limits, no one [test] method can be said to be either 'right' or 'wrong.'"[25] The parameters of the proposed second test -- as the Commission noted in its proposal -- are within the range of human puffing behavior reported in the studies that were cited in the 1988 Surgeon General's report.[26] Specifically, the Commission's proposed lower-tier and upper-tier puff volumes (35 milliliters and 55 milliliters) fall within the reported range of human puff volumes (21 to 66 milliliters), and the Commission's proposed lower-tier and upper-tier interpuff intervals (60 and 30 seconds) fall within the reported range of interpuff intervals (18 to 64 seconds).

At the same time, it should also be emphasized that the range of yields "likely to be experienced by most smokers" (in the Commission's phrase) -- *i.e.*, the range of quantities

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[24] The average puff volume for the population was 46.9 milliliters, but individual average volumes ranged from 18.5 to 64.3 milliliters. The mean flow rate for the population was 24.4 milliliters/second, but the individual average flow rates ranged from 16.2 to 28.8 milliliters/second. The population average interpuff interval was 40.7 seconds, but the individual average puff intervals ranged from 20.2 to 71.4 seconds. The population average puff duration was 1.98 seconds, but the individual average durations ranged from 0.88 to 2.98 seconds. The average number of puffs per cigarette for the population was 10.8, but the individual averages ranged from 6 to 18.

[25] FTC To Begin Cigarette Testing, FTC News Release, Aug. 1, 1967.

[26] *See* U.S. Department of Health and Human Services, *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General*, 156-57 (1988) (Table 2).

of smoke that may reach their *mouths* -- is likely to fall within *or below* the range of machine yields likely to be produced by the Commission's proposed two-tier system. Bentrovato and colleagues, in the study discussed above, gathered data on the average smoking parameters of 13 Canadians smoking a single brand -- their own -- in the laboratory.[27] To generate the average yield that each smoker might receive in his or her mouth, the researchers calibrated a specially designed smoking machine to reflect the smoking parameters of each of the 13 smokers. The standard of comparison was the ISO smoking machine test method, whose parameters are similar to the FTC test method. The researchers found that:

> Duplicated smoke deliveries . . . showed a wide range of values. However, the average values obtained for tar, nicotine and carbon monoxide were relatively close to the machine derived [*i.e.*, ISO standard] deliveries with respectively 17%, 5% and 14% higher values.[28]

By contrast, as reported to the Commission, it appears that the Commission's proposed upper-tier test parameters would produce smoking machine yields about *100% higher* than the current FTC test parameters.[29] Thus, the research would suggest that the proposed upper-tier testing method is likely to overstate the yields that a smoker typically would receive in his or her mouth.

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[27] Bentrovato, B., *et al.*, "Variations in Tar, Nicotine And Carbon Monoxide Deliveries Obtained by Smokers of The Same Brand," *CORESTA Report of The Joint Meeting of The Smoke And Technology Groups,* App. VII (1995).

[28] *Id.*

[29] Philipp, C., St. Charles, K., Norman, V., Whidby, J., Garman, J., Lewis, L., Borgerding, M., *An Experiment To Determine The General Relationship Between Cigarette Smoke Yields Using An Alternative Puffing Regimen (55/30/2) And The Standard FTC Method*, compiled by Borgerding, M., Bodnar, J., Willard, B., R.J. Reynolds Tobacco Company, Winston-Salem, N.C. (1997).

c. Should the butt length specified in the current FTC test method -- that cigarettes be smoked to a length of 23 millimeters or to 3 millimeters beyond the filter and overwrap, whichever is longer -- be changed? Is there evidence that smokers smoke more than 3 millimeters beyond the end of the overwrap? If so, what is the effect of that behavior in terms of the number of puffs they get from their cigarette?

1. The manufacturers are aware of no sound reason to alter the butt length specified in the current FTC method.

The manufacturers are aware of no sound reason to alter the butt length specified in the current FTC method. Like the other parameters, the specified butt length is intended to provide a standard procedure for testing to rank brands. Even assuming that the butt length specified in the FTC test method was intended to reflect human behavior, there is no reliable scientific basis for concluding that the butt length specified by the FTC method is too short or too long when compared with the length of the butt typically left when a U.S. smoker has finished a cigarette.

There is some evidence from other countries that the standard test-method butt length may be *shorter* than the length of the butt generally left by smokers. In his 1988 Report, Sir Peter Froggatt, Chairman of the U.K. Independent Scientific Committee on Smoking and Health stated "[r]eported studies investigating the average butt length left by smokers have indicated that smokers have a tendency to discard their cigarette leaving a longer butt than used in the standard machine procedure."[30/] In the International Organization for Standardization ("ISO") smoking method used in the U.K. and throughout Europe, the butt length for unfiltered cigarettes is 23 millimeters, and for filtered cigarettes, overwrap plus

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[30/] Froggatt, P., *Fourth Report of the Independent Scientific Committee on Smoking and Health* (1988), App. 3 at 55; Bentrovato, B., *et al.*, "Variations in Tar, Nicotine And Carbon Monoxide Deliveries Obtained by Smokers of The Same Brand," *CORESTA Report of The Joint Meeting of The Smoke And Technology Groups*, App. VII (1995).

three millimeters, or filter length plus eight millimeters, whichever is longer.[31] The first two lengths are the same as those specified in the FTC method, and the third ordinarily is longer than FTC specifications. Thus, if U.K. smokers generally leave a longer butt than the ISO method specifies, it follows that they are leaving a longer butt than the FTC method specifies.

2. Changing the butt length specified in the test method could destroy the historical continuity of the data.

H. Pillsbury, who oversees "tar" and nicotine testing under the current FTC method, has written that, as a result of FTC adoption of a uniform analytical procedure for measuring "tar" and nicotine yields in 1967, "long-term pictures of tar and nicotine levels over the years . . . were possible."[32] The Commission's proposal likewise recognizes that retaining the current test method "would preserve the historical continuity of the existing test method, and thus permit long term trends in ratings to be identified."[33]

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[31] ISO 4387, *Cigarettes -- Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine* § 7.2.1, at 3 (1991). The paper that joins the filter segment and the tobacco column is called "tipping paper." The tipping paper completely covers the filter plug and then overlaps the tobacco column by a few millimeters. The portion of the tipping paper that extends beyond the filter plug is the "overwrap." The overwrap portion ensures that the filter remains tightly attached to the tobacco rod and does not fall off. As filter length increased over the years, tipping paper became wider, and butt length therefore became longer as well.

[32] Pillsbury, H., "Review of the Federal Trade Commission Method for Determining Cigarette Tar and Nicotine Yield," in U.S. Department of Health and Human Services, *Smoking and Tobacco Control, The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes, Report of the NCI Expert Committee* 9, 11 (1996). Mr. Pillsbury was the director of the FTC's "tar" and nicotine testing laboratory during the twenty years that it was in operation. When Mr. Pillsbury wrote the article cited above, he was serving as an independent contractor retained by FTC's Bureau of Consumer Protection to oversee the TITL testing laboratory.

[33] Federal Trade Commission, "Cigarette Testing," 62 Fed. Reg. 48,158, 48,159 (1997) [hereinafter "FTC Proposal"].

Changing the butt length -- or any other parameter of the current method -- could destroy this historical continuity, making it substantially more difficult, if not impossible, to track long-term trends. It would not serve any discernible purpose to alter the testing method in a way that could diminish the value of the database established over the course of thirty years by the Commission and the industry.

3. The evidence does not indicate that people smoke the overwrap.

Some have suggested that the method for testing "tar" and nicotine yields should require that cigarettes be smoked to a butt length shorter than 23 millimeters, or overwrap plus three millimeters (whichever is longer), because -- they claim -- people smoke the overwrap.[34/] There is no scientific support for the contention that people typically smoke the overwrap, and the possibility that a small number of people may do so is not a sufficient reason to change the butt length specified in the FTC testing method.

A preliminary observational study by Grunberg, *et al.* (which was conducted in 1985 and was based on data collected by the Commission from 1962 through 1979) *assumed* -- incorrectly -- that people smoke the overwrap.[35/] The authors, however, did not provide any evidence that smokers actually *do* smoke the overwrap portion of the paper. Although it may be hypothetically possible to smoke the overwrap, the smoke generated from the burning tipping paper is considered unpalatable. There is no reason to alter the butt length parameter specified in the FTC method.

[34/] *E.g.*, Grunberg, N., *et al.*, "Changes in overwrap and butt length of American filter cigarettes," *N.Y. St. J. Med.*, 85(7):310, 311 (1985); 60 Fed. Reg. 41,453, 41,721 (Aug. 11, 1995).

[35/] Grunberg, N., *et al.*, "Changes in overwrap and butt length of American filter cigarettes," *N.Y. St. J. Med.*, 85(7):310, 311 (1985).

4. There is no demonstrated relationship between butt length and number of puffs.

Regardless of the butt length chosen for machine smoking, the butt length bears no demonstrated relationship to the number of puffs that a smoker will take on a cigarette. Smokers may take more or fewer puffs than the machine does, and a smoker's puff number can vary from cigarette to cigarette.

For a typical 85 millimeter cigarette with 25 percent air dilution that yields about 10 milligrams of "tar" under the FTC testing method, there are about eight puffs per cigarette under the current FTC testing method. The same cigarette smoked under the Commission's proposed upper-tier method -- a 55 milliliter puff every 30 seconds -- gives about 11 puffs. Assuming that there are 49 millimeters of tobacco rod available for smoking and a uniform burn rate, a simple calculation shows that about 6.1 millimeters of tobacco rod would be consumed during the one-minute puffing cycle (puff and smolder) under FTC's current method. Under the proposed upper-tier method, about 4.5 millimeters of the tobacco rod would be consumed per puffing cycle, again assuming uniform burning down the rod.

In either case, smoking beyond the standard butt length through the overwrap would yield no more than one additional puff, and quite possibly no puff at all if the previous puff occurred close to the machine cutoff mark on the tobacco rod.

d. What effect, if any, would reducing the sample size from 100 to 50 cigarettes, as proposed, have on both the reliability and the replicability of the machine yield estimates? If there is an effect on reliability, does the fact that consumers would be given dual ratings, rather than a unitary rating, lessen the importance of that reduction?

1. The sample size should be maintained to preserve historical continuity.

Although the manufacturers make every effort to standardize their brands, as an agricultural product tobacco differs over time and from place to place. Therefore, cigarettes have some variation in "tar" and nicotine. The current sample size should be retained to ensure that the numbers generated by the test are an accurate representation of the brand-style for which they are to be published. As noted above, and as the Commission has stated, it is important to "preserve the historical continuity of the existing test method, and thus permit long term trends in ratings to be identified."[36]

2. Decreasing the sample size could affect the representativeness of the sample.

Currently, the Tobacco Institute Testing Laboratory purchases 100 samples of each brand style according to a validated sampling method. Reducing the sample size from 100 to 50 could call into question the representativeness of the sample, and the new sampling method would need to be validated.

There is no good reason to decrease the current sample size and risk making the sample less representative.[37] To preserve the current representativeness of the sample,

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[36] FTC Proposal, 62 Fed. Reg. at 48,159.

[37] As discussed below, if the Commission decides to adopt a two-tier method, the cigarette manufacturers believe that the lower-tier results should continue to be generated in the laboratory using a sample size of 100 cigarettes, and the upper tier should be generated by applying the proposed multiplier to the lower-tier machine-testing results. *See* Responses to Questions 1f and 1g.

and avoid the need for validating a new sampling method, the sample size should be maintained at 100 cigarettes per variety tested.

e. Can the machines presently used to smoke cigarettes pursuant to the FTC test method operate under the parameters in the Commission's proposed new protocol? If not, could they be modified to operate under those parameters or would new machines have to be purchased? What testing would be necessary to ensure the validity of the proposed modifications to the test method -- that is, to ensure that the revised protocol will produce highly reliable and replicable results? How long would such validation take?

Development of a sound and properly validated testing method for the proposed upper tier would take considerable time and effort, and would require consideration of the technical issues highlighted below. As discussed in more detail below, testing cigarettes under both the existing and the proposed new test method -- including the development of a protocol for the upper-tier test method -- would also be time-consuming and require a substantial commitment of resources.[38]

1. The machines presently used to smoke cigarettes pursuant to the Commission's testing method cannot operate under the parameters in the proposed upper-tier regimen without substantial modification.

The cigarette companies and the TITL currently use the Filtrona model number SM 350 smoking machine or a substantially similar machine for conducting "tar" and nicotine testing according to the FTC method. The SM 350 has a long history as a robust and reliable piece of equipment. The smoking machine's robustness is demonstrated each year by the TITL, which uses only two SM 350's to smoke over 50,000 cigarettes and produce yield data for over 520 cigarette brand styles.

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[38] A protocol is a "precise step-by-step description of a test." National Institute of Environmental Health Sciences, Department of Health and Human Services, *Validation and Regulatory Acceptance of Toxicological Test Methods, A Report of The Ad Hoc Interagency Coordinating Committee on the Validation of Alternative Methods*, NIH Publication No. 97-3981 (1997), at 53. To date, no protocol has been developed for the proposed upper-tier method.

Operating the SM 350 under the parameters in the Commission's proposed upper-tier test method is not simply a matter of modifying the commands to the machine, like pressing down on the gas pedal of a car to make it go faster, or adjusting a thermostat to make a room warmer. The SM 350 itself would have to be modified in a number of respects in order to operate under the parameters in the Commission's proposed upper-tier test method. Those modifications would result, for all practical purposes, in the construction of a new machine.[39] The modifications would involve, *inter alia*, changes in Cambridge filter capacity, syringe volume, motor stroke length, and flow-rate instrumentation.[40]

The machine as modified would have its own strengths and weaknesses, which would have to be evaluated on their own merits without reference to the existing SM 350. A modified smoking machine used to generate official yields for FTC reporting would have

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[39] *See* Borgerding, M., "The FTC Method in 1997 - What Alternative Smoking Condition(s) Does the Future Hold?" *Recent Adv. Tob. Sci.*, 23:75, 104-05 (1997) (discussing changes that would have to be made to adopt the smoking machine to a second, more intensive smoking method).

[40] **Filter capacity.** Increasing the puff volume to 55 milliliters and the puff frequency to once every 30 seconds would essentially double the quantities of "tar" and nicotine that a single Cambridge filter must capture. In some instances, the filter may become saturated, and some "tar" and nicotine may break through the filter. To avoid filter "break through," either a modified filter would have to be used, or fewer cigarettes would have to be smoked per test.

Syringe volume. The SM 350 is equipped with 50 milliliter syringes that are capable of drawing 35 milliliter puffs from each cigarette as specified by the current FTC testing method. Larger syringes are necessary for the upper-tier test. Once syringes are changed and set up, it is neither advisable nor practical to switch the twenty syringes back and forth on a routine basis.

Motor stroke length. As is required for setting up the current syringes, motor stroke length adjustment is required to assure proper puff volumes. This contributes to the non-practicality of switching syringes on a routine basis.

Flow rate instrumentation. There is an optional quality assurance accessory for the SM-350 known as the VFA which is used to assure proper puff profiles and valve timings. The VFA is not able to accommodate the higher flow rates generated by the upper tier test. New instrumentation would need to be developed to maintain proper quality assurance.

to go through a validation process along with other elements of the Commission's proposed upper-tier testing method.

Since the testing machines currently in use are not readily convertible to different testing parameters, it could take a significant amount of time and effort to convert and reconvert the machines between the two proposed testing regimes if the same machines were to be used for both tests. This is of particular importance for both the manufacturers and TITL, which probably would not be able to use their existing machines to test cigarettes under *both* the existing *and* the proposed new methods.

In light of the availability of a "multiplier" that can be used to closely approximate the results that actual testing under the upper-tier test would produce -- without requiring the conversion of the SM 350 or the validation of testing using a converted smoking machine -- requiring the manufacturers to convert the SM 350's and validate testing using the converted machines would not be justified.

2. Unlike a "multiplier," a new protocol would require an extensive period of validation to produce "highly reliable and replicable results."

The only way to ensure that results are "highly reliable and replicable" is to put the proposed upper-tier testing method through a formal validation process. Once such a process is completed, a new method would be ready for day-to-day application in the laboratory. The complex and time-consuming nature of this process reinforces the desirability of utilizing a "multiplier" to avoid the need for testing under the upper-tier. Since the "multiplier" approach does not require day-to-day testing, an experiment (albeit an extensive experiment) is appropriate to determine the multiplier rather than an extensive method validation process. Also, if upper-tier ratings are generated by means of a

multiplier from the FTC yield figures, those ratings would be based on results obtained from a method that, in effect, has already been validated.[41]

Absent the use of a multiplier, an extensive method validation process would be required. In the National Institutes of Health Revitalization Act of 1993, Pub. L. 103-43, § 1301, 107 Stat. 122, Congress instructed the National Institute of Environmental Health Sciences ("NIEHS") to establish criteria for the validation and regulatory acceptance of alternative testing methods. The NIEHS convened the Inter-Agency Coordinating Committee on The Validation of Alternative Methods ("ICCVAM").[42] Although the ICCVAM focused on validation of testing methodologies in the field of toxicology, the validation criteria that the ICCVAM proposed are applicable to any validation process.

In its report, the ICCVAM described validation as "the process by which the reliability and relevance of a test method are evaluated for the purpose of supporting a specific use."[43] The ICCVAM defined "reliability" as a "measure of the degree to which

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[41] *See* National Institute of Environmental Health Sciences, Department of Health and Human Services, *Validation and Regulatory Acceptance of Toxicological Test Methods, A Report of The Ad Hoc Interagency Coordinating Committee on the Validation of Alternative Methods*, NIH Publication No. 97-3981 (1997), at 16 ("Many test methods currently accepted by Federal agencies have been considered validated based on their history of use by the scientific community, even though their operational characteristics (*e.g.*, reproducibility and predictivity) may not have been fully established at the time of adoption. Calculation of current performance using existing data is necessary so that the performance of new or revised methods can be compared to the existing method.").

[42] The following government agencies participated: Consumer Products Safety Commission, Department of Agriculture, Department of Defense, Department of Energy, Department of Health and Human Services, Department of the Interior, Department of Labor and Department of Transportation.

[43] National Institute of Environmental Health Sciences, Department of Health and Human Services, *Validation and Regulatory Acceptance of Toxicological Test Methods, A Report of The Ad Hoc Interagency Coordinating Committee on the Validation of Alternative Methods*, NIH Publication No. 97-3981 (1997), at 15.

a test can be performed reproducibly within and among laboratories over time."[44] The ICCVAM concluded that "[v]alidation of a test method is a prerequisite for it to be considered for regulatory acceptance."[45]

To be considered validated for purposes of regulatory acceptance, a test method should meet the following criteria, among others[46]:

- The scientific rationale for the test method, along with a clear statement of its proposed use, should be available. A statement of the regulatory rationale also should be available.
- A detailed protocol for the test method should be available.[47]
- Information on the extent of within-test variability and the reproducibility of the test within and among laboratories should be gathered, evaluated and described.
- The limitations of the method should be described.
- "Ideally, all data supporting the validity of a test method should be obtained and reported in accordance with Good Laboratory Practices."[48]
- All data supporting the assessment of the test method should be available for review. The method(s) and results should be published in an independent, peer-reviewed publication and should be subjected to independent scientific review.[49]

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[44] *Id.* at 54.

[45] *Id.* at 24.

[46] These criteria are adapted from the list developed by the ICCVAM. *Id.* at 23-24.

[47] The protocol should include "a description of the materials needed, a description of what is measured and how it is measured, acceptable test performance criteria . . ., a description of how data will be analyzed, . . . [and] a description of the known limitations of the test." *Id.* at 23-24.

[48] *Id.* at 24.

[49] *Id.* at 25. The ICCVAM also provided an outline of the practical steps that a validation process ordinarily should include. An adaptation of that outline to the difficulty of validating the FTC's proposed upper-tier testing method is attached as Appendix B.

The process of validating the protocol for the FTC's proposed upper-tier testing method -- if testing rather than a "multiplier" was required -- should include at least the following steps[50]:

- preparation of a precise statement of the test protocol objective;
- preparation of a precise statement of the scope of the analysis;
- method development research to study and optimize possible technical alternatives that address the stated objective while taking into consideration practical constraints;
- determination of the best -- *i.e.*, the most accurate, precise and robust -- technical alternative for the cigarette sample range of interest[51]; and

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[50] *See* Borgerding, M., "The FTC Method in 1997 - What Alternative Smoking Condition(s) Does the Future Hold?" *Recent Adv. Tob. Sci.*, 23:75, 89-92 (1997).

[51] FDA has published definitions of "accuracy," "precision," and "robustness" in the context of its work with the International Conference on Harmonization ("ICH") to develop a "Text on Validation of Analytical Procedures," 60 Fed. Reg. 11,260 (1995):

> The *accuracy* of an analytical procedure expresses the closeness of agreement between the value which is accepted either as a conventional true value or an accepted reference value and the value found.

Id. at 11,261 (emphasis added).

> The *precision* of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions.

Id. (emphasis added).

> The *robustness* of an analytical procedure is a measure of its capacity to remain unaffected by small, but deliberate, variations in method parameters and provides an indication of its reliability during normal usage.

Id. at 11,262 (emphasis added).

- interlaboratory testing to ensure that the results are reproducible -- *i.e.*, that meaningful and comparable results can be obtained by the industry and other laboratories.[52]

According to the "Guidelines for Collaborative Study Procedures To Validate Characteristics Of A Method Of Analysis" ("Guidelines") adopted by AOAC International, the first four steps on the above list ordinarily would be performed in a single laboratory.[53] All of the manufacturers, however, would need to play a role in the first two steps and participate actively in the third and fourth.

Several commentators have stated that designing and directing a validation study should be the responsibility of a steering committee or a management team.[54] Here such a committee might consist of representatives from each of the manufacturers, an independent laboratory, and the Commission. The committee would have responsibility for determining that there is sufficient information about a method to support a validation study. The

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[52] In the context of its work with ICH, FDA has stated that:

> "*Reproducibility* expresses the precision between laboratories (collaborative studies, usually applied to standardization of methodology)."

Id. (emphasis added).

[53] "Guidelines for Collaborative Study Procedures of A Method of Analysis" *in 1 Official Methods of Analysis of AOAC International* at App. D-1 (P. Cunniff, ed. 1997). AOAC International formerly was known as the Association of Official Analytical Chemists.

[54] *See* National Institute of Environmental Health Sciences, Department of Health and Human Services, *Validation and Regulatory Acceptance of Toxicological Test Methods, A Report of The Ad Hoc Interagency Coordinating Committee on the Validation of Alternative Methods*, NIH Publication No. 97-3981 (1997), at 18 (citing commentators); *accord* American Society for Testing And Materials, "Standard Practice for Conducting An Interlaboratory Study to Determine the Precision of a Test Method," E 691-92, at 4 ("Either the task group that developed the test method, or a special task group appointed for the purpose, must have overall responsibility for the [interlaboratory study] . . . the design of the [interlaboratory study], and decision-making with regard to questionable data.").

committee would define the study's purpose, ensure the development of an adequate protocol, develop a recordkeeping system, select participating laboratories, oversee the collection and distribution of the sample to be analyzed, and monitor laboratory performance.

According to AOAC International's Guidelines, the fifth step on the list -- the interlaboratory study -- is intended to "provide a realistic estimate of the attributes of a method, particularly the systematic and random deviations to be expected when the method is used in actual practice."[55] An interlaboratory study to validate the Commission's proposed upper-tier testing method should involve, at a minimum, the TITL, the laboratories of the manufacturers, and, very likely, laboratories of some smaller cigarette companies and some foreign cigarette companies, or others, that would wish to participate in the interlaboratory validation study.[56] Indeed, AOAC International's Guidelines state that the minimum number of laboratories that should participate in an interlaboratory validation study is *eight* laboratories.[57]

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[55] "Guidelines For Collaborative Study Procedures To Validate Characteristics Of A Method Of Analysis," *in* 1 *Official Methods of Analysis of AOAC International* at App. D-4 (P. Cunniff, ed. 1997).

[56] Twenty-nine laboratories located all over the world participated in the CORESTA effort to develop a standard testing method for ISO. Thomsen, H., "International Reference Method for the Smoking of Cigarettes," *Recent Adv. Tob. Sci.*, 18:69, 69 (1992) (abstract). The ISO and FTC test methods are virtually identical.

[57] "Guidelines For Collaborative Study Procedures To Validate Characteristics Of A Method Of Analysis," *in 1 Official Methods of Analysis of AOAC International* at App. D-4 (P. Cunniff, ed. 1997) ("The optimum number of laboratories, balancing logistics and costs against information obtained, often is 8-10. However, larger studies are not discouraged.").

The American Society for Testing and Materials ("ASTM") has stated that an interlaboratory study "should include 30 or more laboratories but this may not be practical." ASTM, "Standard

(continued...)

Ideally, the entire validation process would be overseen by either the Commission or an independent standards organization with competence in the relevant areas, such as the American National Standards Institute or ISO. Regardless of who performs the oversight function, the validation process would have to comply with any special requirements that the overseer might impose. For example, proposed ISO standards must pass through multiple layers of committee review before obtaining final approval from the organization. Meeting the overseer's administrative and procedural requirements will likely lengthen the validation process.

The manufacturers estimate that a validation process to ensure that the protocol for the proposed upper-tier testing method will produce "highly replicable and reliable results" would require two years or more. This estimate could be optimistic. In order to meet the needs of the European Union, the ISO effort to harmonize the smoking machine test method -- a far less ambitious undertaking than validating a new testing regimen -- had to comply with a very strict two-year time limit. Hans Thomsen, reporting to the Tobacco Chemists Research Conference in 1992, described the ISO process as "work which at the beginning may have appeared fairly straightforward and manageable, but quickly grew into a 'monster' -- the largest and most resource-consuming task ever undertaken by CORESTA."[58] It is

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[57] (...continued)
Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method," E 691-92, at 6. According to ASTM, "*[u]nder no circumstances should the final statement of precision of a test method be based on acceptable test results for each material from fewer than 6 laboratories*. This would require that the [interlaboratory study] begin with 8 or more laboratories in order to allow for attrition." *Id.* (emphasis in original).

[58] Thomsen, H., "International Reference Method for the Smoking of Cigarettes," *Recent Adv. Tob. Sci.* 18:69, 76 (1992).

possible that the process of validating the proposed upper-tier testing method also could become a "monster" and consume more than two years.

f. Could the ratings for the upper tier of the revised test method be obtained from mathematical equations or "multipliers"? Why or why not? Would the continuing validity of the equations have to be reconfirmed periodically through actual machine smoking and, if so, how often?

1. The ratings for the upper tier of the upper-tier test method can be obtained from mathematical equations or "multipliers."

The ratings for the upper tier of a two-tier test method can be obtained from mathematical equations or "multipliers." This has been demonstrated for cigarettes currently sold in the U.S. by an experiment conducted during 1997 that has been reported to the Commission.[59] The experiment was conducted in the laboratories of the four manufacturers to determine the general relationship between (a) smoke yields when cigarettes are smoked according to the proposed upper-tier testing method with a puff volume of 55 milliliters and a puff frequency of one every 30 seconds (the "55/30/2 method") and (b) smoke yields when cigarettes are smoked with the standard FTC method protocol of 35 milliliters and a puff frequency of one every 60 seconds.[60] In the 55/30/2 method, puff duration was the same as in the standard FTC protocol, *i.e.*, two seconds.

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[59] Philipp, C., St. Charles, K., Norman, V., Whidby, J., Garman, J., Lewis, L., Borgerding, M., *An Experiment To Determine the General Relationship Between Cigarette Smoke Yields using an Alternative Puffing Regimen (55/30/2) and the Standard FTC method*, compiled by Borgerding, M., Bodnar, J., Willard, B., R.J. Reynolds Tobacco Company, Winston-Salem, N.C. (June 23, 1997).

[60] In the report on the experiment, puff volumes are described in cubic centimeters rather than milliliters. A volume of 55 cubic centimeters is equivalent to a volume of 55 milliliters, and thus the terms can be used interchangeably. In these comments, we refer to milliliters because the Commission has used milliliters in its proposal.

The laboratories each tested 50 different cigarettes: 46 commercial brand styles and four University of Kentucky Reference cigarettes.[61] The laboratory of R.J. Reynolds Tobacco Company, which coordinated the experiment, supplied each laboratory with five commercial brand styles from a single purchase. Each laboratory chose independently the remaining 41 commercial brands to be tested. The laboratories were instructed to select brand styles that would provide a comprehensive insight into the smoke yields of cigarettes that currently are sold in the marketplace. Because the laboratories chose brands independently, there was some duplication among the brands tested. The laboratories tested a total of 126 commercial brands, representing a broad range of cigarette lengths, circumferences, filter types, price tiers, pack styles, menthol inclusion and FTC "tar" yields.[62]

The four laboratories reported 1,840 results (each laboratory reported 10 ports each of 46 commercial brand styles times four companies). Regression analysis demonstrated that "tar," nicotine and carbon monoxide ("CO") data from the two puffing regimens can be related by quadratic functions. The following functions can be used to predict yields for cigarettes smoked under the 55/30/2 method from standard FTC smoke yield data:

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[61] *See Research Cigarettes* at 7 (Tobacco and Health Research Institute, 1990). Kentucky Reference Cigarettes are standard reference cigarettes used for biological testing and smoke chemistry studies. They were developed by the University of Kentucky and are for sale to laboratories by the University. All physical characteristics were determined in consultation with various cigarette manufacturers.

[62] Philipp, C., St. Charles, K., Norman, V., Whidby, J., Garman, J., Lewis, L., Borgerding, M., *An Experiment To Determine the General Relationship Between Cigarette Smoke Yields using an Alternative Puffing Regimen (55/30/2) and the Standard FTC method*, compiled by Borgerding, M., Bodnar, J., Willard, B., R.J. Reynolds Tobacco Company, Winston-Salem, N.C. (June 23, 1997) at App. E.

$$55/30/2\ \text{"Tar"} = -0.0237*(\text{FTC "Tar"})^2 + 2.5042*(\text{FTC "Tar"}) + 1.9394$$
$$R^2 = 0.9819$$

$$55/30/2\ \text{Nicotine} = -0.1192*(\text{FTC Nicotine})^2 + 2.0529*(\text{FTC Nicotine}) + 0.2650$$
$$R^2 = 0.9724$$

$$55/30/2\ \text{CO} = -0.0051*(\text{FTC CO})^2 + 1.4718*(\text{FTC CO}) + 6.6969$$
$$R^2 = 0.9186$$

With respect to "tar," the observed differences between the values predicted by the quadratic function and the measured values tend to be within 10 to 15 percent of the actual response or less,[63] which is typical of analytical methods. Thus, the function provides a reasonable means of predicting "tar" yields for the 55/30/2 method based on measured FTC "tar" yields. Indeed, similar variations of 10 to 15 percent are expected from repeated measurements within and between days when a single laboratory measures cigarettes with "tar" yields as high as 50 milligrams. In absolute terms, differences as large as six milligrams of "tar" per cigarette between predicted and measured values for the 55/30/2 method were observed. However, 85 percent of the differences were two milligrams per cigarette or less, and 63 percent of the differences were one milligram per cigarette or less.[64]

There also was good agreement between predicted values and observed values for nicotine and CO tested under the 55/30/2 method.[65] In both cases, the differences tended to be 10 to 15 percent of the actual response, or less. With respect to nicotine, differences as high as 0.4 milligrams per cigarette were observed, but 93 percent of the differences

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[63] *Id.* at 7.

[64] *Id.* at 7-8.

[65] *Id.* at 8.

observed were 0.2 milligrams or less and 76 percent were 0.1 milligram or less, which is within the rounding error for the standard method.[66]

Consequently, based on data gathered in the experiment conducted by the manufacturers, it is clear that the yield ratings for the upper-tier testing method can be predicted by means of an equation.

2. The continuing validity of the quadratic equations can be reconfirmed periodically through actual machine testing.

The continuing validity of the equations used to obtain estimated yield ratings can be reconfirmed periodically through actual machine smoking at the 55/30/2 conditions. In an effort to ensure that the equations already submitted to the Commission are replicable and reliable, the manufacturers propose to replicate the experiment from which the equations were derived within one year of the date on which the Commission approves a testing method that utilizes the equations. The manufacturers recommend that an experiment be conducted every five years thereafter to reconfirm the validity of the equations used to obtain ratings for the upper-tier testing method. The experiment should be similar to the one discussed above. This recommendation is consistent with the Commission's proposal to conduct a quinquennial review of its test method to assess the operation of the proposed system.[67]

The use of a multiplier is preferable to the upper-tier testing method because it does not require the development of a new protocol or implementation of a complex system of

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[66] See Federal Trade Commission, Report of "Tar", Nicotine, and Carbon Monoxide of the Smoke of 1249 Varieties of Domestic Cigarettes for the year 1995 (Jan. 15, 1998) (explaining "rounding").

[67] FTC Proposal, 62 Fed. Reg. at 48,161.

testing cigarettes, including the extensive level of validation required for a method practiced day-to-day in many different laboratories, and would serve the Commission's purpose.

The manufacturers recognize that the use of a multiplier (or, indeed, the existing test method itself) cannot automatically be assumed to be appropriate in the case of cigarettes with design parameters that fall outside of the wide range of design parameters of the cigarettes that were used to establish the quadratic equation proposed by the manufacturers to the Commission. Until cigarettes with alternative design parameters proliferate, these instances should be dealt with on a case-by-case basis.

g. Should the cigarette manufacturers be permitted to use the mathematical equations they submitted to the Commission to calculate the ratings that would be produced by testing under the proposed upper-tier parameters? Why or why not? If the industry is permitted to use such mathematical equations, should it continue to use 100 cigarettes, rather than 50, to determine the lower-tier ratings? Why or why not?

1. The manufacturers should be permitted to use the mathematical equations they have submitted to calculate the ratings that would be produced by testing under the proposed upper-tier parameters.

The manufacturers are not convinced that a second number is warranted. If, however, a second number is required, they strongly support use of the mathematical equations submitted to the Commission to calculate the ratings that would be produced by testing under the proposed upper-tier parameters. In an experiment conducted in four different laboratories, the mathematical equations were carefully evaluated and found to be viable. For a wide range of cigarette brand styles, the scientists found good agreement between measured values and values predicted by empirically derived equations. Thus, the equations will serve the purpose that they were intended to serve.

There are at least two additional reasons why the equations submitted by the manufacturers should be used to generate the ratings sought to be produced by the upper-tier testing method. *First*, as discussed, implementation of a two-tier testing system in which the upper-tier ratings were produced in the laboratory on smoking machines would be time-consuming and costly, while the time and cost associated with generating upper-tier results by means of an equation would be comparatively small.[68] *Second*, the use of an equation to generate the upper-tier results would eliminate the need to validate the protocol for the 55/30/2 testing method, a process that could require two or more years and countless hours of labor. Although the current FTC testing method has never undergone a formal validation process, it has been validated for the purpose it was designed to serve through 30 years of interlaboratory use. This history of use serves as "de facto validation":

> Many test methods currently accepted by Federal agencies have been considered validated based on their history of use by the scientific community, even though their operational characteristics (*e.g.*, reproducibility and predictivity) may not have been fully established at the time of adoption. Calculation of current performance using existing data is necessary so that the performance of new or revised methods can be compared to the existing method.[69]

In addition, the manufacturers and the TITL conduct semi-annual "round-robin" interlaboratory tests to ensure the reproducibility of results that are communicated to FTC. Consequently, if upper-tier ratings were generated by means of an equation premised on

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[68] The costs associated with performing an experiment every five years to reconfirm the validity of the equations would be substantial. Nevertheless, the costs would not approach the annual costs associated with producing ratings for the upper-tier testing method in the laboratory.

[69] National Institute of Environmental Health Sciences, Department of Health and Human Services, *Validation and Regulatory Acceptance of Toxicological Test Methods, A Report of The Ad Hoc Interagency Coordinating Committee on the Validation of Alternative Methods*, NIH Publication No. 97-3981 (1997), at 16.

yield figures from the existing FTC test method, those ratings would be based on results obtained from a method that, as a practical matter, already had been validated over time.

2. If the manufacturers are permitted to use a mathematical equation to generate the upper-tier results, a 100-cigarette sample should be used to generate the lower-tier results.

As discussed, reducing the sample size from 100 cigarettes to 50 cigarettes could have a negative impact on the reliability of the current FTC testing method. *See* answer to question 1(d). Maintaining the current sample size would avoid that potential problem, avoid the need for validation, and ensure historical continuity.

h. How much would the proposed two-tier testing system cost the cigarette industry to implement as compared to the current system? How much would the proposed two-tier testing system cost the cigarette industry to implement if 100 cigarettes, rather than 50, were smoked under each test condition? How much would the proposed revisions to the test method cost the industry to implement if mathematical equations were used to generate the upper-tier ratings?

1. The cost of implementing a two-tier system would be high if results for the upper tier must be generated in the laboratory.

The greatest "costs" of implementing a two-tier system are costs in time -- the time it would take to develop and validate the upper-tier test method, and the time it would take to conduct the second set of tests using the upper-tier test method, once developed and validated.

The dollar costs of implementing the upper-tier test method are impossible to quantify with any confidence. The manufacturers are able to offer, as very preliminary estimates, that implementation of the upper-tier method would entail, for them, approximately $25 million in capital costs and $9 million in annual operating costs

thereafter.[70] These estimates, however, do not include the costs of method development and validation, or costs to TITL or any other manufacturers.

2. The cost advantages associated with reducing the sample size would not be significant.

Reducing the sample size from 100 to 50 would not affect the capital costs associated with implementing an upper-tier method of laboratory testing. Reducing the sample size might somewhat reduce the ongoing annual costs of each tier of testing by both TITL and the manufacturers. Fewer hours might be spent testing 50 cigarettes than are spent testing 100. However, the cost of testing 100 cigarettes using *two* methods -- *i.e.*, 50 cigarettes with the current FTC method and 50 with the 55/30/2 method -- would not be the same as the cost of testing 100 cigarettes using *one* method. Compared to the high costs associated with establishing and maintaining a second laboratory at the TITL and a second or expanded laboratory at each manufacturing location dedicated to the upper-tier method, any cost reductions that might be associated with reducing the sample size would be relatively insignificant.

Reducing the sample size also may not affect the ongoing costs. Round-robin testing conducted by the TITL and the manufacturers uses a sample size of 100 cigarettes. Even if the manufacturers reduced the sample size, there is no reason to believe that a 50 percent reduction in sample size would lead to a 50 percent reduction in ongoing annual costs. With

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[70] Capital costs would include the purchase of additional smoking machines, computers and software, chromatography equipment and modifications to or construction of, laboratory space. Annual operating costs would include personnel and supplies needed to run and maintain the laboratory, including conducting semi-annual "round-robin" studies by the TITL and the laboratories of the four manufacturers to ensure that measured results remain comparable from laboratory to laboratory.

respect to the semi-annual round robin, the cost of testing 50 cigarettes under the current FTC method and 50 under the proposed upper-tier method is likely to exceed the costs of testing 100 cigarettes under the current method.

3. The cost of adding an upper tier if a multiplier would be small compared to the cost if testing was required.

The cost of generating an upper tier of numbers using a multiplier would be (1) small compared to the cost of retesting every brand under the second set of test parameters, and (2) a far more rational allocation of human and financial resources given the reliability of the data. No new computer equipment or software would be necessary.

Although there would be costs associated with periodically reconfirming the equations used to generate the upper-tier numbers, the investment in capital and personnel that would be required for ongoing second-tier laboratory testing would not be necessary. Periodic testing to reconfirm the equations would require the manufacturers to modify existing equipment or purchase new equipment. It also would entail a recurring disruption of normal procedures for using smoking machines, computers and chromatographs. Personnel already in place would have to be trained and temporarily shifted to new tasks.

The manufacturers estimate that the costs associated with a single experiment to reconfirm the equations for predicting yields at the upper tier could be as much as $100,000 to $150,000 per company.

2. *Alternative Options For Revising the Test Method*

a. Should the upper tier of the two-tier test method reflect the tendencies of smokers of lower rated and heavily aerated (i.e., vented) cigarettes to smoke more intensively (by taking more puffs, bigger puffs, etc.) or to block some or all of the ventilation holes while smoking? If so, how should the test protocol be modified in order to obtain tar and nicotine ratings that would accurately reflect the effect of these and other forms of compensatory smoking behavior? Would ratings generated by such a test protocol affect smoking intensity, brand choice, and/or the decision whether to quit smoking, and if so, how?

1. The testing protocol should not be modified to reflect "compensatory" smoking.

As the Commission's question reflects, the hypothesized phenomenon called "compensatory smoking" is often viewed as a collection of discrete behaviors -- *e.g.*, puff size, puff duration, puff frequency, and (possibly) vent-blocking. The manufacturers submit that the use of such behaviors to define "compensatory smoking" is misconceived because everyday smoking involves variability in each of these behaviors, and determining empirically when such behaviors constitute "compensation" rather than normal variability in everyday smoking is problematic.

Even if such behaviors were appropriate markers of "compensatory smoking," current knowledge about these behaviors is too sparse to be usable for modeling purposes; and even if sufficient data existed to model those behaviors, routine analytical smoking machines cannot be used to model human behavior because such machines do not smoke like people. The only purpose that the FTC testing method or any other routine analytical

smoking-machine testing method of which we are aware can serve is "to determine the amount of tar and nicotine generated when a cigarette is smoked by machine in accordance with the prescribed method."[71]

2. The evidence suggests that any compensation that may occur is partial and may be of limited duration.

The Commission asks whether all or most smokers of lower-rated and more heavily aerated cigarettes "compensate" for the lower yields by altering their puffing behavior in order to increase the yield.[72] The evidence in support of such a phenomenon, however, is highly equivocal. In fact, studies repeatedly have shown that "tar" and nicotine intake decreases when a smoker shifts to a cigarette with a lower FTC reported yield. Moreover, to the extent that compensation occurs, all available evidence indicates that it is not complete and it may be a phenomenon of limited duration. More important, the manufacturers are unaware of evidence in the literature suggesting that it is possible to determine any "average" amount of compensation applicable to all smokers (or any given subset) that would be an essential prerequisite to any meaningful attempt to adjust the proposed upper-tier test to reflect such behavior. In short, there does not appear to be a scientifically valid basis to modify the upper-tier test in response to a phenomenon of unknown applicability across the spectrum of smokers.

Before reviewing the evidence, it may be useful to place the discussion of "compensation" in perspective. Compensation generally is taken to mean increasing puff

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[71] *FTC To Begin Cigarette Testing*, FTC News Release, (Aug. 1, 1967).

[72] Question 2a also raises the issue of vent blocking. For purposes of clarity, the response to question 2a *does not* discuss the issue of vent blocking, which is addressed in the response to question 2c.

count or puff volume on a consistent and sustained basis in response to a change from higher-yield to lower-yield cigarettes. However, everyday smoking involves variability in the same discrete smoking behaviors and distinguishing between such everyday variability and compensation is problematic. In order to understand the phenomenon of compensation, it is important to focus on biological measures of human intake, not smoking behaviors. Limited research has been conducted to date to determine actual smoker intake and what research has been conducted has not been replicated in multiple laboratories. The methods currently in use to conduct such research are not suitable for standardized testing, and are limited to estimating nicotine intake and not "tar" intake. In addition, the results of these studies do not, in any way, predict the likely intake of other smokers or even of the same smokers in other environments or under other circumstances.

- **The most extensive studies to date have tended to find direct and linear relationships between actual intake and FTC method yield.**

Even those researchers who report finding some compensation in smoking behavior generally conclude that smokers inhale somewhat lower quantities of "tar" and nicotine when they smoke cigarettes with lower yields as measured by the FTC method. In any event, the studies discussed below do not provide support for the notion that "compensation" is an across-the-board behavior pattern that can be ascribed in any particular degree to the majority of smokers. Thus, the manufacturers do not believe that a meaningful adjustment to the upper tier test can be made that would rationally reflect the behavior of smokers generally.

According to Russell, for example, despite some apparent compensatory behavior by some smokers of lower-yield cigarettes, "their intake of the three major smoke

components [is] still lower [than that of smokers of higher-yield cigarettes] to a statistically and clinically significant degree."[73] Thus, even a smoker who may appear partially to compensate while smoking lower-yield cigarettes still has a lower intake of "tar" and nicotine.[74]

Similarly, a 1992 study of 125 smokers by Rosa and colleagues showed that plasma cotinine levels varied directly with the yield of nicotine (as measured by a smoking machine) in the cigarettes that they smoked. "The findings revealed a linear correlation between daily nicotine intake and serum levels of cotinine."[75] The report concluded that smokers did not compensate when smoking low-nicotine cigarettes and compensated only partially when smoking ultra-low-yield brands.[76]

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[73] Russell, M., *et al.*, "Reduction of tar, nicotine and carbon monoxide intake in low tar smokers," *J. Epidemiology & Community Health* 40:80, 83 (1986). *See also* Zacny, J. & Stitzer, M., "Cigarette Brand-Switching: Effects on Smoke Exposure and Smoking Behavior," *J. Pharm.& Experimental Ther.* 246(2):619 (1988).

[74] Stephen, A., *et al.*, "Estimating the Extent of Compensatory Smoking," *in* Wald, N. & Froggatt, P. (eds.), *Nicotine, Smoking, and the Low Tar Programme* 101-114, 112 (1989) ("The studies are consistent in demonstrating that compensation is not complete. Low tar cigarette smokers inhale less CO and nicotine than high tar cigarette smokers."); Rosa, M., *et al.*, "How the steady-state cotinine concentration in cigarette smokers is directly related to nicotine intake," *Clinical Pharm. Ther.* 52(3):324, 324 (1992) (cotinine levels of smokers decreased proportionally to the FTC method yield of nicotine in the cigarettes smoked); Bridges, R., *et al.*, "Population Characteristics and Cigarette Yields as Determinants of Smoke Exposure," *Pharm., Biochem. & Behav.* 37(1):17, 22 (1990) (plasma nicotine and cotinine concentrations "appeared to increase progressively with increasing nicotine yield of the cigarette"); Bridges, R., *et al.*, "Smoking History, Cigarette Yield and Smoking Behavior as Determinants of Smoke Exposure," *Eur. J. Respiratory Disease* 69 (Supp. 146):129, 129 (1986) (FTC method nicotine yields of cigarettes correlated significantly with plasma cotinine levels in smokers, showing a linear relationship between the FTC method yield and the plasma cotinine measurements).

[75] Rosa, M., *et al.*, "How the steady-state cotinine concentration in cigarette smokers is directly related to nicotine intake," *Clinical Pharm. Ther.* 52(3):324, 327-328 (1992).

[76] *Id.* at 328.

In 1988, Zacny and Stitzer conducted a brand-switching study in which smokers were switched from their usual brand of cigarettes to a brand with a higher or lower yield (measured by the FTC method) in order to determine any changes in the levels of blood serum cotinine and other biomarkers.[77] Zacny and Stitzer reported that the cotinine levels in the smokers of ultra-low-yield cigarettes were significantly lower than the levels in smokers of medium-yield cigarettes, and that the cotinine levels in the smokers of low-yield cigarettes were significantly lower than the levels in smokers of high-yield cigarettes. Although the authors thought that there had been some compensation, they concluded that "nicotine, cotinine and CO exposure levels from commercial brand cigarettes are related in an orderly manner to cigarette yield."[78]

A 1990 study of 170 male smokers also found that plasma nicotine and cotinine concentrations "appeared to increase progressively with increasing nicotine yield of the cigarette."[79] The study found "linear relationships between plasma nicotine or cotinine concentrations and the cigarette yield in smokers consuming filter cigarettes."[80] In addition, a 1986 study similarly found that the nicotine yield of cigarettes correlated

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[77] Zacny, J. & Stitzer, M., "Cigarette Brand-Switching: Effects on Smoke Exposure and Smoking Behavior," *J. Pharma. & Experimental Ther.* 246(2):619 (1988).

[78] *Id.* at 627.

[79] Bridges, R., *et al.*, "Population Characteristics and Cigarette Yields as Determinants of Smoke Exposure," *Pharm., Biochem. & Behav.* 37:17, 22 (1990).

[80] *Id.*

significantly with plasma cotinine levels and that the relationship between the reported FTC yield and the plasma cotinine levels was linear.[81]

Byrd and others investigated the inter-individual variation of nicotine intake of 72 smokers who smoked *ad libitum* their usual brand cigarette.[82] Nicotine and some of its metabolites were determined in 24-hour urine samples for smokers of brands with FTC method yields from 0.1 to 1.2 milligrams of nicotine per cigarette. The correlation between nicotine absorbed and FTC nicotine yield was positive and statistically significant, though weak. These data show that, on average, compensation occurs for smokers of low yield cigarettes but is incomplete.

Benowitz and Henningfield, in an editorial, have suggested that "[t]he variation in intake [of nicotine] per cigarette is considerable . . . ranging from 0.3 to 3.2 mg . . . depending on how the cigarette is smoked."[83] Thus, they suggested that a person who smokes a cigarette that typically delivers about one milligram of nicotine could increase the yield of that cigarette to 3.2 milligrams -- a result that is 320 percent of the stated yield. In fact, this claim is based on data that are too limited to support any general conclusions.

Benowitz and Henningfield cited two articles by Benowitz and colleagues as the sole support for their 320-percent figure. One of those studies reported that, under certain test

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[81] Bridges, R., *et al.*, "Smoking History, Cigarette Yield and Smoking Behavior as Determinants of Smoke Exposure," *Eur. J. Respiratory Disease* 69 (Supp. 146):129, 136 (1986).

[82] Byrd, G. *et al.*, "A Further Study of FTC Yield and Nicotine Absorption in Smokers," 3rd Annual Meeting of the Society for Research on Nicotine and Tobacco, Nashville TN, June 13-14, 1997.

[83] Benowitz, N. & Henningfield, J., "Establishing A Nicotine Threshold for Addiction," *New Eng. J. Med.* 331(2):123, 124 (1994).

conditions, the nicotine derived by a group of smokers ranged from one-third to 1½ times the yields derived by the FTC method.[84] Quite apart from the fact that this range simply brackets the FTC-predicted yield, the 1½-times maximum is less than *half* the 320-percent figure claimed by Benowitz and Henningfield.

The second article did state that *one* person derived 3.2 milligrams of nicotine from a *single* cigarette with an FTC yield of one milligram. Other smokers apparently derived as little as 0.37 milligrams from the one milligram cigarette that they were given to smoke. But in the report on that study, Benowitz acknowledged that the conditions of the study were extremely artificial and probably resulted in an *excessive amount* of compensation:

> It is likely that the unusually high level of nicotine intake in our subjects reflects the fact that the subjects (who had not smoked for the previous 10 to 12 hours) knew that they could smoke only one or two cigarettes during the next 12 hours. When access to cigarettes is restricted, cigarette smokers can increase their per-cigarette smoke intake by threefold or greater. Presumably this is what was occurring in our cigarette-deprived volunteers, despite instructions to smoke naturally. In addition, our subjects smoked these cigarettes through a cigarette holder (part of the smoke dosimeter), which is an unnatural way to smoke and could have influenced smoking behavior and nicotine intake. Effects of tobacco abstinence, either before testing or anticipated after testing, and the use of cigarette holders on smoking behavior should be considered by other investigators.[85]

- **Recent review articles indicate that "tar" and nicotine intake decreases when people switch to cigarettes with lower FTC reported yields.**

An analysis of the recent literature confirms that FTC reported deliveries are related to relative nicotine intake. In a recent meta-analysis of 18 brand-switching studies, Scherer

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[84] Benowitz, N. & Jacob, P., "Daily intake of nicotine during cigarette smoking," *Clinical Pharm. Ther.* 35:499, 501-02 (1984).

[85] Benowitz, N., *et al.*, "Stable isotope studies of nicotine kinetics and bioavailability," *Clinical Pharm. Ther.* 49:270, 275-276 (1991) (footnote omitted).

and Klus calculated a weighted average compensation index ("CI"), which was designed to show the extent to which the subjects studied compensated when researchers switched them from their own brands to brands with lower yields.[86] (A "CI" of 0 means no compensation; a "CI" of 1 means complete compensation.) Scherer and Klus reported a weighted average CI of 0.38. This CI suggests that while many study subjects altered their smoking behavior to compensate upon switching to lower-yield brands, they did not compensate sufficiently to bring their intake of "tar" and nicotine to the level obtained while smoking their prior higher-yield cigarettes.

A 1996 review of brand-switching experiments conducted for the NCI Expert Committee on the FTC Cigarette Test Method reached a similar conclusion.[87] Kozlowski and Pillitteri presented a chart describing the results of six brand-switching studies. The largest study reported 12 percent compensation for smokers who were switched from their own brands to brands with a lower-reported yield. Three other studies reported compensation rates in the 30-percent range. The smallest study showed a compensation rate of 49 percent and the remaining study showed a rate of 62 percent. It appears that intake was determined on the basis of plasma nicotine or plasma cotinine, depending on what was available.

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[86] Scherer, G. & Klus, H., "Cigarette Smoking And Compensation: An Evaluation of the Literature," *Recent Adv. Tob. Sci.*, 23:197, 197 (1997).

[87] Kozlowski, L. & Pillitteri, J., "Compensation for Nicotine by Smokers of Lower Yield Cigarettes," *in* U.S. Department of Health and Human Services, *Smoking and Tobacco Control, The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes, Report of the NCI Expert Committee* 161, 163 (1996).

A 1996 review by Pritchard and Robinson examined blood cotinine data from eight studies involving smokers who, instead of being subjected to a brand-switching experiment in the laboratory, had voluntarily switched to a lower-yield brand that at the time of the experiment was their usual brand.[88] The authors reported that "[t]he linear correlation between blood cotinine and usual-brand nicotine yield is 0.542."[89] The correlation was statistically significant and the authors characterized it as "remarkably high" considering the range of factors that might influence study results.[90] They stated:

> The regression line . . . indicates incomplete compensation on the order of 50%, that is, roughly midway between complete compensation (all smokers absorbing the same level of nicotine regardless of FTC yield) and smokers absorbing the exact FTC yield of nicotine for their particular brand. These data indicate that on average a smoker switching from a 1.0-mg product to a 0.5-mg product would, after several weeks of adjustment, achieve a 25% reduction in nicotine intake. This is not to say one could not find an *individual* 'permanent switcher' who completely compensates (or find one who does not compensate at all). It is to say that, *on average*, lower nicotine-yield cigarettes are associated with a lower intake of nicotine.[91]

These reviews of the scientific literature on compensation strongly suggest that smokers who compensate when switching to lower-yield cigarettes decrease their intake of

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[88] Pritchard, W. & Robinson, J., "Examining the relation between usual-brand nicotine yield, blood cotinine concentration and the Nicotine-'Compensation' Hypothesis," *Psychopharmacology*, 124:282-284(1996).

[89] *Id.* at 283-84.

[90] *Id.* at 284.

[91] *Id.* at 284 (emphasis in original).

"tar" and nicotine. Thus, whatever compensatory smoking behavior may be occurring, the FTC ratings should not be adjusted in an attempt to reflect this behavior.[92]

- **Studies suggest that compensation is at most a phenomenon of limited duration.**

Even those studies reporting that smokers compensate when switching from higher-yield to lower-yield cigarettes acknowledge that compensation is a phenomenon of limited duration. For example, in their review of brand-switching studies, Kozlowski and Pillitteri recognized that many of the existing brand-switching studies were conducted over a very short term.[93] Thus, although such studies may provide insight into changes in smoking behavior that occur immediately after a person switches from a higher-yield to a lower-yield brand, they do not necessarily reflect changes that might occur after a person has grown accustomed to smoking a lower-yield brand. Surely it would not be a surprise to discover that some smokers take time to become acclimated to a new cigarette with a different yield, and that this process of acclimation is reflected in their puffing behavior.

A 1992 study by Rosa and colleagues that examined compensatory behavior over time found that those smokers who compensate do so for only limited periods.[94] The

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[92] Stephen, A., *et al.*, "Estimating The Extent of Compensatory Smoking," *in* Wald, N. & Froggatt, P. (eds.) *Nicotine, Smoking And The Low Tar Programme* 101, 112 (1989) ("The studies are . . . consistent in demonstrating that compensation is not complete. Low tar cigarette smokers inhale less CO and nicotine than high tar cigarette smokers.").

[93] Kozlowski, L. & Pillitteri, J., "Compensation for Nicotine by Smokers of Lower Yield Cigarettes," *in* U.S. Department of Health and Human Services, *Smoking and Tobacco Control, The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes, Report of the NCI Expert Committee* 161, 162 (1996).

[94] Rosa, M., *et al.*, "How the steady-state cotinine concentration in cigarette smokers is directly related to nicotine intake," *Clinical Pharm. Ther.* 52(3):324, 328 (1992). *See also* Bridges, R., *et*

(continued...)

authors found that several studies do not take into consideration the time of accommodation to fit a new level of nicotine.

In a 1995 study, Reeves and Dixon switched smokers from one brand to another but kept each smoker within his or her accustomed yield category. In theory, this eliminated the time factor and allowed the authors to examine the effect of brand switching in isolation. Discussing the results of their study, they stated:

> The data outlined in this paper clearly demonstrates [*sic*] that puff volumes, durations and pressures, both in terms of 'per cigarette' and 'puff-by-puff,' were similar for the three products with machine derived tar yields of 14, 9 and 6 mg. *These results appear to contradict the results of previous short-term switching studies which claim that low tar products are smoked more intensely than higher tar products.*[95]

Commenting more generally on the issue of short-term studies that detect evidence of compensatory smoking behavior, Reeves and Dixon observed:

> Short-term switching studies may indeed demonstrate that a smoker who is unfamiliar with a product of lower delivery may smoke in a more 'intense' manner. Smokers are driven by a number of sensory cues such as taste, irritation, impact, and mouth feel. The intensities of many of these sensory cues are related to the tar and nicotine deliveries of the product. Thus a smoker accustomed to a specific set of sensory intensities from a full flavour product may, when smoking a lower delivery product, alter his behaviour in an attempt to 'maximize' the sensory intensities from the lower delivery product.[96]

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[94] (...continued)
al., "Smoking History, Cigarette Yield and Smoking Behavior as Determinants of Smoke Exposure," *Eur. J. Respiratory Disease* 69 (Supp. 146):129-137 (1986).

[95] Reeves, N. & Dixon, M., "The Measurement of Human Smoking Behaviour And the Influence of Mainstream Smoke Deliveries on Changes in Behavioural Parameters," *CORESTA Smoke & Technology Groups*, Vienna, Austria, Presentation No. ST19 (Sept. 10-14, 1995) (emphasis added).

[96] *Id.* at 5-6. *But see* Djordjevic, M., *et al.*, "Self-Regulation of Smoking Intensity. Smoke Yields of The Low-Nicotine, Low-'Tar' Cigarettes," *Carcinogenesis* 16(9):2015, 2015 (1995) (in
(continued...)

Benowitz and Henningfield -- perhaps the leading proponents of the "compensation" theory today -- stated in 1994 that compensation appears to be temporary:

> Overcompensation (*i.e.*, inhaling more smoke from low-nicotine cigarettes than from higher-yield brands) appears, however, to persist only for days or weeks. In long-term studies of carbon monoxide exposure after subjects switched to lower-yield cigarettes, compensatory oversmoking appears not to persist.[97]

b. Could compensatory smoking behavior be incorporated into the test by using different test parameters for different groups of cigarettes (i.e. higher test parameters for lower rated cigarettes and lower test parameters for higher rated cigarettes)? If so, how many different groups of cigarettes should there be, and what parameters should be applied to each group? Where should the line(s) separating the groups be drawn? Would using different sets of parameters overemphasize differences in yields between brands on either side of the dividing line(s)? Would it cause cigarettes on either side of the dividing line(s) to "switch rankings" with respect to their upper tier ratings? If so, do these potential outcomes make the use of different parameters for different cigarettes undesirable?

1. Different groups of cigarettes should not be tested under different testing parameters.

The fundamental flaw in implementing a protocol that smoked some cigarettes more intensively than others is that such a protocol would conflict with one of the central tenets of the Commission's testing -- the need for a uniform test method. The FTC stated in 1967 that "the uniform method determined by the Commission has as its purpose measurement of the tar and nicotine generated by cigarettes when smoked according to that procedure."[98]

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[96] (...continued)
a preliminary study of 12 subjects, finding that people smoking their own "low-nicotine" brands under laboratory conditions smoked more intensively than people smoking their own "medium-nicotine" brands).

[97] Benowitz, N. & Henningfield, J., "Establishing a Nicotine Threshold for Addiction," *New Eng. J. Med.* 331(2):123, 125 (1994).

[98] FTC To Begin Cigarette Testing, FTC News Release (Aug. 1, 1967).

In 1978, the FTC explained the significance of a "uniform method":

> [T]he FTC's "tar" and nicotine values represented valid standards for making comparisons among different cigarettes. Thus, if the consumer smoked each different cigarette the same way, he would inhale "tar" and nicotine in amounts proportional to the relative value of the FTC figures.[99]

A testing method that smoked lower-yield cigarettes more intensely and higher-yield cigarettes less intensively would not provide a "valid standard[ ] for making comparisons." That is because such a method would not allow the consumer to determine the relative amounts of "tar" and nicotine that he or she would inhale if he or she smoked different cigarettes in "the same way" (or even in a "similar way"), as the degree of difference between the tests would itself be arbitrary.

In addition, a testing method that smoked lower-yield cigarettes more intensely than higher-yield cigarettes would not provide a "valid standard[ ] for making comparisons" even to a smoker who actually *did* smoke different cigarettes in different ways. If a smoker changes puffing behavior in response to changes in cigarette yield, the smoker will do so in a unique way, not in a uniform and consistent way. The routine analytical smoking machine, by contrast, can incorporate only a uniform and consistent change in puffing parameters that almost certainly would not reflect possible changes in the puffing behavior of *any* smoker, let alone changes in the behavior of *each* individual smoker.

Since routine analytical smoking machines cannot replicate human smoking behavior, a system that smokes lower-yield and higher-yield cigarettes differently could mislead consumers. A test protocol under which lower-yield cigarettes were smoked more

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[99] FTC, *Cigarette Advertising and Other Promotional Practices*, 43 Fed. Reg. 11,856 (1978) (announcement of decision).

intensively and higher-yield cigarettes less intensively would *not* reflect the effects of reported compensatory smoking behavior. As the FTC stated in 1967, such a protocol would only "determine the amount of tar and nicotine generated when a cigarette is smoked by machine in accordance with the prescribed method."[100/]

Thus, from a consumer information standpoint, it would be misleading to implement a test protocol under which lower-yield cigarettes were smoked more intensely than higher-yield cigarettes. Any line drawn between higher-yield and lower-yield cigarettes would be arbitrary and not based on objective, scientific considerations.

2. A protocol under which higher-yield cigarettes were smoked less intensely than lower-yield cigarettes could lead to misleading shifts in the cigarette ratings.

The Commission stated that it declined to propose a protocol under which higher-yield cigarettes are smoked less intensively than lower-yield cigarettes because "using different puff parameters for different groups of cigarettes could artificially distort the rankings of brands near the dividing line between those groups."[101/] The manufacturers concur with the Commission's reasoning and oppose the implementation of such a protocol.

Regardless of where the line between higher-yield and lower-yield cigarettes was drawn, it is possible that subjecting higher-yield brands to a less intensive smoking regimen than lower-yield brands would result in misleading shifts in the ratings. If, for example, all brands with an FTC reported "tar" yield of 6 milligrams or less were classified as "lower-yield," then all such brands would be subjected to a more intensive smoking regimen

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100/ FTC To Begin Cigarette Testing, FTC News Release (Aug. 1, 1967).

101/ FTC Proposal, 62 Fed. Reg. at 48,160.

than brands with an FTC reported "tar" yield of seven or higher. Thus, for example, following the Commission's rules for rounding yield data, a brand with a "tar" yield of 6.4 milligrams (which rounds down to 6 milligrams) would be smoked more intensively than a brand with a yield of 6.6 milligrams (which rounds up to 7 milligrams). The effect could be to raise the rating of the lower-yield brand *above* the rating of the higher-yield brand. In the FTC's words, the brands would "switch rankings."

Such switches in the rankings would be misleading and a testing method that causes brands to "switch rankings" should be avoided. Those who support the application of more intense smoking parameters to lower-yield cigarettes do so because they apparently believe that scientific studies show that people smoke lower-yield brands more intensely than higher-yield brands. As far as the manufacturers are aware, however, no one has claimed that scientific studies show that people smoke a cigarette with an FTC reported "tar" yield of 6.4 milligrams more intensely than they smoke a cigarette with an FTC reported "tar" yield of 6.6 milligrams. Indeed, the scientific literature on "compensation" *assumes* that a person will smoke two brands with similar FTC reported yields *in a similar manner*.

Drawing a line between two brands with very similar FTC yields and subjecting them to different smoking regimens could mislead consumers, potentially conveying an apparently erroneous message that two very similar brands ordinarily provide significantly different yields to the smoker.

c. Could the effect of compensatory smoking behavior be incorporated into the test by blocking some or all of the aeration vents during testing? What does the available evidence demonstrate about the prevalence of vent blocking and about the percentage of vents that are blocked by those smokers who do engage in vent blocking? What effect, if any, does vent blocking have on smokers' puff frequency, puff volume, and puff duration? If vent blocking were to be included in the upper tier of testing, how should that blocking be accomplished? If vent blocking were used to generate upper-tier tar and nicotine yields, would this lead cigarette companies to switch from filter aeration to some other method of creating lower yield cigarettes? If so, what would be the effect on the relevance of the upper-tier yields?

1. Filter ventilation is an important means of reducing "tar" and nicotine yields.

Filter (or "tip") ventilation is provided by rendering a portion of the filter wrap (tipping and plugwrap) air-permeable.[102] During puffing, some air enters the filter directly, reducing the amount of air drawn past the cigarette coal, and thereby reducing the effective puff volume. As a consequence, the overall reduction in smoke yield is roughly proportional to the degree of ventilation. Filter ventilation has been one of the most effective cigarette design tools available to reduce FTC reported smoking yields, as evidenced by the trends in FTC "tar" and nicotine yields obtained over 30 years of testing.

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[102] Browne, C., *The Design of Cigarettes* 74 (1990); Kiefer, J., "Ventilated Filters and Their Effect on Smoke Composition," *Recent Adv. Tob. Sci.*, 4:69-83 (1978); Norman, V., "The Effect of Perforated Tipping Paper on the Yield of Various Smoke Components," *Beitr. Tabakforsh.*, 7(5):282-287 (1974).

Filter ventilation is achieved through the use of a perforated tipping paper (outer layer that is generally cork or white in color) and a porous or nonporous plugwrap, which is the paper holding the filter fibers together in a rod-shaped configuration. Tipping papers may be perforated by mechanical, electrostatic, or laser methods prior to cigarette making, and these tippings are used with a porous plugwrap. Other tipping and plugwrap papers are nonporous, and the filter ventilation is achieved through laser perforation of the filter tip after cigarettes are made. The degree of ventilation with both types of perforations is varied by the number and size of the perforations. In cases of highly air-diluted cigarettes, multiple rows of perforations may be necessary to achieve the ventilation level desired. Regardless of the method used, a discrete region of air permeability is provided around the filter circumference between about 11 and 17 mm from the mouthend of the filter.

2. Incorporating a vent blocking parameter into the puffing regimen presents a number of technical problems that may affect the replicability of results.

Dr. Borgerding has outlined some of the difficulties that are likely to arise if ventilation hole blocking is performed in the laboratory as part of a testing method.

> The practical aspects of 50% vent blocking are prohibitive. No automated procedure currently exists for blocking filter ventilation holes halfway with tape or glue. In experiments reported to date, filter ventilation has been partially occluded by manual application of tape or glue. It is likely that such a process will increase smoke yield variability for a given cigarette population. . ..[103]

According to Dr. Borgerding, effects that may occur in the laboratory when technicians attempt to block vent holes are deformation of the cigarette and loss of tobacco from the cigarette rod. He stated: "Both effects will increase variability." He concluded that "it is best to avoid manual manipulation of cigarettes if consistent, reproducible analysis results are desired."[104]

Under regulations published by the Massachusetts Department of Public Health, the manufacturers recently reported nicotine yields obtained when cigarettes were tested on a smoking machine using smoking parameters that incorporated a partial vent-blocking condition. During the course of that testing, researchers discovered a variety of practical issues and problems. Many of those practical issues and problems are discussed in Appendix A.

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[103] Borgerding, M., "The FTC Method in 1997 - What Alternative Smoking Condition(s) Does the Future Hold?" *Recent Adv. Tob. Sci.* 23:75, 124-127 (1997).

[104] *Id.* at 127.

3. The protocol should not be modified to incorporate a vent-blocking condition.

A routine analytical smoking machine cannot reflect hypothesized human vent-blocking behavior because such a smoking machine cannot smoke the way a human being smokes. Consequently, any effort to make that smoking machine reflect vent-blocking behavior would generate new numbers, but those numbers would not necessarily bear any real relationship to actual individual smoking behavior.

As discussed in more detail below, the available literature appears to support the view that some smokers may block some ventilation holes during some puffs, but there is not support for the proposition that a "significant" percentage of smokers engage in vent-blocking to a large degree. More important, to the extent that vent-blocking may occur, it clearly varies from smoker to smoker and, for a particular smoker, it may vary from one cigarette to the next. Therefore, it is entirely unclear how, if at all, the upper-tier method could be adjusted to reflect this behavior in a way that would be meaningful to a majority of smokers. Finally, the effects of any vent-blocking that does occur are at least partially "incorporated" already in the proposed upper-tier test method, which includes puffing conditions that, according to the Commission, are "substantially more intensive than the 'average' smoking conditions identified by the Surgeon General."

4. The evidence that vent-blocking occurs is extremely limited and inconclusive.

The Commission has stated its tentative conclusion that "[r]esearch suggests that a significant number of smokers of ventilated 'low tar' and 'ultra low tar' cigarettes block

some aeration holes some of the time."[105] In fact, to the contrary, research indicates that *a relatively small fraction* of smokers *may* block *some* ventilation holes *some* of the time. Such scattered evidence is not sufficient to justify occluding ventilation holes as a test parameter.

Stain Pattern Studies. The evidence commonly cited in support of the view that a "significant" number of smokers block ventilation holes comes from five studies that use the stain-pattern method developed by Kozlowski. That method is based on the hypothesis that the stain patterns on the mouthend of a filter tip will differ depending upon the percentage of ventilation holes that the smoker has blocked. To determine whether a particular filter shows evidence of hole blocking, a trained observer must look at the stain patterns on the mouthend and compare them with a purportedly "standard" set of patterns developed with the assistance of a smoking machine.

The evidence from studies using the stain-pattern method is summarized in Table 1.[106] Combining the data from the studies listed in Table 1 shows that overall approximately *4 percent* of examined filters were judged by researchers to be *totally* blocked while up to *29 percent* were judged to be *partially* blocked. Both Zacny and Kozlowski have expressed doubts about the reliability of some of the classifications made by their researchers.[107] If all of the filters with questionable classifications are omitted, then only

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[105] FTC Proposal, 62 Fed. Reg. at 48,160 n.16.

[106] Baker, R. & Lewis, L., "Filter Ventilation -- Has There Been A 'Cover-Up'?," *Recent Adv. Tob. Sci.*, 23:152, 162 (1997).

[107] Zacny indicated that, although he classified 28 percent of filters studies as partially blocked, in fact over 78 percent of those filters were in a "questionable category in which the discrimination

(continued...)

10 percent of all filters were judged with some degree of confidence to have been "partially blocked." If -- deferring to Kozlowski's recent comments on this issue -- we omit only those filters that Zacny stated were questionable and retain the Kozlowski filters, the figure rises to 11 percent.[108]

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[107] (...continued)
between unblocked and partially blocked was difficult." Zacny, J. & Stitzer, M., "Cigarette Brand-Switching: Effects on Smoke Exposure and Smoking Behavior," *J. Pharmacology & Experimental Therapeutics* 246(2):619-27, 623 (1988). Similarly, in a 1982 study, Kozlowski reported that 44 percent of the filters studied were partially blocked but that these filters were in fact "impossible to judge with any confidence." Kozlowski, L. *et al.*, "Estimating the Yields to Smokers of Tar, Nicotine, and Carbon Monoxide From the 'Lowest Yield' Ventilated Filter-Cigarettes," *Brit. J. of Addiction* 77:159, 161 (1982).

[108] In a letter to the Director of the Massachusetts Tobacco Control Program, Kozlowski has explained that when he wrote that the stain pattern on certain filters was "impossible to judge with any confidence," he did not mean that he lacked confidence regarding whether ventilation holes were blocked or not. His lack of confidence apparently was related to the *source* of the vent blocking. Letter from Dr. Lynn Kozlowski to Dr. Gregory Connolly, Massachusetts Tobacco Control Program, March 23, 1997, at 6 [hereinafter "Letter to Connolly"]. Regardless of what Kozlowski meant when he said that the stain patterns on some filters were "impossible to judge with confidence," the relatively small number of filters involved -- 17 -- does not change the analysis.

Table 1

Literature Reports of Vent Blocking Incidence

Reference	# Filters Examined	Percent Completely Blocked (#)	Percent Partially Blocked (#)	Number of Smokers
Kozlowski[109] (1982)	39	15 (6)	44 (17)	39
Zacny[110] (1988)	1631	0.1 (2)	28 (457)	10
Kozlowski[111] (1988)	135	19 (25)	39 (53)	n.a.
Kozlowski[112] (1989)	14	21 (3)	29 (4)	14
Kozlowski[113] (1994)	158	27 (43)	26 (42)	n.a.
Combined	1977	4 (79)	29 (573)	

What evidence there is from the stain-pattern method suggesting that vent blocking occurs has been derived almost exclusively from filters of brands with FTC reported "tar"

109/ Kozlowski, L., *et al.*, "Estimating the Yields to Smokers of Tar, Nicotine, and Carbon Monoxide From the 'Lowest Yield' Ventilated Filter-Cigarettes," *Brit. J. of Addiction* 77:159-65 (1982).

110/ Zacny, J. & Stitzer, M., "Cigarette Brand-Switching: Effects on Smoke Exposure and Smoking Behavior," *J. Pharm. & Exper. Therapeutics* 246 (2):619-27 (1988).

111/ Kozlowski, L., *et al.*, "Prevalence of the Misuse of Ultra-Low-Tar Cigarettes by Blocking Filter Vents," *Am. J. Public Health* 78-6:694-95 (1988).

112/ Kozlowski, L., *et al.*, "Self-Selected Blocking of Vents on Low-Yield Cigarettes," *Pharm. Biochem. & Behavior* 33(4):815-19 (1989).

113/ Kozlowski, L., *et al.*, "Misuse of 'Light' Cigarettes by Means of Vent Blocking," *J. of Substance Abuse* 6:333-336 (1994).

yields of one to four milligrams. Only in his 1994 study did Kozlowski gather any evidence with respect to "light" cigarettes.[114]

Some researchers have called into question the validity of the stain-pattern method as a means of detecting ventilation hole blocking. In 1983 Lombardo reported the results of a study designed to evaluate the method. Lombardo stated:

> The mean accuracy of correct labeling of the 10 unblocked cigarette butts which subjects smoked without a cigarette holder was only 37%, or little better than chance. In contrast, 82% of unblocked cigarettes smoked by subjects through holders were correctly labelled . . . . This finding underscores the need for rigid control in the preparation and standardization of cigarette butts in evaluating ventilation hole blocking detection accuracy.[115]

Lombardo concluded: "It is possible that, even with trained raters, the detection of ventilation hole blocking in smokers may prove *too* unreliable to be useful."[116]

Kozlowski himself recently expressed doubts about the usefulness of the method.

> The results of this study indicate that the stain pattern technique (Kozlowski et al., 1988) is best suited to detect the presence versus absence of vent blocking rather than the extent of vent blocking. . . . [T]he stain pattern technique cannot validly discriminate between a 50% effective lip block and a 100% effective tape block. This difficulty in discriminating

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[114] In his letter to the Director of the Massachusetts Tobacco Control Program, Kozlowski states: "What scientific evidence we have indicates that the blocking of vents for Lights is about as likely as the blocking of vents in Ultra-lights." Letter to Connolly, Massachusetts Tobacco Control Program, at 6. The point, however, is that there is virtually *no* scientific evidence on "lights," and that the evidence concerning "ultra-lights" is of questionable validity.

[115] Lombardo, T. *et al.*, "When Low Tar Cigarettes Yield High Tar: Cigarette Filter Ventilation Hole Blocking and Its Detection," *Addictive Behav.* 8:67-69, 68 (1983).

[116] *Id.* at 69 (emphasis in original).

> extent of blocking is consistent with other recent research on the use of this technique (Pillitteri *et al.*, 1994).[117]

In fact, even this may be an overstatement of the method's value because Kozlowski did not attempt to evaluate the method's ability to discriminate between, for example, 5 percent effective vent-blocking and 100 percent effective vent-blocking. In other words, given the available evidence, the most that might be said for the stain-pattern method by its advocates is that it can show that *some* people *sometimes* block *some* ventilation holes.

Studies of the stain patterns on unblocked filters have cast further doubt on the utility of the stain pattern method.[118] In a recent discussion of these studies, Baker and Lewis wrote:

> [E]ven with completely unblocked ventilation zones and standard smoking machine test conditions, the filter stain pattern obtained depends on a number of factors such as the degree of ventilation, the number and size of the ventilation holes, the number of rows of holes, and the depth into which the holes perforate the filter (as when holes are perforated by on-line laser). Depending on the combination of these factors, stain patterns of unblocked ventilated filters can range from a distinct "bull's eye" pattern to an almost uniform diffuse pattern with staining across the entire filter end.[119]

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[117] Kozlowski, L. *et al.*, "Blocking Cigarette Filter Vents With Lips More Than Doubles Carbon Monoxide Intake From Ultra-Low Tar Cigarettes," *Exper. and Clin. Pharm.* 4(4), 404-408, 407 (1996). The article cited in the quotation is: Pillitteri, J., *et al.*, "Detection of Vent-Blocking on Light And Ultralight Cigarettes," *Pharmacol. Biochem. and Beh.* 48(2):539-542 (1994).

[118] Helms, A., "The Concentration of Tar, Nicotine, And Carbon Monoxide in the Smoke of Ventilated Filter Cigarettes: Comparison of Different Types of Filter Ventilations," Presented at CORESTA Smoke Study Group Meeting, Florence, Italy (October 1983); Helms, A., "Influence of Laser Perforation of Cigarette Filters on The Smoke Composition: Influence of The Depth of Holes," Presented at CORESTA Congress, Vienna Austria (October 1984); Shibata, M., *et al.*, "Study of Cross Sectional Smoke Distribution in Cigarette Filters," in *Collection of The Smoke And Technology Group Papers at The CORESTA Congress -- Yokohama, Japan* 69-77 (1996).

[119] Baker, R. & Lewis, L., "Filter Ventilation -- Has There Been A 'Cover-Up'?," *Recent Adv. Tob. Sci.*, 23:152, 164 (1997).

Baker and Lewis concluded that "the presence or absence of a distinctive 'bull's eye' staining pattern, as used by Kozlowski and co-workers, is not necessarily related to the incidence of vent blocking."[120]

The difficulties with the studies in Table 1 are not confined to problems with the stain pattern method. A number of other problems must be addressed before attempting to draw any conclusions from the published data:

- The total number of smokers whose behavior has been examined directly by researchers in published hole blocking studies is fewer than 100.[121] Kozlowski has attempted to downplay the relatively small number of people sampled by emphasizing the overlaps in the confidence intervals in the published literature.[122]

- The 1989 Kozlowski study involved people smoking in a laboratory and the 1982 Kozlowski study involved interviews conducted at work. Subjects may smoke differently when smoking at home alone, at work, or in other more "natural" settings.

- Some of the studies have been conducted using test cigarettes or brands other than those ordinarily smoked by the study subjects. People may smoke differently when smoking their own brands.

- Of the five studies listed in Table 1, only three report the number of smokers studied and of those only one -- Zacny (1988) -- examined more than one filter per smoker. Thus, from the published literature it is impossible to determine whether a smoker who reportedly blocks vent holes always blocks vent holes or always blocks the same number of vent holes, whether smoking the same cigarette or from cigarette to cigarette.

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[120] *Id.* at 166.

[121] In his 1994 study, Kozlowski indirectly examined the behavior of an indeterminate number of smokers when he collected a large number of butts from ash trays in a public space and then examined stain patterns on the filters of 158 butts from "light" cigarettes. In his 1988 study, Kozlowski indirectly examined the behavior of an indeterminate number of smokers when he collected a large number of butts from ash trays in a public space and then examined stain patterns on the filters of 135 butts from "ultra-light" cigarettes. Even assuming these 293 butts were produced by 293 smokers, the total number of smokers discussed in the literature is extremely small.

[122] Letter to Connolly, Massachusetts Tobacco Control Program, at 3.

- Because the stain pattern method requires examination of the mouthend of the cigarette only after the cigarette has been entirely smoked, the method cannot be used to determine whether smokers who apparently block vent holes do so during every puff. It also cannot be used to determine whether smokers who block vent holes block the same number of vent holes during each puff.

Mouth insertion studies. Other researchers have studied the depth to which smokers typically insert a cigarette in their mouths. Most of these researchers have made measurements on used filter cigarette butts from ash trays in pubs, restaurants, shopping areas, and other public areas. The results of these studies are summarized in Table 2.[123] In a 1974 study, Schulz obtained a visible imprint of the smoker's lips using lipstick marks.[124] One study tested for a starch-iodine reaction on the tipping paper.[125] In studies conducted during the 1980s, researchers calculated insertion depths by measuring the enzyme alpha-amylase in dried saliva on the filter tips.[126] More recent studies have used a solution of ninhydrin in water on the tipping paper to detect amino acids in dried saliva.[127] Finally, Hill tried a different technique in 1983 when he video recorded smokers in profile in the laboratory then measured insertion depths on the video screen.[128]

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[123] Baker, R. & Lewis, L., "Filter Ventilation – Has There Been A 'Cover-Up'?," *Recent Adv. Tob. Sci.* 23:152, 174 (1997) (Tab III).

[124] *See id.* at 171.

[125] *See id.*

[126] *See id.*

[127] *See id.*

[128] *See id.* at 171-72.

The results of the mouth insertion depth studies are remarkably consistent across four countries over 20 years. With the exception of the laboratory-based studies of Hill, the mean values of insertion depth all fall in a narrow range between 10.1 and 11.5 millimeters. It should be noted, moreover, that with the exception of the results reported by Hill, all values reported are maximums. They represent the distance from the mouthend of the cigarette to the outer limit of the region covered by the smoker's lips during the smoking of that cigarette. There is no way to determine whether the smoker's lips reached that outer limit during one puff, during every puff, between puffs, or before the cigarette was lit.

TABLE 2
Cigarette Mouth Insertion Depth Studies

Reference	Study description	Maximum Insertion Depth (mm) Mean	Standard Deviation	Number of Butts	Technique
Schulz (1974)	Germany, 300 smokers (pubs, etc.)	10.9	2.1	441	Lipstick
Barkemeyer (1984)	Germany, 41 smokers (pubs, etc.)	11.5	3.0	560	Amylase
Barkemeyer (1984)	Switzerland (pubs, etc.)	10.4	3.8	1410	Amylase
McBride (1984)	Canada, non-ventilated cigs (shopping malls)	11.0	4.6	290	Amylase
McBride (1984)	Canada, ventilated cigs (shopping malls)	11.1	4.8	205	Amylase
Dunn (1997)	Canada, non-ventilated cigs (shopping malls)	11.0	3.6	1003	Ninhydrin
Dunn (1997)	Canada, ventilated cigs (shopping malls)	10.6	3.6	1229	Ninhydrin
Lewis (1995)	USA (in-house and public ashtrays)	10.1	3.9	236	Ninhydrin
Hill (1983)	UK (laboratory)	Max. 8.3 Min. 5.3	2.6 3.0	26	Starch-coated filter
Hill (1983)	UK (laboratory)	Max. 9.1 Min. 4.3	1.4 1.1	23	Video recording

Baker and Lewis used information from the recent large Canadian study of insertion depth to calculate the proportion of smokers that may block, partially block or not block ventilation holes with their lips. The results show that:

> the percentage of smokers who leave the ventilation zone completely uncovered by their lips increases from 53 percent to 97 percent as the ventilation zone is moved from 10 mm to 18 mm from the cigarette mouth end. Of those smokers who do cover the ventilation zone, at a vent zone position of 10 mm less than one-fifth of them would cover the zone completely.[129]

Baker and Lewis note that the 10 most popular brands of ventilated cigarettes in the United States have ventilation zones positioned 11 or more millimeters from the mouthend of the cigarette.[130] As the ventilation zone moves from 11 millimeters to 18 millimeters, the percentage of people who might be blocking ventilation holes during at least one puff drops from 36% to just over 3%.[131]

The results of the lip insertion depth studies appear to corroborate the view that *some* smokers may block *some* ventilation holes during *some* puffs. The data do not support any other generalization. In particular, there is no basis for the Commission's statement that the percentage of people who block ventilation holes is "significant."

Even if one concludes that some vent-blocking occurs some of the time, recent studies suggest that concerns about the effects of any vent-blocking on cigarette yields may be overdrawn. Baker and Lewis have reported that there is a non-linear relationship

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[129] Baker, R. & Lewis, L., "Filter Ventilation – Has There Been A 'Cover-Up'?," *Recent Adv. Tob. Sci.* 23:152, 177 (1997).

[130] *Id.* at 190.

[131] *Id.* at 177.

between the degree of blockage and its effect on filter ventilation.[132] This means, for example, that blocking 50 percent of the vent holes will not necessarily lead to a 50 percent drop in the ventilation of the cigarette. This non-linearity increases as the percentage of filter ventilation increases.[133] For example, 50 percent blocking of a 20 percent ventilated filter reduced the ventilation from 20 percent to 12 percent.[134] The equivalent blocking of a 90 percent ventilated filter, however, reduces the effective ventilation to about 81 percent.

Perhaps more importantly, research suggests that there is a non-linear relationship between the percentage of ventilation holes blocked and the "tar" and nicotine yield of the cigarette.[135] Using Röper's results, Baker and Lewis assumed that a smoker might cover a maximum of 25 percent of the ventilation holes with fingers and a maximum of 50 percent with the lips.[136] They concluded that "maximum vent blocking by fingers in every puff would increase the TPM [*i.e.*, total particulate matter] of the ultra low 'tar' cigarette from

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[132] Baker, R. & Lewis, L., "Filter Ventilation -- Has There Been A 'Cover-Up'?," *Recent Adv. Tob. Sci.*, 23:152, 181 (1997).

[133] The percentage of filter ventilation is a measure of the proportion of air that enters a puff through the filter perforations rather than through the tobacco rod of a cigarette. If a vented filter design affords 50 percent ventilation, 17.5 milliliters of air enter through the vents, and 17.5 milliliters are drawn through the coal for a standard puff volume (as defined by the FTC test method) of 35 milliliters.

[134] Baker, R. & Lewis, L., "Filter Ventilation -- Has There Been A 'Cover-Up'?," *Recent Adv. Tob. Sci.*, 23:152, 182 (1997).

[135] Darrall, K., "Smoking Machine Parameters And Cigarette Smoke Yields," *The Sci. of the Total Env.*, 74:263-278 (1988); Röper, W., Reemtsma, Germany, Unpublished results (1997) discussed in Baker, R. & Lewis, L., "Filter Ventilation -- Has There Been A 'Cover-Up'?," *Recent Adv. Tob. Sci.* 23:152-96 (1997).

[136] Baker, R. & Lewis, L., "Filter Ventilation -- Has There Been A 'Cover-Up'?," *Recent Adv. Tob. Sci.*, 23:152, 183 (1997).

1.3 to 1.6 mg and from 6.7 to 7.4 mg for the light 'tar' cigarette."[137] "Maximum vent blocking by lips in every puff would increase the TPM yield of the ultra low 'tar' cigarette from 1.3 to 2.5 mg and from 6.7 to 8.1 mg for the light 'tar' cigarette."[138]

Baker and Lewis also described Röper's attempt to combine data on the likely distribution of vent blocking in the smoking population with data on the yield effects of ventilation hole blocking.[139] Table 3 indicates the estimated percentage of smokers that might obtain a specified yield or range of yields from a cigarette.[140] ("Tar" yields were obtained on a smoking machine set to the standard FTC/ISO smoking parameters for puff volume, frequency and interval.) The estimates assume that vent-blocking takes place in every puff. If this assumption is false, then the yields would be lower across the board than those specified in Table 3.

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[137] *Id.*

[138] *Id.*

[139] *Id.*

[140] *Id.* at 186 (Table IV).

Table 3
Effect of Distribution of Ventilation Zone Cover by Lips on "Tar" Yields

Full Flavor		Light		Ultra Light	
Yield (mg)	% Smokers	Yield (mg)	% Smokers	Yield (mg)	% Smokers
11.9	48	6.7	64	2.2	55
12.0-12.4	43	6.8-7.2	22	2.3-2.7	13
12.5-12.9	5	7.3-7.7	10	2.8-3.2	11
13.0-13.4	3	7.8-8.2	3	3.3-3.7	7
13.5-13.9	1	8.3-8.7	1	3.8-4.2	3
				4.3-4.7	4
				4.8-5.2	4
				5.3-5.7	2
				5.8-6.2	1

Although much more research would need to be done before firm conclusions could be drawn, the implications of Table 3 nevertheless are quite important. Critics have focused attention on reported ventilation hole blocking in lower-yield products, suggesting that ventilation hole blocking boosts yields to the point where the distinctions between full flavor, light and ultra- light cigarettes might become meaningless.

In fact, according to Table 3, assuming that some ventilation hole blocking does occur among smokers of ultra-light products, between 79 and 86 percent of such smokers would still obtain yields that were more than 50 percent less than the yield of the lowest-yield *light* products tested (*i.e.*, 6.7 mg). Under these conditions, the research indicates no smoker of ultra-light cigarettes obtained a yield that would equal the FTC reported yield of a light cigarette and, *a fortiori*, no smoker of ultra-light cigarettes would obtain a yield that approached that of a full flavor cigarette. To put the same point another way, smokers of

ultra-light cigarettes would ordinarily obtain an ultra-light yield, although sometimes the yield may be higher than the yield measured by the FTC method.

It is therefore possible that even if *some* smokers do block *some* ventilation holes *some* of the time, the actual effect on the yields that they obtain may be relatively small. Moreover, if there is any effect on yields, it is not sufficient to undermine the basic distinction between full flavor, light and ultra-light cigarettes. Thus, when smokers smoke cigarettes with lower FTC reported yields, the yield that they receive in their mouths will be lower. They also will inhale lower quantities of "tar" and nicotine.

5. Evidence concerning the effect of vent blocking on puff volume, frequency and duration is limited and inconclusive.

Studies that measure changes in puff volume, frequency and duration are conducted in laboratory settings under unnatural conditions. Sometimes flow-measuring devices actually are attached to the cigarette while the smoker smokes. Typically, such studies are limited to a small number of subjects.

In a 1986 study, Zacny and colleagues studied people smoking cigarettes with the vent holes unblocked, 50-percent blocked, or 100-percent blocked.[141/] In one phase of the study, researchers allowed the smokers' puffing behavior to vary, but measured smoking topography. They reported that subjects took significantly more puffs at shorter interpuff intervals and larger puff volumes with vent holes unblocked than with 50 or 100 percent of the holes blocked.[142/]

[141/] Zacny, J., *et al.*, "Cigarette Filter Vent Blocking: Effects on Smoking Topography And Carbon Monoxide Exposure," *Pharmacol. Biochem. and Behav.* 25:1245-1252 (1986).

[142/] *Id.* at 1248.

Researchers from Brown & Williamson Tobacco and British American Tobacco recently reported results from a study showing that, for cigarettes with FTC "tar" yields of from one to three milligrams, the mean puff number showed a statistically significant *drop* from more than nine with ventilation holes unblocked to approximately seven with ventilation holes 100 percent blocked.[143] The change in puff number for cigarettes with higher yields was not statistically significant. The researchers also reported that, for cigarettes with "tar" yields of one to three milligrams and cigarettes with "tar" yields of four to six milligrams, there was a statistically significant drop in mean puff volume and total puff volume when 50 percent or 100 percent of ventilation holes were covered. They concluded that vent-blocking does alter smokers' puffing behavior.

Clearly, a great deal more research would have to be conducted before the FTC could draw any conclusions about the relationship between ventilation hole blocking, puff volume, puff frequency and puff duration.

d. Could the effects of compensatory smoking behavior be incorporated into mathematical equations or multipliers that could be applied to the current FTC ratings to calculate "compensation-adjusted" ratings? Do existing studies of smoking behavior provide a sufficient basis to create an equation or set of multipliers that could be used to approximate the compensation effect? How closely could equations approximate the compensation effect? What degree of accuracy is necessary? Would an approximation be acceptable? Can existing studies measuring nicotine intake of smokers be used to make inferences about tar intake, or is the effect of compensation behavior likely to be different for tar and nicotine?

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[143] Ayya, N., *et al.*, "Measurement of Puffing Behaviour in Lights & Ultra Smokers with Ventilation Holes Partially And Fully Blocked," Presented at the 51st Tobacco Chemists Research Conference, Winston-Salem, NC (September 1997).

1. A multiplier is not appropriate to reflect compensation because compensation, to the extent it actually occurs, is a behavior that varies among smokers and cigarettes smoked.

The FTC test method was not designed to reflect -- and cannot be made to reflect -- human smoking behavior. Moreover, existing studies concerning compensation and vent blocking are insufficient to justify making changes in the FTC smoking method or in the proposed upper-tier testing method. Consequently, such studies do not "provide a sufficient basis" for developing an equation to "adjust" the current FTC ratings to take account of purported compensatory behavior and vent-hole blocking.

The Commission asks how closely equations could "approximate the compensation effect." For the reasons discussed above, any notion of "the compensation effect" is questionable. Assuming that compensation and vent-hole blocking do occur, these behaviors will vary from smoker to smoker and, for a particular smoker, from one cigarette to the next. Thus, an equation or set of multipliers could not approximate a single "compensation effect" because "the" compensation effect does not exist. There is no equation to simulate human behavior or compensation. Such a multiplier would therefore, of necessity, be arbitrary.

While theoretically an equation might *attempt* to approximate the "average" effects of compensation or vent-blocking as reported in scientific studies, as the Commission stated in 1967, "[t]here are too many variables as to both smokers and smoking conditions for any average to be meaningful."[144/] As discussed above, Kozlowski and Pillitteri cited six

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144/ FTC To Begin Cigarette Testing, FTC News Release, (Aug. 1, 1967).

studies reporting *average* rates of compensation ranging from 12 to 62 percent.[145] Consequently, it would not be meaningful to speculate about the "degree of accuracy" that an equation approximating an "average" should achieve.

2. Equations could be developed that would "adjust" current FTC yields to produce desired results.

On purely mathematical grounds, of course, it always is possible to devise an equation that will relate two sets of numbers. Thus, one could *define* a particular set of numbers as "ratings that take into account compensation and ventilation hole blocking," and develop an equation that would relate those "ratings" to the current FTC ratings. The equation would do no more, however, than state a mathematical relationship between two arbitrarily defined sets of numbers.[146]

3. Advertising Disclosures and Consumer Education

a. Is the language of either of the proposed disclosures for cigarette advertising (Attachments A and B) likely to communicate effectively to consumers that their tar and nicotine intake from a cigarette will vary depending on how they smoke it?

The legend of Attachment B ("How much tar and nicotine you get from a cigarette depends on how intensely you smoke it") conveys in a simple and straightforward fashion

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[145] Kozlowski, L. & Pillitteri, J., "Compensation for Nicotine by Smokers of Lower Yield Cigarettes," in U.S. Department of Health and Human Services, *Smoking and Tobacco Control, The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes, Report of the NCI Expert Committee* 161, 163 (1996).

[146] As noted above, the Massachusetts Department of Public Health has mandated that the manufacturers report nicotine yield data obtained from a testing method that incorporates a ventilation hole blocking parameter. *See* 105 CMR 660.102(B)(3) and Appendix 2C. The manufacturers offered to develop an equation or "multiplier" that would allow them to generate such yield data without conducting laboratory tests, but the Department did not permit them to do so for purposes of the initial report. The Department has *permitted* the manufacturers to use a multiplier in 1998 for cigarettes with a national market share of 1.5 percent or less.

the precise message that "tar" and nicotine intake from a cigarette will vary depending on how it is smoked, with the clear implication that more intense smoking produces higher "tar" and nicotine delivery and less intense smoking produces lower "tar" and nicotine delivery.

The legend of Attachment A also conveys two messages. But the first message ("There's no such thing as a safe smoke") is a message about smoking and health -- not a message about the relationship between smoking behavior and "tar" and nicotine intake. Because it is a message about smoking and health, it would not be within the Commission's power to require.[147] The second message ("Even cigarettes with low ratings can give you high amounts of tar and nicotine. It depends on how you smoke.") is ambiguous because it uses terms of comparison that are themselves undefined (What is a "low amount" of "tar" and nicotine? What is a "high amount" of "tar" and nicotine?). The manufacturers believe that the second message is also incomplete, because it does not mention, conversely, the possibility that smokers may be able to get as little "tar" and nicotine from a higher-yield cigarette as from a lower-yield cigarette, depending on how they smoke.

b. Are the proposed disclosures likely to be more effective in conveying useful information to consumers than current advertising disclosures? What changes, if any, should be made to either the content (including the specific words used) or the layout of either of the disclosures? Are there other disclosure formats that would be more effective?

The legend set forth in Attachment B would appear to provide a simple and straight-forward way of conveying the precise message that "tar" and nicotine intake from a

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[147] Federal Cigarette Labeling and Advertising Act ("FCLAA"), 15 U.S.C. § 1331 *et seq.* Compare the proposed statement ("There's no such thing as a safe smoke.") with the statements required by FCLAA. *See, e.g.*, FCLAA, 15 U.S.C. § 1333(a)(1) & (2) ("Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.").

cigarette will vary depending on how it is smoked, with the clear implication that more "intense" smoking produces higher "tar" and nicotine delivery and less "intense" smoking produces lower "tar" and nicotine delivery. As also discussed, it is unnecessary, and may be misleading, to include dual smoking-machine yield ratings to help reinforce that message. Research should be undertaken to determine consumer take-away and the likelihood of resultant behavior changes prior to the implementation of educational efforts.

The dual ratings and legend should not be included within a border, as Attachments A and B both appear to contemplate. Such a format would place the ratings and legend on a par with the Surgeon General's warnings. The ratings and any legend should continue to be presented, as the ratings are presented today, in conspicuous type in contrasting color with the background on which it appears, and in the same size and place.

c. What effect, if any, is either of the proposed disclosures likely to have on consumers' purchases of cigarettes and/or their smoking behavior? Is there reason to believe this information will affect smoking intensity, brand choice, and/or the decision whether to quit smoking, and if so, how?

See answer to Question 1a, above. Extensive consumer research would be required to predict with confidence the effect on consumers of either disclosure.

d. The proposed disclosures do not contain information regarding carbon monoxide ratings. Should information regarding carbon monoxide ratings be included in any disclosure format that is adopted? Why or why not? If such information is provided, how should it be done? How closely do carbon monoxide ratings obtained in smoking machine tests correlate with tar and nicotine ratings?

Cigarette advertisements currently carry, as one of the four rotating Surgeon General's health warnings, the message that "Cigarette Smoke Contains Carbon Monoxide." Without research, it cannot be known whether including the CO ratings for a particular brand style with the "tar" and nicotine ratings that are currently displayed for the brand style would influence a smoker's choice of cigarette or the smoker's basic decision to smoke.

Results from an experiment conducted last year to determine the general relationship between cigarette yields using an alternative puffing regimen and the standard FTC puffing regimen[148/] provide insight into the correlation between CO yields with either "tar" or nicotine ratings obtained in machine tests. From the study, it is clear that CO ratings increase as either "tar" or nicotine ratings increase when cigarettes are tested with the standard FTC puffing regimen. For filtered cigarettes, a strong linear relationship is observed between CO yields and either "tar" or nicotine yields.[149/] Non-filtered cigarettes yield less CO than would be expected from a filtered cigarette with equivalent "tar" or nicotine yields. Similar relationships between CO yields and either "tar" or nicotine yields

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[148/] Philipp, C., St. Charles, K., Norman, V., Whidby, J., Garman, J., Lewis, L., Borgerding, M., *An Experiment to Determine the General Relationship Between Cigarette Smoke Yields Using an Alternative Puffing Regimen (55/30/2) and the Standard FTC Method*, compiled by Borgerding, M., Bodnar, J., Willard, B., R.J. Reynolds Tobacco Company, Winston-Salem, N.C. (June 23, 1997).

[149/] While the relationship is not perfect, filtered-cigarette carbon monoxide yields are highly correlated with standard "tar" yields (carbon monoxide rating = 0.93 * FTC "tar rating +1.31; R^2 = 0.90) and nicotine yields (carbon monoxide rating = 13.6 * FTC "tar" rating + 0.6; R^2 = 0.88).

are observed at the proposed upper-tier regimen. Data from this study are presented in two charts on the following pages.

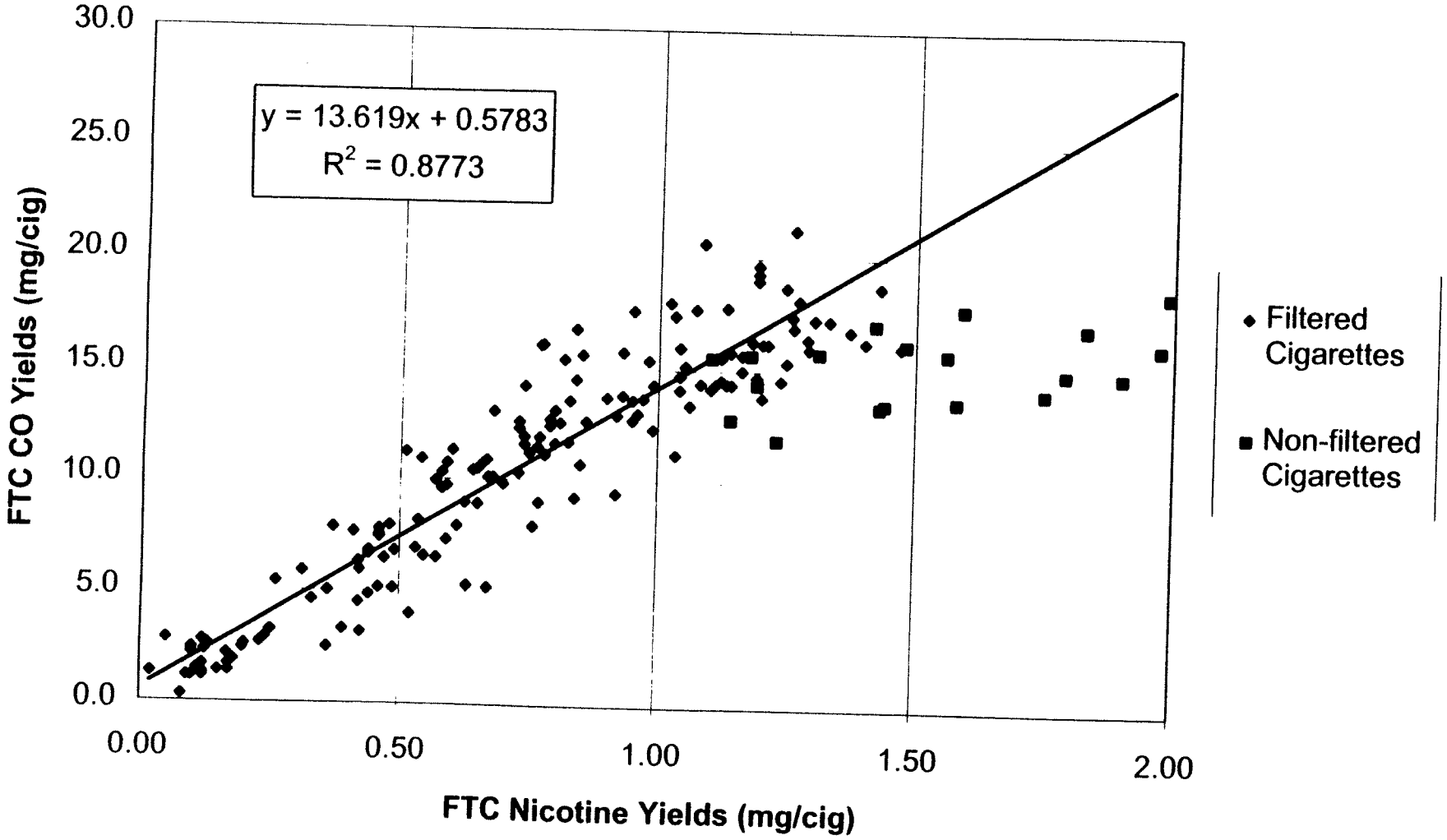
e. Should the disclosures include information concerning the ratio of the cigarette's tar and nicotine ratings? Would these ratios provide useful information to smokers?

The disclosure should not include information on ratios. The inclusion of such information would further complicate a proposed rating system that is already too complicated and would appear to serve no meaningful purpose. In addition, interested consumers could calculate such a ratio for themselves. Research should be undertaken to determine consumer take-away and the likelihood of resultant behavior changes prior to the implementation of educational efforts.

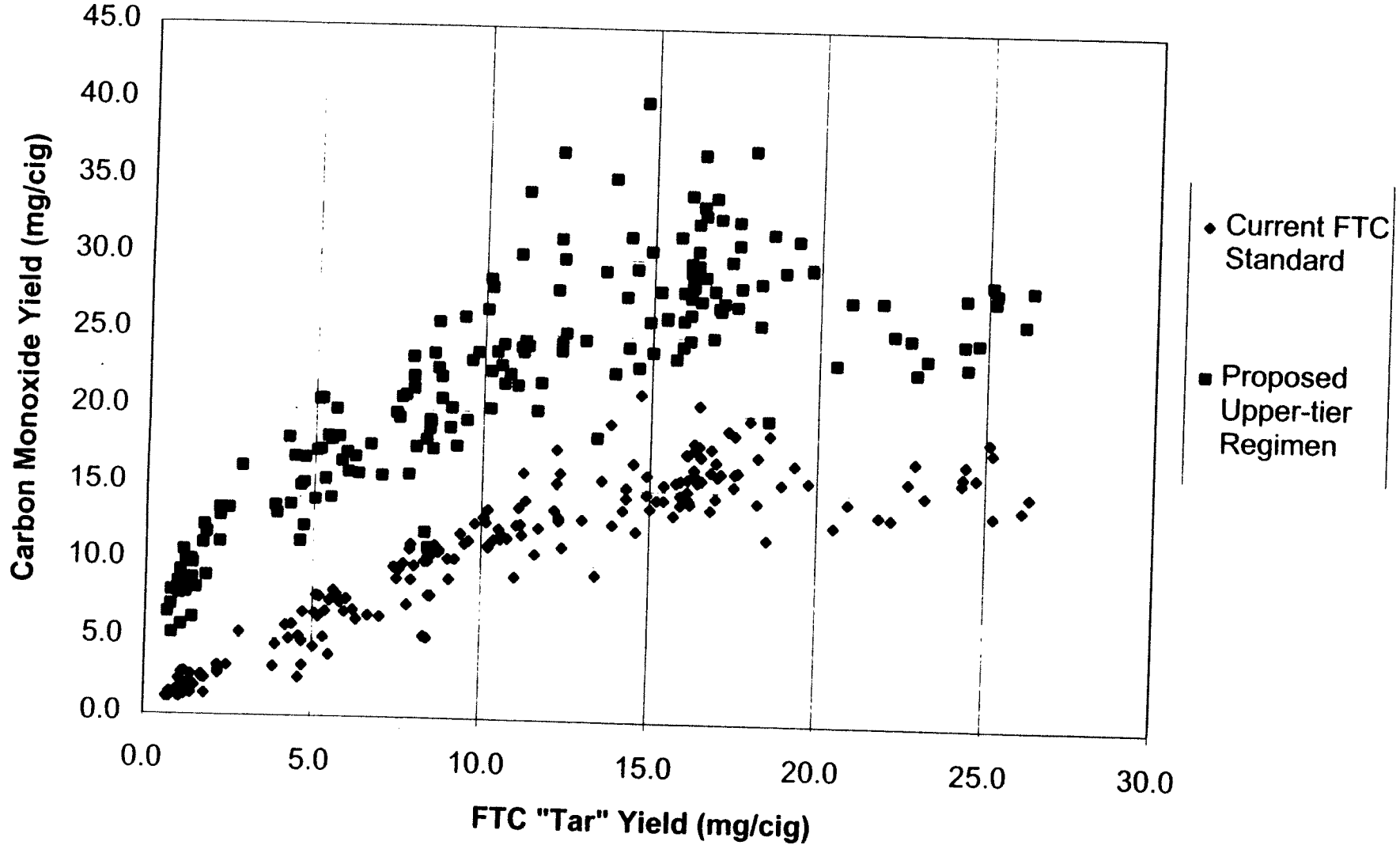
f. Would it be necessary to require that the disclosures be printed in black text on a white background, or would it be sufficient to retain the standard embodied in the cigarette manufacturers' 1970 agreement -- that is, that the disclosure be clear and prominent?

The terms of the 1970 agreement that the disclosures be made "clearly and prominently" and "in a color (including black or white) clearly contrasting with the color of the background should be continued. Requiring that the disclosures be printed in black text on a white background would place the disclosures on a par with the Surgeon General's warnings.

Relationship Between Carbon Monoxide and Nicotine Yields When Cigarettes are Smoked with the Standard FTC Puffing Regimen



Comparison of Carbon Monoxide Upper and Lower Tier Yields to Standard FTC "Tar" Yields



g. What kinds of disclosures and public education efforts should be undertaken to inform smokers about compensatory smoking? What evidence exists on the likelihood that smokers will change their behavior when advised of compensatory smoking techniques and how to avoid them? Can graphic techniques used by researchers to measure compensatory smoking (e.g., color and stain pattern matching) be used by consumers to evaluate the extent of their own compensatory smoking?

As discussed above, "compensatory smoking" is a weakly documented phenomenon, and such documentation as there is indicated that such behavior is partial and may be of limited duration. We are unaware of any evidence showing that smokers do change their behavior when advised of "compensatory smoking techniques," and we are unaware of any evidence showing how they change their behavior when so advised.

h. What kinds of consumer education messages should be created to inform smokers of the presence of filter vents and of the importance of not blocking them with their fingers or lips?

The manufacturers are not convinced that vent-blocking is a sufficiently common or documented phenomenon that smokers should be alerted to the presence of filter vents and instructed not to block the vents. The manufacturers believe that extensive consumer research would need to be conducted to determine the pervasiveness of vent blocking as well as consumer perception of any proposed messages and their likely effect upon consumer behavior, if any, prior to dissemination of the proposed messages.

The Commission in any event is authorized to ensure that advertising is truthful, not to instruct consumers about how to act.

i. What other kinds of consumer education messages should accompany the Commission's revision of the cigarette test method?

The manufacturers are not opposed to the dissemination of consumer education messages with the Commission's revision of the cigarette test method. However, the

manufacturers believe that consumer research would need to be conducted to determine the consumer perception of proposed educational messages, and their likely effect upon consumer behavior, if any, prior to the dissemination of consumer education messages.

j. How would the proposed new testing method and each of the various alternative methods that were considered likely complement or detract from possible consumer education initiatives?

In the absence of consumer research, the manufacturers can express no opinion with respect to how the proposed new testing method and each of the various alternative methods considered would likely complement or detract from any proposed consumer education initiatives.

The legend set forth in Attachment B is sufficient to convey the message that a smoker can receive varying amounts of "tar" and nicotine from a cigarette depending on how the cigarette is smoked, with more intense smoking producing higher yields and less intense smoking producing lower yields. On the other hand, the proposed two-tier test method threatens to undermine the message that smoking machine yields are not reliable surrogates for actual smoker intake.

4. Other Possible Policy Options

a. Rather than move to a two-tier test method, would it be preferable to continue to test cigarettes under a single protocol and use consumer education and an advertising disclosure to inform consumers what the ratings do and do not represent, and that what smokers get from any particular cigarette depends in large part on how they smoke it? If so, should cigarettes continue to be tested under a protocol that uses a 2 second, 35 milliliter puff every minute, or should different smoking parameters be used? What form should such consumer education take (e.g., informational materials at the point of purchase) and what should it say?

As discussed above, the manufacturers are not convinced that a two-tier test method is necessary to communicate the message that how much "tar" and nicotine a smoker gets from a cigarette depends on how the cigarette is smoked, and indeed such a method has the downside potential of misleading smokers into believing that the new test results bracket the range of actual human intake. For that reason, the manufacturers believe that a rating system with a single "tar" and nicotine number per brand style should be continued. For purposes of historical continuity, and to avoid the potential for confusing smokers, we believe that the current smoking-machine test parameters should continue to be used. A new arbitrary set of parameters would be no better than the current arbitrary set of parameters. Despite our belief that adequate information is currently available to consumers, supplementing the rating with the legend set forth in Attachment B to reinforce the message that how much "tar" and nicotine a smoker gets from a cigarette depends on how intensely the cigarette is smoked would appear to be an appropriate means of communicating with consumers.

b. Rather than move to a two-tier test method, would it be preferable to drop all FTC approval of the tar and nicotine testing system? Are all potential ratings so inherently flawed and misleading, and the possibilities for improving the system so unlikely to succeed, that use of any numerical tar and nicotine ratings should be ended? Would such a change affect smoking intensity, brand choice, and/or the decision whether to quit smoking, and if so, how?

"Tar" and nicotine ratings have been an established feature of cigarette advertising for over 25 years, and the manufacturers believe that some smokers use those ratings in making brand style choices. Such ratings are not "flawed": they are produced by operating the smoking machines according to the prescribed test method. Neither are such ratings misleading: the real issue is whether they are properly understood by smokers. The FTC reported ratings certainly are misunderstood if they are thought to represent actual human intake (a misunderstanding that a dual-rating system may inadvertently foster), or if they are thought to signify that a smoker receives the same amount of "tar" and nicotine indicated from a cigarette regardless of how the cigarette is smoked. What is important is that smokers understand what the ratings do and do not represent. Such an understanding can be fostered through public education efforts by the Commission as well as by a legend in cigarette advertising making clear that how much "tar" and nicotine a smoker gets from a cigarette depends on how intensely the cigarette is smoked.

c. Should the cigarette test method attempt to measure or otherwise account for the bioavailability of the nicotine in different cigarettes? If so, how should it do so? Is the alkalinity of the nicotine a surrogate for bioavailability? Is there a mathematical model by which bioavailability can be computed from nicotine yield, alkalinity, and other information?

1. The test method should not attempt to measure or otherwise account for the bioavailability of nicotine in different cigarettes.

Rather than attempt to measure or otherwise account for the "bioavailability" of the nicotine delivered to smokers, the test should assume what is widely known, that almost all

of the nicotine inhaled by smokers is absorbed,[150] and that the "alkalinity of nicotine" or cigarette smoke will not increase the amount of or rate at which nicotine is absorbed by smokers in the lung.[151]

The manufacturers do not believe that the term "bioavailability" is meaningful or useful in this context. "Bioavailability" is defined in a recent text as "[t]he degree and rate at which a substance (as a drug) is absorbed into a living system or is made available at the site of physiological activity."[152] The "bioavailability" of nicotine could depend on many independent variables *other than those associated with the cigarette itself*, including (but not limited to) number of puffs taken by a smoker; nature of the puffs (inhaled or not, depth of puff, duration of puff, frequency of puffs, time the puff remains in the body); nature of

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[150] U.S. Department of Health and Human Services, *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General* 29 (1988).

[151] See, *infra*, notes 153 to 157 and accompanying text. *See, e.g.*, U.S. Department of Health and Human Services, *The Health Consequences of Smoking Nicotine Addiction: A Report of the Surgeon General* 29 (1988); Russell, M., "Cigarettes Smoking: A Dependence on High Nicotine Boli," *Drug Metabolism Rev.* 8(1): 29-57, 41 (1978); Slade, J., "Nicotine Delivery Devices," in *The Disease of Nicotine Addiction* 3-23, 4 (1993); Benowitz, N., "Pharmacologic Aspects of Cigarette Smoking and Nicotine Addiction," *New Eng. J. Med.* 319 (20): 1318-30 (1988); and Schievelbein, H., "Nicotine Reabsorption and Gate in Nicotine and the Tobacco Smoking Habit," in Balfar, D. (ed.), *International Encyclopedia of Pharmacology and Therapeutics*, Section 119:4 (1984).

Absorption of nicotine in the mouth has been shown to be pH-dependent. However, the amount of nicotine absorbed in the mouth of a cigarette smoker is so small as to be nearly meaningless. Moreover, nicotine is absorbed more slowly when it is absorbed in the mouth. U.S. Department of Health and Human Services, *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General* 29 (1988). Lunell, E., *et. al.*, "Nicotine Deposition and Body Distribution from A Nicotine Inhaler And A Cigarette Studied With Positron Emission Tomography," *Clin. Pharma. Ther.*, 59(5): 593-94 (1996); Schuh, K., *et. al.*, "Nicotine Nasal Spray And Vapor Inhaler: Abuse Liability Assessment," *Psychopharm.* 130: 352-61 (1997); Bergstrom, M., *et. al.*, "Regional Deposition of Inhaled ^{11}C-Nicotine Vapor in The Human Airway as Visualized by Positron Emission Tomography," *Clin. Pharm. Ther.* 57(3): 309-17(1995).

[152] *Merriam Webster's Medical Desk Dictionary*; Merriam-Webster Inc.: Springfield, MA, 1986.

the smoker (weight, individual metabolism characteristics, possibly age and sex, time of day of smoking) and what activities the smoker has performed. Because of the independent variables, there is no uniformly accepted experimental technique or measurement to quantify "the bioavailability of the nicotine in different cigarettes." Based on the above definition, there is no specification as to what "degree and rate" means and no indication as to what "site of physiological activity" means. Consequently, use of the term "bioavailability" is both ambiguous and vague.

2. Is the alkalinity of the nicotine a surrogate for bioavailability?

As noted above, the manufacturers believe that the cigarette test method should not attempt to measure or otherwise account for the "bioavailability" of the nicotine delivered to smokers. This means, therefore, that the manufacturers do not believe that using a "surrogate" for bioavailability would be appropriate. To the extent that others seek to have such a surrogate, the use of the "alkalinity of nicotine" as such a surrogate would be inappropriate. As the Surgeon General noted in 1988:

> When tobacco smoke reaches the small airways and alveoli of the lung, the nicotine is rapidly absorbed. The rapid absorption of nicotine from cigarette smoke through the lung occurs because of the huge surface area of the alveoli and small airways *and because of dissolution of nicotine at physiological pH (approximately 7.4), which facilitates transfer across cell membranes.*[153]

Similarly, in 1978, Russell stated:

> Although the pH of the smoke of many cigarettes is acidic . . ., *absorption of nicotine via the lungs is nevertheless extremely rapid.* This is probably partly due to the vast surface area for absorption and partly that the pH of

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[153] U.S. Department of Health and Human Services, *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General* at 29 (1988) (emphasis added).

> the alveolar surface fluids is around 7.4 as opposed to 5.5 in the case of cigarette smoke.[154]

A number of researchers have acknowledged that the "pH of cigarette smoke" has little effect on the ability of a smoker to "absorb" nicotine following inhalation. For example, Slade stated that:

> [t]he lungs present an enormous surface area for inhaled smoke, and *even ionized nicotine is readily absorbed across the respiratory epithelium with an efficiency of over 90%.*[155]

Similarly, Benowitz acknowledged that the "pH of tobacco smoke" has little effect on the absorption of nicotine: "When tobacco smoke reaches the small airways and alveoli of the lung, the nicotine is absorbed rapidly, *regardless of the pH of the smoke.*"[156] Other researchers similarly have stated that "the absorption of nicotine through the alveoli of [the] lung seems to be related simply to the concentration of the alkaloid in the smoke, and *that the influence of the pH of the aqueous phase of the smoke is negligible.*"[157]

3. There is no mathematical model for predicting the bioavailability of nicotine.

The manufacturers believe that the cigarette test method should assume that almost all of the nicotine inhaled by smokers is absorbed and that the "alkalinity of nicotine" or

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[154] Russell, M., "Cigarette Smoking: A Dependence on High-Nicotine Boli," *Drug Metabolism Revs.* 8(1):29, 41 (1978) (emphasis added).

[155] Slade, J., "Nicotine Delivery Devices," *in The Disease of Nicotine Addiction* 3, 4 (1993) (citation omitted and emphasis added).

[156] Benowitz, N., "Pharmacologic Aspects of Cigarette Smoking and Nicotine Addiction," *New Eng. J. Med.* 319(20):1318, 1321 (1988) (emphasis added).

[157] Schievelbern, H., "Nicotine Resorption and Fate in Nicotine and the Tobacco Smoking Habit," *in* Balfar, D. (ed.), *International Encyclopedia of Pharmacology and Therapeutics* § 119:4 (1984).

cigarette smoke will not increase the rate at which nicotine is absorbed in the lung. Accordingly, the creation of a mathematical model by which to measure bioavailability is unnecessary.

d. If the effect of compensatory smoking behavior is not incorporated in the tar and nicotine ratings, should a disclosure warning smokers about compensatory smoking behavior be required in all ads? Would such a disclosure likely be effective in reinforcing the consumer education efforts?

The manufacturers are not convinced that compensatory smoking behavior is a sufficiently common or documented phenomenon that consumers should be alerted to its existence, and they believe that consumer research would need to be conducted to determine the pervasiveness of the behavior as well as consumer perception of any proposed disclosure and its effect, if any, on consumer behavior. However, should the Commission determine that a disclosure is warranted, the manufacturers believe the legend set forth in Attachment B is sufficient to convey the message that a smoker can receive varying amounts of "tar" and nicotine from a cigarette depending on how the cigarette is smoked, with more intense smoking producing higher yields and less intense smoking producing lower yields.

5. Other Issues

a. What available evidence exists concerning how consumers view cigarettes with relatively low tar and nicotine ratings and their perception of the relative risks of smoking such cigarettes rather than full flavor cigarettes?

The manufacturers are unaware of evidence concerning such consumer views and perceptions except to the extent that such evidence is presented in the Report of the NCI Expert Committee.[158/]

[158/] U.S. Department of Health and Human Services, *Smoking and Tobacco Control, The FTC*

(continued...)

b. Do the biological markers used to estimate nicotine ingestion in human smoking studies provide adequate estimates of likely tar ingestion? If not, what other evidence can be used to predict tar intake?

1. There are no good biomarkers for "tar" ingestion, although nicotine and its metabolites have been used.

The ideal quantitative biomarker of "tar" intake should be: (1) specific to cigarette smoke; (2) highly correlated with "tar" yield across diverse cigarette constructions and across individual and situational differences in smoking style; and (3) detectable by well-validated and sensitive analytical methods. There are no biomarkers that satisfy all of these criteria fully.

Nicotine is *not* a good biomarker for "tar" for many reasons, though it may well be the best candidate currently available, given that all other possibilities have many experimental and conceptual problems with their use as biomarkers for "tar."

First, nicotine and "tar" are very different in terms of their chemical and physical properties. "Tar" is a mixture of thousands of compounds; there is no one "tar," as "tar" can vary from cigarette to cigarette, from brand to brand, and from day to day. Indeed, the chemical composition of "tar" can change during storage. Nicotine is a specific, unique and well-documented single substance of defined chemical and physical properties. It is perhaps naive to consider that any one substance can serve as a surrogate or biomarker for "tar."

158/ (...continued)
Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes, Report of the NCI Expert Committee (1996).

Nicotine, and all metabolites of nicotine, have a specific problem in their potential use as a biomarker for "tar." The nicotine-to-"tar" ratio (by the FTC method, by the ISO method, and by the various other methods which attempt to determine possible compensation and vent blocking by smokers) varies with the "tar" yield. It is well-known that products with higher filtration and dilution have a lower nicotine-to-"tar" ratio than full-flavored products. The existence of different nicotine-to-"tar" ratios in commercial cigarettes makes nicotine an inaccurate biomarker for "tar." Consider, for example, a smoker who smokes one full-flavor cigarette with 16 mg "tar" and 1.1 mg. nicotine, and a smoker who smokes eleven low delivery cigarettes with a delivery of 1 mg "tar" and 0.1 mg of nicotine in the same fashion. The research conducted to date would suggest that both smokers would absorb the same amount of nicotine (1.1 mg); however, there would be a vast difference in their absorption of "tar": one smoker gets 16 mg, and the other gets 11 mg. The difference between these two "tar" numbers approaches 50%. Therefore, at any given nicotine level, a smoker could absorb a vast range of "tar" yields -- which could vary as much as 50% -- depending on the number and type of cigarettes smoked. As a result, from the perspective of the products themselves, nicotine is not an accurate biomarker for "tar."

In addition, from the perspective of the individual smoker, the significantly different ways consumers smoke and the consequent unpredictable relationship between nicotine yield and "tar" yield can also render the use of nicotine as a biomarker ineffective for "tar." This conclusion holds for all metabolites of nicotine, as the concentration of a nicotine metabolite (as a function of time) must, in some fashion, be related to the concentration (as a function of time) of nicotine.

Some have cited variations in the "tar"/nicotine ratio as a ground for criticizing the use of nicotine as a biomarker for "tar." In his presentation to the NCI Ad Hoc Committee on the FTC test method, Benowitz stated that:

> when cigarettes are smoked more intensely, the tar-to-nicotine ratio of low-yield cigarettes increases substantially. Thus, when smokers compensate for low-yield cigarettes by smoking them more intensely, the tar-to-nicotine ratio increases. Therefore, tar-to-nicotine ratios published by the FTC method cannot be used to make estimates of what the overall tar exposure will be for actual smokers.[159]

2. Carbon monoxide (CO) and thiocyanate are not reliable as biomarkers.

"Tar," as the term relates to cigarette yield, refers specifically to a gravimetric quantity of condensable smoke particles (not gas phase) caught on a specific filter under strictly controlled smoking conditions. CO and hydrogen cyanide are gas phase components of cigarette smoke. Thiocyanate, in turn, is a human metabolite of hydrogen cyanide.[160] Thiocyanate levels may be determined in plasma and saliva. CO can be measured in plasma or expired breath. However, CO and thiocyanate are not markers specific to smoking. CO is ubiquitous in the environment, coming from sources such as automobile exhaust, open fires, and human respiration. Moreover, thiocyanate measures are influenced by other factors, including individual differences in metabolic conversion, physiological differences,

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[159] Benowitz, N., "Biomarkers of Cigarette Smoking," *in* U.S. Department of Health and Human Services, *Smoking and Tobacco Control, The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes Report of the NCI Expert Committee*, 93, 106 (1996).

[160] McMorrow, M. & Foxx, R., "Cigarette Brand Switching: Relating Assessment Strategies to the Critical Issues," *Psychol. Bull.* 98(1):139, 148 (1985).

diet, and sampling and storage problems.[161] McMorrow and colleagues therefore concluded that it is doubtful that thiocyanate can serve as an accurate quantitative measure of tobacco consumption.[162] Thus, different studies have failed to obtain reproducible results.[163] A special committee of the National Research Council proposed guidelines for the selection of biomarkers for the measurement of passive smoking.[164] These are as follows. The ETS biomarker --

1. should be unique or nearly unique for ETS so that other sources are minor in comparison;

2. should be easily detectable;

3. should be emitted at similar rates for a variety of tobacco products;

4. should have a fairly constant ratio to other ETS components of interest under a range of environmental conditions encountered.

It is reasonable that a similar set of guidelines should apply to mainstream smoke. In this regard, substances such as carbon monoxide and thiocyanate that are either gas phase or generated from gas phase components may be ruled out because of criteria 1, 3 and 4.

c. Earlier this year, the National Institutes of Health issued Smoking and Tobacco Control Monograph 8 - Changes in Cigarette-Related Disease and Their Implication for Prevention and Control. The Monograph, which presents the results of three large new epidemiological studies and additional follow-up data for two older studies from the 1950's, notes (pp. ix-x) that:

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[161] McMorrow, M. & Foxx, R., "Cigarette Brand Switching: Relating Assessment Strategies to the Critical Issues," *Psychol. Bull.* 98(1):139, 148 (1985).

[162] *Id.*

[163] Diding, N., "Machine smoking results compared to human uptake of cigarette smoke," *Int'l J. of Clinical Pharm., Therapy and Toxicology* 25(3):143 (1987).

[164] Nat'l Research Council, "Environmental Tobacco Smoke: Measuring Exposures And Assessing Health Effects," at 70, Washington, D.C. (1986).

When observations from the more contemporary studies are compared with those from the 1950's, one important but disturbing conclusion is apparent -- mortality risks among continuing smokers, both males and females, have increased.

What effect, if any, do the findings reported in this Monograph have on the Ad Hoc Committee's conclusion that the smoking of "cigarettes with lower machine-measured yields has a small effect in reducing the risk of cancer caused by smoking"?

The manufacturers take no position with respect to the effect of these findings on the Ad Hoc Committee's conclusion. The manufacturers do not claim that lower-yield cigarettes are "safe" or are "safer" than higher-yield cigarettes, and every cigarette advertisement and every cigarette package includes one of four federally-mandated health warnings that are incompatible with the belief that *any* cigarette is "safe" or is "safer" than any *other* cigarette.

II. Cigarette Descriptors

1. Is there a need for official guidance with respect to the terms used in marketing lower rated cigarettes? If yes, why? If no, why not?

The manufacturers are not convinced that there is a need for official guidance with respect to the terms used in marketing lower rated cigarettes. The terms "light" or "low tar" generally are used to describe cigarettes with "tar" ratings of 7 to 15 milligrams, while "ultra light" or ultra low tar" describes cigarettes with ratings of 6 milligrams or less. These terms are usually used as a point of comparison for an established brand in order to distinguish among related brand styles. The manufacturers believe smokers understand that these descriptors are terms of comparison rather than signifiers of absolute value. The manufacturers believe that the historical decline in average sales-weighted "tar" of cigarettes purchased by consumers is indicative of the clear communication of relative rankings

provided by the descriptors. Changes in the established use of those terms could lead to substantial confusion and brand-switching among consumers, further muddying communication of relative rankings.

2. *What data, evidence or other relevant information on consumer interpretation and understanding of terms such as "ultra low tar," "ultra light," "low tar," "light," "medium," "extra light" and "ultima," as used in the context of cigarettes exists? Do consumers believe they will get significantly less tar from cigarettes described as "light" or "low tar" than from regular or full flavor cigarettes, and do they believe they will get significantly less tar from cigarettes described as "ultra low tar" or "ultra light" than from "light" or "low tar" cigarettes? Do the descriptors convey implied health claims?*

The manufacturers believe that consumers choose "light" or "ultra" products for a variety of reasons, including lighter flavor, lighter taste, less menthol (or other flavor) taste, and smoother smoking characteristics. Some consumers may choose such products for other reasons. The manufacturers do not intend the descriptors to convey any level of "safety" with regard to their products. In fact, the health warnings required on every cigarette package and in every cigarette advertisement are incompatible with the suggestion that any cigarette is "safe" or is "safer" than any other cigarette.

3. *Do consumers use descriptors, rather than the FTC tar and nicotine ratings, as their primary source of information about the tar and nicotine yields of different cigarette brands? What data or evidence examines this question? If consumers use descriptors as their primary source of information about tar and nicotine yields, what implications does this have for the proposed revisions to the test method and the advertising disclosure?*

As noted in response to the last question, the reasons consumers choose lower-yield products are varied and complex. The manufacturers are not aware of evidence that consumers use descriptors in lieu of the FTC numbers as their primary source of information about the "tar" and nicotine yields of different brand styles.

APPENDIX A

DISCUSSION OF DATA SUBMITTED TO THE COMMONWEALTH OF MASSACHUSETTS PURSUANT TO SECTION 660.102 OF REGULATIONS PROMULGATED BY THE MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH (105 CMR 660.000).

INTRODUCTION

On December 15, 1997, the nation's cigarette manufacturers provided the Commonwealth of Massachusetts with the first test results required under the Commonwealth's new cigarette testing law.[1] The data included information on cigarette brand families sold in the United States that had more than a 5% national market share during the previous year. Testing conducted to comply with the Massachusetts regulations included evaluations of smoke nicotine, tobacco nicotine, "smoke pH" and filter ventilation.

This Appendix reviews the results of the testing conducted pursuant to the Massachusetts requirements. Those results, and any conclusions drawn from those results, may or may not be reliable since the testing requirements do not represent scientifically validated methods. Because the data were obtained without the benefit of methods validation or interlaboratory comparison of common cigarette brand styles (*i.e.*, each manufacturer was required to test only its own brand styles), the data summarized in this Appendix are necessarily crude and imprecise.

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[1] Letter from Mitchell A. Neuhauser, Product Litigation Counsel for Brown & Williamson Tobacco Corporation, to Gregory N. Connolly, Director, MA Tobacco Control Program, Dec. 12, 1997, Re: Brown & Williamson Tobacco Company's Annual Report. Letter from Vello Norman, Vice President, Research & Development, Lorillard Tobacco Company, to Gregory N. Connolly, Director, MA Tobacco Control Program, Dec. 12, 1997, Re: Report of Nicotine Yield Ratings. Letter from Jerry F. Whidby, Technology Fellow, Philip Morris Research & Development, to Gregory N. Connolly, Director, MA Tobacco Control Program, Dec. 15, 1997, Re: 1997 Annual Report of Philip Morris Incorporated - Nicotine Yield Rating Information. Letter from Michael F. Borgerding, Master Chemist, R.J. Reynolds Tobacco Co., to Gregory N. Connolly, Director, MA Tobacco Control Program, Dec. 12, 1997 (regarding 1997 nicotine yield reporting).

PRACTICAL ISSUES

The prescribed testing requirements were marked by certain ambiguities, inconsistencies and errors that could be eliminated or resolved by a method validation process and interlaboratory testing. For example:

- The regulations specify the puff volume for determining smoke nicotine both as a 43 cc puff volume and a 45 cc puff volume. The manufacturers chose to use a 45 cc puff volume.
- Conditioning of cigarettes prior to ventilation testing and testing of tobacco nicotine content, required by the regulations, is inconsistent with common practice in the United States.
- The method prescribed for determining tobacco nicotine content uses a poor choice of solvent (methyl t-butyl ether is extremely volatile and sample is lost during the GC injection process).
- The requirements also inaccurately specify both tobacco nicotine-standard preparation procedures (generally with an error of about 10%) and nicotine recovery estimates (generally with an error of about 50%).
- The standard Cambridge filter pad used in the FTC method has a limited collection capacity that is often exceeded under the conditions specified in the Massachusetts requirements. Consequently some of the nicotine produced by the cigarettes under the conditions specified by Massachusetts DPH may not be collected by the pad.
- The "smoke pH" trap specified by the requirements is not commercially available.
- The Scotch-brand tape specified to partially block filter ventilation holes cannot be easily used to block holes on cigarettes that have circumferences greater than or less than 25 millimeters. This creates a great potential for inconsistency and imprecision in vent-hole blocking.

As required by the Massachusetts regulation, the FTC nicotine yields reported to the Commonwealth in 1997 were those values found in the most recent FTC report, which represented values for cigarettes purchased in 1994. Also as required by the Massachusetts regulation, these FTC values were submitted along with values generated from tests of cigarettes purchased in Massachusetts in 1997. Comparing these two sets of numbers may be problematic because, in some cases, design parameters of particular brand-styles may have changed between 1994 and 1997.

In contrast to scientifically validated method, the requirements provided by the Commonwealth of Massachusetts did not represent a set of definitive directions because they were subject to differences in interpretation and implementation. Consequently it was possible for different laboratories to follow the same requirements and obtain different results -- even when testing the same cigarette brand-styles. For example:

1. The variation in the "smoke pH" values achieved by the four cigarette manufacturers is apparently the direct result of the fact that no standardized "smoke pH" method exists.

2. The wide discrepancy in Massachusetts nicotine yields at any given standard FTC nicotine yield is apparently the result of differences in the application of the requirements between laboratories (see, especially, FTC nicotine yields of 1.2 mg/cig and greater in Figure 1).

Also, as R.J. Reynolds Tobacco Co. noted in its December 12, 1997, cover letter to Dr. Gregory N. Connolly, director of the Massachusetts Tobacco Control Program at the Massachusetts Department of Public Health:

> "To better understand the serious limitations posed by a lack of methods validation, consider that even a very cursory comparison of the two data sets provided by RJR reveals significant differences (generally on the order of ~ 10% - 20% for the measurement of nicotine in tobacco and tobacco smoke) for the same products, despite the fact that RJR and Labstat [the contract laboratory used by RJR] each attempted to follow to the letter the instructions contained within the regulations. Because many of those instructions are subject to multiple interpretations and implementations, the results obtained by our two laboratories are not directly comparable even for the same brand-styles of cigarettes. The values obtained from the tests in R.J. Reynolds laboratories are generally greater than those obtained by Labstat. We do not, however, know which (if either) of the two data sets is "accurate", so we have provided both for your review. We are currently performing a comparative analysis of these two data sets. This points out an even larger problem. If we cannot obtain consistent interlaboratory results for the same cigarette brand styles, how can meaningful comparisons be made among different brand styles from different manufacturers tested in different laboratories?"

SUMMARY OF MASSACHUSETTS TESTING RESULTS

Despite the problems presented by the fact that the Massachusetts testing requirements have not been scientifically validated, several observations about the results can be made:

- **Smoke Nicotine** - The smoke nicotine values obtained using the Massachusetts testing requirements were roughly twice the values obtained under standard FTC smoking conditions for the brands tested. At the same time, the relative ranking of cigarette brand styles produced under standard FTC machine smoking conditions was maintained by the Massachusetts tests for the tested brands.[2]

- **Filter Ventilation** - Cigarettes with the highest degrees of filter ventilation yielded smaller amounts of nicotine than cigarettes with lesser degrees of filter ventilation both (1) when cigarettes were smoked as manufactured with the standard FTC smoking conditions (i.e., the filter vents open) and (2) when cigarettes were smoked with the filter vents half-blocked, as specified by the Massachusetts testing requirements.

- **Tobacco Nicotine** - The amount of nicotine in the cigarette itself provided no consistent indication of how much smoke nicotine the cigarette would yield when cigarettes were tested with either the standard FTC smoking condition or the smoking conditions specified in the Massachusetts requirements. This result is consistent with the view that mainstream cigarette smoke contains only a small and variable portion of the nicotine contained in the cigarette itself.

- **"Smoke pH"** - Substantial differences were not observed in "smoke pH" levels among the cigarette brand styles that were tested by any <u>single</u> method by any <u>one</u> company. As such, no correlation between "smoke pH" and smoke nicotine yields was observed for the brand styles tested. Differences in "smoke pH" levels were observed from laboratory to laboratory (company to company). This result was not surprising since no standard method for "smoke pH" exists and each laboratory employed a different test (or tests) to comply with the Massachusetts reporting deadline.

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[2] Some small differences are to be expected because of the considerations noted in the *Practical Issues* section above. Specifically, problems arising from (1) the fact that cigarettes purchased in 1994 (and reported in the most recent FTC report) may not be directly comparable to cigarettes purchased in 1997 (and tested according to Massachusetts requirements) and (2) the fact that the specified testing requirements did not undergo a method validation process (*i.e.*, there were a number of interlaboratory testing differences based on different interpretations of the specified requirements).

TESTING RESULTS AND DISCUSSION

Data submitted to the Massachusetts Department of Health on December 15, 1997, along with a brief discussion of some of the problems encountered by the companies in generating those data, follows.

SMOKE NICOTINE RESULTS

1) The relative ranking of cigarette brand styles produced under standard FTC machine smoking conditions was generally maintained by the Massachusetts tests for the brands tested.

Figure 1 compares smoke nicotine yields generated under the Massachusetts requirements with those generated under standard FTC conditions.[3] The chart includes data for five different brand families. Each manufacturer generated data for its own brand styles. In addition, one manufacturer contracted with an outside laboratory to independently assess its brand styles. All data are reported in the chart. Because the requirements specified by the Massachusetts regulations do not yet represent validated scientific methods, the results from the five laboratories that generated data may or may not be directly comparable.

The cigarettes tested represent FTC nicotine yields ranging from approximately 0.4 mg/cig to 1.4 mg/cig. The Massachusetts yields were higher than the value of the FTC yields for any particular brand-style tested. The Massachusetts yields were, in fact, approximately twice as high as the FTC yields for the tested cigarettes. Because this relationship was consistent from brand style to brand style, the relative ranking of the brands was maintained (see Footnote 2), regardless of which testing condition was used.

It should be noted that the discrepancy in the results at standard FTC nicotine yields of 1.2 mg/cig and above (see Figure 1) may be the result of differences in the application of the requirements between laboratories. This highlights the need for a validated, standardized method.

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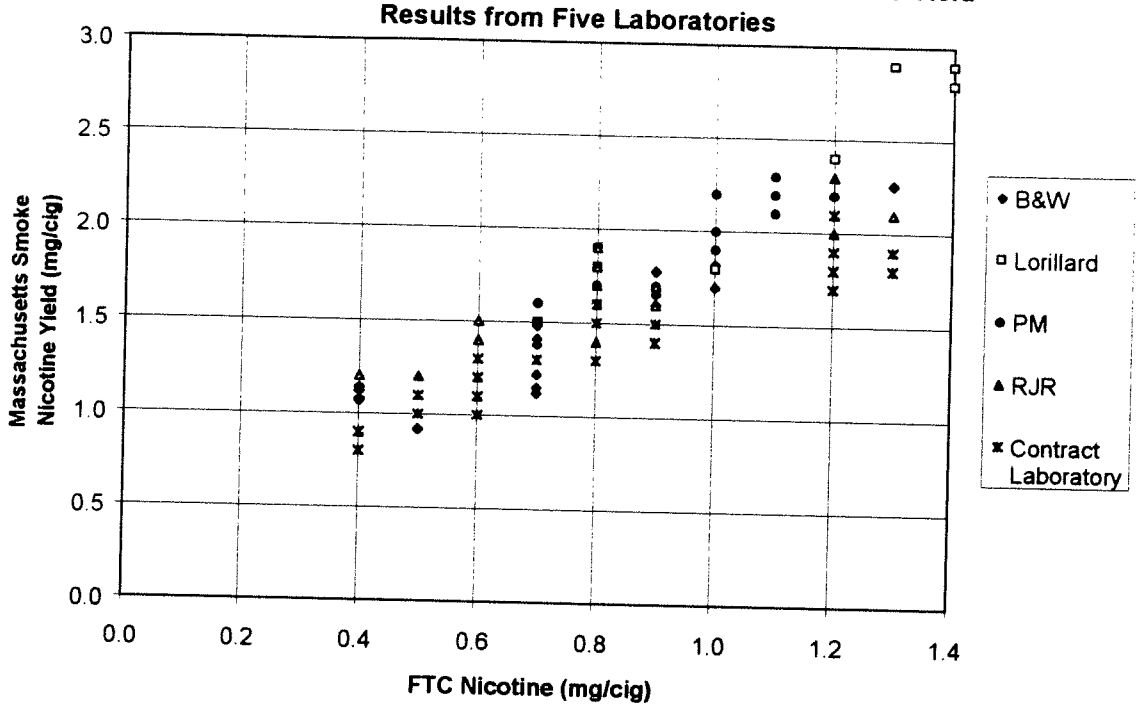
[3] As noted, comparing these two sets of numbers may be problematic because, in some cases, design parameters of particular brand-styles may have changed between 1994 and 1997. It should also be noted that Figure 1 is based on rounded FTC nicotine values, as specified by FTC protocol. This rounding reduces natural variation along the x axis and tends to exaggerate the apparent "scatter" along the y axis.

Figure 1. Comparison of Massachusetts Smoke Nicotine Yield Results from Five Laboratories



2) Massachusetts smoke nicotine yields fell within the range of yields produced by the proposed FTC two-tier system.

The nicotine yield numbers generated for the brand styles tested under the Massachusetts conditions fell within the range of numbers produced by the proposed FTC two-tier system.

Figure 2 compares the test results recently submitted to the Massachusetts Department of Public Health with results from an experiment reported to the FTC staff June 23, 1997.[4] As Figure 2 shows, the Massachusetts yields were less than or similar to the FTC upper-tier yields. It should be noted that the 1997 Massachusetts testing results only included cigarettes with FTC nicotine yields ranging from approximately 0.4 mg/cig to 1.4 mg/cig. Yields for other cigarettes when tested under the Massachusetts requirements may, or may not, fall within the range of the proposed FTC two-tier testing system.

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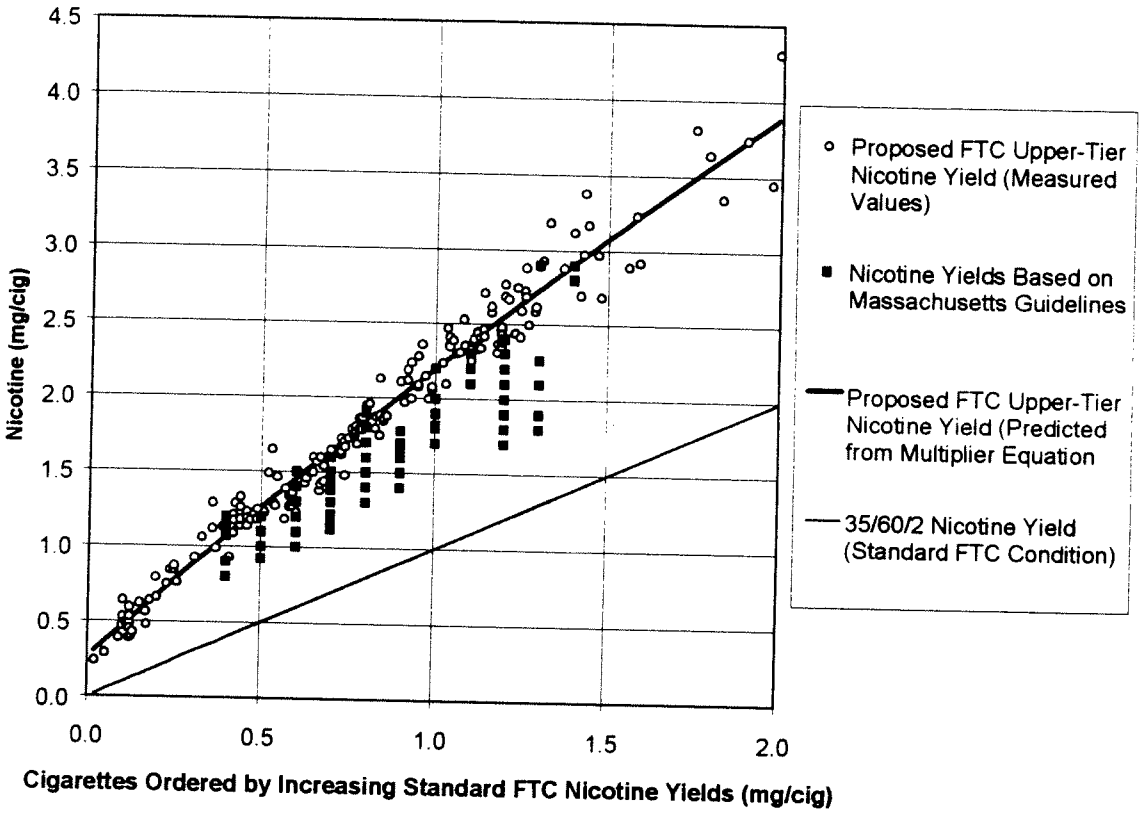
[4] Philipp, C., St. Charles, K., Norman, V., Whidby, J., Garman, J., Lewis, L., Borgerding, M., *An Experiment to Determine the General Relationship Between Cigarette Smoke Yields Using An Alternative Puffing Regimen (55/30/2) And The*

Figure 2. Comparison of the Nicotine Yield Range Obtained with the FTC's Proposed Two-Tier System and Nicotine Yields Produced by the Massachusetts Guidelines



FILTER VENTILATION

Even with partial vent-blocking, nicotine yields of cigarettes generally decreased as filter ventilation increased.

Figure 3 describes the relationship between standard FTC nicotine yields and the percentage of filter ventilation in unblocked cigarettes. The figure clearly shows that nicotine yields tended to decrease as filter ventilation increased for the cigarette brand-styles tested.

Standard FTC Method, compiled by Borgerding, M., Bodnar, J., Willard, B., R.J. Reynolds Tobacco Company, Winston-Salem, NC (1997).

Figure 3. Comparison of Standard FTC Nicotine Yields and the Percentage of Filter Ventilation in Unblocked Cigarettes

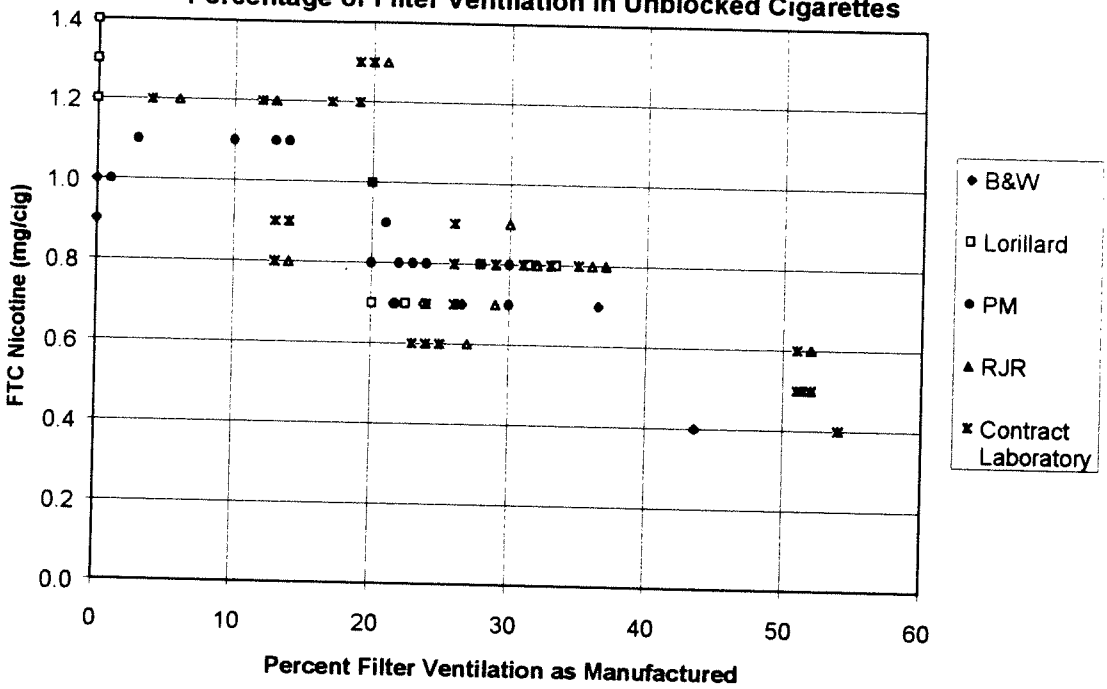
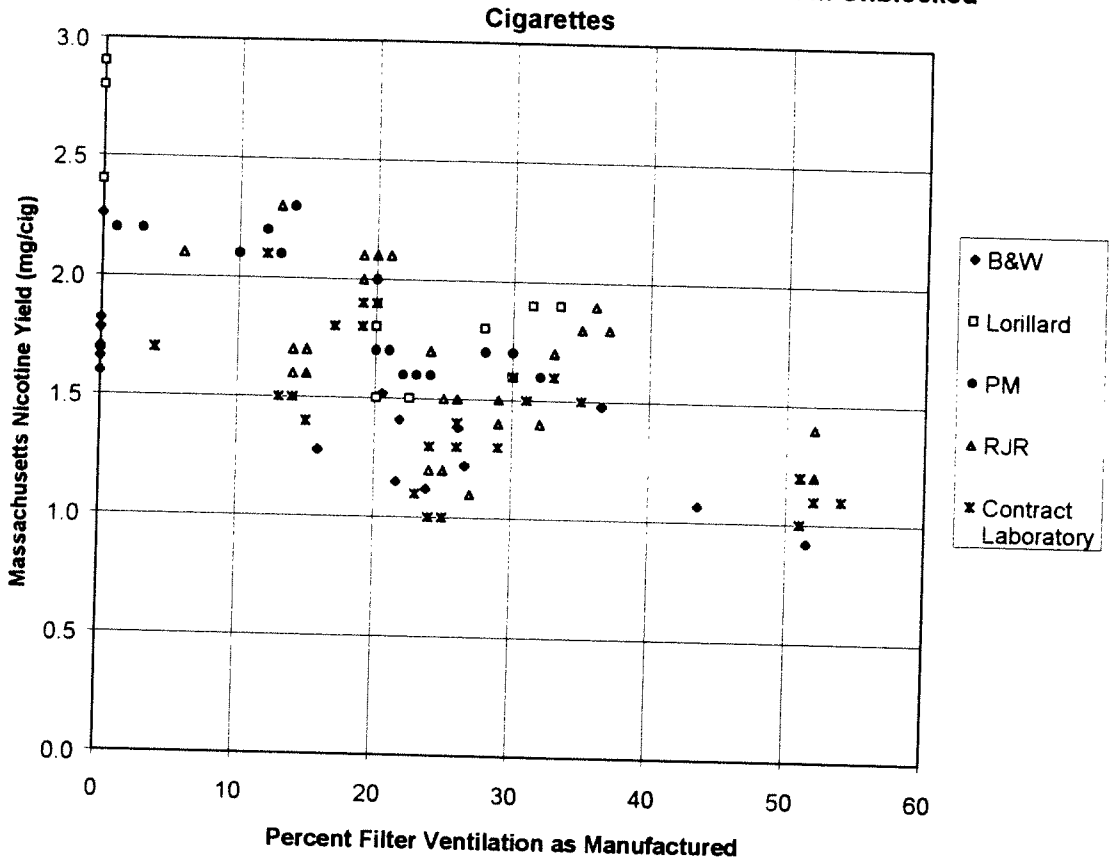


Figure 4 shows the analogous relationship between Massachusetts nicotine yields (*i.e.*, yields when filter vents for the tested brands are half blocked) and the percentage of filter ventilation in the unblocked cigarettes (*i.e.*, the cigarettes as they are manufactured). Figure 4 shows that even with the vents half blocked, nicotine yields tended to decrease as filter ventilation increased.

Figure 4. Comparison of Massachusetts Nicotine Yields (with Vents Half Blocked) and the Percentage of Filter Ventilation in Unblocked Cigarettes



TOBACCO NICOTINE

The amount of nicotine found in the tested cigarettes did not provide a consistent indication of how much nicotine would appear in the smoke from those cigarettes.

Figure 5 compares smoke nicotine yields generated under standard FTC conditions to the total amount of nicotine found in the cigarette itself. Figure 6 similarly compares smoke nicotine yields generated under the Massachusetts requirements with the total amount of nicotine found in the cigarette itself for the tested brands. It is clear from both figures that the amount of nicotine per cigarette did not predict machine-generated smoke nicotine yields for the cigarettes tested. These figures also show that, in general, mainstream cigarette smoke contained only a small and variable portion of the nicotine contained in the cigarette.

The amount of nicotine in the cigarettes tested was one – but by no means the only – factor in determining the smoke nicotine yields observed. Such design variables as filter ventilation and the use of expanded tobacco, among others, also played a role. It was the combined effects of these design factors in each of the cigarettes tested that ultimately determined how much nicotine was transferred to the smoke under machine smoking conditions.

Figure 5. Comparison of FTC Nicotine Yield and Tobacco Nicotine Results from Five Laboratories

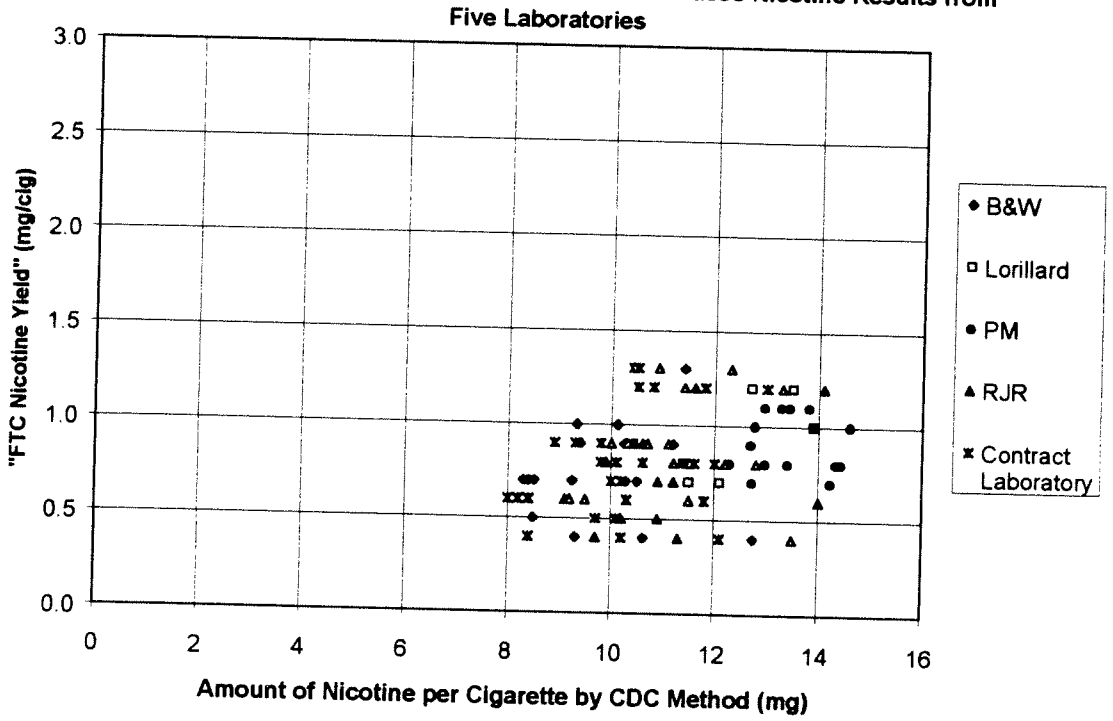
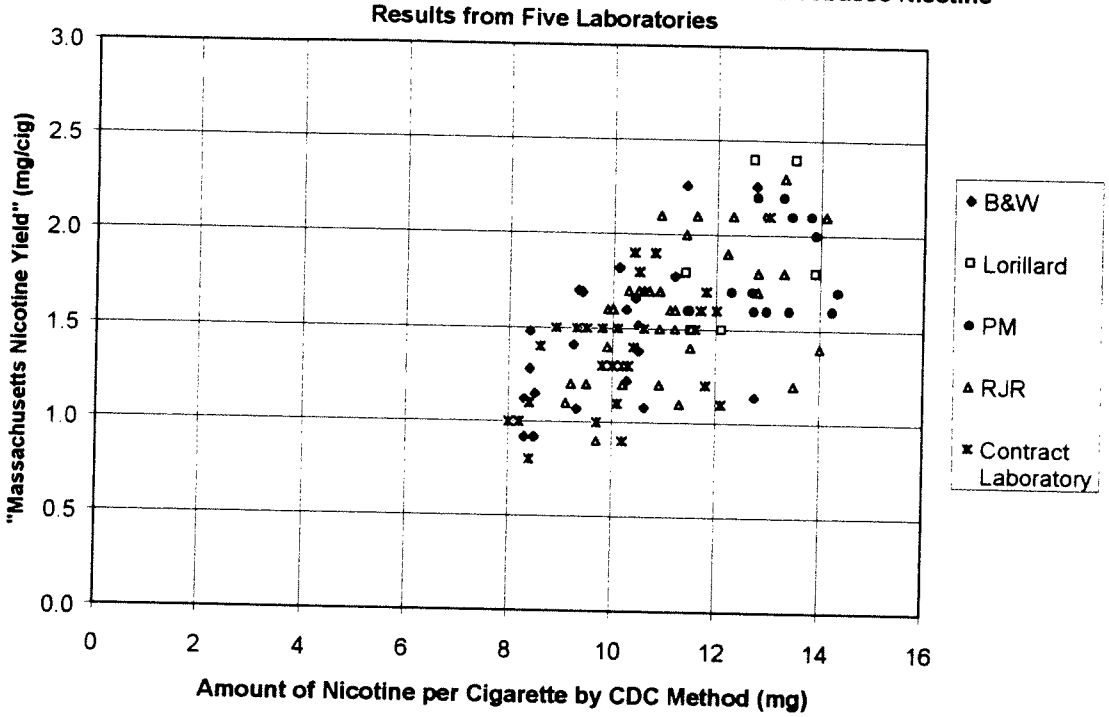


Figure 6. Comparison of "Massachusetts Nicotine Yield" and Tobacco Nicotine Results from Five Laboratories



"SMOKE pH"

The results of tests mandated by the Massachusetts regulations indicate that there is very little variation in "smoke pH" among the products tested.

Figure 7 compares Massachusetts "smoke pH" values with standard FTC smoke nicotine yields, using a pH scale that includes the entire range of possible pH values. Figure 8 shows the same data compared on a pH scale that includes only pH values actually measured. A number of important points are clear from both charts:

1) There do not appear to be any substantial differences in "smoke pH" levels among the cigarette brand styles that were tested by any single method by any one company (despite the broad range of standard FTC nicotine yields for the brand styles tested).

2) The larger differences that were observed comparing the brand families from different companies were likely due to differences in testing methodology, rather than to actual "smoke pH" differences between those brand families. This is most evident in the data from Brown & Williamson Tobacco Co., which tested its brand styles with two different methods and generated quite different results for the same cigarette brand-styles ("smoke pH" values using one method -- "whole smoke" -- ranged from 4.63 to 4.96, while the values for the same cigarette brand-styles ranged from 5.69 to 5.89 for the other method -- "Mass-TPM").

These differences are the direct result of the fact that "smoke pH" is a theoretical concept concerning smoke (rather than an actual property of smoke) and no standardized "smoke pH" method exists. As a result, in the tests conducted to comply with the December 15, 1997 deadline, methodological differences included:

- a number of different smoking machines were used;
- the number of cigarettes smoked per determination varied widely;
- the smoke fraction(s) that were collected were inconsistent (one company collected smoke particles only, one collected smoke particles and smoke vapors separately, and two companies collected whole smoke);
- the water volume used to collect smoke varied; and
- the total number of cigarettes tested varied substantially.

The importance of these methodological differences is demonstrated by "smoke pH" values derived by the four companies for the Kentucky reference cigarette 1R4F. Testing of this standard reference cigarette in different laboratories yielded values ranging from approximately 4.5 to 6.0 – roughly the same range observed for the brand families tested by the various companies. Because these differences can be attributed to methodological inconsistencies, it is likely that there would be minimal differences, if any, in "smoke pH" levels among all of the cigarettes brand-styles tested by the four manufacturers if they were all tested using a single, standard, validated method.

Figure 7. Comparison of Massachusetts "Smoke pH" Results with Standard FTC Smoke Nicotine Yields

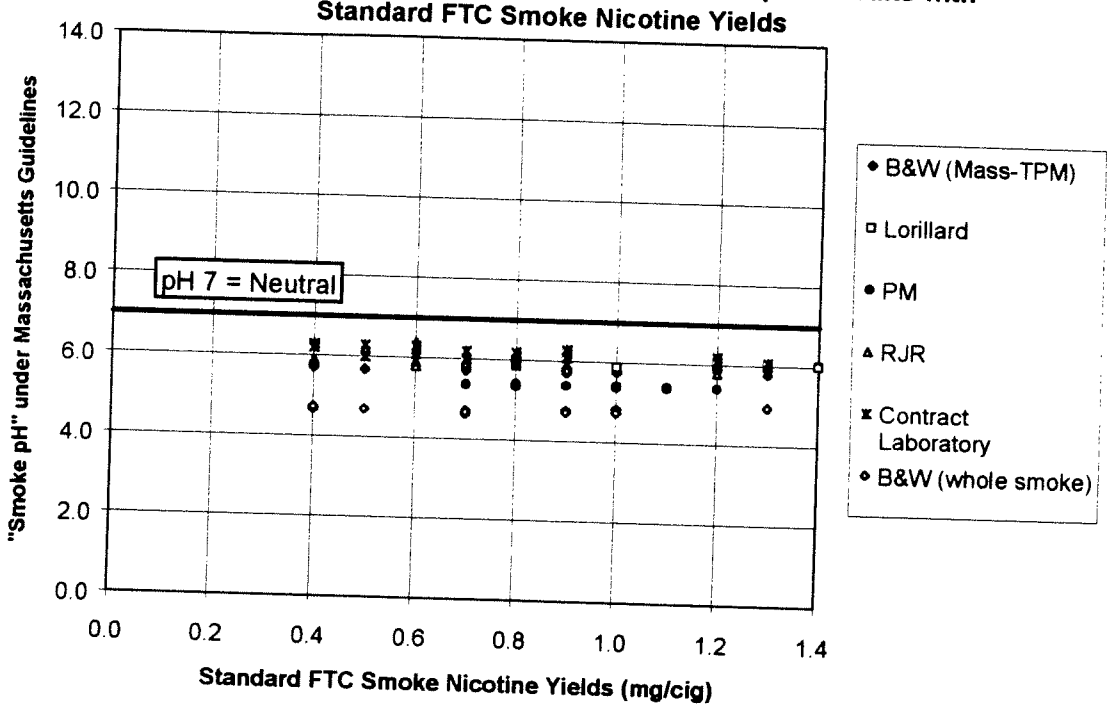
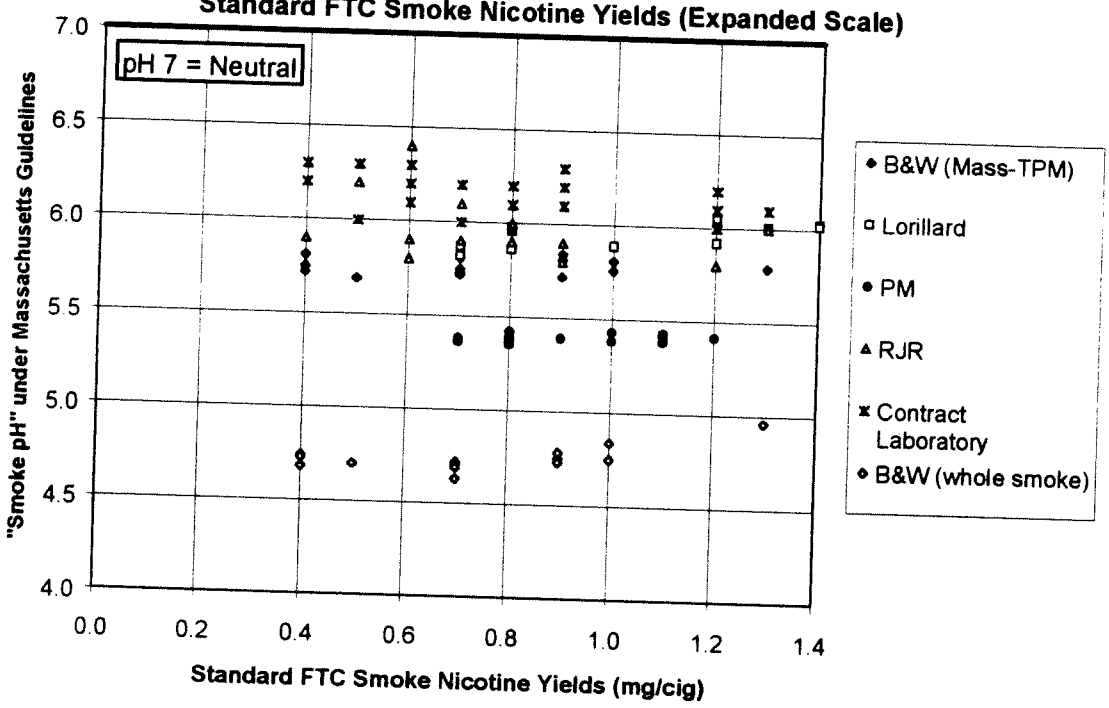


Figure 8. Comparison of Massachusetts "Smoke pH" Results with Standard FTC Smoke Nicotine Yields (Expanded Scale)



APPENDIX B

STATUS OF PENDING NICOTINE TESTING LEGISLATION AS OF FEBRUARY 4, 1998[1/]

STATE	BILL NO.	STATUS
DELAWARE	S.B. 40 (1997)	01/28/97 INTRODUCED. 01/28/97 To SENATE Committee on HEALTH AND SOCIAL SERVICES. 05/07/97 Committee substitute offered; bill is still pending in committee.
ILLINOIS	H.B. 1043 (1997)	02/27/97 INTRODUCED. 02/27/97 To HOUSE Committee on RULES. 02/28/97 TO HOUSE Committee on HUMAN SERVICES. 03/11/97 In HOUSE. Fiscal Note filed. 03/14/97 In HOUSE. State Mandates Fiscal Note filed. 03/20/97 In HOUSE Committee on HUMAN SERVICES: Motion do pass lost. Remains in committee. 03/21/97 Re-referred to HOUSE Committee on RULES.
ILLINOIS	S.B. 403 (1997)	02/05/97 INTRODUCED. 02/05/97 To SENATE Committee on RULES. 02/06/97 To SENATE Committee on EXECUTIVE. 02/28/97 In SENATE Committee on EXECUTIVE: To Subcommittee. 03/15/97 To SENATE Committee on RULES; INACTIVE. 05/31/97 Re-referred to SENATE Committee on EXECUTIVE.
INDIANA	H.B. 1095 (1998) (linking ratings to "federally established standards")	01/06/98 INTRODUCED. 01/06/98 To HOUSE Committee on PUBLIC HEALTH.

[1/] Includes bills with language similar or identical to Massachusetts legislation enacted in 1996 and Texas legislation enacted in 1997 and does not include other pending legislation which would also subject manufacturers to smoke testing requirements.

STATE	BILL NO.	STATUS
IOWA	H.B. 115 (1997)	01/30/97 INTRODUCED. 01/30/97 To HOUSE Committee on COMMERCE AND REGULATIONS. Assigned to Subcommittee.
IOWA	S.B. 46 (1997)	01/22/97 INTRODUCED. 01/22/97 To SENATE Committee on HUMAN RESOURCES. Assigned to Subcommittee.
MAINE	S.B. 508 (1997)	03/18/97 INTRODUCED. 03/18/97 To JOINT Committee on HEALTH AND HUMAN SERVICES. 04/14/97 Committee requested to carry over the bill to next year. Will carry over. 01/20/98 Work session scheduled for 1/22. 01/30/98 Work session re-scheduled for 2/2.
MICHIGAN	H.B. 4778 (1997)	05/13/97 INTRODUCED. 05/13/97 To HOUSE Committee on HEALTH POLICY.
NEW JERSEY	A.B. 1257 (1998)	01/13/98 INTRODUCED. 01/13/98 To ASSEMBLY Committee on HEALTH.
NEW YORK	S.B. 2622 (1997)	02/13/97 INTRODUCED. 02/13/97 To SENATE Committee on HEALTH. 01/07/98 Referred back to SENATE Committee on HEALTH.

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DELAWARE 139TH GENERAL ASSEMBLY

SENATE BILL 40

DELAWARE STATE SENATE
139TH GENERAL ASSEMBLY
SENATE SUBSTITUTE NO. 1
TO
SENATE BILL NO. 40

1997 DE S.B. 40

VERSION: Substituted

VERSION-DATE: May 8, 1997

SYNOPSIS:

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO DISCLOSURE OF CERTAIN INFORMATION RELATING TO TOBACCO PRODUCTS SOLD IN DELAWARE.

DIGEST:

SYNOPSIS

This Bill requires manufacturers of cigarettes, snuff or chewing tobacco sold in Delaware to provide the Department of Health and Social Services with an annual report identifying non-tobacco ingredients and nicotine yield ratings.

TEXT: BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Part II, Title 16, Delaware Code by adding thereto the following:

"Chapter 29A Tobacco Products and the Public Health

Section 2901 A Tobacco product information

(a) For the purpose of protecting the public health, any manufacturer of cigarettes, snuff or chewing tobacco sold in the State shall provide the Department of Health and Social Services with an annual report, in a form and at a time specified by the Department, which lists for each brand of such product sold the following information:

(1) The identity of any added constituent other than tobacco, water or reconstituted tobacco sheet made wholly from tobacco to be listed in descending

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order according to weight, measure or numerical count; and

(2) The nicotine yield ratings, which shall accurately predict nicotine intake for average consumers based on standards to be established by the Department.

(b) The nicotine yield ratings so provided, and any other such information in the annual reports with respect to which the Department determines that there is a reasonable scientific basis for concluding that the availability of such information could reduce risks to public health, shall be public records.

(c) This section shall not require a manufacturer, in its report to the Department or otherwise, to identify or disclose the specific amount of any ingredient that has been approved by the Food and Drug Administration, Public Health Service. United States Department of Health and Human Services ('FDA'), or its successor agency, as safe when burned and inhaled or that has been designated by the FDA, or its successor agency, as generally recognized as safe when burned and inhaled, according to the Generally Recognized As Safe list of the FDA.

Section 2902A Penalties; jurisdiction

(a) Failure of a manufacturer to disclose all information required to be reported in the annual report mandated by Section 2901 A(a) of this Chapter shall be punishable by a civil penalty of not less than $ 1,000 nor more than $ 10,000. Each brand for which said information was not so disclosed shall constitute a separate violation. Each day of continued failure to disclose shall constitute a separate violation.

(b) The Superior Court shall have jurisdiction over all violations of this Chapter."

Section 2. The annual reports required in Section 1 of this Act shall be filed beginning in 1998.

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ILLINOIS 90TH GENERAL ASSEMBLY -- 1997-98 REGULAR SESSION

HOUSE BILL **1043**

1997 IL H.B. **1043**

VERSION: Introduced

VERSION-DATE: February 27, 1997

SYNOPSIS:

AN ACT concerning tobacco.

TEXT: Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the Disclosure of Ingredients in Tobacco Products Act.

Section 5. Annual report.

(a) For the purpose of protecting the public health, any manufacturer of cigarettes, snuff, or chewing tobacco sold in this State shall provide the Department of Public Health with an annual report, in a form and at a time specified by the Department of Public Health, that lists for each brand of product sold the following information:

(1) the identity of any added constituent other than tobacco, water, or reconstituted tobacco sheet made wholly from tobacco, to be listed in descending order according to weight, measure, or numerical count; and

(2) the nicotine yield ratings, which shall accurately predict nicotine intake for average consumers, based on standards to be established by the Department of Public Health.

(b) The nicotine yield ratings so provided, and any other information in the annual reports with respect to which the Department of Public Health determines that there is a reasonable scientific basis for concluding that the availability of such information could reduce risks to public health, shall be public records. However, before any public disclosure of this information, the Department of Public Health shall request the advice of the Attorney General whether the disclosure would constitute an unconstitutional taking of property and shall not disclose the information unless and until the Attorney General advises that the disclosure would not constitute an unconstitutional taking.

(c) This Section shall not require a manufacturer, in its report to the

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Department of Public Health or otherwise, to identify or disclose the specific amount of any ingredient that has been approved by the Food and Drug Administration, Public Health Service, United States Department of Health and Human Services (FDA), or its successor agency, as safe when burned and inhaled or that has been designated by the FDA, or its successor agency, as generally recognized as safe when burned and inhaled, according to the Generally Recognized As Safe list of the FDA.

(d) The annual reports required in this Section shall be filed beginning in the year 1998.

SPONSOR:
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ILLINOIS 90TH GENERAL ASSEMBLY -- 1997-98 REGULAR SESSION

SENATE BILL **403**

1997 IL S.B. **403**

VERSION: Introduced

VERSION-DATE: February 5, 1997

SYNOPSIS:

AN ACT concerning tobacco.

TEXT: Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the Disclosure of Ingredients in Tobacco Products Act.

Section 5. Annual report.

(a) For the purpose of protecting the public health, any manufacturer of cigarettes, snuff, or chewing tobacco sold in this State shall provide the Department of Public Health with an annual report, in a form and at a time specified by the Department of Public Health, that lists for each brand of product sold the following information:

(1) the identify of any added constituent other than tobacco, water, or reconstituted tobacco sheet made wholly from tobacco, to be listed in descending order according to weight, measure, or numerical count; and

(2) the nicotine yield ratings, which shall accurately predict nicotine intake for average consumers, based on standards to be established by the Department of Public Health.

(b) The nicotine yield ratings so provided, and any other information in the annual reports with respect to which the Department of Public Health determines that there is a reasonable scientific basis for concluding that the availability of such information could reduce risks to public health, shall be public records. However, before any public disclosure of this information, the Department of Public Health shall request the advice of the Attorney General whether the disclosure would constitute an unconstitutional taking of property and shall not disclose the information unless and until the Attorney General advises that the disclosure would not constitute an unconstitutional taking.

(c) This Section shall not require a manufacturer, in its report to the

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Department of Public Health or otherwise, to identify or disclose the specific amount of any ingredient that has been approved by the Food and Drug Administration, Public Health Service, United States Department of Health and Human Services (FDA), or its successor agency, as safe when burned and inhaled or that has been designated by the FDA, or its successor agency, as generally recognized as safe when burned and inhaled, according to the Generally Recognized As Safe list of the FDA.

(d) The annual reports required in this Section shall be filed beginning in the year 1998.

SPONSOR:
Smith

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INDIANA 110TH GENERAL ASSEMBLY -- SECOND REGULAR SESSION

HOUSE BILL **1095**

SECOND REGULAR SESSION 110TH GENERAL ASSEMBLY (1998)
HOUSE BILL NO. **1095**

1998 IN H.B. **1095**

VERSION: Introduced

VERSION-DATE: January 6, 1998

SYNOPSIS:

A BILL FOR AN ACT to amend the Indiana Code concerning health.

NOTICE:
[A> UPPERCASE TEXT WITHIN THESE SYMBOLS IS ADDED <A]

TEXT: Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 16-18-2-351.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS (EFFECTIVE JULY 1, 1998): [A> SEC. 351.5. "TOBACCO PRODUCT", FOR PURPOSES OF IC 16-40-3, HAS THE MEANING SET FORTH IN IC 16-40-3-1. <A]

SECTION 2. IC 16-40-3 IS ADDED TO THE INDIANA CODE AS A NEW CHAPTER TO READ AS FOLLOWS (EFFECTIVE JULY 1, 1998):

[A> CHAPTER 3. TOBACCO PRODUCT REPORTS <A]

[A> SEC. 1. AS USED IN THIS CHAPTER, "TOBACCO PRODUCT" MEANS A PRODUCT MADE FROM TOBACCO THAT IS MADE FOR ANY OF THE FOLLOWING: <A]

[A> (1) SMOKING. <A]

[A> (2) CHEWING. <A]

[A> (3) SNUFF. <A]

[A> SEC. 2. A PERSON WHO MANUFACTURES A TOBACCO PRODUCT SHALL PROVIDE THE STATE DEPARTMENT WITH AN ANNUAL REPORT FOR EACH BRAND OF TOBACCO PRODUCT SOLD IN INDIANA. THE REPORT MUST CONTAIN THE FOLLOWING INFORMATION: <A]

[A> (1) EXCEPT FOR TOBACCO, WATER, OR A RECONSTITUTED TOBACCO SHEET THAT IS WHOLLY MADE FROM TOBACCO, THE IDENTITY OF ANY ADDED INGREDIENT LISTED IN DESCENDING ORDER ACCORDING TO WEIGHT OR VOLUME. HOWEVER, THE MANUFACTURER IS NOT

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REQUIRED TO IDENTIFY AN INGREDIENT THAT THE FEDERAL FOOD AND DRUG ADMINISTRATION HAS APPROVED AS SAFE WHEN BURNED AND INHALED OR RECOGNIZED AS SAFE WHEN BURNED AND INHALED ACCORDING TO THE "GENERALLY RECOGNIZED AS SAFE" LIST OF THE FOOD AND DRUG ADMINISTRATION. <A]

[A> (2) THE NICOTINE YIELD RATING BASED ON FEDERALLY ESTABLISHED STANDARDS. THE TESTS TO DETERMINE THE NICOTINE YIELD RATING MUST BE PERFORMED BY AN INDEPENDENT LABORATORY APPROVED BY THE STATE DEPARTMENT. <A]

[A> SEC. 3. THE FOLLOWING ARE PUBLIC RECORDS: <A]

[A> (1) THE NICOTINE YIELD RATINGS PROVIDED IN ANNUAL REPORTS SUBMITTED UNDER SECTION 2 OF THIS CHAPTER. <A]

[A> (2) OTHER INFORMATION PROVIDED IN THE ANNUAL REPORTS SUBMITTED UNDER SECTION 2 OF THIS CHAPTER FOR WHICH THE STATE DEPARTMENT DETERMINES THERE IS A REASONABLE SCIENTIFIC BASIS TO BELIEVE THAT THE AVAILABILITY OF THE INFORMATION MAY REDUCE RISKS TO PUBLIC HEALTH. <A]

[A> SEC. 4. THE STATE DEPARTMENT SHALL ADOPT RULES UNDER IC 4-22-2 THAT: <A]

[A> (1) ESTABLISH THE FORM OF THE ANNUAL REPORTS REQUIRED UNDER THIS CHAPTER; <A]

[A> (2) ESTABLISH DUE DATES FOR ANNUAL REPORTS REQUIRED UNDER THIS CHAPTER; AND <A]

[A> (3) ARE NECESSARY FOR THE ADMINISTRATION OF THIS CHAPTER. <A]

[A> SEC. 5. (A) A MANUFACTURER OF A TOBACCO PRODUCT THAT FAILS TO SUBMIT AN ANNUAL REPORT FOR A BRAND OF TOBACCO PRODUCT AS REQUIRED BY THIS CHAPTER MAY NOT SELL THAT BRAND OF TOBACCO PRODUCT IN INDIANA UNTIL THE REQUIRED ANNUAL REPORT IS SUBMITTED. <A]

[A> (B) IF A MANUFACTURER OF A TOBACCO PRODUCT SELLS A BRAND OF TOBACCO PRODUCT WITHOUT HAVING FILED THE ANNUAL REPORT REQUIRED UNDER THIS CHAPTER, THE ATTORNEY GENERAL SHALL INITIATE PROCEEDINGS TO ENJOIN THE MANUFACTURER FROM SELLING THE TOBACCO PRODUCT IN INDIANA. <A]

SECTION 3. (EFFECTIVE UPON PASSAGE) [A> (A) THE ATTORNEY GENERAL SHALL ADVISE THE STATE DEPARTMENT OF HEALTH BEFORE JULY 1, 1998, AS TO WHETHER ANY PUBLIC DISCLOSURE OF THE INFORMATION REQUIRED IN THE ANNUAL REPORT UNDER IC 16-40-3-2, AS ADDED BY THIS ACT, WOULD BE AN UNCONSTITUTIONAL TAKING OF PROPERTY. <A]

[A> (B) NOTWITHSTANDING IC 16-40-3-3, AS ADDED BY THIS ACT, THE STATE DEPARTMENT OF HEALTH MAY NOT RELEASE INFORMATION TO THE PUBLIC THAT THE STATE DEPARTMENT OF HEALTH BELIEVES WOULD BE AN UNCONSTITUTIONAL TAKING OF PROPERTY. <A]

[A> (C) THIS SECTION EXPIRES JULY 1, 2002. <A]

SECTION 4. [A> AN EMERGENCY IS DECLARED FOR THIS ACT. <A]

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Murphy

LOAD-DATE: January 7, 1998

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IOWA 77TH GENERAL ASSEMBLY -- FIRST SESSION

HOUSE BILL 115

HOUSE FILE 115
BY DODERER

1997 IA H.B. 115

VERSION: Introduced

VERSION-DATE: January 30, 1997

SYNOPSIS:

A BILL FOR

An Act relating to the disclosure of certain information relating to tobacco products and cigarettes sold in the state and providing a penalty.

DIGEST:

EXPLANATION

This bill requires a manufacturer of tobacco products or cigarettes doing business in this state to submit an annual report to the Iowa department of public health which provides information including the identity of any added constituent and the nicotine yield rating of the product. The information submitted is only to be made a public record if the attorney general determines that disclosing the information is not an unconstitutional taking of property. The bill does not require that a manufacturer disclose the specific amount of any ingredient that has been approved by a federal agency as safe when burned and inhaled or which is generally recognized as safe when burned and inhaled by the United States food and drug administration. A manufacturer who violates the requirements of the bill is subject to denial or revocation of a permit and is guilty of a serious misdemeanor.

TEXT: BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. NEW SECTION. 453A.57 DISCLOSURE OF INFORMATION -- TOBACCO PRODUCTS AND CIGARETTES.

1. Any manufacturer of tobacco products or cigarettes sold in this state shall submit to the Iowa department of public health for the prior calendar year, in a form specified by the Iowa department of public health a report annually, on or before January 15 which lists for each brand and product sold

during the prior calendar year, all of the following information:

a. The identity of any added constituent, other than tobacco, water, or reconstituted tobacco sheet made wholly from tobacco, to be listed in descending order according to weight, measure, or numerical count.

b. The nicotine yield ratings, which shall accurately predict nicotine intake for an average consumer, based upon standards to be established by the Iowa department of public health.

2. The nicotine yield ratings provided, and any other information in the annual reports with respect to which the Iowa department of public health determines that there is a reasonable scientific basis for concluding that the availability of the information could reduce risks to public health, shall be public records subject to examination and copying under chapter 22, provided that before the information is publicly disclosed the Iowa department of public health shall request the advice of the attorney general as to whether the disclosure would constitute an unconstitutional taking of property, and shall not disclose the information unless and until the attorney general advises that the disclosure would not constitute an unconstitutional taking.

3. A manufacturer shall not be required to identify or disclose the specific amount of any ingredient that has been approved as safe when burned and inhaled by the United States food and drug administration, the United States public health service, or the United States department of health and human services, or that has been designated by the United States food and drug administration as generally recognized as safe when burned and inhaled.

4. A manufacturer who violates this section is subject to denial of issuance of a permit or revocation of a permit issued under this chapter and is guilty of a serious misdemeanor.

SPONSOR:
Doderer

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IOWA 77TH GENERAL ASSEMBLY -- FIRST SESSION

SENATE BILL 46

SENATE FILE 46
BY HAMMOND

1997 IA S.B. 46

VERSION: Introduced

VERSION-DATE: January 22, 1997

SYNOPSIS:

A BILL FOR

An Act relating to the disclosure of certain information relating to tobacco products and cigarettes sold in the state and providing a penalty.

DIGEST:

EXPLANATION

This bill requires a manufacturer of tobacco products or cigarettes doing business in this state to submit an annual report to the Iowa department of public health which provides information including the identity of any added constituent and the nicotine yield rating of the product. The information submitted is only to be made a public record if the attorney general determines that disclosing the information is not an unconstitutional taking of property. The bill does not require that a manufacturer disclose the specific amount of any ingredient that has been approved by a federal agency as safe when burned and inhaled or which is generally recognized as safe when burned and inhaled by the United States food and drug administration. A manufacturer who violates the requirements of the bill is subject to denial or revocation of a permit and is guilty of a serious misdemeanor.

TEXT: BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. NEW SECTION. 453A.57 DISCLOSURE OF INFORMATION -- TOBACCO PRODUCTS AND CIGARETTES.

1. Any manufacturer of tobacco products or cigarettes sold in this state shall submit to the Iowa department of public health for the prior calendar year in a form specified by the Iowa department of public health a report, annually, on or before January 15, which lists for each brand and product sold during the

prior calendar year, all of the following information:

a. The identity of any added constituent, other than tobacco, water, or reconstituted tobacco sheet made wholly from tobacco, to be listed in descending order according to weight, measure, or numerical count.

b. The nicotine yield ratings, which shall accurately predict nicotine intake for an average consumer, based upon standards to be established by the Iowa department of public health.

2. The nicotine yield ratings provided, and any other information in the annual reports with respect to which the Iowa department of public health determines that there is a reasonable scientific basis for concluding that the availability of the information could reduce risks to public health, shall be public records subject to examination and copying under chapter 22, provided that before the information is publicly disclosed the Iowa department of public health shall request the advice of the attorney general as to whether the disclosure would constitute an unconstitutional taking of property, and shall not disclose the information unless and until the attorney general advises that the disclosure would not constitute an unconstitutional taking.

3. A manufacturer shall not be required to identify or disclose the specific amount of any ingredient that has been approved as safe when burned and inhaled by the United States food and drug administration, the United States public health service, or the United States department of health and human services, or that has been designated by the United States food and drug administration as generally recognized as safe when burned and inhaled.

4. A manufacturer who violates this section is subject to denial of issuance of a permit or revocation of a permit issued under this chapter and is guilty of a serious misdemeanor.

SPONSOR:
Hammond

LEVEL 1 - 1 OF 1 DOCUMENT

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MAINE 118TH LEGISLATURE -- FIRST REGULAR SESSION

SENATE BILL 508

STATE OF MAINE
IN THE YEAR OF OUR LORD
NINETEEN HUNDRED AND NINETY-SIX

1997 ME S.B. 508

VERSION: Introduced

VERSION-DATE: March 18, 1997

NOTICE:
[A> UPPERCASE TEXT WITHIN THESE SYMBOLS IS ADDED <A]

TEXT: Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA Section 1553-B is enacted to read:

[A> SECTION 1553-B. DISCLOSURES RELATED TO TOBACCO PRODUCTS <A]

[A> 1. DEFINITIONS. AS USED IN THIS SECTION, UNLESS THE CONTEXT OTHERWISE INDICATES, THE FOLLOWING TERMS HAVE THE FOLLOWING MEANINGS. <A]

[A> A. "ADDED CONSTITUENT" MEANS ANY **INGREDIENT**, SUBSTANCE, CHEMICAL OR COMPOUND OTHER THAN **TOBACCO**, WATER OR RECONSTITUTED **TOBACCO** SHEET THAT IS KNOWN BY THE MANUFACTURER TO BE ADDED TO THE TOBACCO, PAPER OR FILTER OF A CIGARETTE OR THE TOBACCO OF A SMOKELESS TOBACCO PRODUCT DURING OR THROUGH: <A]

[A> (1) THE GROWING AND PROCESSING OF THE TOBACCO LEAF, INCLUDING THE USE OF PESTICIDE; <A]

[A> (2) THE PROCESSING AND MANUFACTURE OF THE PAPER, PACKAGING AND FILTER USED IN THE CIGARETTE OR SMOKELESS TOBACCO PRODUCT; OR <A]

[A> (3) THE PROCESSING, MANUFACTURE OR PACKING OF THE CIGARETTE OR SMOKELESS TOBACCO PRODUCT, INCLUDING THE USE OF FLAVORANTS, CONTAMINANTS, PROCESSING AIDS, CASING SAUCES, COMBUSTION MODIFIERS AND PACKING MATERIALS. <A]

[A> B. "CIGARETTE" MEANS ANY PRODUCT, INCLUDING COMPONENTS, ACCESSORIES OR PARTS OF THE PRODUCT, THAT CONTAINS OR DELIVERS NICOTINE, IS INTENDED TO BE BURNED UNDER ORDINARY CONDITIONS OF USE, AND CONSISTS OF: <A]

[A> (1) ANY ROLE OF TOBACCO WRAPPED IN PAPER OR IN ANY SUBSTANCE NOT CONTAINING TOBACCO; OR <A]

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[A> (2) ANY ROLL OF TOBACCO WRAPPED IN ANY SUBSTANCE CONTAINING TOBACCO THAT, BECAUSE OF ITS APPEARANCE, THE TYPE OF TOBACCO USED IN THE FILLER, OR ITS PACKAGING AND LABELING, IS LIKELY TO BE OFFERED TO, OR PURCHASED BY, CONSUMERS AS A CIGARETTE. <A]

[A> C. "MANUFACTURER" MEANS ANY PERSON, INCLUDING ANY REPACKER OR RELABELER, WHO MANUFACTURES, FABRICATES, ASSEMBLES, PROCESSES OR LABELS A FINISHED CIGARETTE OR SMOKELESS TOBACCO PRODUCT. THE TERM DOES NOT INCLUDE ANY PERSON WHO ONLY DISTRIBUTES FINISHED CIGARETTES OR SMOKELESS TOBACCO PRODUCTS. <A]

[A> D. "NICOTINE" MEANS THE CHEMICAL SUBSTANCE NAMED 3-(1-METHYL-2-PYRROLIDIYL) PYRIDINE, OR CH10H14N2, INCLUDING ANY SALT OR COMPLEX OF NICOTINE. <A]

[A> E. "SMOKELESS TOBACCO" MEANS ANY CUT, GROUND, POWERED OR LEAF TOBACCO THAT CONTAINS OR DELIVERS NICOTINE AND THAT IS INTENDED TO BE PLACED IN THE ORAL CAVITY WITHOUT BURNING. <A]

[A> 2. ANNUAL DISCLOSURES. FOR THE PURPOSES OF PROTECTING THE PUBLIC HEALTH, ANY MANUFACTURER OF CIGARETTES OR SMOKELESS TOBACCO SOLD IN THE STATE SHALL PROVIDE THE DEPARTMENT WITH AN ANNUAL REPORT, IN A FORM AND AT A TIME SPECIFIED BY THE DEPARTMENT, THAT LISTS FOR EACH BRAND OF THE PRODUCT SOLD THE FOLLOWING INFORMATION: <A]

[A> A. THE IDENTIFY OF ANY ADDED CONSTITUENT TO BE LISTED IN DESCENDING ORDER ACCORDING TO WEIGHT, MEASURE, OR NUMERICAL COUNT; AND <A]

[A> B. THE NICOTINE YIELD RATINGS, WHICH MUST ACCURATELY PREDICT NICOTINE INTAKE FOR AVERAGE CONSUMERS, BASED ON STANDARDS TO BE ESTABLISHED BY THE DEPARTMENT. <A]

[A> 3. PUBLIC RECORDS. THE NICOTINE YIELD RATINGS PROVIDED, PURSUANT TO THIS SECTION, AND ANY OTHER SUCH INFORMATION IN THE ANNUAL REPORTS WITH RESPECT TO WHICH THE DEPARTMENT DETERMINES THAT THERE IS A REASONABLE SCIENTIFIC BASIS FOR CONCLUDING THAT THE AVAILABILITY OF THAT INFORMATION COULD REDUCE RISKS TO PUBLIC HEALTH, ARE PUBLIC RECORDS. BEFORE PUBLIC DISCLOSURE OF ANY SUCH INFORMATION, THE DEPARTMENT SHALL REQUEST THE ADVICE OF THE ATTORNEY GENERAL WHETHER SUCH DISCLOSURE WOULD CONSTITUTE AN UNCONSTITUTIONAL TAKING OF PROPERTY AND MAY NOT DISCLOSE INFORMATION UNTIL THE ATTORNEY GENERAL ADVISES THAT THE DISCLOSURE WOULD NOT CONSTITUTE AN UNCONSTITUTIONAL TAKING. <A]

[A> 4. EXCEPTIONS. THIS SECTION DOES NOT REQUIRE A MANUFACTURER, IN ITS REPORT TO THE DEPARTMENT OR OTHERWISE, TO IDENTIFY OR DISCLOSE THE SPECIFIC AMOUNT OF ANY INGREDIENT THAT HAS BEEN APPROVED BY THE FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, REFERRED TO IN THIS SECTION AS THE FDA, OR ITS SUCCESSOR AGENCY, AS SAFE WHEN BURNED AND INHALED OR THAT HAS BEEN DESIGNATED BY THE FDA, OR ITS SUCCESSOR AGENCY, AS GENERALLY RECOGNIZED AS SAFE WHEN BURNED AND INHALED. <A]

[A> 5. RULES. THE DEPARTMENT SHALL ADOPT RULES NECESSARY TO IMPLEMENT THIS SECTION. RULES ADOPTED UNDER THIS SECTION ARE ROUTINE TECHNICAL RULES PURSUANT TO TITLE 5, CHAPTER 375, SUBCHAPTER II-A. <A]

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SUMMARY

This bill requires manufacturers of cigarettes and smokeless tobacco sold in this State to disclose annually in reports to the Department of Human Services added constituents and nicotine yield ratings. This legislation is modeled on recently enacted Massachusetts law.

SPONSOR:
Mills

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MICHIGAN 89TH LEGISLATURE -- 1997 REGULAR SESSION

HOUSE BILL **4778**

HOUSE BILL NO. **4778**

1997 MI H.B. **4778**

VERSION: Introduced

VERSION-DATE: May 13, 1997

SYNOPSIS:

A bill to require manufacturers to report the ingredients and nicotine content of tobacco products; to prescribe the powers and duties of certain state agencies and officials; and to provide for penalties.

TEXT:

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 1. This act shall be known and may be cited as the "tobacco products reporting act".

Sec. 2. As used in this act:

(a) "Chewing tobacco" means loose tobacco or a flat, compressed cake of tobacco that is inserted into the mouth to be chewed or sucked.

(b) "Cigarette" and "cigar" mean a roll for smoking made wholly or in part of tobacco, irrespective of size or shape and irrespective of the tobacco being flavored, adulterated, or mixed with any other ingredient, which roll has a wrapper or cover made of paper, tobacco, or any other material.

(c) "Department" means the department of community health.

(d) "Manufacturer" means a person who manufactures or produces a tobacco product.

(e) "Noncigarette smoking tobacco" means tobacco sold in loose or bulk form that is intended for consumption by smoking.

(f) "Smokeless tobacco" means snuff, chewing tobacco, and any other tobacco that is intended to be consumed by means other than smoking.

(g) "Snuff" means shredded, powdered, or pulverized tobacco that may be inhaled through the nostrils, chewed, or placed against the gums.

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(h) "Tobacco product" means cigarettes, cigars, noncigarette smoking tobacco, or smokeless tobacco.

Sec. 3. A manufacturer shall not sell a tobacco product in this state unless the manufacturer has complied with this act.

Sec. 4. (1) Not later than February 1, 1998, a manufacturer of tobacco products sold in this state shall file with the department, on a form provided by the department, a report for each brand of tobacco product providing all of the following information:

(a) Any ingredient of the tobacco product, other than tobacco, water, or reconstituted tobacco sheet made wholly form tobacco. The ingredients shall be listed in descending order according to weight, measure, or numerical count. However, the manufacturer does not have to list the specific weight, measure, or numerical count of the ingredients.

(b) Nicotine yield ratings of the tobacco product. Nicotine yield ratings shall be established by the department and shall accurately predict nicotine intake for average consumers.

(2) After January 1, 1998, if a manufacturer introduces a new tobacco product or changes the ingredients or nicotine yield of an existing tobacco product, not later than 60 days from the introduction or change, the manufacturer shall file with the department a report as required by subsection (1) for the new or changed tobacco product.

(3) This act does not require a manufacturer to identify or disclose the specific amount of any ingredient identified by the United States department of health and human services, food and drug administration, as generally recognized as safe when burned and inhaled.

Sec. 5. (1) The report filed under section 4 is a public record subject to the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.

(2) The department shall file with the legislature an annual report listing all filings and providing the information required by this act.

Sec. 6. A manufacturer that violates section 3 or 4 knowingly provides false information under section 4 is responsible for a state civil infraction and may be ordered to pay a civil fine of not more than $ 1,000.00 for each day the manufacturer is in violation.

Enacting section 1. This act takes effect January 1, 1998.

SPONSOR:
Fitzgerald

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NEW JERSEY 208TH LEGISLATURE

ASSEMBLY BILL **1257**

ASSEMBLY, NO. **1257**
STATE OF NEW JERSEY
208TH LEGISLATURE
PRE-FILED FOR INTRODUCTION IN THE 1998 SESSION
SPONSORED BY:
ASSEMBLYMAN KEVIN J. O'TOOLE
INTRODUCED PENDING TECHNICAL REVIEW BY LEGISLATIVE COUNSEL.

1998 NJ A.B. **1257**

VERSION: Introduced

VERSION-DATE: January 13, 1998

SYNOPSIS:

An Act requiring disclosure of certain information relating to tobacco products and supplementing Title 24 of the Revised Statutes.

DIGEST:

STATEMENT

This bill requires a manufacturer of cigarettes, snuff or chewing tobacco sold in this State to provide the Department of Health and Senior Services with an annual report, in a form and manner specified by the Commissioner of Health and Senior Services, which lists for each brand of tobacco product sold, the following information:

a. The identity of any added constituent other than tobacco, water or reconstituted tobacco sheet made wholly from tobacco, to be listed in descending order according to weight, measure or numerical count; and

b. The nicotine yield ratings, which shall accurately predict nicotine intake for average consumers, based on standards established by the department.

The nicotine yield ratings provided to the department and any other information in the annual report with respect to which the department determines that there is a reasonable scientific basis for concluding that the availability of the information could reduce risks to public health, shall be considered a public record, except that, before the department provides any public disclosure of the information, the department shall request the advice of the Attorney

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General whether the disclosure would constitute an unconstitutional taking of property, and shall not disclose the information until the Attorney General advises that the disclosure would not constitute an unconstitutional taking.

The bill also provides that it shall not require a manufacturer, in its report to the department or otherwise, to identify or disclose the specific amount of any ingredient that has been approved by the Food and Drug Administration (FDA) as safe when burned and inhaled, or that has been designated by the FDA as generally recognized as safe when burned and inhaled, according to the Generally Recognized As Safe list of the FDA.

The provisions of this bill are based on a recently enacted statute in Massachusetts.

TEXT: Be It Enacted by the Senate and General Assembly of the State of New Jersey:

1. a. A manufacturer of cigarettes, snuff or chewing tobacco sold in this State shall provide the Department of Health and Senior Services with an annual report, in a form and manner specified by the Commissioner of Health and Senior Services, which lists for each brand of tobacco product sold, the following information:

(1) The identity of any added constituent other than tobacco, water or reconstituted tobacco sheet made wholly from tobacco, to be listed in descending order according to weight, measure or numerical count; and

(2) The nicotine yield ratings, which shall accurately predict nicotine intake for average consumers, based on standards established by the department.

b. The nicotine yield ratings provided pursuant to paragraph (2) of subsection a. of this section and any other information in the annual report with respect to which the department determines that there is a reasonable scientific basis for concluding that the availability of the information could reduce risks to public health, shall be considered a public record, except that, before the department provides any public disclosure of the information, the department shall request the advice of the Attorney General whether the disclosure would constitute an unconstitutional taking of property, and shall not disclose the information until the Attorney General advises that the disclosure would not constitute an unconstitutional taking.

c. The provisions of this section shall not require a manufacturer, in its report to the department, or otherwise, to identify or disclose the specific amount of any ingredient that has been approved by the Food and Drug Administration in the United States Department of Health and Human Services as safe when burned and inhaled, or that has been designated by the Food and Drug Administration as generally recognized as safe when burned and inhaled, according to the Generally Recognized As Safe list of the Food and Drug Administration.

2. The Commissioner of Health and Senior Services, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), shall adopt rules and regulations necessary to carry out the purposes of this act.

3. This act shall take effect January 1, 1997.

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SPONSOR:
O'Toole
LOAD-DATE: January 17, 1998

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NEW YORK 220TH ANNUAL LEGISLATIVE SESSION

SENATE BILL **2622**

STATE OF NEW YORK
2622
1997-1998 REGULAR SESSIONS
IN SENATE
FEBRUARY 13, 1997
INTRODUCED BY SENS. LACHMAN, ABATE, KRUGER, OPPENHEIMER, SAMPSON, SANTIAGO,
SMITH, WALDON -- READ TWICE AND ORDERED PRINTED, AND WHEN PRINTED TO BE
COMMITTED TO THE COMMITTEE ON HEALTH

1997 NY S.B. **2622**

VERSION: Introduced

VERSION-DATE: February 13, 1997

SYNOPSIS:

AN ACT to amend the public health law, in relation to requiring disclosure of certain information by manufacturers of cigarettes

NOTICE:
[A> UPPERCASE TEXT WITHIN THESE SYMBOLS IS ADDED <A]

TEXT: THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. The public health law is amended by adding a new article 49-A to read as follows: [A> ARTICLE 49-A DISCLOSURE BY MANUFACTURERS OF CIGARETTES <A]

[A> SECTION 4950. DISCLOSURE REQUIRED. <A]

[A> 4951. VIOLATIONS. <A]

[A> 4952. TRADE SECRETS. <A]

[A> 4953. REPORTS. <A]

[A> 4950. DISCLOSURE REQUIRED. 1. FOR THE PURPOSE OF PROTECTING THE PUBLIC HEALTH, ANY MANUFACTURER OF CIGARETTES SOLD IN THE STATE SHALL PROVIDE TO THE DEPARTMENT AN ANNUAL REPORT, IN A FORM AND AT A TIME SPECIFIED BY THE DEPARTMENT, WHICH CONTAINS THE FOLLOWING INFORMATION FOR EACH PRODUCT SOLD: <A]

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[A> (A) THE IDENTITY OF ANY CONSTITUENT OTHER THAN TOBACCO, WATER OR RECONSTITUTED TOBACCO SHEET MADE WHOLLY FROM TOBACCO, TO BE LISTED IN DESCENDING ORDER ACCORDING TO WEIGHT, MEASURE OR NUMERICAL COUNT; AND <A]

[A> (B) THE NICOTINE YIELD RATINGS, WHICH SHALL ACCURATELY PREDICT NICOTINE INTAKE FOR AVERAGE CONSUMERS BASED ON STANDARDS TO BE ESTABLISHED BY THE DEPARTMENT. <A]

[A> 2. THE NICOTINE YIELD RATINGS PROVIDED, AND ANY OTHER INFORMATION IN THE ANNUAL REPORTS WHICH THE DEPARTMENT DETERMINES THAT THERE IS A REASONABLE SCIENTIFIC BASIS FOR CONCLUDING THAT THE AVAILABILITY OF SUCH INFORMATION COULD REDUCE RISKS TO PUBLIC HEALTH, SHALL BE PUBLIC RECORDS. <A]

[A> 3. THE PROVISIONS OF THIS SECTION SHALL NOT BE DEEMED TO REQUIRE A MANUFACTURER, IN ITS REPORT TO THE DEPARTMENT OR OTHERWISE, TO IDENTIFY OR DISCLOSE THE SPECIFIC AMOUNT OF ANY INGREDIENT THAT HAS BEEN APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) AS SAFE WHEN BURNED AND INHALED OR THAT HAS BEEN DESIGNATED BY THE FDA AS GENERALLY RECOGNIZED AS SAFE WHEN BURNED OR INHALED, ACCORDING TO THE "GENERALLY RECOGNIZED AS SAFE" LIST MAINTAINED BY THE FDA. <A]

[A> 4951. VIOLATIONS. WHERE A VIOLATION OF SECTION FOUR THOUSAND NINE HUNDRED FIFTY OF THIS ARTICLE IS ALLEGED TO HAVE OCCURRED, THE ATTORNEY GENERAL MAY APPLY IN THE NAME OF THE PEOPLE OF THE STATE OF NEW YORK TO THE SUPREME COURT OF NEW YORK ON NOTICE OF FIVE DAYS, FOR AN ORDER COMPELLING COMPLIANCE WITH THIS ARTICLE. IN ANY SUCH PROCEEDING THE COURT MAY IMPOSE A CIVIL PENALTY IN AN AMOUNT NOT TO EXCEED FIVE THOUSAND DOLLARS FOR EACH VIOLATION. <A]

[A> 4952. TRADE SECRETS. THE INFORMATION SUBMITTED TO THE COMMISSIONER AND ANY REQUESTS FOR SUCH INFORMATION SHALL BE SUBJECT TO THE PROVISIONS OF ARTICLE SIX OF THE PUBLIC OFFICERS LAW. <A]

[A> 4953. REPORTS. THE COMMISSIONER SHALL SUBMIT A REPORT TO THE GOVERNOR AND THE LEGISLATURE WITHIN ONE YEAR OF THE EFFECTIVE DATE OF THIS ARTICLE ON THE INFORMATION SUBMITTED TO HIM OR HER PURSUANT TO THE PROVISIONS OF THIS ARTICLE ALONG WITH RECOMMENDATIONS HE OR SHE DEEMS APPROPRIATE. <A]

2. This act shall take effect on the thirtieth day after it shall have become a law provided, however, that the commissioner of health shall promulgate any rules or regulations necessary for the timely implementation of this act on or before such effective date.

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APPENDIX C

Outline of Steps for Validation Process

I. Test Development

II. Prevalidation/Test Optimization

A. Preliminary planning

1. Define basis and purpose of test
2. Develop protocol
3. Develop control values
4. Develop data/outcome prediction model

B. Activities

1. Qualify and train laboratories
2. Measure intra- and interlaboratory reproducibility
3. Identify limitations of test

III. Determine Readiness for Validation

A. Analyze test development and prevalidation data

B. Standardize protocol

IV. Test Validation

A. Form steering committee/management team

1. Define purpose of validation study
2. Design study
3. Select participating laboratories
4. Establish management evaluation and oversight procedures

B. Pretest procedures

1. Implement data recordkeeping procedures
2. Select reference sample
3. Code and distribute reference sample

C. Test coded sample

1. Measure interlaboratory performance
2. Compile and evaluate data

D. Evaluate test

1. Analyze and summarize test results
2. Challenge data with prediction model
3. Peer review of protocol and data
4. Accept, revise, or reject model

V. Submission of Test for Regulatory Approval

A. Prepare report

B. Make supporting data available

C. Prepare results for publication