



PHILIP MORRIS

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DR. RICHARD H. COX
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CONFIDENTIAL

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December 1, 1998

BY HAND

Gregory N. Connolly, D.M.D., M.P.H.
Director, Massachusetts Tobacco Control Program
Massachusetts Department of Public Health
250 Washington Street, Fourth Floor
Boston, Massachusetts 02108

**Re: 1998 Annual Report of Philip Morris Incorporated -
Nicotine Yield Rating Information**

Dear Dr. Connolly:

In accordance with Massachusetts General Laws, Chapter 94, Section 307B, the regulations promulgated by the Department of Public Health ("DPH") pursuant thereto, and discussions with you, Mr. Saxner and your scientific advisor, Dr. William Rickert, Philip Morris Incorporated ("Philip Morris") hereby submits its 1998 annual report to the DPH. In addition to this hard copy submission, Philip Morris submits the attached disc containing its submission in electronic form.

In accordance with Sections 660.102 (A)(1) and (B)(1) of the Code of Massachusetts Regulations ("CMR"), this comprehensive annual report includes in Attachment A the "most recent nicotine level" reported to the Federal Trade Commission ("FTC"), as published in the FTC Report in 1998 entitled "*Tar, Nicotine, and Carbon Monoxide of the Smoke of Varieties of Domestic Cigarettes*" (the "FTC Report"), for each cigarette brand style and generic cigarette manufactured by Philip Morris and distributed within the Commonwealth of Massachusetts.

The FTC Report included brand styles collected in 1995 by the Tobacco Institute Testing Laboratory for inclusion in Market Sample #38. Attachment B, the "Cigarette Nicotine Yield Rating Forms", includes the average per cigarette nicotine delivery, determined by Philip Morris in accordance with the FTC method, of certain

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Philip Morris brand styles distributed within the Commonwealth of Massachusetts but not included in Market Sample #38 and therefore not included in Attachment A.

In accordance with Section 660.102(A) and (B) of the CMR and our subsequent agreement, Attachment B contains additional nicotine yield rating information for each cigarette brand style and generic cigarette manufactured by Philip Morris and distributed within the Commonwealth of Massachusetts with a national market share in excess of three percent of the United States cigarette market as reported in the year-end 1997 and second-quarter 1998 Maxwell Reports published by Davenport & Company LLC as successor publisher of Maxwell Reports to Wheat First Butcher Singer. The Marlboro and Basic brand families of cigarettes are the Philip Morris brand families satisfying the criteria of a national market share greater than three percent, and both brand families include brand styles currently distributed within the Commonwealth of Massachusetts. Therefore, Philip Morris provides the information included in Attachment B, in the form requested by the DPH, with respect to all Marlboro and Basic brand styles manufactured by Philip Morris and currently distributed within the Commonwealth of Massachusetts.

Attachment B also contains nicotine yield rating test results for brand styles designated orally on July 17, 1998 by Mr. Jeff Wayne on behalf of the DPH in response to the written request of Philip Morris dated July 8, 1998, a copy of which is included as Attachment C. The additional brand styles designated by DPH are listed in Attachment D.

As you requested, the additional brand styles listed in Attachment D were also tested to determine the "pH" of smoke on a puff-by-puff basis. In accordance with our agreement, Philip Morris did not test the "pH" of smoke pursuant to Section 660.500(D) of the CMR.

In accordance with Section 660.102(A)(4) of the CMR and our subsequent agreement, a quadratic equation relating Massachusetts and FTC smoke nicotine yields was derived by the industry from 1997 Massachusetts smoke nicotine testing data and smoke nicotine yields reported by the FTC in 1997 for the same brand styles. The quadratic equation was applied to all Philip Morris brand styles distributed in Massachusetts with a market share of less than three percent as reported in the year-end 1997 and second-quarter 1998 Maxwell Reports. The resultant calculated nicotine yield data are included in Attachment B. Additional details of the quadratic equation and its application are provided in Attachment E.

Sampling and Conditioning

The cigarettes tested for total nicotine content, percent filter tip ventilation, "pH" of cigarette smoke measured pursuant to a puff-by-puff method, and nicotine delivery under "average smoking conditions" were collected through a market sampling conducted at the wholesale level in accordance with your advance approval. The samples were conditioned in accordance with the guidelines set forth in Standard 3402, entitled "Tobacco and tobacco products - Atmosphere for conditioning and testing", of the International Organization for Standardization and the CMR. Philip Morris retained thirty-five samples of each brand style for internal testing. Twenty-five samples of each brand style were previously delivered to your attention for analysis by the DPH.

Test Methodologies

With the exception of the FTC testing methods referenced above, all of the procedures designated by the DPH, namely, the testing of total nicotine content in filler, percent filter tip ventilation measurement, "pH" of cigarette smoke pursuant to a puff-by-puff method, and nicotine delivery under "average smoking conditions" (as defined by DPH), are non-validated procedures. Philip Morris urges that appropriate procedures be developed and validated prior to submission of the 1999 Annual Report or as soon as possible thereafter.

Philip Morris remains willing to participate in a cigarette industry inter-laboratory validation process for each of the recommended procedures discussed below and would welcome the participation of DPH or its designee in such a validation process.

Nicotine Measurement

In accordance with our discussions, in an effort to both comply with Section 660.102(B)(2) of the CMR and address concerns previously raised, Philip Morris measured the quantity of nicotine contained in the cigarette filler utilizing a methodology equivalent to the Center for Disease Control's "Protocol for Analysis of Nicotine, Total Moisture and pH in Smokeless Tobacco Products" published in the Federal Register on May 2, 1997, Vol. 62, No. 85, pp. 24115-9 (the "CDC Protocol").

In the interest of completeness, Philip Morris restates here the concerns previously raised with utilization of the CDC Protocol to measure the nicotine content in cigarette filler, as opposed to measuring nicotine content in the six categories of smokeless tobacco products for which the CDC Protocol was developed.

Philip Morris remains concerned with the "Quality Control Pool" referenced at page 24117, Par.II.C. of the Federal Register. The CDC Protocol states that the "smokeless tobacco product should be enriched with nicotine at the high and low ends of expected values for the smokeless tobacco product". As previously discussed with you, Philip Morris did not follow the CDC Protocol regarding the "Quality Control Pool" for two reasons: (1) Philip Morris was concerned that the addition of extraneous nicotine to the sample of tobacco could result in a nonhomogeneous sample, causing inaccurate test results; and, (2) Philip Morris was concerned with safety issues related to enriching cigarette filler with extraneous nicotine, a procedure that is not practiced in Philip Morris laboratories.

In addition, Philip Morris remains concerned with various calculations described in the CDC Protocol. For example, Equation 3 (referenced at page 24118, Par.II.D.8 of the Federal Register) - which is used to calculate the amount of nicotine in the cigarette filler - may be inaccurate because of a flawed recovery factor. The recovery factor may be flawed because the nicotine and internal standard concentrations (referenced at page 24117, Par.II.B of the Federal Register) do not have adequate corrections for dilution effects.

The equivalent method utilized by Philip Morris in lieu of the CDC Protocol for measuring the quantity of nicotine contained in the cigarette filler is CORESTA Recommended Method No. 35, "Determination of Total Alkaloids (as nicotine) in Tobacco by Continuous Flow Analysis", dated November 1994 ("Coresta Method 35"). Minor modifications were made to Coresta Method 35 in order to accommodate existing laboratory equipment and related procedural requirements. Coresta Method 35 is an internationally recognized test method Philip Morris determined was preferable to the CDC Protocol. Philip Morris submits, as Attachment F, a description of the methodology reflecting the procedure followed by Philip Morris and previously explained to you.

Section 660.102(B)(2) of the CMR requires manufacturers to report the measurement of the quantity of nicotine content in cigarette filler on a per cigarette basis. Philip Morris is here reporting the total nicotine content on a milligram per gram of tobacco basis, which is consistent with the CDC Protocol originally designated by the DPH and the reporting method we subsequently agreed upon. In recognition of your request for like information earlier this year, Philip Morris is also providing, in Attachment G, the tobacco weight of each of the brand styles tested.

Please note that, as was true for the test results reported by Philip Morris in 1997, the testing did not disclose a correlation between nicotine content in the cigarette and nicotine delivery under "average smoking conditions." In light of that fact, the test

results reported do not disclose a meaningful basis for distinguishing among any of the brand styles tested. Philip Morris therefore respectfully requests that the DPH eliminate from the regulations the obligation to measure and report the quantity of nicotine contained in the cigarette filler.

Filter Tip Ventilation Measurement

As was done in connection with the 1997 annual report, Philip Morris measured Percent Filter Tip Ventilation in accordance with Section 660.102(B)(3) of the CMR utilizing a Fidus instrument identical in functionality to the Filter Dilution (Ventilation) Testing Instrument (FDT) product no. FDT 232 required to be utilized by Section 660.102(B)(3) and producing similar results.

Philip Morris continues to urge consideration of the International Organization of Standardization method 9512, "Cigarettes - Determination of ventilation - Definitions and measurement principles", for measuring percent filter tip ventilation.

"pH" Measurement Pursuant to a Puff-by-Puff Method

The measurement of "pH" is, by definition, a measurement of the degree of the acidity or alkalinity of an aqueous solution. Cigarette smoke, which is an aerosol comprising a vapor phase and a particulate phase, is not an aqueous solution and therefore does not meet the criteria for "pH" measurement. The "pH" of smoke is reported here in quotes to indicate that what is reported are not actual or true measurements but rather empirical measurements dependent upon the conditions under which the measurements are made. As Philip Morris noted in prior submissions, Philip Morris does not believe that the evaluation of smoke "pH" data provides meaningful or insightful information into the chemical nature of smoke.

Philip Morris is not aware of a standard or accepted method used by the cigarette industry or others to conduct a "pH" of smoke measurement. However, given your request that a "puff-by-puff" method be applied, Philip Morris developed, utilized and submits the attached test results generated by the method detailed in Attachment H, which was previously presented to your scientific advisor, Dr. Rickert.

The method detailed in Attachment H for the puff by puff "pH" of smoke determination consists of isolating and capturing a single puff of mainstream cigarette smoke at a specified interval (i.e. puff number) during the smoking process. The puff is generated using a linear analytical smoking machine and is collected in a glass impinger containing a degassed 0.1 N potassium chloride aqueous solution. The "pH" measurement is performed on the aqueous solution, after smoke collection, using a pH

meter equipped with a glass combination electrode with Ag/AgCl internal reference element. Philip Morris believes that the method should be reproducible across laboratories.

In light of the fact that neither the test results reported in 1997 for the "pH" of smoke measured on a per cigarette basis, nor the test results reported in Attachment B for the "pH" of smoke measured on a puff-by-puff basis, disclose a meaningful basis for distinguishing among any of the brand styles tested, Philip Morris therefore respectfully reiterates its request that the requirement for testing the "pH" of smoke be eliminated in its entirety from the regulations.

If DPH continues to require "pH" of smoke testing, Philip Morris again urges the implementation of a cigarette industry inter-laboratory validation process and would welcome the participation of DPH or its designee in that process.

Nicotine Delivery Under "Average Smoking Conditions"

In confirmation of prior discussions and as explained in the industry's letter to you dated April 8, 1998, Philip Morris tested sixty cigarettes of each brand style, smoking three cigarettes per each of twenty ports in order to determine nicotine delivery under "average smoking conditions". A copy of the April 8th letter, without the annexures originally delivered to you, is included as Attachment I.

Philip Morris suggests that an improved procedure should be developed and validated prior to submission of the 1999 Annual Report or as soon as possible thereafter. Such a procedure should be developed through a cigarette industry inter-laboratory validation study and Philip Morris welcomes the participation of DPH or its designee.

Miscellaneous

Please note, when reviewing the reported puff counts for nicotine delivery under "average smoking conditions" (average of 60 cigarettes) and "pH" of smoke (average individual puff of 2 cigarettes), that the natural variation of the cigarette product, in addition to the variation associated with the smoking process, can result in a reported "pH" puff count that differs by approximately one puff per cigarette from the reported puff count for nicotine delivery under "average smoking conditions" for samples of the same cigarette brand style.

As previously noted in Philip Morris' 1997 annual report, the 43 milliliter puff volume referenced in Section 660.500(E)(1) is inconsistent with the 45 milliliter puff volume required by Section 660.102(B)(5) of the CMR with respect to nicotine delivery under "average smoking conditions". Philip Morris used the 45 milliliter puff volume required by Section 660.102(B)(5) to calculate the nicotine delivery under "average smoking conditions". The Philip Morris method utilized to measure the "pH" of smoke on a puff-by-puff basis also used the 45 milliliter puff volume.

Designated Contact

The complete name, title, business address and telephone number of the individual designated by Philip Morris as the DPH contact person for inquiries related to 105 CMR 660.000 et seq. follows.

Dr. Richard Cox
Vice President, Scientific Technical Services
Philip Morris Research, Development & Engineering
2000 Bells Road
Gate S/Door 100
Richmond, Virginia 23234
(804) 274-4806

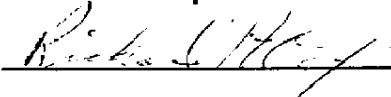
Dr. Cox is familiar with the nicotine yield rating information set forth herein.

Gregory N. Connolly, D.M.D., M.P.H.
Director, Massachusetts Tobacco Control Program
Massachusetts Department of Public Health
December 1, 1998
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Please acknowledge your receipt of the 1998 Annual Report of Philip Morris Incorporated by signing and returning one copy of this letter in the pre-addressed, postage paid mailer provided for your convenience.

Sincerely,

Philip Morris Incorporated

By: 

Title: Vice President, Scientific Technical Services

ACKNOWLEDGMENT OF RECEIPT

Commonwealth of Massachusetts

By: _____

Title: _____

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