# Attachment 8

# Public Comments from 60-day FRN

# July 23, 2012

AMERICAN LUNG ASSOCIATION®
Fighting for Air

Albert A. Rizzo, M.D.
Chair
National Board of Directors

Ross P. Lanzafame, Esq.
Chair-Elect
National Board of Directors

H. James Gooden
Past-Chair

Christine L. Bryant
Secretary/Treasurer

Geri Reinardy, M.P.A.
Speaker
Nationwide Assembly

Marcia D. Williams, Ed.D.
Speaker-Elect
Nationwide Assembly

NATIONAL HEADQUARTERS

Charles D. Connor
President &
Chief Executive Officer

1301 Pennsylvania Ave., NW
Suite 800
Washington, DC 20004-1725
Phone: (202) 785-3355
Fax: (202) 452-1805

14 Wall St.
Suite 8C
New York, NY 10005-2113
Phone: (212) 315-8700
Fax: (212) 608-3219

www.LungUSA.org

June 7, 2012

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

RE: FR Doc No: 2012-12017

Dear Dr. Collins:

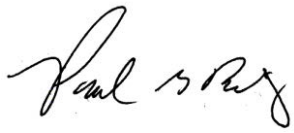
The American Lung Association wishes to express its support for the efforts of the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) in the launching of the Population Assessment of Tobacco and Health study (PATH) to monitor and evaluate the effects of FDA regulation of tobacco products. The American Lung Association is proud of our role in fighting for the passage of the Family Smoking Prevention and Tobacco Control Act, and this effort to evaluate its impacts on public health and behavior is crucial to its success. With this study and other activities, NIH will play an invaluable role with the FDA in implementing this legislation and saving lives.

Establishing the PATH study will allow the tobacco control community and public to see the positive effects of regulating tobacco product advertising, labeling, marketing, constituents, ingredients and additives. This system will be invaluable in informing the public of the positive effects of tobacco regulation and measuring the long term health and behavior of tobacco consumers.

A careful evaluation of FDA's policies such as this will help understand the impact FDA's policies have on tobacco use and ultimately drive down the rate of tobacco use in the United States. Reducing tobacco use will prevent disease, save lives and reduce tobacco-related health care costs. As you know, the 45 million Americans who currently smoke are at heightened risk for a variety of cancers, heart disease, chronic obstructive pulmonary disease, and other serious medical conditions.

The American Lung Association strongly supports the FDA and NIH's mission to improve the health of the American people. We are encouraged by NIH and FDA's efforts to measure the impact of current and future smoking regulations and communications. Thank you for you continued leadership.

Sincerely,



Paul Billings, Vice President of National Policy and Advocacy
American Lung Association

Cc: Dr. Margaret Hamburg, Commissioner, Food and Drug Administration
Dr. Laurence Deyton, Director, Center for Tobacco Products

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute on Drug Abuse
Bethesda, Maryland 20892

June 20, 2012

Mr. Paul Billings
Vice President
National Policy and Advocacy
American Lung Association
1301 Pennsylvania Avenue, N.W.
Suite 800
Washington, D.C. 2004-1725

Dear Mr. Billings:

Thank you for your letter to Dr. Francis S. Collins, Director of the National Institutes of Health (NIH), in support of the efforts of the NIH and the Food and Drug Administration (FDA) in launching the Population Assessment of Tobacco and Health (PATH) study. Your letter has been forwarded to the National Institute on Drug Abuse for reply.

We agree that this research will provide important new data on tobacco use behaviors in the U.S. population and on the near- and long-term effects of tobacco use on the health of individuals and of the Nation. The NIH and FDA together have long recognized that tobacco use is the leading preventable cause of disease and death in the U.S., including cancers, heart disease, chronic obstructive pulmonary diseases, and other serious medical conditions. This new collaboration will measure the population-based impact of tobacco product use on public health. Its data will inform new efforts to promote public understanding of the contents and consequences of tobacco use on health; to reduce tobacco use initiation among our Nation's youth; to help those who use tobacco to quit; and to advance the scientific knowledge base for FDA's development, implementation, and evaluation of effective tobacco product regulations to reduce the toll of tobacco-related disease, disability, and death.

Thank you again for the expression of support by the American Lung Association for the PATH study.

Sincerely,

Nora D. Volkow, M.D.
Director

cc: Dr. Margaret Hamburg, Commissioner, Food and Drug Administration
Dr. Lawrence Deyton, Director, Center for Tobacco Products

Altria
Altria Client Services

**Jane Y. Lewis, Ph.D.**
Senior Vice President
Tobacco Regulatory & Health Sciences

July 17, 2012

Kevin P. Conway, Ph.D.
National Institute on Drug Abuse
6001 Executive Blvd., Room 5185
Bethesda, Maryland 20892-9561

**Re: 77 Fed. Reg. 29,667 (May 18, 2012) – Comments on the "Population Assessment of Tobacco and Health (PATH) Study"**

Dear Dr. Conway:

Altria Client Services ("ALCS")[1] submits these comments on the above-captioned study described in the May 18, 2012 Federal Register notice (the "Federal Register Notice").[2] The Federal Register Notice solicits comments on the Population Assessment of Tobacco and Health Study (the "PATH Study"), a national longitudinal cohort study that the National Institute on Drug Abuse ("NIDA") plans to initiate in 2013. The Federal Register Notice describes the PATH Study purpose as establishing "a population based framework for monitoring and evaluating the behavioral and health impacts of regulatory provisions by FDA as it meets its mandate under the Family Smoking Prevention and Tobacco Control Act."

The Federal Register Notice indicates NIDA is seeking input on the proposed PATH Study design and that it plans to field test the PATH Study design prior to implementation. We obtained the PATH Study data collection plans and instruments[3] from NIDA and offer four suggestions to improve the quality, utility, and clarity of the information NIDA intends to collect.

---

[1] Altria Client Services ("ALCS") is making this submission on behalf of Philip Morris USA ("PM USA"), U.S. Smokeless Tobacco Company ("USSTC") and John Middleton Co. ("JMC"). ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" is used throughout to refer to PM USA, USSTC and JMC.

[2] See 77 Fed. Reg. 29,667 (May 18, 2012), available at: http://www.gpo.gov/fdsys/pkg/FR-2012-05-18/pdf/2012-12017.pdf.

[3] Our comments on the PATH Study data collection plans and instruments refer to the "*Supporting Statement B for Population Assessment of Tobacco and Health (PATH) Study (NIDA)*" (hereinafter the "Supporting Statement") and "*Attachment 2 PATH Study Data Collection Instruments*" (hereinafter the "Data Collection Instruments"), both dated April 30, 2012.

Altria Client Services Inc.
2325 Bells Road
Richmond, VA 23234
(804) 335-2610
Jane.Y.Lewis@altria.com

First, we ask NIDA to examine its use of dichotomous, "yes" or "no" question formats throughout the PATH Study. The Supporting Statement indicates, "[m]any of the major objectives of the PATH study require the estimation of the prevalence of various tobacco-related attitudes, behaviors, health consequences, and changes in these measures over time. In order to achieve these objectives, the PATH study was designed to produce reliable estimates for these characteristics for various population sub-groups. Characteristics of most interest are dichotomous, having "yes" or "no" outcomes." We agree that "yes/no" questions present practical advantages in that they are easy to construct, administer and score. They are also well suited to questions with simple "yes/no" responses.[4]

The Data Collection Instruments, however, sometimes use "yes/no" questions where other question formats could provide more complete information. For example, the Data Collection Instruments contain two "yes/no" questions to examine adult respondents' first use of cigarettes:

- "When you first started smoking cigarettes, did you start with cigarettes flavored to taste like menthol or mint?"
- "When you first started smoking cigarettes, did you start with cigarettes flavored with clove, spice, alcohol (wine or cognac), candy, fruit, chocolate, or other sweets?"[5]

The Data Collection Instruments contain similar "yes/no" questions to examine youth respondents' first use of cigarettes, as well as adult and youth respondents' first use of other tobacco products.[6] Limited and narrowly constructed "yes/no" questions on complex topics, such as initiation, would fail to capture and convey other relevant factors.[7] Further, the dichotomous format may not capture complete information where more than one answer may exist.[8]

Second, we ask NIDA to consider steps to enhance the quality of the brand information that the PATH Study will collect. For example, the Data Collection Instruments ask adult respondents to identify the cigarette brand they "last purchased" and the cigarette brand they "regularly smoke" by selecting from images of "major brands" on a touch screen.[9] The Data Collection Instruments

---

[4] *See, e.g.*, questions HM0009, HM0010, AG1002.

[5] *See* question AC1008.

[6] *See* questions AE1008, AP1008, AH1008, AU1008, AS1008, AD1008, YC1008, YX1008, YE1101, YG1014, YP1009, YH1018, YU1009, YS1009, YD1009, and YX0009.

[7] *i.e.*, are there other circumstantial factors, such as product availability, or other product attributes that also may have influenced initiation. A question format offering respondents multiple response options, including a self-described response if the prelisted options are insufficient, could collect other relevant information.

[8] For example, in question AC1008, a respondent could have "started" smoking both flavored and non-flavored cigarettes. The "yes/no" format would not accurately capture this scenario.

[9] *See* question AC1045 and AC1048. If none of the "major brands" are applicable, respondents can describe their brand in a subsequent question.

ask respondents to provide similar brand information on their use of other tobacco products.[10] The Data Collection Instruments do not provide a definition of a "brand" or copies of the images that they will provide to respondents; we are, therefore, unable to discern what level of brand detail NIDA will prompt respondents to provide. We encourage NIDA to prompt respondents to report product-level information.[11] NIDA could achieve this by providing respondents a comprehensive selection of product label images to choose from[12] or providing a clear definition of a "brand."[13] Such steps could increase the consistency and utility of brand information that the PATH Study collects.

Third, we encourage NIDA to take steps to address data misinterpretation due to acquiescence effects in the proposed PATH Study.[14] Research suggests that acquiescence effects of up to 10% may occur in surveys that depend heavily on the use of dichotomous questions.[15] While the intent of the PATH Study is to "[p]rovide an empirical evidence base to inform the development, implementation, and evaluation of tobacco-product regulations in the U.S.," it is unclear from the available documents what, if any, steps NIDA will take to deal with this form of response bias. NIDA should convey the measures or controls it plans to take to address this effect in the PATH Study.

Lastly, we ask NIDA to publish the final proposed 2013 PATH Study design if results from the field test suggest the need for further study design changes. This would enable a variety of stakeholders to provide input on any proposed changes.

---

[10] *See* questions AE1045, AE1048, AG1045, AG1048, AP1045, AP1048, AH1045, AH1048, AU1045, AU1048, AS1045, AS1048, AD1045, AD1048, YC1018, YC1021, YE1015, YE1019, YG1018, YG1021, YX1012, YX1014, YH1020, YH1023, YU1013, YU1016, YS1013, YS1016, YD1013, YD1016, YX0010, and YX0013.

[11] Subsequent questions suggest that the Data Collection Instruments will collect some product-level information on products that respondents may possess at the time of study participation (e.g., collecting barcode data). *See, e.g.*, question AX0214.

[12] Under the Family Smoking Prevention and Tobacco Control Act ("FSPTCA"), manufacturers are required to provide the Food and Drug Administration, on a bi-annual basis, a complete listing of currently manufactured products, including a copy of product labels. *See* 21 U.S.C §387e.

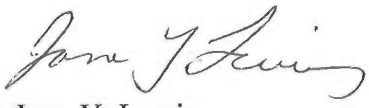
[13] The FSPTCA defines a brand as a "[v]ariety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes." *See* 21 U.S.C. 387. In its guidance for ingredient reporting, FDA states that "[e]ach product for which an ingredient list is submitted is to be clearly and uniquely identified by its brand and subbrand, which includes identifying the type or category of tobacco product…You are to include additional identifiers (e.g., Stock-keeping unit (SKU), catalog numbers or Universal Product Codes (UPCs)) as needed to uniquely identify the brand and subbrand of the product." *See Guidance for Industry: Listing of Ingredients in Tobacco Products* (November 2009), available at: http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM192053.pdf.

[14] Acquiesence is "the observed tendency for respondents to endorse any assertion made in a question regardless of content." *See* Krosnick, J (1999). *Survey research.* Annual Review of Psychology, 50, 537-567 at 552-553.

[15] *See* Krosnick, J (1999). *Survey research.* Annual Review of Psychology, 50, 537-567 and Podsakoff, P. et al. (2003). *Common method biases in behavioral research: A critical review of the literature and recommended remedies.* Journal of Applied Psychology, 88, 879-903.

We would be happy to meet with you to discuss our suggestions in more detail. If you have any questions, please contact me at (804) 335-2610.

Sincerely,



Dr. Jane Y. Lewis
Senior Vice President
Tobacco Regulatory & Health Sciences

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service
National Institutes of Health

**DIVISION OF EPIDEMIOLOGY, SERVICES, AND PREVENTION RESEARCH**

National Institute on Drug Abuse
6001 Executive Boulevard
Room 5160, MSC 9589
Bethesda, Maryland 20892-9589
(301) 443-6504

July 20, 2012

Jane Y. Lewis, Ph.D.
Senior Vice President
Tobacco Regulatory & Health Sciences
Altria Client Services Inc.
2325 Bellis Road
Richmond, VA 23234

Dear Dr. Lewis:

Thank you for submitting comments on behalf of Altria Client Services in response to the Federal Register Notice of May 18, 2012 (Federal Register Volume 77, Number 97; pages 29667-29668), which solicited public comment on the NIDA Population Assessment of Tobacco and Health (PATH) study.

We appreciate the four suggestions you have offered to improve the quality, utility, and clarity of information NIDA intends to collect. The PATH study will employ the use of a field test and cognitive testing to examine the study protocol, including the instrumentation, prior to the launch of the baseline wave of data collection. These efforts will help to address many methodological issues, including those that you describe in your letter, i.e., the use of dichotomous, "yes" or "no" question formats; the consistency and utility of brand information collected; and the potential for acquiescence bias.

We will also submit a memorandum to the Office of Management and Budget (OMB) on findings from the field test, including any revisions to the study instruments, materials, and procedures, as a necessary step to obtain OMB approval for the baseline wave of data collection. As with other materials associated with the PATH study, this memorandum will be available for public viewing.

Sincerely,

Kevin P. Conway, Ph.D.
Deputy Director
Division of Epidemiology and Prevention Services