Attachment 2

Public Comments from 60-day FRN

January 29, 2013

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January 11, 2013

Department of Health and Human Services
National Institutes of Health
Attn: PATH Project Officer

RE: FR Doc. 2012-28575 – Proposed Collection; Comment Request; Methodological Studies for the Population Assessment of Tobacco and Health (PATH) Study

To Whom It May Concern:

The Campaign for Tobacco-Free Kids supports the request to the Office of Management and Budget (OMB) from the National Institute on Drug Abuse (NIDA) for generic approval for methodological studies to improve the Population Assessment of Tobacco and Health (PATH) study instrumentation and data collection procedures. With the passage in 2009 of the Family Smoking Prevention and Tobacco Control Act (FSPTCA), the Food and Drug Administration (FDA) finally has the authority to regulate the product that is the leading preventable cause of death in the United States and around the world. The PATH study is critical to successful implementation of many provisions of the FSPTCA, and generic approval is critical to successful execution of the PATH study.

For the first time ever, the FDA has the authority to regulate the manufacture, sale, and marketing of tobacco products. This authority includes, among other things, the following:

- Authority to set conditions on the sale of tobacco products
- Authority to place restrictions on the time, place, and manner of tobacco marketing
- Requirement that all new tobacco products be reviewed by the FDA to ensure that their introduction to the market is appropriate for the protection of public health
- Requirement that any modified risk claims for tobacco products are reviewed by FDA to ensure that they benefit the population as a whole
- Authority to set product standards for tobacco products
- Authority to require large graphic warning labels on tobacco products

The PATH study is critical to the FDA because it will provide information on how youth and adult smokers and non-smokers respond to tobacco marketing (including modified risk claims), use different tobacco products over time, use different approaches to smoking cessation, etc. By providing this information on the same

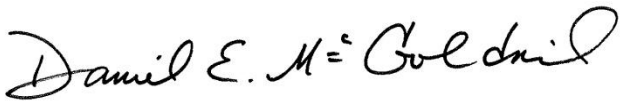
respondents over time, it will allow FDA to both develop and evaluate actions taken under its new authority to reduce the toll that tobacco takes on health.

To maximize the benefit of the PATH study, NIDA and FDA will need to act regularly and quickly to refine and improve the study in response to new developments, including actions taken by the tobacco companies. For example, in recent years, a plethora of new and novel tobacco products (e.g., dissolvable tobacco products, e-cigarettes, and numerous cigar and smokeless tobacco products) have been introduced to the market. It is critical understand how these products and their marketing affect tobacco use initiation, cessation, frequency of use, etc. so the FDA can take appropriate action to improve public health.

With such a dynamic market and an ever-innovative industry, it is critical that NIDA be able to refine the PATH study in a timely fashion to capture changes in the market and their impact on tobacco use over time. Generic approval will allow NIDA to conduct the kind of methodological studies to refine the PATH study in a timely fashion so FDA can act appropriately under its authority to protect public health. This cannot be done effectively or efficiently if NIDA has to seek OMB approval each time it wants to conduct research to refine the PATH study.

We urge OMB to grant the request from NIDA for generic approval and are happy to provide further information regarding this request.

Sincerely,



Daniel E. McGoldrick
Vice President, Research
Campaign for Tobacco-Free Kids

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

DIVISION OF EPIDEMIOLOGY, SERVICES, AND PREVENTION RESEARCH

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January 14, 2013

Daniel E. McGoldrick
Vice President, Research
Campaign for Tobacco-Free Kids
1400 Eye Street, N.W., Suite 1200
Washington, D.C. 20005.

Dear Mr. McGoldrick:

Thank you for submitting comments on behalf of the Campaign for Tobacco-Free Kids in response to the Federal Register Notice of November 26, 2012 (FR Doc. 2012-28575) regarding the proposed collection for methodological studies for the Population Assessment of Tobacco and Health (PATH) Study.

We agree that the PATH Study is critical to providing information on how youth and adult smokers and non-smokers respond to tobacco marketing over time. Moreover, as your letter points out, the ability to conduct methodological studies will allow us to refine the PATH Study in a timely fashion so that it captures changes in the market that may be associated with changes in tobacco use behaviors.

We appreciate your support for conducting methodological studies as part of the PATH Study.

Sincerely,

Kevin P. Conway, Ph.D.,
PATH Study Project Officer
Deputy Director
Division of Epidemiology, Services, and Prevention Research

Altria
Altria Client Services

Jeffrey P. Walker, M.D.
Vice President & Chief Medical Officer

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January 25, 2013

Kevin P. Conway, Ph.D.
National Institute on Drug Abuse
6001 Executive Blvd., Room 5185
Rockville, Maryland 20852

Re: 77 Fed. Reg. 70,451 (November 26, 2012) – "Methodological Studies for 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 November 26, 2012, Federal Register notice (the "Federal Register Notice").[2] The Federal Register Notice solicits comments on methodological studies in support of 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 implemented as part of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) by the Food and Drug Administration (FDA)."

The Federal Register Notice states NIDA intends to conduct methodological studies to "improve the PATH study instrumentation and data collection procedures." The breadth and depth of information that the PATH Study intends to collect will be significant in informing FDA's future decisions about tobacco products under the FSPTCA.[3]

We previously offered NIDA four suggestions to improve the quality, utility, and clarity of the information that it intends to collect in the PATH Study and attach these comments for your

[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. 70,451 (November 26, 2012), available at: https://federalregister.gov/a/2012-28575.

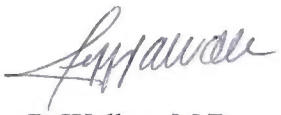
[3] "Findings from the study will provide a scientific framework for the FDA to make decisions about future changes in tobacco products that will help achieve objectives of the 2009 FSPTCA." *See* NIDA PATH Study website, accessible at: https://pathstudyinfo.nih.gov/UI/StudyOverview.aspx.

reference.[4] It is our understanding that NIDA may further revise the data collection instruments depending upon on the results of a field test.[5] After a review of the latest data collection plans and instruments,[6] we believe our suggestions are still applicable and again urge NIDA to consider them.

In addition, we again ask NIDA to publish the final proposed 2013 PATH Study design, in particular 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.

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,



Jeffrey P. Walker, M.D.
VP and Chief Medical Officer

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[4] *See* letter from Dr. Jane Y. Lewis, Senior Vice President, Altria Client Services, to Dr. Kevin P. Conway, "*77 Fed. Reg. 29,667 (May 18, 2012) – Comments on the Population Assessment of Tobacco and Health (PATH) Study,*" dated July 17, 2012.

[5] "After the field test has been completed but before commencing the first wave of data collection, NIH must submit a non-substantive change that clearly justifies the structure of incentives, addresses OMB concerns regarding the wording for some survey items, and otherwise ensures that the protocol and instruments maximize the utility of the data collection, minimize burden on participants, avoid duplication with existing Federal surveys, and comply with HHS data standards. If NIH plans to make significant changes (e.g., to the sample design) a full revision may be necessary." See Office of Management and Budget website, Office of Information and Regulatory Affairs conclusion on OMB Control Number: 0925-0664, accessible at: http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201208-0925-002#.

[6] Our comments on the latest data collection plans and instruments refer to "*Attachment 2a PATH Study Data Collection Instruments: Household Screener,*" dated July 23, 2012, accessible at: http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201208-0925-002#.

Altria
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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
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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.

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[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.

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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

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[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.

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[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.

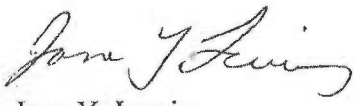
[13] The FSPTCA defines a brand as a "[v]ariety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes." *See* 21 U.S.C. 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
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January 29, 2013

Jeffrey P. Walker, M.D.
Vice President and Chief Medical Officer
Altria Client Services Inc.
2325 Bells Road
Richmond, VA 23234

Dear Dr. Walker:

Thank you for submitting comments on behalf of Altria Client Services (ALCS) in response to the Federal Register Notice of November 26, 2012 (Federal Register Volume 77, Number 227; page 70451), which requested public comment on the Proposed Collection by the National Institutes of Health, National Institute on Drug Abuse, on Methodological Studies for the Population Assessment of Tobacco and Health (PATH) Study.

In our letter of reply on July 20, 2012 to Dr. Jane Y. Lewis, Senior Vice President, ALCS, we noted our appreciation of the four suggestions offered by Dr. Lewis to improve the quality, utility, and clarity of information NIDA intends to collect in the PATH Study. Similarly, we appreciate your letter of January 25, 2013, which affirms your belief that these suggestions are still applicable and again urges NIDA to consider them.

Your letter says "we again ask NIDA to publish the final proposed 2013 PATH Study design, in particular if results from the field test suggest the need for further study design changes," and that "This would enable a variety of stakeholders to provide input on any proposed changes." As we originally mentioned in reply to Dr. Lewis on July 20, 2012, we plan to 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. This memo, as with other materials related to the PATH Study and submitted to OMB, will be available for public viewing.

Sincerely,

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