

Attachment F

QFT Intro and Informed Consent

INTRODUCTION AND INFORMED CONSENT FOR INTERVIEW RESPONDENTS AGE 18+

IF INTERVIEW RESPONDENT IS NOT SCREENING RESPONDENT,
INTRODUCE YOURSELF AND STUDY AS NECESSARY: Hello, I'm _____,
and I'm working on a nationwide study sponsored by the U.S. Department of
Health and Human Services. You should have received a letter about this study.
(SHOW LEAD LETTER, IF NECESSARY.)

READ THE BOXED INFORMATION BELOW BEFORE STARTING EVERY INTERVIEW

This year, we are interviewing about 70,000 people across the nation. You have been randomly chosen to take part. You may choose not to take part in this study, but no one else can take your place. We will give you \$30 when you finish the interview.

GIVE GRAY STUDY DESCRIPTION TO R IF YOU HAVE NOT ALREADY DONE SO.

This study asks about tobacco, alcohol, and drug use or non-use, knowledge and attitudes about drugs, mental health, and other health issues. It takes about an hour. You will answer most of the questions on the computer, so I will not see your answers. We are only interested in the combined responses from all 70,000 people, not just one person's answers. This is why we do not ask for your name and we keep your answers separate from your address. RTI may contact you by phone or mail to ask a few questions about the quality of my work. This is why we ask for your phone number and mailing address at the end of the interview.

While the interview has some personal questions, federal law keeps your answers private. We hope that protecting your privacy will help you to give accurate answers. You can quit the interview at any time and you can refuse to answer any questions.

If it is all right with you, let's get started.

(Can we find a private place to complete the interview?)

INTRODUCTION AND INFORMED CONSENT FOR INTERVIEW RESPONDENTS AGE 12-17

FIRST, OBTAIN PERMISSION FROM THE PARENT AND READ THE BOXED INFORMATION BELOW

Your (AGE) year-old child has been selected to be in this study. Your child's participation is voluntary. This interview asks about tobacco, alcohol, and drug use or non-use, knowledge and attitudes about drugs, mental health, and other health related issues. All of your child's answers will be confidential and used only for statistical purposes. Since your child will answer most of the questions on the computer, I will never see the answers, and you are not allowed to see them either. If it is all right with you, we'll get started.

(Can we find a private place to complete the interview?)

THEN, READ THE BOXED INFORMATION BELOW BEFORE STARTING EVERY INTERVIEW WITH A 12-17 YEAR OLD

This year, we are interviewing about 70,000 people across the nation. You have been randomly chosen to take part. You may choose not to take part in this study, but no one else can take your place. We will give you \$30 when you finish the interview.

GIVE GRAY STUDY DESCRIPTION TO R IF YOU HAVE NOT ALREADY DONE SO.

This study asks about tobacco, alcohol, and drug use or non-use, knowledge and attitudes about drugs, mental health, and other health issues. It takes about an hour. You will answer most of the questions on the computer, so I will not see your answers. Your answers will never be seen by either your parents or your school. We are only interested in the combined responses from all 70,000 people, not just one person's answers. This is why we do not ask for your name and we keep your answers separate from your address. RTI may contact you by phone or mail to ask a few questions about the quality of my work. This is why we ask for your phone number and mailing address at the end of the interview.

While the interview has some personal questions, federal law keeps your answers private. We hope that protecting your privacy will help you to give accurate answers. You can quit the interview at any time and you can refuse to answer any questions.

If it is all right with you, let's get started.

Attachment G

QFT Study Description



Study Description

Your address is one of several in this area randomly chosen for the 2012 National Survey on Drug Use and Health. This study, sponsored by the U.S. Department of Health and Human Services, collects information for research and program planning by asking about:

- tobacco, alcohol, and drug use or non-use,
- knowledge and attitudes about drugs,
- mental health, and
- other health issues.

You cannot be identified through any information you give us. Your name and address will never be connected to your answers. Also, federal law requires us to keep all of your answers confidential. Any data that you provide will only be used by authorized personnel for statistical purposes according to the Confidential Information Protection and Statistical Efficiency Act of 2002.

The screening questions take just a few minutes. If anyone is chosen, the interview will take about an hour. You can refuse to answer any questions, and you can quit at any time. **Each person who is chosen and completes the interview will receive \$30 in cash.**

If you have questions about the study, call the Project Representative at 1-800-848-4079. If you have questions about your rights as a study participant, call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number). You can also visit our project website: <http://nsduhweb.rti.org/> for more information.

Thank you for your cooperation and time.

Michael Jones, Project Officer
Center for Behavioral Health Statistics and Quality
Substance Abuse and Mental Health Services Administration (SAMHSA)
U.S. Department of Health and Human Services

Your confidentiality is protected by the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, PL 107-347). Any project staff or authorized data user who violates CIPSEA may be subject to a jail term of up to 5 years, a fine of up to \$250,000, or both.

Attachment R
Confidentiality Agreement

This agreement is intended for review and signature by employees of RTI International and all its subcontractors who have access to information designated as confidential on a research study sponsored by SAMHSA/CBHSQ covered under CIPSEA. This agreement must be renewed each year as part of mandated CIPSEA training to maintain access to confidential project information.

Assurances of Confidentiality under CIPSEA

For any research study sponsored by the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Behavioral Health Statistics and Quality (CBHSQ) that is covered under the **Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2002*** and Section 501(n) of the Public Health Service Act, all data and associated materials collected and/or utilized on that study are subject to protection by CIPSEA. CIPSEA ensures the confidentiality of all information provided is protected by Federal Law and stipulates that all information collected shall be used exclusively for statistical purposes. All research subjects contacted on SAMHSA/CBHSQ's behalf by RTI International are notified of these protections prior to study participation.

You have been identified as a person who has access to confidential information on a SAMHSA/CBHSQ-sponsored study covered under CIPSEA (NSDUH and/or DAWN**) and therefore have been designated as an **Agent under CIPSEA**. This confidential information includes (but is not limited to) all electronic and hard copy documents containing respondent information and data, as well as non-data related records containing information that could identify a location or respondent associated with a particular study.

Protection Agreement under CIPSEA

Per CIPSEA regulations, you agree that any materials that would permit the identification of research subjects are to be treated as confidential, and that you will never share or use that confidential information with anyone else or in a manner other than those authorized by CBHSQ. This includes never disclosing confidential information with law enforcement officials, officers of the court or your supervisor (if not also authorized as an Agent).

To ensure the protection of all confidential information in both physical and electronic form, as an Agent, you also agree to:

- 1) keep all confidential information in a space where access is limited only to authorized personnel, whether on a computer or in hard copy form;
- 2) keep all confidential information within computer memory controlled by password protection;
- 3) maintain a secure location (such as file cabinet or locked drawer) for printed materials, diskettes, and data on hard disks of personal computers when not in use;
- 4) never remove confidential information from your approved worksite without prior approval from CBHSQ and/or RTI International;
- 5) never permit any unauthorized removal of any confidential project information from the limited access space protected under the provisions of this agreement without first notifying and obtaining written approval from RTI;
- 6) notify RTI when you no longer have access to electronic or hard copy files or printed materials containing confidential project information;

* Public Law 107-347, Title V; for more info: http://www.whitehouse.gov/omb/fedreg/2007/061507_cipsea_guidance.pdf

**National Survey on Drug Use and Health (NSDUH); Drug Abuse Warning Network (DAWN)

- 7) when appropriate, return all confidential project information to RTI;
- 8) complete annual training on restrictions associated with the use of confidential information;
- 9) agree that representatives of CBHSQ have the right to make unannounced and unscheduled inspections of the facilities where you work to evaluate compliance with this agreement;
- 10) notify RTI International immediately upon receipt of any legal, investigatory, or other demand for disclosure of confidential project information;
- 11) notify RTI International immediately upon discovering any breach or suspected breach of security or any disclosure of confidential project information to unauthorized parties or agencies.
- 12) and agree that obligations under this agreement will survive the termination of any assignment with SAMHSA/CBHSQ and/or RTI International.

Penalties under CIPSEA

Any violation of the terms and conditions of this agreement may subject you, the Agent, to immediate termination of access to confidential information by RTI International or CBHSQ, and will require the immediate return of all electronic and hard copy files and materials in your possession.

Any violation of this agreement may also be a violation of Federal criminal law under Title V, subtitle A of the E-Government Act of 2002 (P.L. 107-347); and/or Section 501(n) of the Public Health Services Act. Alleged violations under the Title V, subtitle A of the E-Government Act of 2002 are subject to prosecution by the United States Attorney. The penalty for violation of subtitle A of the E-Government Act of 2002 is a **fine of not more than \$250,000 and imprisonment for a period of not more than 5 years**. In addition to the above, all relevant statutory and regulatory penalties apply.

Your signature (whether in electronic or written form) below affirms your understanding and acknowledgement of all the regulations, requirements and penalties associated with CIPSEA as part of your work on this SAMHSA/CBHSQ project for RTI International.

Name

ID Number (if applicable, RTI employees only)

Signature

Company Name

Date

Job Title

Attachment S

Response to FR Comment

Lawrence G. Wasden, Chair
Attorney General of Idaho
Boise, ID

Susan Curry, Ph.D., Vice-Chair
Dean, College of Public Health
Distinguished Professor, Health Management and Policy
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Gary R. Herbert
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Tom Miller
Attorney General of Iowa
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Jeremiah W. (Jay) Nixon
Governor
State of Missouri
Jefferson City, MO

Charles K. Scott
Wyoming State Senator
Casper, WY

Leticia Van de Putte
Texas State Senator
San Antonio, TX

Cass Wheeler
Chief Executive Officer Emeritus
American Heart Association
Dallas, TX

Ritney Castine, Youth Board Liaison
Southern University
Baton Rouge, LA

Lee Storrow, Youth Board Liaison
University of North Carolina at Chapel Hill Alum
Chapel Hill, NC

Cheryl G. Heaton, Dr. P.H. Ex-Officio
President and CEO
Legacy

April 30, 2012

VIA ELECTRONIC MAIL

Summer King
SAMHSA Reports Clearance Officer
Room 8-1099
One Choke Cherry Road
Rockville, MD 20857

RE: 2012 National Survey on Drug Use and Health
Questionnaire Field Test -- NEW

Dear. Ms. King:

Legacy appreciates the opportunity to comment on the 2012 National Survey on Drug Use and Health (NSDUH) Field Test for the NSDUH 2015 survey year. We respectfully submit the following comments that focus on emerging tobacco products, cigar products and smokeless tobacco products.

The tobacco product landscape is changing and many novel tobacco products have found their way to the market. In addition, products that have been around for decades are undergoing changes in order to take advantage of the new world where cigarettes and smokeless tobacco are regulated for the first time, but for now, other tobacco products are not. In order for federal, state and local policy makers to develop policies to protect the public health from the devastating toll tobacco exacts, particularly on youth, national surveys must monitor these new tobacco products and the trends in their use. NSDUH is an important example of a national study that garners critical information from a wide audience of both youth and adults. The Field Test study for the redesigned 2015 NSDUH presents a perfect opportunity to introduce and test new questions regarding various tobacco products. While we have and will continue to suggest similar questions for NSDUH surveys prior to 2015, at the least, the 2015 survey should contain questions that are on the cutting edge of tobacco control.

First, as the Food and Drug Administration (FDA) implements the Family Smoking Prevention and Tobacco Control Act



(Tobacco Control Act), it is critical that all studies, whether funded or conducted by FDA or other agencies, be harmonized, so that information can be compared across studies. For example, FDA is currently funding the Population Assessment of Tobacco and Health (PATH) study that will monitor tens of thousands of tobacco users and non-users over time. It will be important to be able to compare the information gathered from that study with surveys such as NSDUH. We strongly urge the Substance Abuse and Mental Health Services Administration (SAMHSA) to coordinate closely with FDA in developing NSDUH questions.

Secondly, Legacy suggests the following regarding questions concerning specific tobacco products.

Cigarettes: The NSDUH Field Test contains several questions regarding the time respondents first smoked a cigarette, including age and date of respondents' first cigarette. Legacy respectfully suggests that a question be added regarding whether or not a respondent's first cigarette was mentholated, a regular flavor cigarette, or if it contained some other flavor. Research suggests that menthol cigarettes are a starter product among youth. For example, studies, including previous NSDUH data, show that among smokers, a disproportionate number of youth and other vulnerable populations smoke menthol cigarettes.^{1,2} In addition, a CDC analysis of the 2004 and 2006 National Youth Tobacco Survey concluded that among established, middle and high school smokers, Newport, a solely menthol brand at that time, was the second most preferred brand.³ A study of earlier NYTS data suggests that menthol cigarettes are a starter product that may be associated with smoking uptake by youth.⁴ However, there are few national studies that ask specifically if the first cigarette used was a mentholated cigarette. Because FDA is currently reviewing the TPSAC report regarding menthol cigarettes, knowing whether respondents started smoking with menthol or other flavored cigarettes is of critical importance, and may be useful to FDA, as well as state and local authorities, in making its policy determinations regarding menthol and other flavored tobacco products. Similarly, in the section asking questions about becoming an everyday smoker, it would be helpful to know if respondents were using mentholated, regular or other flavored cigarettes when they started smoking every day. We suggest asking such questions for each category of tobacco product.

Smokeless tobacco: Smokeless products in particular are on the forefront of the changing landscape of tobacco products. For example, snus is a relatively new smokeless tobacco product in the United States. In addition, products known as dissolvable tobacco products may be considered smokeless tobacco by FDA.⁵ As newcomers to the U.S. tobacco market, there is a paucity of information on these products. Therefore, it is critical that national surveys include questions regarding these products in order to get a better picture of what respondents are actually using. This will also aid FDA as well as state and local policy makers in making prudent public health policy decisions regarding these products.

With regard to smokeless products, Legacy suggests that the current iteration of the Field Test does not adequately capture information about the various smokeless tobacco types. While the Field Test has added snus to the "smokeless category", at the same time it has combined snus, snuff and chewing tobacco products into one question. We suggest that questions be asked separately for each of the different smokeless products to get the most accurate information. Indeed, in the 2013

NSDUH, as revised, questions are asked separately about snuff and chewing tobacco.⁶ We do not recommend lumping together all the smokeless products but rather suggest that it would be beneficial to separate out snuff and chewing tobacco and *add* questions about additional types of smokeless tobacco, such as dissolvable tobacco or snus.[±] Whether questions about the different smokeless products are asked at the same time or asked separately, it may be helpful to add brand name prompts into the initial questions regarding smokeless tobacco products. This can help ensure that respondents understand which products they are being asked about, and may be particularly helpful with newer products, such as snus.

At the same time, Legacy suggests that questions regarding brand names of smokeless tobacco be added. There are brand name questions associated with cigarette and cigar products in the NSDUH Field Test, the same should hold for smokeless products. The 2013 NSDUH, as revised, contains brand name questions about snuff and chewing tobacco.⁷ We recommend keeping the questions regarding brand names in the Field Test, and the subsequent 2015 NSDUH, and adding questions about brand names of other smokeless products, such as snus or dissolvable tobacco.

Finally, Legacy recommends that questions regarding flavors of smokeless products be added. As we suggested in the cigarette section, it would be valuable to add a question about the first time respondents used a smokeless tobacco product and whether or not that product was flavored. In addition, we suggest that a question or questions be added regarding whether or not the products respondents are currently using are flavored. It may be helpful to include a list of potential flavors and allow respondents to choose which they use currently or have used in the past.

Cigars: Legacy has submitted suggestions for changes to NSDUH questions in previous comments submitted to SAMHSA. We reiterate those here. First, because the users and the usage patterns appear to vary across the different types of cigars, Legacy encourages NSDUH to ask questions about typical large cigars, sometimes referred to as “stogies,” separately from the questions about little cigars or cigarillos. Research suggests large cigar users and little cigar and cigarillo users have different demographic profiles and may have different patterns of multiple product use, with little cigars and cigarillos being more popular among young adults, males, African-Americans, individuals with lower education and those reporting current cigarette, marijuana and blunt use.^{8,9,10} Furthermore, since the 2009 federal excise tax that increased the tax on little cigars to equal that of cigarettes, some little cigar manufacturers have slightly increased the weight of their little cigars (though not so much as to look very different to the average consumer) and they now qualify as large cigars and get a more preferable tax treatment.^{11,12,13} This conflation of cigar products creates a need to be more specific in survey questions regarding cigar products.

In addition, we recommend that NSDUH amend and re-structure questions about brand use for little cigars and cigarillos. Research indicates that little cigar and cigarillo users may not recognize these products as cigars or even as tobacco products.^{14,15} Studies demonstrate that little cigar and cigarillo

[±] Snus, moist snuff in tea bag-like packets, may also be addressed in the snuff category. While the 2013 NSDUH does ask about snuff separately as we advocate, it does not ask about snus products, and no snus brand names are included in the questions on snuff brand names. SAMHSA should either add snus and snus brand names to the snuff questions or ask about snus separately from snuff products.

users do not self-report as cigar users despite reporting that they smoke a little cigar or cigarillo when asked specifically about brands like Swisher Sweets or Black & Mild.^{16,17} Little cigar and cigarillo *brands* may be more reliably reported than cigar *type* (i.e., little cigar or cigarillo), particularly among at-risk groups such as younger and African-American users.^{18,19,20} Asking only about little cigar or cigarillo use without specific brand item prompts may lead to underestimates of prevalence.²¹

Currently in the NSDUH, only respondents who report past 30 day cigar use are asked brand-specific questions. Those who do not report smoking cigars at least once in their lifetime and those who report smoking cigars at least once in their lifetime but not in the past 30 days are not subsequently asked about brand use. To improve the precision of prevalence estimates, we recommend that the NSDUH include brand-specific prompts, particularly of little cigar and cigarillo brands, for questions regarding cigar ever and current use for all respondents.

The lack of significant data regarding the different types of cigar products is illustrated in a recent analysis using 2002-2008 NSDUH data. That analysis showed that the top 5 cigar brands smoked by respondents (Black & Mild, Swisher Sweets, Phillies, White Owl, and Garcia y Vega) include large cigars, cigarillos and little cigar products. Yet, the authors were unable to determine whether respondents were smoking large cigars as opposed to little cigars or cigarillos due to the grouping together of cigar products in the questions.²²

As we have suggested for other tobacco products, SAMSHA should include questions regarding the use of flavored and non-flavored cigars for little cigars and cigarillos in the NSDUH. This is especially important for cigar products given the fact that flavored cigarettes, except for menthol, were banned by the Family Smoking Prevention and Tobacco Control Act. Furthermore, there is evidence that some brands of flavored cigarettes simply changed their products to flavored cigars.²³

Finally, we suggest adding a question regarding the number of cigar products smoked per day for those who report usage in the past 30 days, as well as questions that ascertain concurrent use of cigars with other tobacco products. These types of questions regarding usage patterns are critical in understanding how and when respondents are using cigar products.

Electronic Cigarettes: Electronic cigarettes are also new products that have been deemed by the courts to be a tobacco product.²⁴ While not yet subject to FDA regulation, FDA has given indications that they intend to regulate these products.^{25,26} There are currently no questions in the Field Test regarding electronic cigarettes. Questions in national surveys about these products would be very helpful to FDA, as well as state and local entities, in making public policy decisions regarding electronic cigarettes. We suggest adding questions regarding ever use and past 30 day use of electronic cigarettes to the NSDUH Field Test.

Legacy appreciates SAMHSA taking these comments into account as it develops this Field Test. As we have stated above, we hope that these comments can be applied to earlier versions of NSDUH, as well as to the 2012 Field Test for the 2015 NSDUH. It is critical that we have the appropriate information about tobacco products in order to best determine how to protect the public health from



LEGACY

FOR LONGER HEALTHIER LIVES

the deadly effects of tobacco, especially as the breadth and variety of tobacco products continues to change. If you have questions or need further information, please contact Diane Canova, Vice President of Government Affairs at dcanova@legacyforhealth.org or 202-454-5559.

Sincerely,

David Dobbins, JD
Chief Operating Officer

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- ¹ Caraballo R. Menthol and Demographics. Presentation to Food and Drug Administration Tobacco Products Scientific Advisory Committee. March 30, 2010.
- ² Substance Abuse and Mental Health Services Administration (SAMHSA). The NSDUH Report: The Use of Menthol Cigarettes. Rockville, MD: Substance Abuse and Mental Health Services Administration, Office of Applied Studies. November 19, 2009
- ³ Centers for Disease Control *Cigarette Brand Preference Among Middle and High School Students Who Are Established Smokers – United States, 2004 and 2006*. February 13, 2009 MMWR 58(05);112-115
- ⁴ Hersey et al, Are menthol cigarettes a starter product for youth? *Nicotine and Tobacco Research*. 2006; 8(3): 403-13.
- ⁵ FDA statement *Clarification About Dissolvable Products*
<http://www.fda.gov/TobaccoProducts/NewsEvents/ucm248801.htm> . Accessed 04-24-12.
- ⁶ Substance Abuse and Mental Health Services Administration *2013 National Survey on Drug Use and Health: Draft CAI Specifications for Programming English Version* Prepared by Research Triangle Institute March 2012
- ⁷ Substance Abuse and Mental Health Services Administration *2013 National Survey on Drug Use and Health: Draft CAI Specifications for Programming English Version* Prepared by Research Triangle Institute March 2012
- ⁸ Cullen J, Mowery P, Delnevo C, et al. Seven Year Patterns in U.S Cigar Use Epidemiology among Young Adults aged 18-25: A Focus on Race/Ethnicity and Brand *American Journal of Public Health*. 2011
- ⁹ Borawski E, Brooks, A., Colabianchi, N., Trapl, ES, Przepyszny, KA., Shaw, N., Danosky, L. Adult use of cigars, little cigars, and cigarillos in Cuyahoga County, Ohio: A cross-sectional study. *Nicotine and Tobacco Research*. 2010;12(6):669-673.
- ¹⁰ Richardson A et al. "Primary and Dual Users of Cigars and Cigarettes: Profiles, Tobacco Use Patterns and Relevance to Policy." *Nicotine and Tobacco Research*, January 17, 2012
- ¹¹ Kesmodal, D. Close and It Is a Cigar: Tobacco Manufacturers Are Accused of Exploiting a Tax Loophole to Boost Sales. *The Wall Street Journal*. September 23, 2010.
<http://online.wsj.com/article/SB10001424052748703399404575505670223138144.html>. Accessed 4-25-12.
- ¹² Government Accountability Office. Illicit Tobacco: Various Schemes Are Used to Evade Taxes and Fees. GAO-11-313. March 2011. <http://www.gao.gov/new.items/d11313.pdf>. Accessed 4-25-12.
- ¹³ Government Accountability Office. Large Disparities in Rates for Smoking Products Trigger Significant Market Shifts to Avoid Higher Taxes. GAO-12-475. April 2012. <http://www.gao.gov/assets/600/590192.pdf> Accessed 4-25-12.
- ¹⁴ Page JB, Evans, S. Cigars, Cigarillos, and Youth: Emergent Patterns in Subcultural Complexes. *Journal of Ethnicity in Substance Abuse*. 2003;2(4):63-76.
- ¹⁵ Yerger VP, C., Malone, M.E. When is a cigar not a cigar? African American youths' understanding of cigar use. *American Journal of Public Health*. 2001;91(2):316-317.
- ¹⁶ Terchek J, Larkin, EMG., Male, ML., Frank, SH. Measuring cigar use in adolescents: Inclusion of a brand-specific item. *Nicotine and Tobacco Research*. 2009;11(7):842-846.
- ¹⁷ Borawski E, Brooks, A., Colabianchi, N., Trapl, ES, Przepyszny, KA., Shaw, N., Danosky, L. Adult use of cigars, little cigars, and cigarillos in Cuyahoga County, Ohio: A cross-sectional study. *Nicotine and Tobacco Research*. 2010;12(6):669-673.
- ¹⁸ Terchek J, Larkin, EMG., Male, ML., Frank, SH. Measuring cigar use in adolescents: Inclusion of a brand-specific item. *Nicotine and Tobacco Research*. 2009;11(7):842-846.
- ¹⁹ Borawski E, Brooks, A., Colabianchi, N., Trapl, ES, Przepyszny, KA., Shaw, N., Danosky, L. Adult use of cigars, little cigars, and cigarillos in Cuyahoga County, Ohio: A cross-sectional study. *Nicotine and Tobacco Research*. 2010;12(6):669-673.
- ²⁰ Trapl ES, Terchek JJ, Danosky L, Cofie L, Brooks-Russell A, Frank SH. Complexity of measuring "cigar use" in adolescents: results from a split sample experiment. *Nicotine and Tobacco Research*. Apr 2011;13(4):291-295.
- ²¹ Cullen J, Mowery P, Delnevo C, et al. Seven Year Patterns in U.S Cigar Use Epidemiology among Young Adults aged 18-25: A Focus on Race/Ethnicity and Brand *American Journal of Public Health*. 2011.
- ²² Cullen J, Mowery P, Delnevo C, et al. Seven Year Patterns in U.S Cigar Use Epidemiology among Young Adults aged 18-25: A Focus on Race/Ethnicity and Brand *American Journal of Public Health*. 2011.



²³ Letter from Rep. Henry Waxman to FDA Commissioner Margaret Hamburg. March 28, 2011. Available at : <http://democrats.energycommerce.house.gov/index.php?q=news/rep-waxman-urges-fda-to-ban-clove-flavored-cigars> Accessed 4-23-12.

²⁴ *Sottera, Inc. v. Food and Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010)

²⁵ Food and Drug Administration letter to industry stakeholders April 2011. Available at: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm> . Accessed 4-25-12.

²⁶ Health and Human Services Semiannual Regulatory Agenda “Tobacco Products Subject to the Federal Food, Drug and Cosmetic Act as Amended by the Family Smoking Prevention and Tobacco Control Act.” RIN 0910-AG38. Published in the Federal Register July 7, 2011, at 40061-40062; and February 13, 2012, at 7952. Available respectively at:

<http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM263819.pdf> (accessed 4-25-12) and <http://www.gpo.gov/fdsys/pkg/FR-2012-02-13/pdf/2012-1647.pdf> (accessed 4-25-12).

May 10, 2012

Mr. David Dobbins, JD
Chief Operating Officer
Legacy for Health
1724 Massachusetts Ave, NW
Washington, DC 20036

Re: Comments on the 2012 National Survey on Drug Use and Health Questionnaire Field Test

Dear Mr. Dobbins:

Thank you very much for your interest in the 2012 National Survey on Drug Use and Health Questionnaire Field Test and for your valuable suggestions. You have provided us with very useful information on the changing nature of the tobacco landscape. These issues are important and we agree that they should be studied.

In the early stages of the redesign, several new items were developed for the tobacco module to capture additional detail as you have suggested. Given that NSDUH has been conducted since 1971, however, maintaining trends is an essential part of the study. After review by senior SAMHSA management and ONDCP, it was decided to give preservation of trends the highest priority. With that in mind, there was a decision not to alter the core drug modules, with the exception of prescription drugs, in the redesigned questionnaire. Therefore, changes to the core tobacco module have been limited. Nevertheless, SAMHSA maintains communications with the FDA and the Office on Smoking and Health to keep abreast of emerging tobacco products that may be considered for future non-core modules.

The one exception that was permitted was to combine the smokeless substances. As you know, the NSDUH provides current data on the use of illicit drugs, alcohol, and tobacco in the U.S. population – aged 12 or older – as well as each state. In an effort to preserve response rates and control respondent burden, we strive to maintain average interview length of 60 minutes. Therefore, we are required to consider the data obtained from each topic and whether valid and reliable national estimates can eventually be produced from the questions. In analyzing our data on chewing tobacco and snuff, we found that a large proportion of respondents could not differentiate between these two classes of smokeless tobacco. This was evident from the brand names reported in response to subsequent questions. Given the uncertainty of these responses, particularly when multiple brand names or no brand names are reported, the most practical thing to do is to combine these data in analysis. Since most respondents seem to be able to report using a smokeless product, but many are unable to differentiate between chewing tobacco and snuff, it was prudent to combine the questions and save time in the instrument. Although we see

the analytic value, we do not feel that producing separate estimates of chewing tobacco and snuff from NSDUH data would be appropriate.

As always, we appreciate and welcome your comments and input. If you have any questions, please let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Jones". The signature is written in a cursive style with a long horizontal flourish at the end.

Michael Jones
NSDUH Project Officer
Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road
Rockville, MD 20857