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June 7, 2012

VIA ELECTRONIC MAIL

Pamela Hyde  
Administrator  
Substance Abuse and Mental Health Services  
Administration  
ATTN: Summer King  
Room 8-1099  
One Choke Cherry Road  
Rockville, MD 20857

RE: 2013 National Survey on Drug Use and Health (OMB  
No. 0930-0110) – Revision

Dear Administrator Hyde:

Legacy appreciates the opportunity to comment on the 2013 National Survey on Drug Use and Health (NSDUH) Questionnaire. We submit the following comments that focus on emerging tobacco products, cigar products and smokeless tobacco products, that reflect similar suggestions we have made in previous submissions regarding various NSDUH surveys.

As we have stated previously, 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. While we have suggested similar questions for other NSDUH surveys, we maintain that the



2013 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. In the response we received from the Substance Abuse and Mental Health Services Administration (SAMHSA) regarding our previously submitted comments, you indicated that SAMHSA was “in communication with” FDA. While communication is an important first step, we hope that SAMHSA will go beyond that and work in concert with FDA in developing the NSDUH questionnaire. We believe NSDUH should ask questions that better reflect the new tobacco product marketplace. While we understand the need to maintain trends in surveys, if a survey does not ask about products that youth and adults are actually using, its utility diminishes. Considering the immense impact that tobacco has on the nation’s health, we hope that you will seriously consider asking more detailed questions about tobacco products, particularly with regard to new tobacco products that have entered the market.

To that end, Legacy suggests the following regarding questions concerning specific tobacco products.

**Cigarettes:** The 2013 NSDUH questionnaire 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.<sup>1,2</sup> 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.<sup>3</sup> A study of earlier NYTS data suggests that menthol cigarettes are a starter product that may be associated with smoking uptake by youth.<sup>4</sup> 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.<sup>5</sup> 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. We understand from your response to our previously submitted comments that you want to maintain trend data. This is understandable, but if questions about new products are not asked, we will not know the extent to which they have infiltrated the marketplace.

With regard to smokeless products, we suggest adding questions about additional types of smokeless tobacco, such as dissolvable tobacco or snus. 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.

Additionally, 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 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 several previous submissions 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 SAMHSA to ask questions in the NSDUH 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.<sup>6,7,8</sup> 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.<sup>9,10,11</sup> This conflation of cigar products creates a need to be more specific in survey questions regarding cigar products.

In addition, we recommend that SAMHSA amend and re-structure questions in the 2013 NSDUH 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.<sup>12,13</sup> Studies demonstrate that little cigar and cigarillo 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.<sup>14,15</sup> 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.<sup>16,17,18</sup> Asking only about little cigar or cigarillo use without specific brand item prompts may lead to underestimates of prevalence.<sup>19</sup>

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.<sup>20</sup>

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.<sup>21</sup>

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.



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**Electronic Cigarettes:** Electronic cigarettes are also new products that have been deemed by the courts to be a tobacco product.<sup>22</sup> While not yet subject to FDA regulation, FDA has given indications that they intend to regulate these products.<sup>23,24</sup> There are currently no questions in the 2013 NSDUH 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 2013 NSDUH.

Legacy appreciates SAMHSA taking these comments into account as it develops the 2013 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 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](mailto:dcanova@legacyforhealth.org) or 202-454-5559.

Sincerely,

David Dobbins, JD  
Chief Operating Officer

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- <sup>1</sup> Caraballo R. Menthol and Demographics. Presentation to Food and Drug Administration Tobacco Products Scientific Advisory Committee. March 30, 2010.
- <sup>2</sup> 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
- <sup>3</sup> 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
- <sup>4</sup> Hersey et al. Are menthol cigarettes a starter product for youth? *Nicotine and Tobacco Research*. 2006; 8(3): 403-13.
- <sup>5</sup> FDA statement *Clarification About Dissolvable Products* <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm248801.htm> . Accessed 04-24-12.
- <sup>6</sup> 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
- <sup>7</sup> 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.
- <sup>8</sup> 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
- <sup>9</sup> 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.
- <sup>10</sup> 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.
- <sup>11</sup> 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.
- <sup>12</sup> Page JB, Evans, S. Cigars, Cigarillos, and Youth: Emergent Patterns in Subcultural Complexes. *Journal of Ethnicity in Substance Abuse*. 2003;2(4):63-76.
- <sup>13</sup> 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.
- <sup>14</sup> 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.
- <sup>15</sup> 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.
- <sup>16</sup> 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.
- <sup>17</sup> 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.
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- <sup>20</sup> 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.

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<sup>21</sup> 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.

<sup>22</sup> *Sottera, Inc. v. Food and Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010)

<sup>23</sup> Food and Drug Administration letter to industry stakeholders April 2011. Available at: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm> . Accessed 4-25-12.

<sup>24</sup> 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).