April 2, 2014

Center for Tobacco Products
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Attn: Caryn Cohen

Re: Docket No. FDA-2014-N-0001, Tobacco Products Scientific Advisory Committee – Written Comments re Approaches to Evaluation of Modified Risk Tobacco Products

The undersigned organizations submit these comments in connection with the April 18 meeting of the Tobacco Products Scientific Advisory Committee on possible approaches for evaluating information on the risks and potential benefits of a proposed modified risk tobacco product (MRTP) to the health of individual tobacco users and to the population as a whole.[1]

I. STATUTORY BACKGROUND AND ROLE OF TPSAC IN EVALUATING MODIFIED RISK PRODUCT APPLICATIONS

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act, or TCA) amended the Food, Drug and Cosmetic Act (FD &C Act) in part by adding §911 to strictly regulate modified risk tobacco products. Under §911(a) and (b), a manufacturer must obtain from FDA a premarket order before the introduction into commerce of any product "sold or distributed for use to reduce harm or the risk of tobacco-related disease . . ." Such modified risk products include, for example, products for which the label or advertising of the product "represents . . . that the tobacco product presents a lower risk of tobacco-related disease or is less harmful" than other tobacco products.

Under §911(g)(1), the burden is on the applicant seeking an order allowing the marketing of an MRTP to demonstrate that the product "as it is actually used by consumers will (A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products."

Sec. 911(g)(4) further requires FDA to take into account the following specific empirical factors in determining whether the (g)(1) standard has been met:

(A) The relative health risks to individuals of the tobacco product that is the subject of the application;

[1] *See* 79 Fed. Reg. 9910 (February 21, 2014).

(B) The increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;

(C) The increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;

(D) The risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under chapter V to treat nicotine dependence.

Thus, FDA must consider not only the effects of the asserted modified risk product on those who use it, but also its population-wide impact on tobacco use initiation, cessation and relapse, including an assessment of the likelihood that smokers would actually switch to the modified risk product. It is not enough for an applicant to show that the MRTP is less hazardous to users than other tobacco products; if its availability and marketing could lead to greater initiation of tobacco use or diminished cessation of tobacco use, the applicant is required to show that the benefits of risk reduction to the individual (considering the likelihood of switching to the modified risk product) outweigh the broader population-wide effects on initiation and cessation. In short, the statute requires FDA to make sound scientific judgments not only about the physical effect of the product's use, but also about the likely responses of potential consumers (both smokers and non-smokers) to the product's marketing as a modified risk product.

Section 911 sets a high bar to insure that any tobacco product seeking MRTP status is both significantly less harmful than the tobacco products to which it is compared and that the actual population impact will also be substantial. This will not occur with products that are only marginally safer. Nor will it occur with products that may be significantly less harmful than a cigarette if the evidence is insufficient to demonstrate that cigarette smokers will actually switch from smoking cigarettes or the manufacturer has failed to meet its burden of demonstrating that the proposed MRTP as marketed and sold will not result in many new tobacco users or prompt ex-smokers to relapse. On the other hand, §911 empowers FDA to authorize carefully crafted, scientifically based claims for products where the evidence is adequate to conclude both that the product is significantly less harmful than cigarettes or other tobacco products and that, as manufactured and marketed, the evidence supports the conclusion that consumers will respond in a way that is very likely to result in substantially fewer people suffering from tobacco-related death and disease. The public health standard clearly gives the FDA the authority to insure that products that are likely to reduce the death toll from tobacco significantly can be promoted in ways designed to maximize the number of lives saved.

The TCA assigns TPSAC a unique and central role in FDA's assessment of whether an applicant has met its burden under §911. Unlike applications for drug approval, where the convening of an advisory committee is discretionary with FDA, the involvement of TPSAC in evaluating modified risk products is mandatory under the TCA. Sec. 911(f)(1) provides that FDA "shall refer" to TPSAC "any application" for a modified risk order. Sec. 911 (f)(2) in turn requires TPSAC to report "its recommendation on the application" to FDA within 60 days of the

referral. Thus, no modified risk application can be approved, or disapproved, without FDA having received a recommendation from TPSAC, although the final decision on approval or disapproval rests with FDA.

Given the mandatory role of TPSAC in making recommendations on all modified risk applications, it is vital that the process for referral of such applications to TPSAC ensure that TPSAC have the opportunity for a thorough review of all the relevant scientific evidence within the 60-day referral period. The Campaign for Tobacco Free Kids presented its views at the TPSAC meeting of April 30, 2013 concerning the modified risk referral process,[2] submitted written comments on the issues to be addressed at that meeting and incorporates those comments by reference. Those comments emphasized: (1) the importance of FDA, prior to referral of a MRTP, having done sufficient preliminary consideration of the application to give TPSAC substantial guidance as part of its referral; (2) the need to ensure the opportunity for public participation throughout FDA review of MRTP applications, including during TPSAC review of such applications; and (3) the importance of FDA, including TPSAC, generally following the recommendations of the Institute of Medicine in its 2012 report *Scientific Standards for Studies on Modified Risk Tobacco Products* (IOM Report).[3]

II. THE HISTORICAL ORIGINS OF SECTION 911 OF THE TCA AND ITS IMPORTANCE TO TPSAC'S REVIEW OF MODIFIED RISK TOBACCO PRODUCT APPLICATIONS

In order to properly evaluate and make recommendations to FDA on MRTP applications, TPSAC must not only faithfully apply the criteria set forth in the TCA, but must also be mindful of the historical underpinnings of §911. In a very real sense, the purpose of §911 is to prevent history from repeating itself.

The provisions of §911 are based on a massive evidentiary record of fraudulent health and "reduced risk" claims made by tobacco product manufacturers over the course of more than fifty years. Those claims caused millions of Americans to initiate cigarette smoking, who otherwise would not have done so, and caused millions of American smokers to continue smoking when they otherwise would have quit. In the absence of this massive industry fraud, literally millions of deaths, and untold suffering, would have been avoided.

In the 1950s, after evidence of the dangers of cigarette smoking first came to the public's attention, the industry responded by launching advertising campaigns alleging that adding filters to cigarettes made them less dangerous to health, even though no evidence supported such a view. Despite growing evidence that cigarettes cause fatal disease, the incidence of smoking

[2] Campaign for Tobacco-Free Kids, Comments filed in Docket No. FDA-2013-N-0001, Tobacco Products Scientific Advisory Committee – Referrals of Modified Risk Applications to TPSAC (April 23, 2013) (CTFK TPSAC Referral Comments).

[3] The CTFK comments did take exception to IOM Recommendation #10, to the extent that Recommendation is intended to provide pre-approval to an independent third-party entity to conduct research related to a specific §911 application. *See* CTFK TPSAC Referral Comments at 6, n.13.

continued to increase, as a large majority of smokers turned to filtered cigarettes in response to the industry's marketing of them as less harmful than unfiltered cigarettes.[4]

In the 1970s, the industry began to promote cigarettes labeled as "light" or "low-tar" as a less harmful alternative, even though the companies were well aware that such cigarettes, as actually used by smokers, were no less dangerous. The industry's knowingly deceptive marketing was successful, as smokers concerned about their health switched to these brands in huge numbers instead of quitting.

In 2001, the National Cancer Institute issued a Monograph entitled "Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine" ("Monograph 13") citing internal tobacco company documents in concluding that the companies themselves recognized the inherent deception of advertising that offered cigarettes as "Light" or "Ultra Light," or as having the lowest tar and nicotine yields.[5] Monograph 13 also found that advertisements of filtered and low-tar cigarettes were intended to reassure smokers who were worried about the health risks of smoking, were intended to prevent smokers from quitting based on those concerns, and were successful in getting smokers to use filtered and low-yield brands, even though, as used, they were just as hazardous as conventional cigarettes.[6] Advertisements for light cigarettes explicitly marketed them as alternatives to quitting. For example, one Lorillard advertising campaign featured an attractive model stating, "Considering all I'd heard, I decided to either quit or smoke True. I smoke True."[7]

The voluminous evidence of the industry's use of these false health-related claims was presented to the United States District Court for the District of Columbia in *United States v. Philip Morris, U.S.A., Inc.*[8] and furnished critical support for the Court's conclusion that the defendant tobacco companies had engaged in a conspiracy to defraud the American public so massive as to constitute racketeering under federal law. The Court found:

> For several decades, Defendants have marketed and promoted their low tar brands as being less harmful than conventional cigarettes. This claim is false, as these Findings of Fact demonstrate. By making these false claims, Defendants have given smokers an acceptable alternative to quitting smoking, as well as an excuse for not quitting.[9]

The Court further found that the industry knew these health claims were false:

> Even as they engaged in a campaign to market and promote filtered and low tar cigarettes as less harmful than conventional ones, Defendants either lacked evidence to substantiate their claims or knew them to be false. Indeed, internal

[4] Today approximately 99.8% of the U.S. cigarette market is made up of filtered cigarettes. Federal Trade Commission (FTC), *Cigarette Report for 2011* (Issued 2013), Table 5A. Data for top five manufacturers only.
[5] National Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Tar Machine-Measured Yields of Tar and Nicotine,* Smoking and Tobacco Control Monograph No. 13 (November, 2001)
[6] *Id.*
[7] Magazine advertisement, 1976.
[8] 449 F. Supp.2d 1 (D.D.C. 2006), *aff'd in relevant part,* 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied,* 130 S.Ct. 3501 (2010).
[9] *Id.* at 430.

> industry documents reveal Defendants' awareness by the late 1960s/early 1970s that, because low tar cigarettes do not actually deliver the low levels of tar and nicotine which are advertised, they are unlikely to provide any clear health benefit to human smokers, as opposed to the FTC smoking machine, when compared to regular, full flavor cigarettes.[10]

The Surgeon General's 2012 report, *Preventing Tobacco Use Among Youth and Young Adults*, presents additional evidence that health claims by major tobacco companies, particularly those marketing light and low-tar cigarettes, may have increased youth initiation to cigarettes, citing studies showing that U.S. youth believed that "light" brands had lower health risks and lower levels of addiction than "regular" brands.[11]

III. THE IMPORTANCE OF CONGRESSIONAL FINDINGS TO TPSAC'S REVIEW OF MODIFIED RISK TOBACCO PRODUCT APPLICATIONS

The deadly history of fraudulent health claims by tobacco companies, and its connection to §911, is reflected in the extraordinarily detailed findings of Congress in enacting the TCA. Congress found, *inter alia*:

- As the National Cancer Institute has found, many smokers mistakenly believe that "low tar" and "light" cigarettes cause fewer health problems than other cigarettes. As the National Cancer Institute has also found, mistaken beliefs about the health consequences of smoking "low tar and "light" cigarettes can reduce the motivation to quit smoking entirely and thereby lead to disease and death. TCA, §2(38)

- Recent studies have demonstrated that there has been no reduction in risk on a population-wide basis from "low tar" and "light" cigarettes, and such products may actually increase the risk of tobacco use. TCA, §2(39)

- The dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk tobacco products are completely accurate, and relate the overall disease risk of the product. TCA, §2(40)

- Permitting manufacturers to make unsubstantiated statements concerning modified risk tobacco products, whether express or implied, even if accompanied by disclaimers, would be detrimental to the public health. TCA, §2(42)

In light of the detrimental effects of unsubstantiated or false claims of reduced risk, Congress concluded that FDA must be given authority to review modified risk products before they are put on the market:

[10] *Id.* at 430-31.

[11] U.S. Dept. of Health and Human Services, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General* (2012) (SG Report 2012), at 531.

- The only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers sold or distributed for risk reduction be reviewed in advance of marketing, and to require that the evidence relied on to support claims be fully verified. TCA, §2(43)

Thus, Congress found that "rigorous criteria" must be applied to ameliorate the risk:

- It is essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products. TCA, §2 (36)

TPSAC's review of MRTP applications, and its recommendations to FDA, must be faithful to the intent of Congress as reflected in these strong and specific findings.

It is also relevant that the industry's history of creating and exploiting consumer confusion about the relative risks of tobacco products has continued even after enactment of the TCA. Despite the fact that the TCA now expressly prohibits the use of the deceptive terms "light," "mild" and "low-tar," tobacco companies are using color-coding schemes to evade the ban and perpetuate the "safer cigarette" deception. Lighter-colored packaging is now used for "light" brands, and terms like "gold" and "silver" have replaced "light" and "ultra-light". For example, consumers who previously smoked Marlboro Lights were told that they could now purchase "Marlboro Gold" and "Marlboro Silver".[12] Philip Morris placed notes on packs of Marlboro Lights reading "Your Marlboro Lights package is changing, but your cigarette stays the same" and directing customers to "in the future, ask for Marlboro in the gold pack."[13]

In light of the history, and continuing efforts, of tobacco companies to mislead health-conscious consumers, and the strong Congressional findings based on that history, TPSAC and FDA must be vigilant, in evaluating applications for MRTPs, to ensure that the companies seeking to market MRTPs be able to meet the rigorous standards of §911 with credible scientific evidence, both on the issue of relative individual harm and on the population-wide impact of their products on public health.

IV. KEY TENETS THAT SHOULD GUIDE TPSAC REVIEW OF MODIFIED RISK TOBACCO PRODUCTS

A. Applicant's burden of proof

TPSAC's consideration of MRTP applications must recognize that the burden is on the applicant to demonstrate that its product meets the §911 standards. Section 911(g)(1) permits the issuance of a MRTP order "only if the Secretary determines *that the applicant has demonstrated that such product, as it is actually used by consumers, will"* substantially reduce individual harm and benefit the health of the population as a whole (emphasis added). Although FDA is permitted to consider evidence from sources other than the manufacturer, the absence of

[12] Duff Wilson, "Coded to Obey Law. Lights Become Marlboro Gold," New York Times, Feb. 18, 2010.
[13] Duff Wilson, "FDA seeks explanation of Marlboro Marketing, New York Times, June 17, 2010.

sufficient evidence to establish any element of the §911 standard justifies a TPSAC recommendation to reject the application.

B. Evaluation of harm to individual users

Even before TPSAC considers the population-wide impact of a proposed MRTP, it is required to evaluate whether the product "as it is actually used by consumers will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users." This, in turn, requires an evaluation of "the relative health risks to individuals of the tobacco product that is the subject of the application." In evaluating individual risk, TPSAC should account for several key considerations.

First, TPSAC must have sufficient information concerning how the product is actually used, a requirement that is mandated specifically in §911. The way the product is consumed is important in evaluating the level of delivery of toxicants and other harmful constituents. For example, how consumers actually smoked cigarettes labeled "light," and the consequent delivery of nicotine and toxicants to those consumers, differed greatly from the results yielded by smoking machines. Thus, it is critical for TPSAC to have available comprehensive information on conditions and manner of actual use. This should include information about the use of the product in conjunction with other tobacco products. Although a proposed MRTP may well reduce harm and the risk of disease to the individual under conditions of actual use, it is also possible for a product that appears to reduce harm under clinical conditions, or by machine measurement, to have the opposite or no effect under actual use conditions.

Moreover, a product that would benefit the individual user if used to displace the use of more hazardous products totally might not benefit such users if it is used in ways that result in the concurrent or dual use of the MRTP and other tobacco products and/or that could also discourage cessation. TPSAC's evaluation of MRTP applications must take this consideration into account and require the production of persuasive evidence about how consumers actually use the product. It is highly relevant to determine whether consumers use the product to displace other products entirely or use them concurrently with other products.

Second, TPSAC should have enough evidence to evaluate whether the product increases the risk of some diseases even if it reduces the risk of others. Thus, solid scientific evidence related to multiple disease risks is required.

Third, TPSAC should consider available evidence bearing on the abuse liability of the product. Although the core of TPSAC's evaluation should be addressed to relative harm to the user when used as directed or intended by the manufacturer, TPSAC also should evaluate whether there is a risk that the product could be modified, or used in some other way, so as to increase the risk of addiction and harm.

C. Importance of pre-market testing and post-market surveillance in assessing population-wide impact

As is made clear in both FDA's Draft Guidance on Modified Risk Tobacco Product Applications[14] and in the IOM Report, assessing the population-wide impact of a MRTP requires both pre-market testing and post-market surveillance. Post-market surveillance is critical, but it should not be regarded as a substitute for pre-market consumer research to minimize the risk that the introduction of a MRTP will harm rather than benefit public health. Given the history of the tobacco industry's fraudulent reduced risk claims and their disastrous effect on public health, it is essential that FDA and TPSAC be as fully informed as possible about MRTP products, how they will be marketed and how consumers are likely to respond to them before an order is issued allowing an MRTP claim.

D. Importance of pre-market testing assessing impact of the product, its labeling and its marketing on key audiences

Companies seeking to make a modified risk claim must be required to show not only the population-wide impact of the product, but also the impact of its labeling, packaging and marketing on consumers. Thus, FDA should require, and TPSAC should have access to, all advertising and promotional material that the applicant expects to use with respect to the product, including all testing and research the applicant has done bearing on the likely impact of such material on consumers. Because consumer behavior is influenced not only by the availability of the product, but also by the way it is labeled, packaged and marketed, TPSAC must satisfy itself that it has sufficient information about the intended advertising and promotional material, as well as its likely impact on consumers. FDA should be in a position to present to TPSAC the results of pre-market testing of the product and its marketing on several key audiences. In some cases applicants may apply to make modified risk claims about products that have already been on the market. In such cases, applicants should be able to provide significant information about the manner in which the product that is the subject of the application is being used and the likely consequences of its being permitted to make the modified risk claims that are the subject of the application.

First, the impact of the proposed modified risk claim, and the labeling and marketing to be associated with the claim, must be assessed as to tobacco users. Thus, assessing the impact of the proposed MRTP on the individual user involves consideration not only of the product, but also of how the user will react to the product and its labeling and marketing. As noted, testing must include actual use by consumers. It also should include an assessment of whether current tobacco users, when exposed to the proposed claim and the intended labeling and marketing, would use more of the product, switch to it completely from more dangerous tobacco products, or use it in conjunction with other products. Such testing must also address the extent to which users who might otherwise have quit tobacco entirely use the MRTP instead of quitting. Because quitting smoking is so difficult, smokers may look for any justification for not doing so, particularly when exposed to appealing promotional and marketing material for modified risk products. In this connection, it is important to account for the availability of FDA-approved smoking cessation products. TPSAC must address the extent to which the availability and

[14] Food and Drug Administration, *Modified Risk Tobacco Product Applications, Draft Guidance* (March 2012). The *Comments on Guidance for Industry on Modified Risk,* Docket FDA-2012-D-0071 (June 4, 2012) filed by the Campaign for Tobacco-Free Kids, et al. discuss in greater detail the issues addressed here and are incorporated by reference. *See also* the comments filed in Docket FDA-2013-N-0001-0056 by the Campaign for Tobacco-Free Kids, et al., which are also incorporated by reference.

marketing of the proposed MRTP would diminish use of FDA-approved cessation products. If the marketing of the proposed MRTP would make smokers less likely to turn to FDA-approved products, or more likely to stop using FDA-approved products, public health may suffer.

Second, TPSAC will need to assess the impact of the proposed MRTP, and its labeling and marketing, on those who have never used tobacco. Because nearly 90% of adult smokers report that they started smoking by age 19,[15] this assessment is particularly important with respect to young people. To the extent that the labeling and marketing of a MRTP influences the perception of risk by young people, it could lead them to initiate use of the MRTP when they would otherwise have remained tobacco-free. Since even adults who have never used tobacco products could be influenced to initiate with a MRTP by claims and marketing emphasizing reduced risk, this analysis of risk perception must also include adults. In addition to understanding how never-smokers might initiate with the MRTP, TPSAC also will need to ascertain whether such initiation may lead them to use other tobacco products as well. Initiation with a less harmful product may be a gateway to more harmful ones.

Third, TPSAC should evaluate the risk that the availability and marketing of a proposed MRTP may convince those who have successfully quit smoking or other tobacco use to relapse into renewed use. Even if the MRTP were minimally harmful, MRTP claims and marketing could draw former smokers back into nicotine addiction and lead them eventually to the more harmful tobacco products they were using before they quit. The health benefits of quitting smoking are well documented and may be realized relatively quickly after quitting. If the marketing of an MRTP were to lead to relapse among smokers, any benefit of the new product to current users could be offset by this impact in the broader population.

Finally, with respect to smokers, never-smokers and former smokers, TPSAC should ensure that sufficient testing and studies have been done regarding consumer understanding among populations at particularly high risk for tobacco use. This, of course, includes youth, but it also includes those with psychological conditions that render them particularly vulnerable to addiction, those in low socioeconomic status, certain ethnic minorities and the LGBT community.

E. Need for analysis of consumer perception and how consumers act based on those perceptions

In assessing the likely impact of a MRTP and its labeling and marketing on the key population groups set out above, TPSAC must evaluate the content of consumer perception of the MRTP and the likely actions consumers will take based on that perception.

FDA's Draft Guidance on MRTP Applications recognizes that "FDA must ensure . . . that the advertising and labeling of the MRTP enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the tobacco-related diseases and health conditions."[16] Consistent with the principle, TPSAC should have available to it sufficient studies

[15] SAMHSA, HHS, 2011 National Household Survey on Drug Use and Health (NSDUH). Calculations based on data available through Substance Abuse and Mental Health Data Archive (SAMHDA).
[16] Draft Guidance, at 5.

focusing not only on the modified risk claim, but on what message consumers actually derive from the claim. For example, modified risk claims may be conveyed using numbers or percentages (i.e. presenting reductions in toxic constituents or claiming reductions in risk of certain diseases). It is important for TPSAC to determine whether consumers understand the numbers used in conveying the reduce risk, the concept of risk itself, and the implications of the claim for their personal health. If a claim is made that a MRTP reduces the risk of cancer by a quantified amount (e.g. 10%), consumer perception studies are important to determine whether consumers have an accurate understanding of what that reduction means. FDA and TPSAC should also consider how consumers will perceive a claim that a product carries a lower risk for one tobacco-related disease, such as lung cancer, but continue to pose a risk comparable to other tobacco products for other tobacco-related diseases.

TPSAC also must be in a position to evaluate likely behavioral responses to the perceived risk. Many consumers who may understand risk do not apply it to themselves. Many smokers, particularly young smokers, overestimate their ability to quit and thus may believe the risks do not apply to them.[17] TPSAC should also be cognizant of the past success of tobacco company marketing in fostering the impression of benefits, real or imagined, from use of tobacco products and that such an impression can outweigh any risk perceptions. The marketing of an MRTP could accentuate the problem.

V. CONCLUSION

The organizations listed below appreciate the opportunity to express their views in connection with TPSAC's upcoming meeting to discuss possible approaches for evaluating information on the risks and potential benefits of a proposed MRTP to the health of individual users and to the population as a whole. TPSAC's central and mandatory role in FDA's consideration of MRTP applications underscores the TCA's requirement that no modified risk claim be permitted without support by thorough and sound research on the full range of issues bearing on the impact of the proposed MRTP on the individual user and on the population as a whole. History provides compelling instruction on the dire public health consequences of unsupported health claims by tobacco product manufacturers. TPSAC plays a pivotal role in ensuring that FDA provide a path to approval for modified risk products that will truly save lives, while protecting the public from tobacco products that purport to reduce risk, but in reality set back the nation's progress toward the elimination of tobacco-related disease and death.

Respectfully,

American Cancer Society Cancer Action Network
American Lung Association
Campaign for Tobacco-Free Kids
Tobacco Control Legal Consortium

[17] Johnston, L.D., et al., *National survey results on drug use from the Monitoring the Future study, 1975-1997, Volume 1.*