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RE: Docket No. FDA-2016-N-0001, Psychopharmacologic Drug Advisory Committee and Drug Safety and Risk Management Advisory Committee

The Campaign for Tobacco-Free Kids submits these written comments in the above-referenced docket.

Introduction

The September 14, 2016 hearing of the above-referenced FDA Advisory Committees is scheduled to focus on the results of a double blind study that examined the safety and efficacy of the only three drugs approved in the last 50 years by the FDA for tobacco cessation, but we believe it is time for a significant and major review of the context and manner in which FDA's Center for Drug Evaluation and Research (CDER) addresses the entire issue of tobacco cessation and its role in curtailing the number of Americans who die from tobacco use.

As a nation we have not treated the death caused by tobacco addiction as a medical emergency and the FDA has not treated the need to develop and effectively deliver high quality medication to assist America's 40 plus million current smokers with the urgency that is merited by close to 500,000 avoidable deaths from tobacco-related disease a year.

It is wrong to think of tobacco use as just a behavior. Rather, we should think of tobacco use and addiction as a disease that kills one out of every two long term users, close to one half million Americans every year; that has become even more deadly over the last 50 years; that kills one half of its victims in middle age; and that first afflicts almost all of its victims during adolescence. If any other preventable disease were having this impact, there would be a hue and cry for the government to do everything possible to promote the development of medications to curtail its impact.

Yet, in the last 50 years, FDA has approved exactly three drugs (nicotine replacement therapy, bupropion, and varenicline) as safe and effective in doing the one thing that can prevent the disease from becoming fatal, that is, help people quit. It has approved no new medications in the last decade; and it places restrictions on existing products and the use of existing products that virtually all experts agree curtail their reach and efficacy.

While each new approved medication made it possible for more people to quit, only one third of all smokers use any of these medications and the treatment is only successful for only 17 to 33% of the individuals who use it. How many lives could be saved if FDA prioritized policies that examined how these medications could be more effective and what could be done to promote the development of medications that could be more effective?

Now more than ever, it is time to ask fundamental questions about CDER's approach to tobacco cessation. While FDA traditionally treated nicotine as such a dangerous drug that FDA imposed stringent access to it, since 2010 consumers have been able to purchase nicotine in products that contain widely varying doses of nicotine, including doses that are higher than approved by FDA for tobacco cessation, and are being sold by a wide variety of individuals and companies for purely recreational purposes.

If nicotine-delivery products like e-cigarettes have a public health value, it is as a way to substantially increase the number of cigarette smokers who quit using tobacco completely, or for those who can't or won't quit smoking, to provide a means to completely switch to the use of products that deliver nicotine in the safest, most regulated ways. Yet today manufacturers who design products to help smokers achieve either goal, and who want to promote them as such to adult smokers, face a regulatory approach that has discouraged innovation. By contrast, manufacturers who sell nicotine-delivery products without regard to whether they will help smokers quit, with marketing and flavors that make them appealing to kids, face far fewer regulatory constraints and a much more lucrative marketplace.

For the first time in history, between the authority that resides in CDER and the authority that resides in the Center for Tobacco Products (CTP), FDA has legal authority over all products that contain nicotine. Only CDER, however, has the authority to encourage the development of, and provide a pathway for, products that can legally be promoted as being effective at helping people quit smoking.

While CTP's recent assertion of authority over electronic cigarettes and other tobacco products can make a major difference, unless there is a major re-evaluation of the approach by CDER to its handling of tobacco cessation, and FDA approaches the regulation of products containing nicotine in a comprehensive manner, designed to reduce the use of products that cause death and disease and maximize the use of products that will help tobacco users quit using the products that cause harm, the death toll from tobacco will remain far higher than necessary.

Therefore, the goal of our comments is not to focus on the specific results of the controlled trial of the neuropsychiatric effects of CHANTIX, ZYBAN, or nicotine replacement therapy; nor on whether the results of that trial support changes to product labeling; nor on the safety and efficacy of any particular drug. Rather, our comments address the larger policy context in which FDA's evaluation of smoking cessation products takes place and we urge the members of these Committees to begin a conversation within FDA to accomplish these goals.

I. The Public Health Imperative for Innovative Approaches to Smoking Cessation Treatments

Although great strides have been made in adopting policies that have reduced the prevalence of smoking among children and adults over the last several decades, smoking remains the leading cause of preventable death in America, claiming over 480,000 lives every year.¹ Life expectancy among smokers is at least 10 years shorter compared to non-smokers.² Smoking kills more Americans than alcohol, AIDS, car accidents illegal drugs, murders and suicides combined.³ Currently, more than 16 million people in the United States suffer from smoking-cause disease, including lung cancer, emphysema and heart disease.⁴

Despite the known risks of smoking and demonstrable benefits of quitting, far too few smokers are able to quit successfully. In 2010, 68.8 percent of smokers reported that they want to quit and 52.4 percent of all smokers made a quit attempt that year, but only 6.2 percent had quit within that year.⁵ While this is largely attributable to the addictive power of nicotine and the sophisticated efforts of the tobacco companies to keep people smoking, the fact that most

¹ U.S. Dept. of Health and Human Services (HHS), *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General*, (2014) 17 (Executive Summary).

² HHS, *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General*, (2014); Jha, P, et al., “21st Century Hazards of Smoking and Benefits of Cessation in the United States,” *New England Journal of Medicine* 368(4):341–50, 2013. U.S. Centers for Disease Control and Prevention (CDC), “Tobacco-Related Mortality,” Smoking & Tobacco Use Fact Sheet, August 18, 2015, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm.

³ HHS, *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*, 2014, <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/>. (AIDS) CDC, “Table 12a. Deaths of persons with diagnosed HIV infection ever classified as stage 3 (AIDS), by year of death and selected characteristics, 2008-2010 and cumulative—United States,” *HIV Surveillance Report, 2011*, Volume 23, February 2013, http://www.cdc.gov/hiv/pdf/statistics_2011_HIV_Surveillance_Report_vol_23.pdf#Page=40; (Alcohol) CDC, *Alcohol-Related Disease Impact (ARDI)*, http://apps.nccd.cdc.gov/DACH_ARDI/Default/Default.aspx; Mokdad, AH, et al., “Actual Causes of Death in the United States, 2000,” *Journal of the American Medical Association (JAMA)* 291(10):1238-1245, March 10, 2004 [with correction in *JAMA* 293(3):298, January 19, 2005]; (Motor vehicle) U.S. Department of Transportation, National Highway Traffic Safety Administration, *Fatality Analysis Reporting System General Estimates System: 2011 Data Summary*, 2013, <http://www-nrd.nhtsa.dot.gov/Pubs/811755DS.pdf>; (Homicide, Suicide, Drug-Induced) Murphy, S, et al., “Deaths: Final Data for 2010,” *National Vital Statistics Reports*, 61(4), May 8, 2013, http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_04.pdf.

⁴ CDC, “Fast Facts,” Smoking & Tobacco Use Fact Sheet, December 11, 2015, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm#toll.

⁵ CDC, “Quitting Smoking Among Adults --- United States, 2001—2010,” *MMWR* 60(44):1513-1519, November 11, 2011, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6044a2.htm?s_cid=%20mm6044a2.htm_w.

smokers do not more often utilize evidence-based treatments – counseling and medication – in their quit attempts also contributes greatly to the low rate of success. Though studies continue to show higher success in quitting among those who use some form of medication,⁶ only one-third of smokers use any of those medications when making a quit attempt.⁷ Unfortunately, even when cessation medications are used, quit rates are less than optimal, roughly 17 to 33 percent.⁸ . The need for more effective smoking cessation therapies is readily apparent.

Between 1984 and 2002, FDA approved new drug applications for five types of nicotine-based smoking cessation therapies: the nicotine patch, gum, lozenge, spray and inhaler, along with two non-nicotine based therapies, bupropion (ZYBAN and generics) and varenicline (CHANTIX).⁹ Thus, in recent years, there has been little development and approval of innovative, new smoking cessation products.

The need to spur the development of new and innovative smoking cessation products was recognized by the United States Congress when it enacted the Tobacco Control Act in 2009. In Section 918 of the Food, Drug & Cosmetic Act, as amended by the Tobacco Control Act, Congress directed FDA to issue a report, within three years, examining “how best to regulate, promote and encourage the development of innovative products and treatments . . . to better achieve” three objectives: (1) total abstinence from tobacco use; (2) reductions in consumption of tobacco; and (3) reductions in the harm associated with continued tobacco use. Section 918 also directed FDA to consider several approaches to expedite approval of new safe and effective tobacco cessation products and to facilitate more effective use of existing approved products, including considering the designation of smoking cessation products as fast track products to benefit from expedited approval, considering the approval of extended use of NRTs for the treatment of tobacco dependence, and considering additional indications for NRTs, such as for craving relief or prevention of relapse.

Through several Citizen Petitions and other communications with FDA, the public health community has repeatedly called on FDA to review its approach to smoking cessation products, both to remove barriers to the effective use of approved products and to create new incentives for the development of new and innovative products.¹⁰

⁶ Siu, AL, “Behavioral and Pharmacotherapy Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Women: U.S. Preventive Services Task Force Recommendation Statement,” *Annals of Internal Medicine* 163(8):622-34, October 20, 2015. Cahill, K, et al., “Pharmacological interventions for smoking cessation: an overview and network meta-analysis,” *Cochrane Database of Systematic Reviews* 4:CD009329, 2013.

⁷ CDC, “Quitting Smoking Among Adults --- United States, 2001—2010,” *MMWR* 60(44):1513-1519, November 11, 2011.

⁸ Siu, AL, “Behavioral and Pharmacotherapy Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Women: U.S. Preventive Services Task Force Recommendation Statement,” *Annals of Internal Medicine* 163(8):622-34, October 20, 2015. Fiore, MC, et al, *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline*, Rockville, MD: U.S. Department of Health and Human Services, May 2008.

⁹ Report to Congress: Innovative Products and Treatments to Achieve Abstinence from Tobacco Use, Reductions in Consumption of Tobacco, and Reductions in the Harm Associated with Continued Tobacco Use, Required by Section 918 of the Federal Food, Drug and Cosmetic Act (Dept. of Health and Human Services, April 22, 2013) 8-9 (FDA Report to Congress).

¹⁰ See generally, FDA Combined Response to Three Citizen Petitions (April 1, 2013); Written comments of Campaign for Tobacco-Free Kids in Docket No. FDA-2012-N-1148 (January 16, 2013).

The need for a far-reaching reevaluation of how FDA can best contribute to public health through its regulation of smoking cessation and nicotine products, however, has become far more compelling in recent years due to two developments that have led to a new market reality for nicotine products: (1) the ruling of the U.S. Court of Appeals for the D.C. Circuit in *Sottera, Inc. v. FDA*, and (2) the exploding growth of the e-cigarette market, resulting in the widespread availability of a wide range of nicotine products, marketed for recreational use, but used by many consumers in the hope that they will help them quit, reduce the number of cigarettes they smoke, or prove to be less dangerous substitutes for cigarettes.

II. The New Market Reality for Nicotine Products

The *Sottera* case arose after FDA denied entry into the United States of multiple shipments of e-cigarettes on the ground that they were unapproved drug-device combination products under the FD&C Act. However, in 2010, the D.C. Circuit held that under the recently-enacted Tobacco Control Act, all products made or derived from tobacco and intended for human consumption that are “marketed for therapeutic purposes” are subject to FDA’s drug/device provisions, whereas “customarily marketed tobacco products” are subject to regulation as “tobacco products” under the TCA.¹¹ Since no therapeutic claims had been made for the e-cigarettes at issue, the Court held they could not be regulated as a drug/device, but could be regulated as tobacco products under the TCA.

The Tobacco Control Act established FDA’s immediate regulatory authority over certain tobacco products (cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco) and also gave FDA power to, by regulation, “deem” other tobacco products subject to its jurisdiction. Although in April 2011, four months after the *Sottera* ruling, FDA announced its intention to regulate e-cigarettes as tobacco products under its TCA deeming authority, the rule did not become final until May, 2016. The combination of the *Sottera* ruling and FDA’s delay in exercising its regulatory authority over e-cigarettes, led to the emergence of an uncontrolled, completely unregulated market in highly-addictive e-cigarettes, giving rise to a host of serious risks to public health, including (1) the use of marketing strategies mimicking those used for many years by cigarette companies to appeal to youth, including celebrity endorsements depicting e-cigarette use as glamorous, rebellious, sexy and masculine, sponsorship of sporting and musical events with large youth attendance, and providing free samples; (2) the marketing of e-cigarettes with a dizzying array of fruit and candy flavors that appeal to youth, from gummy bear to cotton candy to bubble gum; (3) an exponential increase in e-cigarette use by middle and high school students, as well as adults; (4) potential adverse health consequences from inhalation of various toxicants, including nicotine, found in e-cigarette aerosol, particularly toxicants generated from vaporization of flavored nicotine liquids; (5) great variability in nicotine content, including variability between labeled content and actual nicotine concentration; (6) exposure of non-users to nicotine and other toxicants through passive exposure to e-cigarette

¹¹ *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010).

aerosol; (7) a dramatic increase in exposure of young children to nicotine poisoning; and (8) exploding batteries in e-cigarette devices, causing serious burns.¹²

The *Sottera* decision and the subsequent explosion of an unregulated e-cigarette market has led to a regulatory situation with the unintended consequence of favoring the introduction and marketing of nicotine products that appear to threaten public health, while actually discouraging the development and marketing of products that help people quit smoking. As we have noted, if novel nicotine-delivery products like e-cigarettes have a public health value, it is as a way to substantially increase the number of cigarette smokers who quit using tobacco completely, or for those who can't or won't quit smoking, to provide a means to completely switch to the use of products that deliver nicotine in the safest, most regulated ways. Yet manufacturers who want to market products to help smokers achieve either goal, and who want to promote them to adult smokers, face a regulatory approach that has discouraged innovation and experimentation. By contrast, manufacturers who market nicotine-delivery products without regard to whether they will help smokers quit, with marketing and flavors that appeal to kids, have faced no regulatory constraints and will face fewer constraints than approved cessation products going forward, as FDA implements its rule deeming other tobacco products, including e-cigarettes, subject to its regulatory authority. The fact is that many e-cigarette consumers use these products because they are looking for alternative nicotine-delivery products that will help them stop smoking, yet thousands of varieties of these products are on the market without any requirement that their manufacturers demonstrate that they actually help smokers quit.

Although FDA issued a final deeming rule on May 10, 2016 that will provide the regulatory foundation to bring the current "Wild West" of the e-cigarette market under some form of science-based control, the reality is that highly-addictive nicotine products will remain widely available for recreational use and will continue to be marketed for non-therapeutic uses. It is not enough for CTP to respond within its statutory framework. CDER and CTP must respond to this new market reality through a carefully coordinated effort to realign the regulatory approach to promote the development and marketing of products that actually serve therapeutic purposes and do the opposite for products that do not and that potentially threaten the progress made over several decades to curb smoking.

III. The Need for an FDA-Wide Reevaluation of Policy Toward Nicotine and Smoking Cessation Products

In light of the continuing devastating toll of smoking-related disease, and the widespread availability of nicotine products to the general public, it is urgent for FDA to engage in an agency-wide reevaluation of its regulatory approach to smoking cessation products and nicotine-delivery products, in order to establish a comprehensive regulatory approach that will

¹² See generally, Memorandum in Opposition to Plaintiffs' Motions for Summary Judgment and in Support of Defendants' Cross-Motion for Summary Judgment, *Nicopure Labs LLC v. FDA*, CA No. 16-878 (August 16, 2016), 8-16; Brief of *Amici Curiae* Public Health Organizations in Support of Defendants' Cross-Motion for Summary Judgment and in Opposition to Plaintiffs' Motions for Summary Judgment, *Nicopure Labs LLC v. FDA*, CA No. 16-878 (August 19, 2016) 5-13.

most effectively reduce disease and death from tobacco. This reevaluation should confront several critical policy issues, requiring a closely coordinated effort by CDER and CTP to craft policy responses that best serve public health.

A. In Evaluating Possible New Indications or Labeling Changes for Existing Products and Possible Barriers to the Development of New Products, FDA's Risk/Benefit Calculus Must Be Based on the Fact that 50% of All Long-term Tobacco Users Will be Killed by Their Tobacco Addiction and that 480,000 Lives a Year are at Stake

In evaluating its approach to the development of products that are effective in breaking the hold of tobacco addiction, FDA should recognize the continued cost of the status quo – that is, the continued use of a product that kills half of its users¹³ – is the critical comparator. With more than 40 million current tobacco users, the introduction of new, more effective cessation products, and the authorization of uses of existing products not now authorized, could potentially save tens of thousands if not hundreds of thousands of lives every year.

This does not require FDA to lower its scientific or safety standards or to allow products or marketing that appeal to youth. FDA possesses both the regulatory authority and regulatory flexibility to evaluate the conditions of the use of existing products, enable changes to existing drugs and promote the development of more effective products, as described further below.

B. CDER Should Evaluate Whether Indications and Labeling for Existing Approved Smoking Cessation Products Need Revision to Encourage Greater Consumer Acceptance and Use of Those Products

Although most smokers want to quit, relatively few of them take advantage of existing cessation medicines. Moreover, despite the fact that those who use such medicines do enhance their likelihood of quitting, their success rate is still relatively low. The limitations of existing NRT products and the way these products are marketed slows our progress toward ending tobacco-related disease. We urge CDER to analyze whether various use restrictions, and aspects of current labeling on NRTs and other cessation products, may be discouraging successful use of existing treatments and whether new indications should be considered that would encourage greater acceptance and use. We note that, in response to various Citizen Petitions and information submitted to FDA in connection with a hearing convened by the agency in November, 2012,¹⁴ CDER did find sufficient evidence to recommend some minor modifications to certain warnings and directions for use relating to the use of OTC NRT concomitantly with cigarettes or with other nicotine-containing products (including other NRTs) and relating to the use of OTC NRT for longer than the labeled period of treatment.¹⁵ However, these are very modest labeling changes and FDA took no action toward specifying new indications. There continues to be a need for FDA to evaluate other potential labeling changes and possible new indications to make existing approved products more appealing and effective.

¹³ HHS, *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*, 2014, <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/>.

¹⁴ See e.g. Comments of Campaign for Tobacco-Free Kids in Docket No. FDA-2012-N-1148 (January 16, 2013).

¹⁵ Modifications to Labeling of Nicotine Replacement Therapy Products for Over-the-Counter Human Use, 78 Fed. Reg. 19718 (April 2, 2013). See also, Report to Congress 16; FDA Response to Citizen Petitions (April 1, 2013) 5.

C. FDA Should Consider Whether Policy Approaches Should be Revised to Drive Innovation in the Development of New Smoking Cessation Products

The relatively low rates of use and effectiveness of currently approved smoking cessation products also argues for a reevaluation by CDER of whether existing indications and other restrictions fail to provide sufficient incentives for the development of new and innovative products. CDER should work closely with industry to assess possible regulatory barriers to innovation in the development of smoking cessation products to determine whether those barriers can be removed without compromising existing safety standards. Section 918(a) specifically calls on FDA to consider approving several new indications for NRT products including the approval of extended use of NRTs for the treatment of tobacco dependence and the approval of NRTs for “relapse prevention” and “craving relief.” Although FDA’s 2013 report to Congress, required by Section 918, indicated that FDA is considering additional indications and suggests that the agency “remains open” to working with sponsors to develop new indications,¹⁶ CDER must give this effort the high priority it deserves.

D. FDA Should Evaluate How Its Procedures for Fast Track and Other Accelerated Approval Authorities Can Facilitate Approval of New and Effective Treatments for Tobacco Dependence

FDA has available to it fast track and other accelerated approval procedures that can be used to address serious and life-threatening conditions for products that can potentially fill an “unmet medical need.” Indeed, in Section 918, Congress directed FDA to consider the designation of smoking cessation products as fast track products to benefit from expedited approval. To our knowledge, such procedures have never been utilized with respect to a smoking cessation product. In its Section 918 Report to Congress, FDA found that “it is generally accepted that a product that helps people stop smoking will be addressing a serious or life-threatening condition.”¹⁷ FDA also indicated that where there are existing therapies, filling an “unmet medical need” has been understood to require a showing of a clear advantage of those available treatments, “such as superior effectiveness or the avoidance of serious side effects.”¹⁸ CDER should evaluate how those standards should be adapted and applied specifically to smoking cessation products where there is such a demonstrable need for innovative products and the current incentive structure is not functioning to generate such innovation. This evaluation of accelerated approval procedures by CDER should be closely coordinated with CTP.

E. In Determining the Jurisdictional Responsibilities of CDER and CTP Consistent with Statutory Law, FDA Should Determine What Division of Responsibilities Yields an Incentive Structure that Best Serves Public Health

In addressing the widespread availability of nicotine-delivery products, a threshold issue for FDA is to properly define the circumstances under which a product made or derived from

¹⁶ FDA Report to Congress 16-17.

¹⁷ FDA Report to Congress 18.

¹⁸ Id.

tobacco that is intended for human consumption will be subject to regulation as a drug, device or combination product under the FD&C Act. Although it has been clear since *Sottera* that tobacco products for which therapeutic claims are made are regulated under FDA's drug/device jurisdiction, and not as tobacco products under the TCA, FDA recently has sought, through a rulemaking proceeding, to clarify the circumstances under which such products intended to affect the structure or function of the body, absent therapeutic claims, are also subject to FDA's drug/device jurisdiction.¹⁹

In clarifying the jurisdictional boundary between CDER and CTP, we urge the agency to consider, within the bounds of the statutory language and the relevant case law, what division of responsibility will be most effective for leading to the development and marketing of products that will benefit the public health. We urge CDER and CTP to use this rulemaking proceeding as an opportunity to consider how both Centers will exercise their respective responsibilities. FDA's proposed rule provides a careful legal analysis of the relevant statutory language and case law, but is devoid of any discussion of how its proposed division of responsibility will be implemented to maximize the manufacture and marketing of products that help smokers quit, while effectively controlling the manufacture and marketing of products that pose public health risks, particularly the risk of nicotine addiction for young people.²⁰

Conclusion

In two fundamental ways FDA's current regulatory approach is inconsistent with the goal of minimizing the number of people who die from tobacco use. The approach to the development, marketing and use of effective tobacco cessation medications has not been consistent with the urgency of reducing the 480,000 plus totally preventable deaths from tobacco use every year. Further, the new reality is that nicotine products are now widely available to smokers and non-smokers alike for a wide range of uses, and that FDA now has regulatory authority over the full range of such products. Unless there is a fundamental reassessment of how all of these products are regulated, there will be even less incentive for responsible manufacturers to develop and scientifically test products for the purpose of helping smokers quit and even more incentive to make and market products that appeal to the broadest marketplace without regard for their impact on the public health.

Because FDA has sought the expertise of the two Advisory Committees that will be meeting on September 14 in connection with the agency's ongoing evaluation of smoking cessation products, we urge both Committees to play an active role in encouraging FDA to seize the unique regulatory opportunity it has been given to take a fresh look at the evaluation of cessation products to ensure that the new market for nicotine becomes a force for public health, not public harm.

¹⁹ Clarification of When Products Made or Derived from Tobacco are Regulated as Drugs, Device, or Combination Products; Amendments to Regulations Regarding "Intended Uses," 80 Fed. Reg. 57756 (September 25, 2015).

²⁰ A more detailed discussion of the policy issues that should be addressed in the pending rulemaking proceeding may be found in the comments filed in Docket No. FDA-2015-N-2000 (December 24, 2015) by the Campaign for Tobacco-Free Kids, the Tobacco Control Legal Consortium and Truth Initiative.

