

**BEFORE THE FOOD AND DRUG ADMINISTRATION  
WASHINGTON DC**

CITIZEN PETITION OF THE  
National Tobacco Reform Initiative  
March 6, 2020

The undersigned submits this citizens petition under the code of Federal Regulations, Title 21, Volume 1 (21CFR10.30) to the United States Food and Drug Administration (FDA) and specifically the Center for Tobacco Products (CTP) in reference to regulations and actions relevant to PUBLIC LAW 111–31, the Family Smoking Prevention and Tobacco Control Act.

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## **A. ACTIONS REQUESTED**

The National Tobacco Reform Initiative (hereafter referred to as the NTRI) hereby submits this citizens petition to the United States Food and Drug Administration (FDA) and specifically the Center for Tobacco Products (CTP) to follow through on its previously asserted science-based comprehensive nicotine focused tobacco product regulatory strategy. This strategy as outlined by the FDA/CTP in 2017<sup>1</sup> recognized that there is a continuum of risk across different nicotine delivery products and suggested that public health could be markedly improved by reducing the addictiveness of combustible tobacco products while at the same time increasing access to less harmful tobacco and nicotine products (i.e., both consumer and medicinal nicotine products). The guiding principle behind the strategy was finding ways to reduce the diseases and premature deaths caused by tobacco products, the vast majority of which are currently the result of addiction to conventional, combustible tobacco cigarettes. This petition is intended to make recommendations to the agency for carrying out its responsibilities pursuant to provisions of the Food Drug and Cosmetic Act and specifically under the Family Smoking Prevention and Tobacco Control Act (hereafter referred to as the Tobacco Control Act ) and to consider ways of modernizing how it chooses to regulate a growing number of diverse tobacco and nicotine products. Specifically, we are urging FDA/CTP to establish a more flexible and workable regulatory framework that recognizes the opportunities associated with a rapidly evolving nicotine delivery product marketplace, and to support stakeholder engagement and dialogue, which can better serve public health goals and objectives consistent with the science-based comprehensive nicotine focused tobacco product regulatory strategy the agency outlined in 2017.

As an informal organization consisting of a small group of distinguished seasoned and independent tobacco control leaders with decades of service to fighting the tobacco epidemic, we feel that we are qualified to call for the actions being requested. NTRI is a voluntary organization and receives no financial assistance from any organization or outside entities. We advocate for civil engagement with all interested stakeholders and

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<sup>1</sup> Gottlieb S, Zeller M. A Nicotine-Focused Framework for Public Health. N Engl J Med. 2017 Sep 21; 377(12):1111-1114.

for open evidenced based discussions about the most effective ways to accelerate a reduction in the current number of adult smokers and associated diseases and premature deaths caused by smoking. One of NTRIs major priority areas is to establish a more rational tobacco and nicotine products regulatory framework based on their relative risks and that is adaptable to the increased speed of innovation in new technology of products that have the potential to displace deadly and addictive combustible tobacco products. The NTRI looks for opportunities to engage and facilitate dialogue with others and to serve as a catalyst for change. This includes but is not limited to public health organizations, health care professionals, the research community, governmental agencies, policy makers at the federal state and local level levels, consumers, the media, tobacco and nicotine trade associations, growers and manufacturers.

### **1. Regulating Based on the Continuum of Risk**

As noted above, it is well established that there are significant differences in the risks and relative risks of tobacco, nicotine and alternative products. The idea that cigarette smoking could be replaced by a less harmful tobacco product is not new. Several decades ago, smokers in Northern Sweden largely replaced smoking with a new type of oral tobacco called snus. Over a generation, smoking-related diseases in Sweden dropped at a much faster pace compared to other countries in Europe, as snus displaced cigarettes as the preferred form of tobacco consumption<sup>2</sup>. Today we have an array of alternative nicotine products that smokers could potentially transition to in place of cigarettes ranging from medicinal nicotine replacement therapies (NRT), oral tobacco products such as SNUS, and cleaner nicotine products such as Zyn, ON , nicotine e-cigarettes, and heated tobacco products (HTPs). There are more innovative science-based products in the pipeline. These are all products that could replace cigarettes with cleaner forms of nicotine delivery. Think of the lives that can be saved not only in the United States but globally if we can move smokers away from combustible products by giving them consumer acceptable lower risk alternatives.

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<sup>2</sup> Rodu, B., & Cole, P. (2004). The burden of mortality from smoking: comparing Sweden with other countries in the European Union. *European Journal of Epidemiology*, 19(2), 129-131.

Regulating based on the **continuum of risk** was a major component of the FDA/CTP July 2017 announcement and has conceptually been supported by many in the public health and scientific community, consumers, and even many in the manufacturing sector<sup>3</sup>.

### **A Few Areas for Consideration**

- Move forward immediately with the proposed product standard for the nicotine level of combusted cigarettes and related combustible tobacco products. By almost any credible standard, cigarettes as currently designed are a defective product. Current estimates indicate that slightly over half of long-term smokers die prematurely because of exposure to cigarette smoke. Importantly, people's persistence in smoking day in and day out is because of nicotine addiction. There is no longer a debate that cigarettes containing nicotine easily inhaled into the airways can be highly addictive. Nicotine is the drug in tobacco that causes cigarette addiction. Lowering the nicotine levels of cigarettes and other combustible tobacco products to render these products minimally addictive addresses one of the primary defects inherent in cigarettes and other combustible tobacco products.
- Simultaneously and immediately focus on developing a more flexible and adaptable regulatory framework that that will allow science-based lower risk products into the market place more expeditiously, while ensuring that such products are not available, targeted or used by any children or adolescent.
- Developing a more flexible and **modernizing** approach to regulating the growing spectrum of products may also need to involve undertaking a review of the Tobacco Control Act, something that is long overdue as noted elsewhere:
  - a) Defining common terminologies and definitions that can allow for greater public understanding, and provide consistency in statutory, regulatory, and legal relevance. This could be achieved by appointing and an expert panel;
  - b) Establishing **product standards** (including the use of biomarkers) for the various categories of products that includes combustible products, non-combustible tobacco, nicotine products, and other possible alternatives;

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<sup>3</sup> Gottlieb S, Zeller M. A Nicotine-Focused Framework for Public Health. N Engl J Med. 2017 Sep 21; 377(12):1111-1114.

- c) Implementing comprehensive labeling, marketing and educational campaigns that would reflect the **risks and relative risks** of the products (both in terms of product categories as well as individual products) so that the public, users of products, the medical profession, parents, the media and others would better understand more clearly what the risks and relative risks (and even benefits) are of using one type of product over another. Package inserts and referrals to an FDA/CTP website designed specifically for providing truthful, accurate and complete information should be given a high priority. Collaborate and engage with all stakeholders in order to provide a more consistent message that is 'user friendly'.
- d) Developing a **science-based** regulatory format that will allow for a variety of *informational* claims and statements (not just health claims) to be used that give the public a better understanding of the risks and relative risks of various products. This type of approach has been used in the food area where the level of scientific evidence determines what kinds of claims or statements can be made.

## 2. **Collectively Resolving Issues Related to Youth Access and Use of Tobacco and Nicotine Products**

The issues and concerns related to adolescent use of tobacco and nicotine products is a major topic of concern, not only by the public health and tobacco control communities but by federal, state, and local policy makers and regulators, parents and teachers, responsible retailers and distributors, and many of those associated with the manufacturing businesses. While many stakeholders share common ground in this area, the polarizing and media driven approach that has been taken over the last several years has, in our view, caused what has become a war of words and rhetoric, with a lot of finger pointing and a failure to bring interested parties together to discuss how to collectively deal with the issue and find workable solutions to protect youth while allowing smokers to have access to cleaner alternative nicotine products. Given that Tobacco 21 is now the law of the land, it would be to everyone's interest to set aside politics and to address the challenges and opportunities collectively. The issue of

flavors has been particularly divisive, polarizing and political with some advocating for a complete ban while others believe that there is insufficient evidence that a flavor ban will solve the issue of adolescent use of tobacco and nicotine. If stakeholders can collectively deal with the broader issue of adolescent use, a compromise on the flavor issue might be attainable. We believe that if managed properly (such as restricting how flavored products should be marketed), flavors should be allowed in science-based lower risk alternatives that would provide adult smokers with 'cleaner' forms of tobacco and nicotine. Flavored NRT products have been on the market for years and there maybe things to learn from those allowances.

The NTRI is therefore, once again (following up on a letter we sent to Commission Gottlieb July 23, 2018), **strongly** recommending that the FDA/CTP convene a **national dialogue/summit** at which civil discussions can take place in an effort to bring all stakeholders together to map out a **coordinated/ collaborative plan** designed to prevent and discourage the use of all tobacco and nicotine products by adolescents while providing adults with 'cleaner' consumer acceptable forms of nicotine. It is irresponsible and not in the public interest for stakeholders to carry out what has become a war of rhetoric and words. Such a dialogue summit would allow for participants to engage in a civil manner, educate one another about challenges and opportunities and agree to specific measurable goals and objectives.

### **3. Improving and Fostering Collaborative Scientific Research and Encouraging Innovation**

It is often said that it should be good science that drives the implementation of sound policies. This is a premise that the FDA/CTP has often said it relies on in carrying out its regulatory responsibilities. The FDA/CTP could be doing much more to encourage academic scientists to partner with manufacturers to advance science in ways that would accelerate the introduction of lower risk products into the market place. Product manufacturers also ought to be incentivized to share their internal research and market data more widely with public health scientists so that there is greater confidence in product claims. The FDA/CTP could in theory invite manufacturers to voluntarily utilize their peer review system to vet proposals designed to manufacturers prepare their

PMTA and MRTP applications thereby opening this process making it more competitive, transparent, and less secretive. There is clearly a need for more discussions within the scientific community both within and between governmental agencies such as the FDA/CTP as well as with the private sector. The FDA/CTP can and should do more to hold scientific workshops that allow scientists and researchers to meet in a safe-haven environment and where opportunities would be allowed for seemingly opposing interests to find common ground in areas of science, research and innovation. Innovators of products should not be shut out because some regard them as industry. Former Commissioner Gottlieb specifically mentioned the importance of innovation in the July 2017 announcement in which he said innovation should be encouraged, not stifled. All parties and stakeholders should be held accountable to meeting and following the strictest standards for peer review. There should be greater collaboration and data sharing, and a shared commitment to open science. Science should not be cherry picked for public relations purposes. The FDA/CTP can play an important role in further facilitating such discussions, helping set research priorities all of which would have a positive impact on the regulatory decision-making.

#### 4. **Educating the Public and Users of Tobacco and Nicotine Products about what Nicotine Is and Isn't**

FDA/CTP has a huge problem which is that the public is massively confused about the health risks of nicotine<sup>4</sup>. As noted above in the preliminary comments, many (including the CTP) have echoed the remarks of Michael Russell when he said: **“people smoke for the nicotine but die from the tar.”** Yet in today’s environment the issue of nicotine as the underlying hazard of using tobacco and nicotine has become front and center. The public, consumers, parents, the medical profession the media and even many in the tobacco control community do not understand the issue of nicotine. Many unfortunately continue to believe that it is the nicotine that causes cancer and other debilitating diseases. While acknowledging that nicotine is addictive, the FDA/CTP

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<sup>4</sup> Fong, Geoffrey T., Elton-Marshall, Tara, Driezen, Pete, Kaufman, Annette R., Cummings, K. Michael, Choi, Kelvin, Kwan, Jonathan, Koblitz, Amber, Hyland, Andrew, Bansal-Travers, Maansi, Carusi, Charles, Thompson, Mary E. U.S. adult perceptions of the harmfulness of tobacco products: Descriptive findings from the 2013-14 baseline wave 1 of the PATH study. *Addictive Behaviors*. 91, 180-187.



recognizes that it is not the nicotine that causes the disease and deaths attributed to tobacco and said so in its July 2017 visionary statement<sup>5</sup>. Despite statements from the FDA/CTP that there needs to be a public education campaign about nicotine little has been done. The FDA/CTP needs to follow through on that commitment. We believe the FDA/CTP must and can do more to engage with those in the private sector so that there is greater clarity about what nicotine is and isn't. This should be given a high priority,

## 5. **Updating and Modernizing the Tobacco Control Act**

It has been over 10 years since the passage of the Tobacco Control Act. Much has been accomplished in that period, but much remains to be done. The statute needs to be critically reviewed and updated to reflect the changing marketplace of nicotine delivery products. The natural evolution of a changing market place requires FDA to adapt and evolve so regulations can be based on new ideas and options that can better address the devastating health consequences caused by combustible tobacco products. Such review and updating of FDA statutes (foods, drugs, medical devices etc.) is routine and given how dramatically the tobacco and nicotine environment has changed over the last 10 plus years it is prudent to at least begin a serious discussion as to how the statute can better serve the interests of public health by focusing on many of the areas that petitioners have identified above. Even a cursory review of the Tobacco Control Act would indicate that it is outdated. Petitioners recognize that changes will not come overnight but we would strongly encourage that the FDA/CTP, even as it develops its own recommendations for modernizing the statute, to ask an agency like the Health and Medicine Division of the National Academies of Sciences (formerly the Institute of Medicine) to do a thorough and comprehensive review, and assessment, as a follow-up to what was done when the FDA commissioned the ***Clearing the Smoke-Assessing the Science Base for Tobacco Harm Reduction*** report twenty years ago. This is a report that many still consider to be one of the most important reports on tobacco and nicotine harm reduction ever written. One overarching thing that needs to

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<sup>5</sup> Gottlieb S, Zeller M. A Nicotine-Focused Framework for Public Health. N Engl J Med. 2017 Sep 21; 377(12):1111-1114.

be considered is bringing all tobacco and nicotine products under a single umbrella and renaming the current Center, the Center for Tobacco, Nicotine and Alternative Products (CTNAP).

## 6. Encouraging and Expanding Stakeholder Engagement

Throughout this petition, petitioners have suggested that the FDA/CTP do more in the way of bringing stakeholders together to civilly discuss the many important issues that we are facing in this dynamically changing environment. We are not suggesting that we dismiss the past bad actions of the cigarette manufacturers. Rather we need to heed the lessons of the past so as not to make the same mistakes going forward. The Tobacco Control Act created a framework that should incentivize manufacturers to move away from profiting from the sale of tobacco products that causes so much harm to consumers. Bringing stakeholders together will not resolve all differences but it will allow serious and responsible stakeholders the opportunity to bring ideas forward and find areas of common ground that can more rapidly advance population health. This could be of great value to the FDA/CTP, and to public health in general. The current climate has become toxic and emotional, non-scientific, and counterproductive to achieving public health goals. We recognize that the FDA/CTP has done a great deal over the last ten years to engage stakeholders, but it is also clear from many of the speeches given by those within CTP that more can and should be done, not only through the leadership at the CTP but also in the private sector. To that end petitioners would encourage that the FDA/CTP review the work that has been done by the University of Virginia's Institute for Engagement and Negotiation (the Morven Dialogues) - including a series of Core Principles/ recommendations issued last April (2019). While not perfect or fully comprehensive, these principles and the process that was used during six dialogues might be of use to all of those working in the CTP as well as in the FDA Commissioner's office. The Core Principles (**Civil Dialogue on Tobacco, Nicotine Alternative Product Harm Reduction - Addressing a National and Global Epidemic, A Product of the Morven Dialogues**) can be accessed at :

<http://morvenprinciples.net>

## **B. STATEMENT OF GROUNDS**

It has been 56 years since the release of the first Surgeon General's Report in 1964. It was the first of what would be many additional reports on a variety of topics, including nicotine. The most recent report of the Surgeon General focused on the topic of adult smoking cessation revealing that despite significant progress in reducing the prevalence of smoking down to 14%, there still remains 34 million smokers in this country<sup>6</sup>. Not only are these smokers suffering devastating premature diseases and deaths from smoking they are also costing society over \$300 billion in health care costs and lost productivity each year. These are facts that are well known to FDA/CTP. If one thinks about such statistics in terms of global use of cigarettes, we can only conclude that there is a global smoking epidemic.

For nearly 50 years (1950-2000) cigarette manufacturers deliberately misled the public about the dangers of cigarette smoking, the addictiveness of nicotine, and the feasibility of providing lower risk alternative nicotine delivery products to addicted smokers. Instead, cigarette manufacturers attempted to reassure smokers that it was not proven that cigarettes were a cause of serious diseases and addiction. They offered concerned smokers filtered tipped and so-called low tar/nicotine cigarettes, knowing that these product modifications would provide little benefit to reducing the health risks posed by smoking. In fact, evidence now suggests that that design changes incorporated into cigarette making since the 1950s have contributed to increased risks premature mortality, lung cancer, COPD, and heart disease<sup>7</sup>.

Before 2009, there wasn't any regulatory oversight of the cigarette industry and its products. When industry whistle blowers came forward in the 1990s and told the world about the cigarette companies' decades long mass deception campaign the companies were forced to turn over their previously secret internal documents. Attitudes about the cigarette companies then changed and momentum shifted to public health efforts to end the cigarette epidemic that had plagued America for nearly a century. In 2009,

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<sup>6</sup> U.S. Department of Health and Human Services. *Smoking Cessation. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.

<sup>7</sup> Thun MJ, Carter BD, Feskanich D, Freedman ND, Prentice R, Lopez AD, Hartge P, Gapstur SM. 50-Year Trends in Smoking-Related Mortality in the United States. *N Engl J Med* 2013;368:351-64.

Congress passed the Family Smoking Prevention and Tobacco Control Act ,P.L. 111-31, (referred to hereafter as the Tobacco Control Act ) which finally gave FDA regulatory authority over cigarettes and smokeless tobacco. The Tobacco Control Act was written in part to rein in the cigarette industry's decades of bad behaviors, which at the time was fully understandable. However, the statute was in many ways **outdated** on the day it was signed into law, particularly in terms of the way it dealt with new tobacco and nicotine delivery products that could potentially offer addicted smokers a lower risk alternative.

We recognize that the Tobacco Control Act was a political compromise involving stakeholders including cigarette manufacturers, pharmaceutical interests, and a few select members of the public health community. Based on over a decade of the law protecting cigarettes from lower risk competition, in stark contrast to past FDA laws (i.e., the 1906 and 1938 FDA laws on food and drugs) that profoundly influenced the food and pharmaceutical industries to develop lower risk products, in retrospect it might be fair to say that the cigarette companies at the time got the better part of the legislative deal. It is important to recognize that today's environment is very different than it was when the Tobacco Control Act was conceived. The internet and global product innovations has allowed for a growing spectrum of lower risk nicotine delivery products to reach consumers, threatening to replace cigarettes much as sanitary food and science-based pharmaceuticals replaced their far more hazardous precursors.

The Tobacco Control Act provides protection for deadly cigarettes which were on the market prior to 2007 while making it extremely difficult to introduce new lower risk alternative nicotine products that could accelerate a decline in cigarette use. Since the Tobacco Control Act was passed in 2009 the landscape of nicotine products and manufacturers has changed. Innovation and technology, new entrants into the market place, consumer demands and preferences and competition are going to continue to evolve, requiring FDA to adapt, so regulations can consider new ideas and options that can better address the devastating health consequences caused by combustible tobacco products.

Director Mitch Zeller and former FDA Commissioner Scott Gottlieb (as well as many others) have often quoted Professor Michael Russell, an addiction medicine physician

from the United Kingdom who in the 1970s wisely pointed out **“People smoke for nicotine, but they die from the tar”**. While recognizing this well accepted reality, the FDA/CTP has been slow to establish a regulatory framework that recognizes the urgency of reducing cigarette use by addicted smokers. The FDA/CTP needs to give greater priority to giving smokers lower risk nicotine products. The current regulatory process is overly bureaucratic, outdated, and extremely costly which is delaying change rather than exploiting opportunities to dramatically reduce the diseases caused primarily by combustible tobacco products. Product innovation ought to be encouraged not stifled. More than two and a half years ago (July of 2017) the agency indicated that it would be taking a new path. In July of 2018, the NTRI sent a letter to then FDA Commissioner Gottlieb commending him and Director Zeller for their leadership and for the visionary path outlined in July of 2017. In that letter the NTRI outlined its positions on many of the recommendations contained in this more formal petition. We encourage the agency to again read that letter as it too mirrors much of what the agency outlined in July of 2017. In that letter, we concluded:

***“We believe there is an urgency (and opportunity) that both the public and private sectors need to become more actively involved in seeing that the FDA’s new tobacco and nicotine policy gets implemented in an expeditious way. We cannot let this opportunity pass us by. Bold and visionary leadership and thinking are essential. It will involve the active participation of all stakeholders who support the idea that we can, in fact, reduce cigarette smoking by employing new strategies and by giving adult users lower-risk nicotine alternatives.”***

A copy of the entire letter can be found on the NTRI website at: <http://www.tobaccoreform.org>. This petition is intended to encourage the FDA/CTP to focus on taking that new path that is now two and half years behind us. Lives depend on it. Time is crucial.

### A New Era – A New Vision – and the Need for New Leadership

In July of 2017, then Commissioner Scott Gottlieb and CTP Director Zeller made an announcement that was welcomed by a broad spectrum of stakeholders<sup>8</sup>. The tobacco

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<sup>8</sup> Gottlieb S, Zeller M. A Nicotine-Focused Framework for Public Health. N Engl J Med. 2017 Sep 21; 377(12):1111-1114.

and nicotine environment had undergone significant changes since the late 20<sup>th</sup> century. This has included the development of not only nicotine replacement products (NRT), but noncombustible forms of tobacco such as SNUS that contains significantly lower levels of cancer-causing chemicals such as tobacco specific nitrosamines (TSNAs) relative to cigarettes and other forms of oral tobacco. New product innovations have also included the introduction of the e-cigarette around 2007 and later commercialization of heat-not-burn products and other novel alternatives combustible nicotine delivery products (i.e., very low nicotine cigarettes). This dynamically changing environment requires an updating of the policies and regulations of the FDA/CTP. The FDA/CTP itself has, both in 2017 and since then, indicated on many occasions that we are at an important crossroads. While there are many challenges in making urgently needed **modernizing** adjustments there are more importantly opportunities that would result in a drastic reduction of disease and death caused by combustible products. As the FDA/CTP Press release in July of 2017 noted:

***“Envisioning a world where cigarettes would no longer create or sustain addiction and where adults who need or want nicotine could get it from less harmful alternative sources, needs to be the cornerstone of our efforts – and we believe it is vital that we pursue common ground.”<sup>9</sup>***

Many have previously called for the regulation of tobacco and nicotine products using what is referred to as the **continuum of risk** which would establish regulations across a spectrum of tobacco and nicotine products based on the risks, relative risks and intended uses of a product. At one end can be found the combustible cigarette by far the deadliest form of tobacco and nicotine consumption. At the other, are nicotine replace products (NRT) such as patches, gums, lozenges, inhalers etc. Setting regulations based on risk is an approach that has been used by the FDA in many other areas including pharmaceuticals, and foods. Products are labeled (and marketed) to give consumers and the public information they need to make ‘informed’ decisions. No product whether it is a drug, or a food is totally risk free. As an example, unhealthy

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<sup>9</sup> ibid

eating habits and the intake of excessive amounts of sugar, salt, cholesterol, fat etc. have resulted in an obesity epidemic that has significantly increased risks of diabetes, heart disease, stroke, cancer and other ailments.

The petitioners fully support the need for rigorous scientific review of tobacco and nicotine products by FDA in order to ensure that products put into the marketplace are understood and appropriately labelled. That said, guidelines for product review need to be made clear and the process of product review not made to be punitive and unnecessarily burdensome and costly. Going forward it is critical that product innovation and investment in new technology be encouraged and not stifled.

Many public health organizations have seemingly returned to the days prior to the passage of the Tobacco Control Act, arguing that **all** tobacco and nicotine products are equally harmful and that **all** manufacturers of tobacco and nicotine products are selling deadly products designed and intended to addict adolescents. In some cases, some of these organizations have urged FDA to prohibit or at least make difficult the ability to introduce and market lower risk nicotine cigarette substitute products. They have dusted off their strategy manuals and are revitalizing the cigarette wars, but this time expanding it to include a focus on alternative nicotine products incorrectly labelling all nicotine products as equally harmful. The unfortunate controversy sells well with the press but is confusing to the general public and smokers and clouds efforts to focus on finding solutions to help protect the public and help addicted smokers' transition away from deadly combustible tobacco products.

The petitioners recognize the need to protect nonsmokers, especially children and to ensure that products that are legally available are appropriately labelled and meet specific regulatory requirements. Petitioners believe that while we must be highly skeptical of the behavior of manufacturers whose motives likely do not align with the goals of public health. We must also be careful not to miss genuine opportunities to support evidence-based innovations that offer the potential to advance public health by offering smokers lower risk alternative tobacco and nicotine products. Effective and workable regulatory oversight can compel business interests to align with public health goals, as has been done with other consumer products, food, airline and auto safety, air quality, unleaded paint and motor fuels and myriad other goods and services. In fact,

this is exactly why the FDA/CTP was given authority to regulate tobacco products to begin with and why many of us worked so diligently to see the Tobacco Control Act enacted.

The most recent report of the Surgeon General on the topic of adult smoking cessation concluded that, despite significant progress made in reducing smoking rates, there are still an estimated 34 million people smoking cigarettes in this country, most of whom are persistent daily smokers<sup>10</sup>. The report makes it clear why progress with smoking cessation has been painfully slow: 1) nicotine addiction makes it very hard to stop smoking; and 2) current treatments for nicotine addiction have limited effectiveness. The reality is most adults who smoke want to stop but find it hard to stay smoke-free because of the way cigarettes are designed. In other words, the crux of the smoking cessation problem has to do with the way cigarettes are engineered to cause and sustain nicotine addiction. The report also concluded that more research is needed to evaluate nicotine vaping products as cessation treatments, which is true, but failed to note that the FDA/CTP has created barriers to make it difficult for researchers to do studies evaluating nicotine vaping products as smoking cessation treatments.

The recent experiences with the rapid increase of nicotine vaping by youth involving JUUL and other similarly designed nicotine vaping products has raised important questions about the unintended consequences of allowing alternative nicotine delivery products to be sold. At the same time, it also demonstrates the value of robust, but flexible regulatory oversight. Youth vaping is an unintended consequence of aggressive industry marketing in an unfettered marketplace born of poor regulatory oversight. Ironically, it is also likely that regulatory restrictions preventing marketing of such products as a carefully regulated reduced risk option for adults who smoke cigarettes has inadvertently contributed to the youth vaping problem, since the simultaneous lack of regulatory action on other marketing has permitted widespread lifestyle advertising and no health-related messaging which would be appealing to current adult smokers. Post-market product surveillance supported by FDA was quick to pick up on the growing

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<sup>10</sup> U.S. Department of Health and Human Services. *Smoking Cessation. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.



level of youth vaping which in turn allowed FDA to use its regulatory authority to implement remedial interventions to address the problem. However, at the same time FDA has been slow to require manufacturers to submit applications for review of presumably lower risk products that have been allowed onto the market under FDA's regulatory discretion. The challenges and opportunities regarding how to best promote population health are not going to go away, and it is incumbent on the FDA/CTP to provide the necessary leadership.

While we commend the work that the FDA/CTP has done in the last 10 years, we believe that we are indeed at a critical turning point and crossroads and that it is far better to engage in civil dialogue and discussions to find workable solutions to advance public health rather than to continue the old war on tobacco, now merely updated to incorporate all nicotine products.

### **C. CONCLUSIONS**

The petitioners believe, as does the FDA/CTP, that we are at an important crossroads in terms of developing and implementing 21<sup>st</sup> century approaches to the regulation of tobacco, nicotine and alternative products, requiring new thinking and greater engagement of stakeholders. Change for many does not come easily and there are many who are more comfortable fighting the polarizing tobacco and nicotine wars of the past rather than engaging in civil discussions about how to manage a dynamically changing environment. The FDA/CTP is in a unique position to provide a leadership role and to serve as a **catalyst** for change. That is a similar role that the NTRI sees itself playing as well and why we have respectfully submitted this petition for consideration. During the January (2020) press conference for the release of the Surgeon General's Report on Smoking Cessation, Surgeon General Adams said, "*Things are evolving and so must we.*" We further believe that what can be done here in the US in fostering greater civil dialogue in safe-haven venues such as the FDA/CTP could be used as a model at the global level including at the World Health Organization (WHO).

**D. ENVIRONMENTAL IMPACT**

We claim categorical exclusion under 25.30, 25.31, 25.32, 25.33, or 25.34 of this chapter or an environmental assessment under 25.40 of this chapter.

**E. ECONOMIC IMPACT**

Economic impact information will be submitted upon request of the commissioner.

**F. CERTIFICATION**

The undersigned certifies that, to the best and belief of the undersigned, this petition includes all information and views on which the petition relies , and that it includes representative data and information known to the petitioner known to the petitioner which are unfavorable to the petition.

Respectfully submitted on behalf of the NTRI Leadership Team,

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## G. APPENDIX 1 – Cover Letter to Mitch Zeller



# NATIONAL TOBACCO REFORM INITIATIVE

Ending Cigarette Use by Adults in a Decade is Possible

March 6, 2020

Mitch Zeller, Director  
Center for Tobacco Products  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

### **RE: Petition of the National Tobacco Reform Initiative**

Dear Mr. Zeller,

The National Tobacco Reform Initiative (hereafter referred to as the NTRI) is an informal organization led by a small group of distinguished, seasoned and independent tobacco control leaders with decades of service fighting the tobacco epidemic. NTRI is a voluntary organization and receives no financial assistance from any organization or outside entities. We advocate for civil engagement with all interested stakeholders and for open evidenced based discussions about the most effective ways to accelerate a reduction in the current number of adult smokers and associated diseases and premature deaths caused by smoking. One of NTRI's major priority areas is to establish a more rational tobacco and nicotine products regulatory framework based on their relative risks and that is adaptable to the increased speed of innovation in new technology of products that have the potential to displace deadly and addictive combustible tobacco products.

Towards this end, NTRI hereby submits this citizens petition to the United States Food and Drug Administration (FDA) and specifically the Center for Tobacco Products (CTP) to follow through on its previously asserted science-based comprehensive nicotine focused tobacco product regulatory strategy. This strategy as outlined by the FDA/CTP in 2017 recognized that there is a continuum of risk across different nicotine delivery products and suggested that public health could be markedly improved by reducing the addictiveness of combustible tobacco products while at the same time increasing access to less harmful tobacco and nicotine products (i.e., both consumer and medicinal nicotine products). The guiding principle behind the strategy was finding ways to reduce the diseases and premature deaths caused by tobacco products, the vast majority of which are currently the result of addiction to conventional, combustible tobacco cigarettes.

This petition is intended to make recommendations to the agency for carrying out its responsibilities pursuant to provisions of the Food Drug and Cosmetic Act and specifically under the Family Smoking Prevention and Tobacco Control Act and to consider ways of modernizing how it chooses to regulate a growing number of diverse tobacco and nicotine products. Specifically, we are urging FDA/CTP to establish a more flexible and workable regulatory framework that recognizes the opportunities associated with a rapidly evolving nicotine delivery product marketplace, and to support stakeholder engagement and dialogue, which can better serve public health goals and objectives

consistent with the science-based comprehensive nicotine focused tobacco product regulatory strategy the agency outlined in 2017. Going forward it is critical that product innovation and investment in new technology be encouraged and not stifled. Public health authorities today are in a unique position to be able to provide solutions for dealing with the issues of adolescent use of tobacco and nicotine, while providing people who smoke cigarettes with viable lower risk alternative products that could dramatically reduce smoking caused diseases.

*In conclusion, the undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition.*

Again, NTRI appreciates the leadership you have shown on this important public health issue and look forward to your response to the ideas contained in this petition.

Sincerely,



K. Michael Cummings, MPH, PhD, on behalf of the undersigned members of the National Tobacco Reform Leadership Team

David Abrams, PhD – Professor, Department of Social and Behavioral Science, College of Global Health, New York University;

Scott D. Ballin, JD – Health Policy Consultant, former Vice President and Legislative Counsel to the American Heart Association, Former Chairman of the Coalition on Smoking OR Health (ACS, AHA, ALA): Advisor to the University of Virginia “Morven Dialogues”;

Aaron Biebert- Former President and CEO, Clear Medical Solutions; Director, ‘A Billion Lives’ & ‘You Don’t Know Nicotine’

Allan C. Erickson – Former Vice President for Public Education and Tobacco Control, American Cancer Society, Former Staff Director, Latin American Coordinating Committee on Tobacco Control;

Ray Niaura, PhD -Professor School of Public Health Global Studies, New York University;

John R. Seffrin, PhD – Retired

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cc: Stephen M. Hahn MD, Commissioner U.S. Food & Drug Administration