



NATIONAL TOBACCO REFORM INITIATIVE

Campaign to end death & disease from smoking

July 23, 2018

SUBJECT: Staying the Course with the Tobacco and Nicotine Vision

Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20857

Dear Commissioner Gottlieb:

We are writing from the National Tobacco Reform Initiative, an organization established by a small group of veteran tobacco control leaders who, like you, recognize that the tobacco and nicotine environment has substantially changed in the last two decades, and that 'status quo' thinking is not going to get us to improved population health as the citizens of this country deserve. Yes, progress has been made in reducing the use of cigarettes over several decades, but now is the time to not only continue with what has worked, but to step up our efforts in other areas. Technology, innovation and new science-based lower risk products are making it possible to provide addicted adult cigarette smokers with consumer accepted alternatives.

When you were confirmed as the Commissioner of the Food and Drug Administration in May of 2017, you wasted no time in looking to make the Agency a more dynamic, forward-thinking, engaged and '**modernized**' organization. Quite a commendable and challenging undertaking! By July of last year, you and Director Mitch Zeller had announced an important vision and direction for the Agency and the Center for Tobacco Products with respect to tobacco and nicotine policy, recognizing that it is the **combustible tobacco, especially cigarettes**, that remains this nation's leading cause of disease and death.

Not since FDA Commissioner David Kessler initiated actions in 1994 to try and bring tobacco under FDA's regulatory purview, has a Commissioner provided such a forward-thinking vision about how to reduce needless deaths and sickness due to smoking. In your July press announcement, you spoke of finding the 'appropriate balance between regulation and encouraging the development of innovative products that may be less dangerous than cigarettes'. You and CTP Director Zeller have used the very words that we at the NTRI embrace and support – that we are indeed at a 'crossroads'; that products should be regulated based on their health risks and relative risks (continuum of risk); and, that serious consideration should be given to substantially reducing the nicotine in cigarettes while providing adult users with cleaner forms of non-combustible nicotine.

We also agree that truthful, accurate and non-misleading information must be provided to the public; that product innovations should be encouraged; that there is a need for reducing regulatory bureaucracies and costs and streamlining product review processes; that unbiased science should be promoted; and, that there is a need to engage stakeholders in civil dialogue.

The FDA and NTRI goals are comparable, and we hope we can work together more closely in the coming year as you continue to make your ‘vision’ a reality. We also hope that many of the mainstream organizations that traditionally take their cue from the Campaign for Tobacco-Free Kids will begin to step back from their more traditional tobacco control positions of the 1990’s and begin to recognize that we are indeed at an important ‘crossroads’. There are 30 million adult smokers in this country and, as you said last year, we must redouble our efforts.

- I. Who is the National Tobacco Reform Initiative (NTRI)?**
- II. What are the goals and objectives of the NTRI and, especially those relevant to tobacco and nicotine product regulation?**
- III. Some suggestions on what FDA might consider doing to more effectively and expeditiously move the ‘vision’ forward.**
- IV. Conclusions**

I. Who is the National Tobacco Reform Initiative (NTRI)?

Led by a small group of distinguished and independent tobacco control leaders with decades of service fighting the tobacco epidemic, the mission of the NTRI is to facilitate open and evidence-based discussions about the most effective ways to reduce the number of current adult smokers. The NTRI looks for special 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 levels, consumers, the media, tobacco and nicotine trade associations, and manufacturers. As you know, today’s environment is radically different from what is often described as the ‘tobacco wars of the 1990’s’, and even different from just nine (9) years ago when the CTP was established. The NTRI seeks to identify major deficiencies and barriers holding back the tobacco control movement in the U.S., to put a spotlight on these issues, and propose ways to resolve them. For more information, visit the NTRI website at <http://www.tobaccoreform.org>.

II. What are the goals and objectives of the NTRI and, in particular, those relevant to tobacco and nicotine product regulation?

There are three (3) primary priorities of the NTRI which are based on the input from 120 tobacco control leaders across the U.S.. They are:

- Increase the federal excise ‘differential’ taxes on combustible cigarettes and cigarette taxes in those states with the lowest levels of taxation;
- Encourage health and life insurers, employers and health professionals to actively promote smoking cessation measures; and,

The third priority, which is the one most directly relevant to FDA/CTP regulatory oversight over tobacco and nicotine products:

- **Establish a more rational tobacco, nicotine and alternative products regulatory framework based on their relative risks, and that is adaptable to the increased speed of innovation and technology development.**

To help achieve this priority goal, the NTRI has delineated eight (8) essential elements/principles that while not all inclusive can and should help guide all stakeholders in moving forward. As noted, these essential elements all parallel much of what the FDA/CTP has laid out in its 'vision'. These elements are:

1. All tobacco, nicotine and alternative products, including but not limited to cigarettes, cigars, smokeless tobacco products (including SNUS), e-cigarettes, heat-not-burn (HnB) products, gums, nicotine replacement products (NRT), etc. should be regulated by the FDA based on their health risks, relative risks and intended uses (continuum of risk). This includes, but is not limited to, product standards, labeling, marketing, advertising and public education efforts;
2. Serious consideration should be given to significantly reducing the levels of nicotine in cigarettes, but only as part of a comprehensive tobacco harm minimization effort. The FDA/CTP should take the lead in engaging stakeholders about the feasibility of achieving this strategy;
3. FDA processes for the review and approval of science-based reduced-risk products should be reconfigured and streamlined. This includes that consideration should be given to the setting of workable, less bureaucratic, cost-effective requirements and regulations for various categories of products. Products that have sufficient scientific backing should be considered for 'fast-tracking' and carefully monitored;
4. Consumers and the public should be given complete, truthful and accurate information by both the public and private sector organizations that includes, but is not limited to, the FDA, CDC, NGOs, health care professionals, retailers, wholesalers, manufacturers, etc.;
5. Adult smokers should have ready access to alternative non-combustible lower-risk tobacco and nicotine products that are 'consumer acceptable'. This should include the allowance of flavors in such products. Flavors are not inherently bad and can have a positive impact in moving smokers to using significantly lower-risk sources of nicotine. However, consideration should also be given to avoiding allowing the use of any descriptors or marketing tactics that target youth;
6. Good science (regardless of who is conducting the research) should be driving policy and regulatory efforts. This should include identifying research priorities, making a concerted effort to reduce 'bias', the sharing of information, and reducing the misuse of research for public relations purposes;
7. Innovation, technology, research and incentives in the development of alternative lower-risk products should be encouraged in both the public and private sectors. This should include governmental research bodies, academic research institutions, entrepreneurs, investors and manufacturers of tobacco and nicotine reduced-risk products; and,

8. Greater engagement and dialogue between stakeholders should be encouraged and undertaken in both the public and private sectors.

III. Some suggestions on how and what the FDA/CTP might consider doing to more effectively and expeditiously implement the 'vision'.

We recognize that the FDA/CTP has 'many irons in the fire', including important ANPRMs. But, there are other important issues which we see as critical pieces in the agency's efforts to establish a more workable regulatory framework. We have some concerns that the agency is already finding itself being pulled in many different directions and falling behind on its ability to focus on the 'vision' that was announced last July. We want to assist and support the agency in ensuring that this doesn't happen. We, therefore, offer the following suggestions in the spirit of supporting the agency as it pursues its short-term and long-term objectives:

1. A cornerstone to last July's announcement was the need to regulate tobacco and nicotine products based on risks and relative risks, and to establish a more flexible and workable regulatory framework to accomplish several important goals. It seems that this issue has been put on the 'back burner' as the agency becomes consumed by debates about product flavorings, 'flavor' debates, the hysteria surrounding the use of JUUL by adolescents, the reduction of nicotine in cigarettes, MRTP product applications, lawsuits filed by the tobacco control community on deeming, etc. It might be useful for the agency to convene a consensus conference (not merely a workshop) on this important topic that would allow all stakeholders to provide input and to hear ideas from others. This issue is not something that should be done using an ANPRM approach. 'The topic is truly too important and transformational, and needs to involve open discussion'.
2. We encourage the agency to open a dialogue on how e-cigarettes can be better incorporated into the FDA's vision. The FDA extended implementation of the 'deeming regulations' until 2022. While this extension has a rational basis in some ways, it may not be the best use of the approximately four-year extension, particularly in terms of aligning the oversight and regulation of e-cigarettes with the agency's harm reduction strategies. We suggest that this may be an opportune time for the various players in the e-cigarette space to have a more civil open dialogue on the issues. We believe that there is a great deal of 'common ground' to be found. The recent hysteria around 'JUUL' is in some ways a 'lost opportunity' for looking to the future and dealing with both challenges and opportunities in terms of innovations and product development while, at the same time, ensuring that we minimize the targeting or use of such products by America's youth.
3. **The FDA's NNN rule should be withdrawn for reconsideration.** In the waning hours of the Obama Administration, the FDA/CTP issued a 'final' rule (subject to comment) on NNN in smokeless tobacco products.
4. Here again, the intentions were admirable, but the goals not only unworkable, but also the objectives inconsistent with tobacco harm-reduction strategies.

It has been long accepted that non-combustible tobacco products are significantly lower in risk (95% lower) than the deadly cigarette, yet the CTP chose these products to issue its first 'product standard' rather than focusing on the deadly cigarette. We propose that the rule be withdrawn and reconfigured keeping in mind that these products could provide an important tobacco alternative to the cigarette.

5. Relevant to the topics previously noted, is the clear and pressing need for the FDA/CDC and the private sector to develop comprehensive truthful educational programs and to ensure that the public and the consumers of tobacco and nicotine products understand more clearly what nicotine is and is not. **It seems inconceivable that a majority of the public still believes that nicotine causes cancer.** But, this need goes far beyond just 'nicotine'. For too long, the FDA, CDC, and the public health community have failed to distinguish between the relative risk of products, choosing instead to mislead the public with the message that all tobacco products are equally harmful. We encourage the FDA to move quickly to correct this long-standing misperception, and that it do so by involving a spectrum of stakeholders that includes the consumer.
6. The FDA has devoted a significant amount of its budget to the funding of scientific research made possible by the industry paid 'user fees' as mandated by the TCA. Is the FDA's science agenda in line with the new 'vision'? Has the Agency taken steps to begin any discussions on how such a realignment can take place? Will future scientific priority decisions be made with the 'vision' in mind? We would suggest that the FDA take some proactive steps that would engage a broader spectrum of stakeholders (even including industry) in helping design a research agenda that will look to the future rather than funding only research that is reflective of the past.
7. Last but not least, as the FDA continues to focus its efforts on what it can do internally in making its 'vision' become a reality, it is critical to also look at the urgent need to 'modernize' the elements of the Tobacco Control Act to reflect the reality of differential risk of evolving nicotine containing products. The statute is nine (9) years old, older if you realize that much of its content is the product of 'thinking' almost 20 years ago. Much has changed, as you well know, and many of the requirements are clearly outdated and real barriers to many of the kinds of things that we believe you are seeking to accomplish. We are not asking that the Agency take its eggs out of the basket of activities you are undertaking to move its agenda forward, but that it begin serious thinking about what could and should be amended in the Act to bring it up to date. This suggestion is obviously not unlike other actions and activities that you, as Commissioner, are taking with respect to other Centers.

IV. Conclusion

We believe there is a sense of 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 afford to let this opportunity pass us by. Bold and visionary leadership and new thinking are essential.

It will involve the active positive 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 of tobacco lower-risk nicotine alternatives. There will be many obstacles and barriers to overcome, but the worst thing we can do is to sit idly by hoping that ‘change’ will happen on its own.

Eighteen years ago, at the request of the FDA (including a young Mitch Zeller), a landmark report was issued by the Institute of Medicine entitled: Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction.

The introduction to the report included a simple, but far-reaching quote by Goethe: “**Knowing is not enough, we must apply. Wiling it not enough, we must do**”. It is indeed time for doing. We should not have to wait another 18 years before we accomplish what so many of us believe must urgently be done at the earliest possible time. You can count on the National Tobacco Reform Initiative to do its important part.

Sincerely,

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