FDA's Nicotine and Tobacco Regulation and the Key Role of Regulatory Science

Remarks by Scott Gottlieb, M.D.,
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It's an honor to be here today, speaking before the leading experts in the field of tobacco regulatory science.

FDA greatly appreciates that NIH and you, as our tobacco regulatory science partners, are committed — like our agency — to conducting the cutting-edge scientific investigation that's crucial in our efforts to address the tobacco use and addiction crisis in this country.

I speak to you during a moment of extraordinary promise for tobacco regulation. The FDA is engaged in a profound dialogue about the best ways to improve public health through the agency's tobacco regulatory approaches under the Family Smoking Prevention and Tobacco Control Act.

As we evaluate the best ways to regulate tobacco products, based on scientific evidence as well as the law, we depend on rigorous science to inform our policies and save lives.

To support and advance the goals of the Tobacco Control Act, the FDA took a unique approach in forming the Tobacco Regulatory Science Program in partnership with NIH.

To best apply the tools Congress has given us, we at the FDA are continually maturing our science base to better understand details about the tobacco products themselves, how products are perceived and used, how they are labeled and advertised, and the impacts that tobacco products have on both individual consumers and population health.

These are the obligations we have under the law.

Since its inception nine years ago, the FDA's Center for Tobacco Products has conducted and funded an extensive portfolio of scientific study. It has been led by preeminent researchers like many of you in this room. In today's swiftly evolving tobacco marketplace, the FDA benefits from access to the capability and flexibility of our regulatory science researchers in responding to ongoing and emerging issues.

As it pertains to regulatory science, one of the primary missions of the Center's Office of Science is to assess existing scientific evidence and support new research to inform our tobacco regulatory actions to protect public health.

Today I am proud to unveil a new report noting CTP's scientific accomplishments. The report, entitled "Tobacco Regulatory Science Research Program at FDA's Center for Tobacco Products: Summary and Highlights" provides an overview of CTP-funded research from 2010 to 2017.

As reflected in this report, which is produced by CTP's Office of Science, FDA and our valued partner, NIH, have funded 231 research projects through the Tobacco Regulatory Science Program in fiscal years 2010 through 2017. These research projects include grants and cooperative agreements that address important FDA research priorities. Funding through fiscal year 2017 totaled $542.3 million.

To learn more about these regulatory science achievements, we have some copies of this report available here today. You will also be able to find the report on CTP's website.

I'd like to focus today on the science-based steps FDA is already taking as it shapes a regulatory plan to tackle the tobacco addiction crisis in this country.

We recognize and celebrate that great progress has already been made by all involved in tobacco control since the landmark 1964 Surgeon General's report on smoking. We're also taking note of recent declines in the use of cigarettes.

But we also have many unanswered questions. And that includes questions about the role for electronic nicotine delivery systems (ENDS), including e-cigarettes. We believe that if more adults are able to fully transition from combustible tobacco products to ENDS, we might be able to significantly reduce the overall morbidity and mortality associated with tobacco use. However, there are still questions associated with this transition I hope researchers here can help us all answer.

For instance, some of the recent data has shown a decline in cigarette use, and at the same time a rise in the use of e-cigarettes. We still need to fully understand the impact of these trends.

The questions include what's really going on with dual use of e-cigs? Is dual use a necessary transition period for most health-concerned smokers? Or is it the "new normal" – one where smokers are seeking to have it both way – continuing to smoke combustible cigarettes where it's OK to smoke cigarettes and vaping when you're in places where it isn't?

If so, is this prolonging or even enabling continued addiction to the combustible products? And if it's primarily the latter, how much diminished interest in quitting cigarettes is seen?

And what impact does this dual use of combustible cigarettes and e-cigs have on individual and population health?

These questions are important to answer in the context of the recent decline in adult smoking rates. We need to fully understand, with good science, the degree to which a migration to the electronic products may be helping.

But we need to also remember that the evidence we have now shows that the predominant pattern of use for adults is still dual use of both combustible cigarettes and e-cigs.

It's a pattern of use we don't fully understand yet.

And we need to better understand the potential benefits of electronic nicotine products as smoking cessation tools.

Clinical trial and product review are essential to answer those questions. And we need to fully understand the impact that these and other products are having on kids.

No child should use any tobacco product. We've seen cigarette use decline among kids, while e-cig use has grown sharply. This is happening even as overall rates of tobacco use among kids has declined, according to recent data.

This is still not acceptable, even if the trends are moving in a more positive direction of reduced overall use of tobacco products. Even if kids are using ENDS instead of cigarettes -- and that migration in part accounts for the decline in youth cigarette use -- that's still not an acceptable trade.

Parents who see their children using e-cigs and say, "well at least my child isn't smoking," should take no comfort.

No child should be using any tobacco product.

These products are addictive.

And the NASEM Report showed that amongst kids who never used a tobacco product, those who initiate on e-cigs are more likely to have experimented with a cigarette one year later than those who did not initiate on e-cigs.

That's why we've launched a broad campaign to target youth access to e-cigs, and the retailers and manufacturers that make that access possible. We announced some additional enforcement actions against retailers on Friday. And we have both civil and criminal work underway in this area.

We are conducting inspections at some of the facilities that manufacture and market e-cigs that have become popular among teens.

We believe in the concept of a continuum of risk related to tobacco products, and we believe there is a role for modified risk products. Further, we want to preserve e-cigs as one among a number of possible options for adult smokers and believe that fully transitioning smokers to ENDS can reduce the morbidity and mortality associated with tobacco use. If we believe in these concepts, and I do – then we must make sure that kids aren't being initiated on, and becoming addicted to these products.

We also need to validate our belief that these products can help adults through research. It's only through good regulatory science, and the work of researchers like those in the room, that we'll get the answers to these critical questions related to patterns of use and cessation. And that kind of research is critical to our mission. We can't make regulatory policy on the basis of anecdotal reports, regardless of how compelling they are.

I want to spend the balance of my time providing some details on where we hope to make progress through science.

Because despite some of the recent headway, tobacco products still remain the leading cause of preventable disease and death in the United States. Tobacco product use — largely cigarette smoking — still kills more than 480,000 Americans each year. And, for every person who dies from a smoking-related disease, about 30 more people will suffer from at least one smoking-related disease.

Cigarette addiction is still a way of life for many adults. Most of these folks know smoking can kill them. But they feel unable to escape cigarettes' addictive grip.

What's more, over 2,300 kids smoke their first cigarette each day. This youth use renders our kids vulnerable, before they even turn 18, to a lifetime of addiction and ultimately health harms like cancer and lung and heart disease.

In protecting youth and adults alike, the FDA is guided in its tobacco regulatory decisions by the comprehensive framework for regulating nicotine and tobacco that we announced last July. That approach is designed to reframe the conversation around nicotine and harm reduction.

The framework recognizes that the current market for tobacco products is fundamentally one for products delivering nicotine. And nicotine is highly addictive and is delivered through products on a continuum of risk.

And given their mix of toxicity, addictiveness, prevalence, and effect on non-users, cigarettes are the category of products that cause the greatest public health burden.

Millions of lives could be saved by moving people away from these most harmful products, while encouraging innovation in potentially less harmful tobacco products for those adults who still seek to use nicotine.

To advance these goals, and the important dialogue around tobacco addiction and nicotine, the FDA has issued advance notices of proposed rulemaking, or ANPRMs, to seek public input on our framework. Cigarettes, I think we all agree, are designed to create and sustain addiction. And addiction causes long-term use that brings with it health risks, like cancer and lung and heart disease.

Because it relates to a cornerstone of our framework -- moving people away from the most harmful tobacco products, notably cigarettes -- I'll start with our ANPRM that addresses a possible reduction in nicotine levels in cigarettes. This advanced notice seeks comment, through July 16, on exploring potentially lowering nicotine levels in combustible cigarettes to minimally or non-addictive levels.

This could be achieved using a regulatory tool known as the product standard. This new regulatory step advances a comprehensive policy framework that we believe could help to save millions of lives, in the near- and longer-term.

The positive health effects that could be achieved include addicted smokers switching completely to a potentially less harmful product or quitting tobacco altogether, and future generations being much less likely to get addicted to cigarettes in the first place. To accompany that ANPRM, CTP scientists published a study in the New England Journal of Medicine, titled "Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States," which assessed a possible scenario for a nicotine product standard.

Using a simulation modeling analysis, the study found that about 5 million additional adult smokers could quit smoking within one year of implementation, compared to a baseline scenario. And an even greater impact could be felt over time.

By the year 2100, more than 33 million people -- mostly youth and young adults -- could avoid becoming regular smokers. This could result in more than 8 million fewer tobacco-related deaths by the end of the century.

A summary of the main findings is available on CTP's website in an article titled "How Could Lowering Nicotine Levels in Cigarettes Change the Future of Public Health?"

Beyond statistics, we're also inspired by other, less quantifiable benefits. These include the joys people will gain from additional quality years with a loved one, and the avoidance of immense pain and suffering by so many.

The ANPRM lays out the issues on which the FDA requests input. They include the potential maximum nicotine level appropriate for the protection of the public health; whether such a product standard should be implemented all at once or with a gradual, stepped approach; and what unintended consequences might result, such as illicit trade or addicted smokers increasing how much they smoke to compensate.

On the subject of illicit trade, the FDA issued a draft concept paper and also invites comments on that through July 16.

Evidence shows that most cigarette smokers are concerned about their health. They want to quit and have tried.

By reducing cigarettes' addictiveness, we could help addicted users quit more easily.

And we could help keep those who are experimenting— especially young people—from becoming regular smokers.

Meanwhile, while we consider this type of reduction in nicotine levels in the most harmful tobacco products – cigarettes – we recognize that some adults may still seek tobacco products that deliver satisfying levels of nicotine.

While much of the attention on our plan has understandably focused on a potential nicotine product standard – and many of our critical efforts are rightly directed at the most harmful end of the continuum of risk – the FDA also must consider the public health effects of other tobacco products.

A recent report by the National Academies of Sciences, Engineering, and Medicine -- commissioned by the FDA at Congress's request -- reflects the complex considerations in evaluating tobacco products' public health consequences.

In the Public Health Consequences of E-Cigarettes report released in January of this year, the National Academies added to the FDA's knowledge base on e-cigarettes and other electronic nicotine delivery systems.

The report also raised some important questions about the public health impact of e-cigarettes.

According to the report, evidence suggests that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems. But, in a troubling finding, the report stated that kids and young adults who use e-cigs are more likely to try smoking combustible cigarettes.

The report identified additional areas for research, including: whether these products are leading to youth initiation of traditional cigarettes; the role of e-cigs in adult dual use with cigarettes; or how e-cigs may impact the transitioning of current adult smokers entirely away from combustible cigarettes. FDA continues to invest in further research to shed more light on these types of questions.

It's worth emphasizing that youth are among those most at risk for tobacco addiction. A lifetime of tobacco addiction almost always starts as youth experimentation. Almost 90% of adult smokers first tried cigarettes by the age of 18. And 98% by age 26. That means that roughly 99% of smokers start smoking before their brains are done developing.

I noted earlier, we have newly released findings from the 2017 National Youth Tobacco Survey about tobacco use among middle and high school students. The FDA and CDC released findings on June 8th in the Morbidity and Mortality Weekly Report showing that, among high school students, current use of any tobacco product decreased from 24.2 percent in 2011 to 19.6 percent in 2017. Among middle school students, current use of any tobacco product decreased from 7.5 percent in 2011 to 5.6 percent in 2017.

Among both middle and high school students, there were decreases in use of cigarettes, cigars, smokeless tobacco, pipes and bidis from 2011 to 2017. But there was also an increase in e-cigarette use over that same period.

In 2017, about 1 in 5 high school students and 1 in 18 middle school students currently used a tobacco product. And many of these students who currently used a tobacco product reported using two or more tobacco products.

This 2017 survey showed, for the fourth year in a row, e-cigs continued to be the most commonly used tobacco product among high school students. The authors concluded that sustained population-based strategies, in coordination with the FDA's regulation of tobacco products, are critical to reducing tobacco product use and initiation among youth.

Even with the recognition that tobacco products fall on a continuum of risk, we can all agree that no youth should ever start using any tobacco product. Toward the all-important goal of stopping nicotine addiction from taking hold of youth, the FDA is pursuing a variety of steps.

Under the agency's new Youth Tobacco Prevention Plan, for example, the FDA has taken action involving JUUL and other e-cigs, and also e-liquids that resemble kid-friendly food products because of how they are labeled or advertised.

To stop youth access to JUUL and other e-cigarettes, the FDA has announced several such actions under the Youth Tobacco Prevention Plan. The FDA understands that many kids are using e-cigarettes with some attributes that may make the products attractive to children and teens. These include an appearance closely resembling a USB flash drive, high levels of nicotine, and emissions that are hard to see.

Use of these types of products may be more difficult for parents and teachers to detect. JUUL is one brand of this type, but other brands have similar attributes.

To address concerns about these products, the FDA has announced a series of new efforts, including conducting a large undercover, nationwide blitz to crack down on the sale of e-cigarettes -- including JUUL products -- to minors by both brick-and-mortar and online retailers.

I mentioned some of FDA's steps earlier. We've issued warning letters to 56 retailers for violations related to youth sales of JUUL e-cigs; sent an official request for information to JUUL Labs and additional companies requiring them to submit important documents to support a better understanding of youth use and appeal of these products; and we're taking steps to preclude online sales to minors.

Our actions serve as notice that the FDA won't tolerate the sale of any tobacco products to youth. The responsibility for preventing kids from getting hooked on nicotine falls not only to the FDA, but also to the companies making these products, the retailers selling them, and the online venues that help enable access to these products by teens.

Also under our plan, which is aimed at limiting youth access to all tobacco products, as I mentioned, the FDA and the Federal Trade Commission issued warning letters to companies selling e-liquids used in e-cigarettes with labeling and/or advertising that cause them to resemble kid-friendly food products such as juice boxes, candy, or cookies.

Several of the companies receiving warning letters were also cited for illegally selling the products to minors.

Examples of the tobacco products resembling food products are "One Mad Hit Juice Box" and "V'Nilla Cookies and Milk."

No tobacco products should be marketed in a way that endangers kids -- especially by using imagery that misleads them into thinking the products are things they would eat or drink. Looking at the side-by-side visual comparisons of these products to actual food and drink products is alarming.

Our federal partner in this effort, the FTC, is likewise committed to protecting kids from these nefarious marketing practices. Acting FTC Chairman Maureen K. Ohlhausen said at the time of our action, that "Protecting young children from unwarranted health and safety risks is one of our highest priorities. Nicotine is highly toxic, and these letters make clear that marketing methods that put kids at risk of nicotine poisoning are unacceptable."

In addition to our regulatory efforts, the FDA also is engaged in robust campaigns to educate the public -- particularly youth – about the dangers of tobacco products.

CTP has developed award-winning public education campaigns, such as "The Real Cost," "Fresh Empire," and "This Free Life," designed to create awareness of tobacco products' risks and to drive behavior change. The first of these, "The Real Cost," has prevented nearly 350,000 youth aged 11 to 18 nationwide from smoking from 2014 to 2016.

These campaigns – which are informed by research, and creatively designed and executed -- will continue to be refreshed with new creative television spots.

We've expanded "The Real Cost" to specifically target youth use of e-cigs and other ENDS through campaign advertising. Last fall, we launched "Hacked"— a new ad under the "The Real Cost" umbrella—that is currently running via online video and radio ads and appearing on platforms used by teens, including YouTube, Hulu and Spotify. In September, we also plan to launch a full-scale campaign focused on youth use of e-cigarettes and other ENDS.

Our efforts aren't limited to preventing youth initiation, however. We also launched a new adult

smoking cessation education campaign called "Every Try Counts."

This campaign is designed to encourage cigarette smokers to "practice the quit," by offering messages of support.

"Every Try Counts" ads are displayed in 35 counties across the country, in locations such as gas stations and convenience stores where smokers face triggers such as cigarette advertisements. In just the first two months of the campaign, more people searched for certain terms such as "quit smoking" and "best way to quit smoking."

For some of these terms, there was an 80 percent year-over-year increase. And smokers are making use of the NCI-created cessation resources on EveryTryCounts.gov.

While we redouble our efforts to prevent youth from initiating with tobacco products, and offer support to help smokers quit, we fully recognize the potential some products may have in transitioning smokers away from the most harmful forms of tobacco use. Potentially less harmful products -- including the wide diversity of ENDS and other novel tobacco products -- must be put through an appropriate series of regulatory gates to fully evaluate their risks and maximize their potential benefits.

And industry must take seriously its responsibility for preventing youth use of these products.

Preventing youth use is the right thing to do. It's critical. But it's also tied to the key statutory concept of evaluating the impact on the public health, and considering youth tobacco use as well as adult use. Even if the evidence ultimately shows that e-cigs may help reduce smoking rates among adults, the initiation of youth to tobacco products is a big factor in determining the overall impact on the public health, which is the legal standard that governs our decisions.

Moving to a related issue, flavors in tobacco products require close examination for their effects on population health. FDA has also issued an ANPRM seeking comment on the role of flavors -- including menthol -- in initiation, use, and cessation of tobacco products. And to examine the potential toxicity or adverse health effects from flavors.

FDA is seeking this information to inform regulatory approaches that the agency could take with respect to tobacco products with flavors. This would take into account how we can better protect kids from tobacco, and how we can significantly reduce overall tobacco-related disease and death. This ANPRM is open for comments through July 19.

In the spirit of our commitment to preventing kids from using tobacco, we're taking a closer look at flavors in tobacco products to better understand the amount of impact they have on youth initiation. And, as a public health agency, it's important that we also explore how flavors, under a properly regulated framework that protects youth, may also be helping some currently addicted adult cigarette smokers switch to certain noncombustible forms of tobacco products.

A third ANPRM seeks comments and data related to premium cigars, an issue that continues to draw interest.

Here, the FDA is seeking information that was not previously submitted to the agency on how we might define and regulate premium cigars, taking into consideration the health effects of these products and their patterns of use.

Comments are invited through July 25.

With respect to all three of these advance notices of proposed rulemaking, the FDA will consider the comments when determining its regulatory options in these areas.

One regulatory area in which progress has already been made -- and must continue to be made -- is the development of safe and effective, FDA-approved cessation products, such as nicotine gums, patches, and lozenges.

FDA has formed a Nicotine Steering Committee -- a collaboration between the Center for Tobacco Products, the Center for Drug Evaluation and Research, and my office – that's charged with re-evaluating and modernizing the agency's approach to the development and regulation of nicotine replacement therapy products.

The work of the steering committee is an important component of our plan. Among adult smokers in the U.S., more than half report that they want to quit.

Nearly half try to quit each year, yet few succeed.

Some nicotine replacements therapies, such as gums and patches, are available over the counter. And a nasal spray and inhaler are available as prescription medications.

Using approved NRTs properly is considered to double the likelihood of a successful quit attempt, with variations between products. But most of the products have been approved for more than 20 years. Since then, novel forms of nicotine delivery have been developed based on new technologies and innovations. And so, the Nicotine Steering Committee will explore how the FDA can best advance these innovations and facilitate their development into FDA-approved therapies to help more American smokers quit.

Already, some ideas have emerged from our consideration.

On the topic of therapeutic product evaluation, for example, there's been new discussion about FDA considering new regimens for cessation, such as "reduce to quit."

Other issues we've been discussing are using smoking cigarettes as the comparator, pharmacokinetic bracketing, concerns about the quantity and types of information needed before sponsors can study a product under an IND, broadening NRT indications, and flexibility on labeling.

In parallel with the FDA's efforts I've already discussed, we have revised the premarket review compliance dates for so-called deemed products on the market as of August 8, 2016.

This additional time will allow the industry to ultimately submit more accurate and complete product applications, and it will give the FDA time to develop and establish certain policies, guidance, and foundational regulations.

For example, the FDA intends to explore development of product standards or other regulations for known public health risks, including battery safety issues for ENDS, and children's exposure to liquid nicotine.

Over that time, we also intend to issue several foundational rules outlining the information we expect to be included in substantial equivalence reports, in premarket tobacco applications, and in modified risk tobacco applications.

The parts of the plan I've introduced are meant as a cohesive package. It's an all or nothing plan. We believe this new, overall approach can dramatically shift the trajectory of tobacco-related disease and death in this country.

Getting on this path to a healthier American population requires us, as an agency and a society, to answer many tough questions, with the help of a sustained dialogue.

For example, what are the implications of using products that are potentially less harmful, but still not safe?

Also, how do we correct some of the misperceptions about nicotine safety? And what do we think about combination therapy and different indications, such as smoking reduction, for nicotine replacement therapies?

The FDA is continually pursuing data to better inform its regulatory decision-making.

And since the creation of the FDA's Center for Tobacco Products in 2009, FDA has benefitted from the groundbreaking research done by investigators like you.

Compared to other government agencies and FDA centers, CTP is still a newer regulatory body. So, many of the policies we'll enact in the next few years are foundational and will pave the way for the future of FDA tobacco regulation.

We're exploring promising concepts such as a nicotine product standard. We're committed to these goals.

And, as FDA continues on a path to help solve this country's tobacco addiction crisis, your research guides the way.

Thank you for attending this meeting and sharing your significant achievements in tobacco regulatory science.

By contributing your experience and dedication, you're invaluable partners in our work to understand and face down the preventable disease and death toll from tobacco use. New research findings being presented and discussed at this meeting can help inform our thinking on future policies.

I appreciate you having me here today.

On FDA's behalf, I extend thanks to you researchers, who are among the finest in this field, for helping to speed our victories in the battle against tobacco's deadly consequences.

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