Public Hearing: To consider including electronic cigarettes in the existing Clean Indoor Air Act and regulating liquid nicotine

Committee: Senate Standing Committee on Health, Chair: Senator Kemp Hannon

Date: May 12, 2014 10:00 am

Location: Van Buren Hearing Room A, Legislative Office Building, 2nd Floor, Albany, New York

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Introduction

Good morning Chairman Hannon and committee members. My name is Dr. Harlan Juster, I am the Director of the Bureau of Tobacco Control with the New York State Department of Health. My Bureau administers the statewide Tobacco Control Program. Thank you for this opportunity to present today regarding the possible inclusion of electronic cigarettes in the existing Clean Indoor Air Act and regulation of liquid nicotine.

Background

The New York State Department of Health's (Department) tobacco control program has been a national leader in promoting tobacco control policy, health systems change, and developing innovative approaches to address the negative consequences of tobacco use. The program is evidence-based, it follows guidance on best practices from the federal Centers for Disease Control and Prevention (CDC)[1], and relies on reports from the U.S. Surgeon General, the Institute of Medicine, the National Cancer Institute, and the peer reviewed scientific literature.

The three pillars of tobacco control are the high cost of tobacco, comprehensive clean indoor air laws that are adequately enforced, and an evidence-based population-oriented tobacco control program. The program combines community action that educates the public and decision makers about the continuing burden of tobacco and evidence-based solutions, health systems change to improve and expand the delivery of tobacco dependence treatment that meets or exceeds clinical guidelines, and health communications and media campaigns with emotionally evocative and

graphic depictions of the outcomes of tobacco use to increase smokers' motivation to quit and to create a social and cultural norm that de-glamorizes tobacco use. The Department collects extensive surveillance and program evaluation data to determine areas of success and areas where public health interventions need to be redirected or improved.

This approach is working in New York. From 2001 to 2012, the adult smoking rate in New York dropped 30 percent from a prevalence of 23 percent to just 16 percent. Prevention activities have produced even more impressive results among youth. In 2000, 27 percent of high school age youth reported smoking in the last 30 days. In 2012, just 12 percent of high school age youth smoked a cigarette in the last 30 days, a 56 percent decline. Among middle school age youth, the decline was 70 percent. Our surveillance data indicates that the declines in New York are occurring at a rate that is faster than in the rest of the nation.[2]

Also, the declines in youth initiation of cigarette use have had a positive impact on the trajectory of adult smoking. That is, youth who did not initiate smoking in the first decade of this century are now non-smoking young adults. In 2010 for the first time since we have been monitoring the data, the 18 to 24 year old, young adult age group is no longer the age group with the highest smoking rate. This positive trend attributed to non-smokers as they age will continue as long as the tobacco initiation rate among youth continues to decline.

There is great concern in the tobacco control community that new products like those discussed today could undermine and potentially reverse the substantial gains that have been made in New York, nationally and worldwide in reducing tobacco use.

Overview of Electronic Nicotine Delivery Systems

In order to effectively evaluate or regulate Electronic Nicotine Delivery Systems or ENDS, it is important to use a comprehensive definition that covers all products. Electronic cigarettes or e-cigarettes are just one of a number of similar personal use devices. There is also e-hookah, vaping pens, e-cigars, hookah pens, and this list will undoubtedly grow. E-cigarettes look like conventional cigarettes. Other devices look like large fountain pens or even small flashlights. Some are refillable and some disposable. All of these devices are designed to heat a liquid containing nicotine so it is hot enough to create an emission or vapor, which is then inhaled by the user. The inhaled emission is absorbed through the lungs and other internal surfaces into the bloodstream where nicotine travels to the brain and binds with specific neurotransmitter sites. No matter what we call them, all of the devices are designed for and capable of delivering nicotine which is the highly addictive component in all tobacco products.

Many of the liquids used in these devices contain flavorings designed to appeal to youth and young adults. There are flavors called french vanilla, cherry crush, watermelon splash, bubble gum, gummy bear, cola, strawberry, cherry and cookies and cream milkshake. Clearly these flavors are meant to appeal to a younger population. It is important to note that flavors like these are prohibited by federal law from being used in traditional cigarettes because federal law recognizes that the purpose of these flavorings is to addict children to nicotine and create new generations of tobacco users.

These devices are different from combusted or burned tobacco cigarettes. There is generally no burning, no tobacco leaf, and they may have fewer or different toxins compared with tobacco cigarettes. However, recent reports from the Food and Drug Administration (FDA) and elsewhere have found contaminants and tobacco-specific compounds believed to be among the more carcinogenic components of tobacco smoke. Another recent study showed that when used in a particular way, levels of formaldehyde in the emissions can reach levels equal to that of combusted or burned cigarettes.

Even if there are fewer toxins than cigarettes, that does not mean they are safer for the individual or for the population as a whole. Much of the analysis depends on how the products are used by the public, and researchers and public health officials are just beginning to learn about attributes of products, consumer behavior, patterns and methods of use, and intended and unintended consequences of use.

Current Research

Today, the safety of ENDS products is unknown and their value as a cessation tool is entirely unproven. Research is scant but what little has been conducted is concerning. We know that a great deal of marketing of ENDS appeals to youth and that youth are responding to the marketing techniques. The vast majority of teens and young adults are aware of ENDS and are exposed to the advertising. As a result, youth use of these products has dramatically increased. We know that most youth who use these products are also smoking cigarettes; a combination that can lead to long-term nicotine addiction and cigarette use.

For adults, we know that there have been no spikes in cessation attempts among adult cigarette smokers concomitant with the spike in ENDS use. We are certain that more research is needed, but to date, no study has shown that quitting is enhanced by ENDS use, and their use may make it even harder to quit cigarette use.

Let me provide you with more information on each of these concerns.

First, the tobacco industry has a long history of marketing to youth and as the industry's biggest players increase their presence in the nicotine delivery device market, our concern will only increase. We know that nearly 90% of adult smokers started before the age of 18 and that very little initiation of smoking occurs after 21.[3] A federal judge concluded that at different times and using various methods, the tobacco industry intentionally marketed to young people under the age of twenty-one in order to recruit replacement smokers to ensure the economic future of the tobacco industry.[4]

More research on youth uptake of electronic nicotine delivery devices in relation to tobacco use initiation is needed. In New York, we are collecting youth and adult surveillance data on the use of these products and we will have baseline data available in a few months.

The industry that markets ENDS has embarked on a major effort to glamorize nicotine delivery product use. The marketing of these devices has already hit all the key elements that the tobacco industry previously used to promote and glamorize tobacco use, and that the industry is now prevented from doing for tobacco products by federal law. The old industry playbook for marketing is in full bloom including celebrity endorsements, candy and fruit flavorings that appeal to youth, sponsorships, and themes of rebelliousness and rugged individuality that pervade the marketing. These marketing tactics, unfortunately appear to be working. Results from an American Legacy Foundation report indicate that awareness of e-cigarettes among young people is pervasive, ranging from 89% for those ages 13-17 to 94% for young adults ages 18-21.[5] These marketing activities clearly appeal to youth and young adults and provide a sense that using these devices is equated with being an adult.

The tobacco control community is concerned that these nicotine devices will be used to maintain and strengthen nicotine addiction in adult smokers who continue to also smoke tobacco cigarettes, rather than act as cessation devices. We already have some data on the explosion in the use of nicotine devices and the claim that they will reduce tobacco use. With the increase in use of these products, one would expect to see increases in cessation attempts by adult smokers. New York specific surveillance data show that in 2009, 62 percent of current smokers made at least one quit attempt in the previous 12 months, in 2012, that rate was 64 percent, a non-significant difference. There has been no such spike in attempts to quit associated with the increase in the use of these products. Clearly, more research is needed before these devices can be declared to have a role in cessation.

As an example of how these products may be used by young people in "real world" conditions, last week the NY Times reported on two new studies, to be published in the journal Nicotine and

Tobacco Research, about youth who disassemble the devices and apply the nicotine liquid directly to the electric heater.[6] This produces a more concentrated nicotine-laced emission, which could increase the addictive qualities of the device. But even more disturbing is that in overheating the liquid, formaldehyde and other toxins are formed in levels that "approach the concentration found in tobacco cigarettes." Formaldehyde is a known human carcinogen.

In another concern, a recent study from the CDC found that calls to poison control centers nationally have increased.[7] In September 2010, there was one poisoning reported from liquid nicotine ingestion; in February of 2014, there were 215 such reports and half were in children under five years old who were attracted to the smell, the color, and the packaging. Nicotine is poisonous when ingested in liquid form.

Cigarette smoke has thousands of constituent products in them. Some cause cancer and some affect the cardiovascular system by increasing the likelihood of strokes due to blood clots. Although highly addictive, nicotine in tobacco smoke is generally considered to be less toxic than the other constituents in cigarette smoke, but nicotine is not without risk. Besides its highly addictive nature which causes tobacco users to experience withdrawal symptoms about every two hours and seek out more nicotine, nicotine can contribute to acute cardiovascular events. There is no public health value in nicotine other than to be used in approved forms to reduce cigarette smoking.

Public Health Concerns

Determining safety and assessing health impacts requires much more research than currently exists and multiple issues have to be considered. The scientific community is only at the beginning stages of determining the safety and health impacts of ENDS. As a public health professional, I am concerned that nicotine delivery devices will result in one or more of the following negative health outcomes.

1. Youth using ENDS will become addicted to nicotine and many will transition to the use of tobacco cigarettes. Tobacco cigarettes deliver nicotine more efficiently than nicotine delivery devices and the transition seems to be a logical extension of ENDS use.

2. Nicotine devices will re-glamorize the act of smoking. This is a battle fought by public health for a long time and continues to be a key strategy to reducing youth initiation.

3. Nicotine devices will be used to maintain and strengthen nicotine addiction in smokers who then continue to also smoke tobacco cigarettes, known as dual use, and

4. Former smokers will return to nicotine use and addiction through the use of these devices and then relapse to tobacco use.

Harm Reduction

Advocates for the use of ENDS as cessation devices argue that because there are likely fewer toxins in the emissions compared with combusted cigarettes, these products must be safe to use. They are attempting to make a "harm reduction" argument, but that argument is incomplete and flawed. Harm reduction works when there is a clear benefit to the user that outweighs the costs to the rest of society. We already have harm reduction products in tobacco control. The Food and Drug Administration (FDA) has approved five nicotine delivery devices that have been shown in extensive research to be safe and effective. These are the nicotine replacement therapies and include the patch, gum, lozenge, inhaler and nasal spray. There are also two other non-nicotine prescription medications, bupropion and varenicline, also shown to be safe and effective at increasing smoking cessation rates. They reduce the harm of nicotine addiction by helping users of combusted cigarettes to quit but they do not attract new users who find these products appealing. That is successful harm reduction.

The only well-designed randomized controlled study to date that I am aware of on the effectiveness of e-cigarettes as a cessation device, found that smokers were equally likely to quit smoking, whether they used e-cigarettes or nicotine patches.[8] This study did not address the quality control issues that abound with ENDS including varying doses of nicotine or the issues of youth initiation and product safety. Another study of callers to telephone quitlines found that e-cigarette users whose stated reason for using the products was to help them quit or reduce the use of combusted cigarettes, were significantly less likely to have achieved cessation of combusted tobacco compared with non-e-cigarette users at a seven month follow-up survey.[9] Using e-cigarettes while trying to quit tobacco made successful quitting less likely.

Advocates for the use of these devices argue that the public health community is on a "slippery slope," making claims of unlikely negative outcomes. On the contrary as I have noted, there is already evidence that negative outcomes are occurring. The CDC recently reported that the use of nicotine devices in high school age youth doubled in just one year. More concerning is that most of the youth using these devices were actually dual users of tobacco cigarettes. Today, there are no studies that support ENDS as an evidence-based cessation approach. The data available so far indicate E-cigarette users are no more likely to quit using combusted cigarettes and in fact, they may even be less likely to quit.

New York's Clean Indoor Air Act

New York's amended Clean Indoor Air Act was signed on March 26, 2003, prohibiting smoking in virtually all workplaces in the State. It remains one of the strongest clean indoor air laws in the nation.

By **every measure** the New York State Clean Indoor Air Act has been successful. Since 2003, exposure to secondhand smoke has largely been eliminated in all indoor workplaces. Public support for this law is strong and has increased since 2003, with over eight out of 10 New Yorkers saying they support the Clean Indoor Air Act.[10] The Act has resulted in reduced exposure to secondhand smoke among the general public and has had direct measureable health impacts. In a 2007 study that I conducted for the Department, the Clean Indoor Air Act was estimated to prevent nearly 4,000 hospital admissions for heart attacks in the first year following the law, saving New Yorkers direct health care costs of at least $56 million.[11] Studies in other states and around the world have shown similar reductions in heart attacks and cost savings.[12]

Clean indoor air laws work in two ways. They reduce exposure to harmful emissions and they create a normative change that the restricted behavior is unacceptable in the presence of others. Both outcomes are equally important. Social norm change is the primary reason that many promote tobacco free outdoor policies. Such policies send the message that tobacco use in public places is unacceptable, unhealthy behavior. A behavior that leads to an addiction, looks just like cigarette use, models cigarette use for youth, and may lead to cigarette use should not be supported behavior.

Policy Solutions

While we await the availability of the results of additional research, the Department will consider a variety of policy solutions. Recent events in which reports to poison control centers that young children have gained access to and drank the liquid nicotine solutions indicate that childproof packaging must be a consideration.

FDA

On April 25, 2014, the Food and Drug Administration (FDA) proposed a new rule, known as the "deeming rule" to extend its authority to include electronic nicotine delivery devices. Proposed regulations include prohibiting the sale and distribution of free samples of "deemed" products to minors (under 18 years of age) and requiring the disclosure of ingredients used in the "deemed" products. However, the proposed regulations do not address many issues of concern to the

tobacco control community including providing a legal definition for "e-cigarettes," prohibiting characterizing flavors such as fruit and candy that appeal to youth, prohibiting internet sales, prohibiting brand name sponsorship of sporting and cultural events, or marketing and advertising restrictions. FDA's proposed timeline is lengthy and the required disclosure of harmful and potentially harmful constituents would not go into effect until 36 months after the effective date of the final rule. And just last week, the tobacco industry requested that the formal comment period be doubled from its current 75 days to 150 days.

This process could take years. In the interim, these products are being sold widely in malls, in stores that are otherwise unlicensed to sell tobacco products, and on the internet. Quality control is highly variable and the devices are being used by our youth in creative but dangerous ways. The companies are using all the old time marketing methods to sell these products to youth.

Conclusion

Dr. Tom Frieden, Director of the CDC recently said that "Tobacco is really the number one enemy of health in this country and around the world." Tobacco use causes 30 percent of all cancers including 85 percent of lung cancers. Cigarette smokers are 2 to 4 times more likely to develop coronary heart disease than nonsmokers. The U.S. Surgeon General has concluded that tobacco use negatively effects every organ system in the human body. The single most effective intervention that could improve the health of more people in New York and around the world, would be to reduce or eliminate tobacco use.

New York State has made great progress in reducing the impact of tobacco use and adult and youth tobacco use rates have come down. This progress is directly attributable to strong tobacco control policies and a strong statewide tobacco control program.

In spite of this progress, 24,000 New Yorkers still die each year from tobacco use, and hundreds of thousands suffer from serious illness that disrupts their ability to live, work, play and enjoy life. Continued suffering by New Yorkers is unacceptable. The financial cost to the state is enormous. We have the tools to end the tobacco problem in New York State for the next generation.

But the unregulated market that is electronic nicotine delivery devices threatens the gains that have been made in New York and must not be allowed to undermine the important progress made in de-normalizing tobacco use, especially among youth and young adults. We must continue to conduct well-designed studies to better understand the impact of these products on public health but the paucity of research cannot be used as an excuse to refrain from action.

Thank you for inviting me to speak with you today. And thank you for your interest and support in safeguarding the health of New Yorkers and for your efforts to explore additional opportunities to protect New York's children and adults against tobacco use. At this time, I would be happy to respond to any questions.

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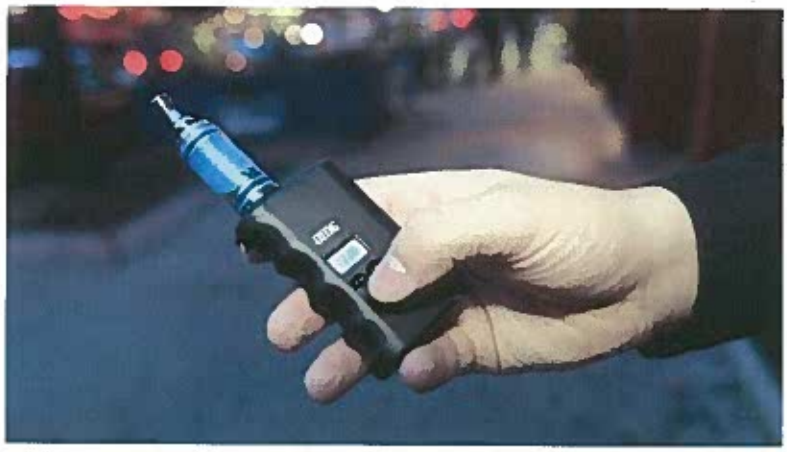
Disposable Electronic Cigarettes

Vaping Pens

Rechargeable Electronic cigarettes



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E- Liquid


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