Statement of

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Science, and Transportation
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Concerning

Aggressive E-Cigarette Marketing and Potential Consequences for Youth

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"At first people refuse to believe that a strange new thing can be done, then they begin to hope it can be done, then they see it can be done --- then it is done and all the world wonders why it was not done centuries ago."

-- "A Secret Garden" Francis Hodgson Burnett

Mr. Chairman and Members of the Committee, I want to thank you for this opportunity to appear before this Committee. I have spent most of my professional career dedicated to working in the public health arena and in particular on tobacco and nicotine issues. FDA regulatory oversight was something I took on at a time when some said I was on a 'fool's errand'.

In those early years it was pleasure and honor to work with a number of members of the House and Senate on not just that issue but others as well. One of the early champions in those efforts was Senator Durbin who was anticipated to be your leadoff witness. Several members of this Committee including Senators Markey and Blumenthal have also been in the forefront on a number of tobacco related issues.

Today we are talking about another potential major monumental shift, possibly as significant as acquiring FDA oversight of tobacco. It entails how best to regulate a growing spectrum of tobacco, nicotine and alternative lower risk products, including e-cigarettes, that hold promise for significantly reducing, or one day virtually eliminating the use of the deadly combustible cigarette.

I come here today representing no one but rather to give you my 35 plus years of experience and thoughts on how all stakeholders might consider 'moving forward'. I include on that list, policy makers, regulators, public health advocates, researchers, manufacturers, healthcare practitioners, consumers, and the general public.

The subject of this hearing raises some important questions that need addressing. I hope that **both** the majority and minority will approach the focus of the subject of this hearing as part of a broader and more comprehensive discussion which encompasses **the need for the regulation of all tobacco, nicotine and alternative products --- regulation which should be set based on <u>the risks, relative risks and intended uses of those products</u>.**

We are in a 'New Era' of Tobacco, Nicotine and Alternative Products Regulation

We are in what I and others have called a 'New Era' and what FDA's Center for Tobacco Products Director Zeller has called a 'New Beginning', an era that demands that we look at more effective and appropriate ways for regulating a growing spectrum of tobacco and nicotine products which have very diverse 'risk profiles'. Gone are the days when we

could make the simple statement that all tobacco products were equally harmful. FDA oversight has changed the equation. Science has changed the equation. Innovation and technology have changed the equation. New entrants into the marketplace have changed the equation and consumers have changed the equation.

The Center for Tobacco Products (CTP) has had and will continue to have many mountains to climb in not only carrying out the many mandates that Congress imposed on it but more importantly in dealing with the challenges for shaping new policy over the next 5-10 years.

In 1976 Professor Michael Russell wrote, 'People smoke for nicotine and die from the tar'. That statement, made decades ago, is what this is all about today. This 'New Era' is therefore about the development and implementation of a ***comprehensive and workable tobacco, nicotine and alternative products policy*** that will require the active involvement of all stakeholders. It is about saving lives. The tobacco nicotine and alternative products environment is at a crossroads.

The swiftness with which e-cigarettes have gained popularity has caught many off guard including the public health community, tobacco control advocates, researchers, policy makers, regulators, the public, and even manufacturers. Today, it is estimated that there are somewhere between 5,000 -10,000 e-cigarette/vaping manufacturers, companies and stores with a growing array of differing products. While I have long believed that there would be new categories and new products entering in the market, I like everyone else have been overwhelmed with what has happened. This presents both challenges and opportunities. We should not forget that the cigarette market in the US is around $ 85 billion. Most smokers want to quit and if we can provide those smokers with science-based, consumer acceptable lower risk products we could fundamentally alter the current marketplace and save hundreds of thousands of premature deaths.

I see and hear a great deal of emotional, adversarial (some of which is unproductive) discussions going on in and outside the public health community about the benefits and harms associated with e-cigarettes. Research studies are coming to very differing conclusions. Unfortunately but not unexpectedly, such research is often 'cherry picked' for both lobbying and public relations impact.

Regulation of All Tobacco, Nicotine and Alternative Products Should Be Based on the Risks, Relative Risks and Intended Uses of the Product

In addition to recognizing the importance of developing a new comprehensive tobacco and nicotine policy, the FDA's 'deeming' proposal has also recognized the need to regulate products based on risks and relative risks -- what is referred to as the

'continuum of risk'. There are significant differences in the risks between products already in the market place as well as new innovative products being developed. This includes not only the categories of products such as the combustible cigarette on one end and nicotine replacement therapies (NRT) on the other, but other smoke-free tobacco products (snus, lozenges, inhalers etc.), e-cigarettes and an array of products within the various categories. As we accept and recognize this reality, we also will need more focused and in some ways better research being done that will have to come from both the public and private sectors including the manufacturers of these products, who will be required to provide data and information to the FDA to back up their products with sound scientific evidence.

In terms of better understanding some of the various components at work with respect these broad- ranging significantly lower risk products (that includes e-cigarettes) and what will be needed to drive change, I use the following equation:

> **REGULATION + Research and Science + Technology + Innovation + Incentives + Competition + Consumer Acceptability =**
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> **A means of advancing public health goals and changing the behaviors of those manufacturing and marketing tobacco, nicotine and alternative products.**

(Side Comment: While seemingly out of context, I think that we may one day be having similar conversations about marijuana, an agriculturally based product; a drug that can be used in both combustible and non-combustible forms and which is used both recreationally as well as for medicinal purposes. Will/should it come under FDA's authority and if so where and how?)

The E-Cigarette Challenges and Opportunities - Critical Elements Needing to be Addressed.

1. First and foremost, e-cigarettes should/must be regulated by the Food and Drug Administration with regulation being designed to advance public health goals. This includes how they are manufactured, labeled, advertised and marketed. When the original statute was drafted the statute provided no real flexibility for considering other products. The statute, in spite of its historic importance was already outdated in many areas the day it was signed into law. FDA has been challenged with 'defining' nontraditional products often having to try and fit a square peg into a round hole. They tried initially to regulate e-cigarettes under the drug and device statutes but gave up on that approach after legal challenges, and have taken a path to regulating them as tobacco products as long as no therapeutic claims are made. Enter the 'deeming' regulations.

While tardy in being issued, the FDA's 'deeming proposal' has opened the door for the involvement of a broader spectrum of stakeholders and interests to submit their views and comments. Input and new ideas need to be heard and discussed if we are to move forward. It is obviously not a process that some believe is fast enough and many want 'action now' particularly when it comes to concerns of children and adolescents. But FDA and all of us who have an interest in the subject of tobacco and nicotine regulation are on a 'learning curve' being challenged to think differently and realizing that like it or not this is not the 1980's or 90's. The e-cigarette issue is not black and white, one size does not fit all and we should be very cautious about over- regulating a product that many believe has the ***potential*** for playing an important role in reducing disease and death caused by the combustible cigarette- the primary product causing close to 3.5 million premature deaths globally and 480,000 premature deaths in the US.

Just as the disrupting technology advances of 100 hundred years ago in the form of 'machine-made' cigarettes that are at the root of today's smoking epidemic, today we are looking at disrupting technologies, that if implemented carefully, could help end that 100 years of cigarette- related disease and death. And people are talking about this possibility in ways that they did not just a couple years ago.

Here are a couple examples of recent statements, reports that can now be added to the numerous states that have been issued or made over the last several years.

A. Letter to WHO Director General Margaret Chan from 53 Tobacco and Nicotine Specialists

A few weeks ago (May 25th) 53 tobacco and nicotine specialists sent a letter to World Health Organization Director General Margaret Chan asking that the WHO give serious consideration to incorporating tobacco harm reduction (which includes e-cigarettes) as part of its efforts to reduce disease and death caused by the use of tobacco. The opening two paragraphs of that letter state:

> **"We are writing in advance of important negotiations on tobacco policy later in the year at the FCTC Sixth Conference of Parties. The work of WHO and the FCTC remains vital in reducing the intolerable toll of cancer, cardiovascular disease and respiratory illnesses caused by tobacco use. As WHO has stated, up to one billion preventable tobacco related premature deaths are possible in the 21st Century. Such a toll of death, disease and misery demands that we are relentless in our search for all possible practical, ethical and lawful ways to reduce this burden.**
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> **It is with concern therefore that a critical strategy appears to have been overlooked or even purposely marginalized in preparation for FCTC COP-6. We refer to 'tobacco harm reduction'- the idea that the 1.3 billion people who currently smoke could do much less harm to their health if they consumed nicotine in low-risk non-combustible form.'**

B. A recent report (June 2014) by Action on Smoking and Health (ASH) in the UK entitled: **Electronic Cigarettes (also known as vapourisers)**

Just released by Action on Smoking and Health in the UK is a report on electronic cigarettes where those in the UK are having conversations similar to those going on here in the US. While the entire document is worth reviewing, here is a brief excerpt on the concept of harm reduction.

> **Smoking in the largest preventable cause of premature mortality in the UK. The goal of tobacco harm reduction is to diminish the harm caused by tobacco products. While the ideal remains that people stop using tobacco completely and permanently, consensus currently supports a properly regulated harm reduction approach for those unable to do so. This is a frame work by which the harmful effects of smoking are reduced without requiring the elimination of a behavior that is not necessarily condoned. Such strategies have proved successful in the past, for example, within the contexts of needle exchange programmes, illicit drug use and the promotion of safer sex to prevent HIV infection.**
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> (The entire report can found at: http://www.ash.org.uk)

C. Position of LEGACY

Last week (June 11, 2014) I attended the Ken Warner Lecture Series sponsored by Legacy--- a one on one discussion between the Legacy's President and CEO, Robin Kovel and FDA/ CTP's Director Mitch Zeller. I also picked up Legacy's latest position statement on e-cigarettes- E-CIGARETTE POLICY: THE FDA SHOULD PROMPTLY EXERCISE REGULATORY AUTHORITY OVER E-CIGARETTES. In reading it I have to say that I concur with much that was presented and believe they have done a very thoughtful job in approaching this very challenging and controversial subject. Here are a couple excerpts, but again I encourage everyone to take a look at this somewhat cautious but 'forward looking' statement in times of uncertainty.

> **"In the US, more than 43.8 million people smoked cigarette in 2011, and about half of lifelong smokers will die premature from their tobacco use. Legacy recognizes that, on an individual level, there is a continuum of risk across tobacco products with combustible products (e.g. cigarettes, cigars, hookah) posing the most danger and Food and Drug Administration (FDA) approved nicotine replacement therapies (NRT's) posing the least harm. Harm reduction is a valuable public health strategy with the potential to reduce, although not eliminate, the preventable disease and death caused by tobacco. E-cigarettes may hold great promise in this regard. While they are not without risk, initial scientific evidence suggests that, for the individual smoker, they are likely less harmful than smoking cigarettes, and they likely**

have significant lower levels of known tobacco toxicants than combusted tobacco products. In addition, e-cigarettes may help some smokers quit. However, the existing evidence is insufficient to support any informed inference on net public health benefits versus harm at this time.

The impact on individuals is only part of the story. We must also consider e-cigarettes' impact on public health at a population level.....

FDA must promptly exercise its statutory authority to regulate e-cigarettes and begin the process of carefully evaluating and resolving these literally life and death questions consistent with that authority. In addition, the Federal Trade Commission (FTC) should put a stop to the unsupported health claims currently being made about certain e-cigarette products that may mislead the public."

(To view the full statement and other related materials on e-cigarettes, go to: www.LEGACYFORHEALTH.ORG)

2. Concerns

One of the concerns being raised and which is the subject of today's hearing is what is happening or may be happening with respect to increased advertising and marketing that intentionally or unintentionally might have an impact on children and adolescents. What is appropriate and what is not, as we wait for FDA to issue its final deeming regulations? Once we have identified the potential abuses we then have to ask how those abuses can be curbed without negatively impacting on how these science-based lower risk products can be used to help cigarette smokers quit.

There are other concerns as well such the role that flavors *might* play in youth imitation, childproof packing of some items, and product safety issues in general. It will be imperative that as we move forward in our efforts to address those concerns we look for productive positive and non-adversarial ways of addressing them. On the issue of flavorings, any concerns about flavoring and youth initiation should be balanced with ensuring that significantly lower risk products such as e-cigarettes are consumer acceptable to the millions of smokers looking to quit. This obviously involves flavorings and palatability. Nicotine replacement therapies (NRT) have long been available in a wide variety of flavors (‘fruit chill’, ‘cherry’, ‘lime’, ‘ mocha’ etc.) and are marketed and promoted in variety of ways. Smokeless tobacco products also have flavoring allowances. Similar types of allowances could be made for e-cigarettes.

The experience that we encountered with the misleading and deceptive advertising and marketing practices of Big Tobacco should never forgotten but this is a very different environment and although we face similar challenges we can and must approach the issues differently especially since we now have a regulatory agency (FDA) in place to address these complex and challenging issues. Big Tobacco fought us at every turn including oversight and regulation and it is easy to see why so many of my colleagues

remain entrenched in their views and resistant to new approaches. Today, like it or not tobacco, nicotine and alternative product manufacturers are considered stakeholders by the FDA in this new era and they will be obligated to comply with FDA's rules and regulations or face severe enforcement penalties.

Juxtaposed to what I laid out above with respect to the need for a more comprehensive, rational and workable tobacco and nicotine policy is the need, therefore, to look at some of the children and adolescent issues being raised.

Without giving Legacy too much attention, I suggest that their e-cigarette paper gives us some direction on issues related to youth initiation and raises issues that need to be addressed. The Durbin et al report, **Gateway to Addiction?** does the same, as do background papers from other organizations -- some who are appearing at this hearing.

Legacy 's position paper on e-cigarettes notes:

- **'Legacy believes that e-cigarettes should not be sold or marketed to youth. This includes enacting many of the marketing/advertising restrictions currently applicable to cigarettes, including age restrictions on sale, placement of the product in retail outlets, and restricting advertising that is directed towards youth. Regulators should carefully research the issue of whether advertising is re-glamorizing smoking in general and monitor the impact on youth uptake of e-cigarettes and combusted products.'**

As part of addressing these and other concerns, manufacturers should be encouraged and be willing to provide non-proprietary information to the FDA and to the public as the 'deeming' regulations are developed.

Can those interested in the e-cigarette issue who are concerned about youth but who also recognize the role that harm reduction could play find common ground to accomplish both?

A. My experience dating back to the 1990's indicates to me that we can and must. I have had the opportunity to be involved both as a participant and now as an advisor to ongoing efforts by the Institute for Environmental Negotiation (IEN) at the University of Virginia to foster 'safe haven' professionally mediated dialogues on issues related to tobacco, nicotine, and alternative products harm reduction. The IEN had been instrumental in bringing the public health community and tobacco growers together that resulted in a series of Core Principles that included FDA regulatory oversight and the tobacco buyout --- something some thought impossible. Today the IEN is carrying on those discussions and has issued a set of Core Principles that suggest a number of areas of focus that might successfully help move a tobacco, nicotine, and alternative products harm reduction strategy forward. In order to encourage and foster dialogue IEN employs

a variation of the Chatham House Rule. The Core Principles are not intended to be ‘owned’ by anyone but can be used 'in toto' or in part by everyone. They are a form of guidance. The IEN hopes that more and more people who support the 'concept' of tobacco, nicotine and alternative harm reduction will become more actively engaged.

These **Core Principles** include topics such as:

1. Definitions and Terminologies: Adapting to a Changing Environment
2. Regulatory Oversight
3. Research and Science
4. Innovation and Technology
5. Monitoring and Surveillance
6. Consumers and the General Public
7. Tobacco Agriculture
8. Engagement and Dialogue

(For a complete copy of the Core Principles (2013), go to the IEN website at: www.virginia.edu/ien/tobacco)

B. So where do I think there might be some general consensus on some general principles by a significant number of stakeholders?

1. That no one under the age of 18 (21) should be able to purchase **any** tobacco or nicotine containing product including e-cigarettes. This should include such things as (as are applied to some tobacco products already) age verification, face to face sales, restrictions on vending machines etc.
2. That **all** tobacco, nicotine, and alternative products are regulated by the FDA. FDA needs to move forward with the deeming regulations as expeditiously as possible but it needs to get it right. Regulations should be designed to advance public health objectives both for the individual and the population as a whole.
3. Advertising, marketing and sponsorships should be carefully scrutinized and restricted where such advertising attracts children and adolescents.
4. That the degree of regulation of products be determined by using the 'continuum of risk' which would regulate products based on risks, relative risks and intended use.
5. That areas of regulation include but not be limited to sales and distribution, labeling, ingredient disclosure, product standards, advertising and marketing, GMP's and the child proof packaging of all tobacco, nicotine and alternative products where appropriate.
6. That FDA in conjunction and with the cooperation of manufacturers, public health authorities, retailers, distributors and others needs to implement a **comprehensive monitoring and surveillance system that covers all tobacco, nicotine and alternative products. We need to know what is happening in the marketplace.**
7. That consumers of all tobacco and nicotine products be given truthful and non-misleading information about the risks and relative risks of products that includes not only warnings but other useful information about the growing spectrum of products;

8. That FDA (and where appropriate the FTC) use its enforcement authorities to take action against any manufacturer, retailer, wholesaler etc. who violates the law;
9. That if the use and possession of any 'nicotine' product by adolescents is of such great public health concern (as many, including myself, clearly think it is) --- that like alcohol and other areas where adolescents must bear some responsibly for their actions, we begin a ***serious discussion*** about expanding minimum age of sale restrictions to include the **use and possession** of any tobacco or nicotine product. Given that initiation is of such great concern, the time may be ripe for trying to prevent anyone under a certain age (18) from buying, possessing or using any tobacco or nicotine product.
10. That FDA, while focusing on the abuses of aggressive advertising targeted at youth, also begin considering how best to convey **truthful, complete and non-misleading information to the public about the risks, relative risks and intended uses** for all tobacco, nicotine and alternative and consider initiating a well- balanced public educational campaign. (It is my feeling that until and unless this happens, confusion will continue to reign in the marketplace and some companies will continue to skirt the fine line between what is appropriate advertising and marketing and what is not).
11. And last not but least that the 'deeming' regulations should be considered the primary avenue for setting balanced, fair and effective standards for regulating all tobacco and nicotine products and that FDA should continue to encourage the active participation of all interested parties in submitting their comments.

While the FDA deeming proposal is where we need to be focusing, are there things that can be done with respect to curtailing the advertising and marketing of e-cigarettes to children and adolescents as we await final regulatory outcomes?

The simple answer is "yes" we can and should do more. But in doing so, we shouldn't be throwing out the baby with the bathwater and we need to not lose sight of the fact that our public health goals should be to reduce disease and death caused by tobacco use --- the primary concern of which has been, is and should continue to be with the deadly toxic cigarette.

Here are some things to consider in keeping attention on this issue ---

1. The public at large and consumers of tobacco and nicotine products need to be **truthfully and honestly educated** about the risks and relative risks of products in the marketplace, including e-cigarettes. This needs to come from all stakeholders. This includes information about what our policies should be with respect to children and adolescents but it goes much further. The time has come to do this in a serious manner and to abstain from what often becomes a ‘media circus’ that does little to nothing to advance the ball forward and that will only continue to confuse the public.

2. In the area of advertising and marketing FDA and the FTC should actively work together to monitor advertising, expeditiously taking action when appropriate and necessary.
3. E-cigarette manufacturers, either through the actions of individual companies or collectively, need to make it clear where they stand on a variety of issues not just to regulators but to policy makers and the public at large. As we wait for the deeming regulations to be issued, some sort of interim 'code of conduct' might help in providing some accountability.
4. This Committee, as well as the Senate Health Education Labor and Pensions Committee, and your counterparts in the House need to play a leadership role and less of a reactionary role in helping to shape the necessary policies to carry us forward. The time is ripe for our policy makers to come into the 21st century and recognize that this is indeed a 'New Era'. Design the policy parameters but let the FDA do its job.
5. FDA needs to consider not just doing 'listening' sessions but also be willing to sponsor/convene workshops and forums in order to keep the discussions on these important issues going and more visible as we await the final deeming regulations.

Mr. Chairman and members of the Committee I thank you for the opportunity to be here today to express my views and to suggest some ideas about how we can move forward in this rapidly changing environment. There is a **balance** that needs to be achieved and the only way we can achieve that balance is to keep the discussions going, our minds open, our willingness to listen and learn, and to remain focused on the goal of reducing disease and death from tobacco use.

My views have remained very consistent for many years. In August of 2011, I gave a key note presentation at the Food and Drug Administration concerning modified risk tobacco and nicotine products saying:

"The sale and marketing of **all** tobacco and nicotine products should (as recommended by the IOM report, **Clearing the Smoke**, be carefully monitored and if legitimate and serious issues are found, corrective actions should be taken by the FDA. Implementing a workable surveillance system for all products (not just MRTP's) should be given a high priority. Since companies (tobacco, pharmaceutical, biotech, etc.) will be the ones that will be required to collect the data, it needs to be done in a collaborative way with the FDA in order to achieve maximum results."

David Abrams, Professor of Health Behavior and Society at the Johns Hopkins Bloomberg School of Public Health has referred to this 'balance' as it relates to e-cigarettes as the Goldilocks test. Regulation should not be too hot (that we prevent smokers from having access to consumer acceptable products) and yet it must not be too cold either (that would allow irresponsible manufacturers the opportunity to make claims and target children and adolescents). They need to be 'just right'. As we pursue our public goals we must therefore be careful not to 'throw the baby out with the bath water'.

THANK YOU.

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