Interagency Committee on Smoking and Health
50 Years of U.S. Tobacco Control
May 13, 2014, 9:00 a.m. - 4:30 p.m.
Ronald Reagan International Trade Center, Polaris Suite
1300 Pennsylvania Avenue, NW, Washington, DC
Meeting Summary

Welcome, Introductions, and Housekeeping

Simon McNabb, Senior Policy Advisor, Office on Smoking and Health, Centers for Disease Control and Prevention

Simon McNabb, Designated Federal Official for the ICSH, welcomed the Interagency Committee on Smoking and Health ("Committee") and presented the Committee's charge: to focus on the history of the tobacco epidemic in the United States; the 50th anniversary Surgeon General's report, *The Health Consequences of Smoking—50 Years of Progress*; and what it will take to end the tobacco epidemic. He informed participants that the meeting was being recorded and noted that the meeting was public and available for the first time by webinar. He provided instructions for offering public comment, and then introduced the Committee's Chair, the Acting U.S. Surgeon General, Rear Admiral Boris Lushniak. The Acting Surgeon General added his welcome to the Committee and asked members to introduce themselves.

A quorum being present, the meeting began as scheduled.

Call to Order and Charge to the Committee

RADM Boris D. Lushniak, MD, MPH, Acting U.S. Surgeon General, Committee Chair

Acting Surgeon General Lushniak welcomed the Committee and informed participants that the purpose of the meeting was for the Committee to learn but also be engaged and ask questions of the presenters. RADM Lushniak noted that as an Acting Surgeon General, the first word in his title is "act," especially in this great year for public health: the 50th anniversary of Surgeon General Luther Terry's report on smoking and health.

RADM Lushniak reflected on the conclusion sentence that came from the 1964 Surgeon General's Report. The report's conclusion reflects the beauty of government language and its subtlety: "It is the final determination of this Committee that cigarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action." Those very subtle words—"appropriate remedial action"—carved a pathway over the past fifty years of incredible activity in tobacco control.

Although progress has been made, 5.6 million kids alive today will die prematurely unless more is done. This epidemic is not over. In 1964, the first Surgeon General's report established the causal link between smoking and one type of cancer. In 2014, this report establishes the causal link with 13 cancers, as well as other health issues.

Dr. Lushniak recalled giving a commencement speech to Heidelberg University, a small university in Tiffin, Ohio. After his remarks, the father of a graduating student thanked him and told him that the release of the 1964 Surgeon General's Report led his father to quit smoking, and live to be 90 years old. Because of a single report and a single line of remedial action, it led to a person making a critical decision.

Today, the United States has established the National Prevention Council, including 20 different federal agencies. The National Prevention Strategy and implementation plan—with the goal of having people live longer, healthier, more productive lives—has seven priority areas, including tobacco-free living.

As chair of the National Prevention Council, Dr. Lushniak provided updates on the Council's progress in tobacco-free living.

- In January 2014, the U.S. Army signed its first tobacco-free living policy for all public health command facilities.

- The Department of Health and Human Services' Tobacco-Free College Campuses Initiative has seen the number of tobacco-free college campuses grow from 774 in 2012 to 1,342 in 2014, including many colleges such as Heidelberg University that decided to go tobacco-free independently of the Initiative.
- Within the Department of Housing and Urban Development, nearly 450 public housing agencies have implemented smoke-free multiunit housing policies.
- The Department of Homeland Security provided cessation services to members of the Coast Guard.
- The United States Public Health Service Commissioned Corps, now in its 125th year, is the only uniformed service whose members are completely tobacco-free while in uniform.

Dr. Lushniak then reminded the Committee that the 50th Anniversary of the first Surgeon General's Report should strengthen resolve to end the tobacco problem, and that we still have far to go. Dr. Lushniak concluded by envisioning a 100th Anniversary that celebrates victory over tobacco, a problem of the past. He exhorted the Committee of experts to work toward this goal with optimism.

Dr. Lushniak then introduced Tim McAfee, Director of the CDC Office on Smoking and Health.

Federal Commitment to Tobacco Control

Tim McAfee, MD, MPH, Director, Office on Smoking and Health, Centers for Disease Control and Prevention

Dr. McAfee began by thanking Acting Surgeon General Lushniak for his leadership and for bringing alive the findings of the 50th Anniversary Report at the White House release. Dr. McAfee indicated that he would focus his remarks on the larger picture of tobacco control, and provide more detail on the Surgeon General's Report recommendations.

Dr. McAfee expressed hope that this meeting would allow for discussion of what is needed for society as a whole to take "appropriate remedial action." One thing that did not come soon enough or forcefully enough after the 1964 report was a plan of action as a follow-up to the 1964 report. The 2014 report should not sit on a shelf. We need to look closely at the report's findings and recommendations, but also think carefully about what we actually need to do to avoid further horrific consequences of smoking in our society.

Dr. McAfee recalled realizing how deeply the tobacco industry and tobacco culture had permeated our society when he found an ash tray that his sister had made as an elementary school art project. Back then, the culture was so permeated, it was acceptable for children to learn art by creating ashtrays.

The reduction in the death and disease from tobacco use is one of the greatest public health achievements of the 20th century, if not the greatest achievement. Today, high school smoking rates are the lowest they have ever been. We have also seen dramatic shifts in secondhand smoke exposure. Most indoor workplaces are now smoke-free. This is not all due to government interventions—some of this is the result of private policies—but now half the States have laws prohibiting smoking in public places. Some communities have also made an effort to incorporate e-cigarettes into these laws. Many colleges and universities are now smoke-free. We're also seeing high-impact national media campaigns. The first year of the *Tips from Former Smokers* campaign led to over 1.5 million quit attempts and one to two hundred thousand have quit for good. The campaign is now in its third year, and FDA launched its *The Real Cost* campaign to prevent youth smoking initiation.

Dr. McAfee reflected on a *Tips* ad participant, Terrie Hall, who participated in ads from the beginning of the campaign, and ultimately invited CDC to film her on her deathbed. Terrie has become a symbol, and images of her even as an adolescent are now recognizable to the public.

Despite this progress, the tobacco epidemic still rages on. Each day more than 2,100 youth and young adults progress to regular smoking, and 16 million people suffer from at least one chronic disease caused by smoking. The tobacco industry continues to outspend prevention efforts by a factor of 18 to one, and states are spending less than two percent of tobacco revenues on prevention. Marketing and glamorization of tobacco use remains rampant: movies remain one of the largest unrestricted media channels and tobacco impressions increased from 2010 to 2012 in top-grossing movies.

The 2014 SGR found that combusted tobacco products are overwhelmingly responsible for tobacco-related death and disease in the United States. We are seeing an increasing array of combustible and noncombustible tobacco products, which pose challenges to regulation, health policy, and research. For example, flavored little cigars are appealing to youth and their low prices are leading to increases in youth use. Electronic nicotine delivery systems (ENDS) such as e-cigarettes are also on the market. ENDS contain nicotine, which has harmful effects that make us concerned about youth use of ENDS. We're also concerned about advertising of ENDS, which is using tactics found to lead to youth smoking, such as themes that resonate with youth, low prices, ease of access, flavors, health claims. These are all reasons for anxiety and concern.

These tactics appear to have resulted in increases in youth e-cigarette use. CDC and FDA released a report last September and found that there had been a doubling between 2011 and 2012 in experimentation with e-cigarettes by youth. We also saw similar increases, though at lower levels, of current e-cigarette use among students. This year there will be $100 million worth of promotion for e-cigarettes on TV.

The Surgeon General's Report points out that that these products could have both negative and positive individual and population-based impacts, and it's likely that there will be both. The report notes that "the promotion of noncombustible products is much more likely to provide public health benefits only in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced." The best we can do is obsolete the sale and use of combustible products.

The negative potential impacts of e-cigarettes include dual use patterns that are long term and not a transition phase, relapse among former smokers, delay of quitting, and/or initiation of nicotine among non-users. There is very little benefit to modest decreases in cigarettes smoked per day compared to quitting completely.

Potential benefits of ENDS are if individuals use them to switch completely away from cigarette smoking, and at the societal level if it helps us to shift away from combusted products.

Dr. McAfee stressed that we have to stay laser focused on the fact that cigarettes are unreasonably dangerous and defective products. They are cheap, ubiquitous, addictive by design, and attractive to kids. The 2014 SGR recommends

- Full funding for comprehensive statewide tobacco control programs;
- Sustaining high-impact media campaigns for 12 months per year for a decade or more (currently *Tips* runs 3 months per year);
- Raising excise taxes;
- Expanding cessation in primary and specialty care settings;
- Expanding tobacco control and prevention research to increase our understanding of this ever-changing landscape;
- Expanding comprehensive smokefree air to 100% of the population; and
- Fulfilling the opportunity of the Affordable Care Act to provide access to barrier-free, proven cessation treatment.

Many of these strategies are underutilized. However, the federal government is doing a number of important things. The Family Smoking Prevention and Tobacco Control Act established FDA's authority to regulate tobacco for the first time in the history of our country. Regulatory action can make tobacco products safer and less addictive. Recently, FDA took an important step to implement the Tobacco Control Act through its proposal to deem authority over a range of tobacco products including e-cigarettes and cigars. If finalized, the rule will establish important protections, but is not sufficient unto itself. There are many things states and municipalities can do that FDA can't do, including clean indoor air.

There are exciting federal initiatives taking place across the federal government, including HUD, DoD, the VA, EPA, and TSA. In the private sector, important actions are taking place including the decision by CVS Caremark not only to stop tobacco sales, but also encourage customer and employee cessation. Many large companies are offering free help to quit on the job, cessation, and group support to employees.

Dr. McAfee concluded his remarks by noting that 480,320 deaths will occur each year unless we do more. He noted that there's no reason we should tolerate that lung cancer is the leading cause of cancer death. The Office on Smoking and Health should not have to work with the Office of the Surgeon General to write another report in 2064. Dr. McAfee then introduced Jonathan Samet.

Findings of the Surgeon General's Report

Jonathan M. Samet, MD, MS, Director, University of Southern California Institute for Global Health, Professor and Flora L. Thornton Chair, Department of Preventive Medicine, Keck School of Medicine of University of Southern California

Dr. Samet, joining the meeting by phone, began his presentation with slides demonstrating the origins of the 1964 Surgeon General's Report (SGR) on Smoking and Health:

- In 1950, there began a serious of key case-control studies on smoking and lung cancer. Notably, the studies all showed convincing links between active smoking and lung cancer risk.
- From 1953-1954 evidence mounted. Experimental animal studies demonstrated the production of carcinogens with tar. Prospective epidemiological studies soon followed, such that convincing epidemiological and animal evidence showed that smoking was a cause of lung cancer.
- The tobacco industry responded to the science through its release of the "Frank" statement published in newspapers, stating that the industry did not believe there was evidence that smoking caused disease, and that they would cooperate with authorities in public health. Tobacco industry-sponsored research originated during this time.
- In 1962, President Kennedy asked for a report on smoking and disease.
- The 1964 SGR was thus developed, written by a large committee chosen from a range of disciplines, whose members were neutral on the controversial topic—indeed, many of the members were themselves cigarette smokers.
    - The SGR was released on a Saturday so as not to disrupt the stock market.
    - The report was developed in systematic way. The committee developed criteria for determining causal inference which are still used today. The committee assembled and reviewed literature for consistency, strength, specificity, temporal relationship, and coherence.
    - Key findings of the SGR include that cigarette smoking is causally related to lung cancer in men, is the most important of the causes of chronic bronchitis in the U.S., and cigarette smokers have a higher death rate from coronary artery disease. The report called for "appropriate remedial action" and noted that more evidence was need.

Dr. Samet then recounted key smoking and health events and SGRs since 1964, as they relate to adult per-capita cigarette consumption.

- Cigarette smoking peaked in 1960's, and the ensuing decline is due to a number of different factors.
- The 1972 SGR was the first report to comment on secondhand smoke ("Tobacco Smoke Pollution"), and mentioned the problem of indoor smoking.
- The 1979 SGR was the first to address the role of youth education in smoking prevention.
- The landmark 1986 SGR released by C. Everett Koop found that involuntary smoking is a cause of disease, including lung cancer, in healthy nonsmokers. The report also addressed the effect of smoking on children by adults, and noted that separating smokers and nonsmokers is not effective in the same air space. The report included an implicit policy message that something must be done besides separation.
- The 1988 report concluded that cigarettes and other tobacco products are addictive, and that nicotine is the addictive drug in tobacco.
- The 2000 SGR addressed policy, offering composite review of various methods to reduce and prevent tobacco use.
- The 2004 SGR was a comprehensive review of active smoking and health that re-standardized descriptions if the evidence for causation to four categories: sufficient, suggestive, inadequate, and suggestive of no causal relationship. The 2004 report concluded that smoking harms nearly every organ of the body, and that there is no benefit from lower/lite/low-tar cigarettes.
- For the 2006 SGR, the scientific community reached consensus that secondhand smoke harms health. The report concluded there is no risk-free level of exposure to SHS, and that ventilation, air cleaning, and separation are insufficient. The strategic release of the report also demonstrated the importance of using media to communicate findings.
- The 2010 report investigated the mechanisms by which smoking causes disease.
- The 2012 report focused on youth smoking prevention, with important conclusions on the impact of the media, movies, and marketing.
- Finally, the 2014 50th anniversary report is particularly long, divided into three sections: 1) a retrospective on the tobacco epidemic and what has happened in the past century; 2) a review of the health consequences of smoking and SHS, and 3) a vision for tobacco control and policy moving forward. The report was four years in the making and has ten major conclusions. Strategic messaging and media included a vision for a tobacco free generation, projections of preventable deaths among children alive today if more progress is not made, revised estimates of health costs and deaths attributable to smoking, new diseases caused by smoking and SHS, and calculations of the effectiveness of tobacco control approaches.

Dr. Samet concluded his presentation by showing some of the headlines in the media covering the report.

Origins of the Cigarette Catastrophe—Context for the 1964 Report
Robert N. Proctor, MS, PhD, Professor of the History of Science, Stanford University

Dr. Proctor began his presentation with six reasons to abolish the sale of cigarettes:

1. First, Dr. Proctor said, cigarettes are the deadliest artifact in the history of human civilization. Cigarettes kill one person for every million smoked, and cause 6 million deaths per year (from 6 trillion smoked per year). In the US alone, about 30 trillion cigarettes were smoked in the 20th century -- killing about 30 million Americans. Cigarette deaths dwarf all battlefield deaths. Dr. Proctor noted that although public health often says that cigarettes cause death, it is important to think about the causes of causes – i.e., the what that makes the cigarette. The factories that produce cigarettes are the deadliest factories in history. Dr. Proctor reviewed the history of cigarette production, which began by hand-rolling small amounts per

day, and became mechanized beginning in the 1880s. Mechanization has made cigarettes extremely cheap and profitable. Total cigarette consumption (billions of cigarettes) peaked in the 1980s, but profits and mortality are peaking now.

2. The second reason to abolish cigarettes, noted Dr. Proctor, is that they are a defective product. Cigarettes are not inherently dangerous; in fact tobacco smoke was not inhaled before the 19th century. The industry manipulates cigarettes to make them inhalable and addictive, and it would be easy to reverse the design flaw and make them not inhalable or addictive. Cigarettes are ten times more deadly per gram compared to 100 years ago, and cigarettes now contain only about half as much tobacco.

3. Cigarettes are a substantial financial burden, resulting in high health care costs, lost productivity, causing fires, and environmental concerns.

4. The tobacco industry, continued Dr. Proctor, is a corrupting force in human civilization. The industry has corrupted nearly every institution in society, including science and academia, the medical profession, government, the Presidency, law, and public media. Tobacco denialism set up a model for global climate denialism.

    a. Dr. Proctor presented a series of slides depicting tobacco marketing tactics, including the tobacco industry's invention of baseball cards; sky writing; racist cigarette brands; life/peace brands with hippy appeal; religious cigarettes; sports/sports-related brands; medicinal cigarettes (e.g., asthma relief); Listerine for breath; Nazi brands, which provided two-thirds of the funding for Nazi storm troopers; Communist brands; labor brands, brands associated with the aristocracy, brands associated with academic institutions such as Harvard and Berkeley; political campaign cigarettes; brand stretching (e.g. Marlboro clothing); marketing depicting cigarettes as love, porn; cigarettes as free speech(e.g., the Virginia Slims *Find your voice* campaign).

    b. Dr. Proctor outlined the history of the corrupt relationship between the tobacco industry and athletes and sports (i.e. women's tennis, car racing); the television and film industry (e.g., the show Dr. Kildare which featured a smoking physician, Sylvester Stallone's agreement to smoke B&W in 5 films for $500,000); the medical profession (e.g., the American Medical Association accepted $20 million to keep silent on cigarettes from 1964-1970); government (e.g., the Marshall Plan exports the epidemic by offering $1 in tobacco for every $2 in food to Europe); science (e.g., 25 Nobel laureates have accepted tobacco industry funding); and academia (e.g., 100 history professors have worked for the tobacco industry).

    c. Dr. Proctor outlined how the tobacco industry has corrupted language, penetrating symbols (e.g. depicting health advocates as Nazis and smokers as Jews); identifying smoking as free speech, inventing the term "young adult smoker" rather than young smoker; and attracting children through animals and candy cigarettes.

5. Fifth, Dr. Proctor noted that cigarettes harm the environment, enabling forest fires, resource waste, global warming. "Denialism" begun by the tobacco industry's campaign against public health is the ideological root of global warming denialism. Factory production of cigarettes generates a large carbon footprint, pumping 16 million metric tons of CO2 annually into the atmosphere.

6. Finally, Dr. Proctor said that smoking is not a recreational drug, unlike alcohol or marijuana. Most smokers say they want to quit, and wish they had never smoked. Smoking is a threat to liberty, said Dr.

Proctor, akin to slavery. Dr. Proctor called for abolition, as opposed to prohibition, and showed a quote from a tobacco industry document: "Like alcoholics, smokers realize that they will always be smokers and can always fall off the wagon. Smoking is not like drinking, it is rather like being an alcoholic."

Dr. Proctor noted that the tobacco industry has never admitted: lying to the public, marketing to kids, or participating in a global conspiracy to hide cigarette hazards; that people have died from their products; that filters, lights and low tars are fraudulent; that cigarettes are as deadly as ever; or that nicotine chemistry has been manipulated so that cigarettes are as addictive as heroin or cocaine.

Dr. Proctor concluded his remarks by recommending three solutions:

1. Reduce nicotine content to below 1mg per cigarette.

2. Raise pH of smoke to 8.0 or above so smoke cannot be not inhaled.

3. Ban sale of cigarettes. Dr. Proctor made a case for "abolition" through banning sale, noting that every state/community has the power to ban the sale of cigarettes. This power is protected by the U.S. Supreme Court (*Austin v. TN 1900*). Between 1890 and 1927 there were 15 states that banned cigarette sales. These bans were overturned voluntarily but were upheld constitutionally.

At this time, DFO Simon McNabb noted that there will be an abbreviated time for questions.

Q and A with the Committee and Presenters

Dr. Lushniak: Dr. Lushniak asked Dr. Proctor what impact he foresees of the corrective statements that are still being agreed on between DOJ and the industry.

Dr. Proctor: Dr. Proctor responded by saying that it's about time for these statements. The industry's lies started 60 years ago and it's about time they told the truth. There is a myth that it is a responsible industry, and it's not. The denial of fundamentals is still important in the sense that they have not admitted the most important facts, said Proctor.

Dr. Lushniak: Dr. Lushniak noted that Dr. Proctor seemed to have been easy on the federal government when it comes to pointing fingers. He asked Dr. Proctor what are his real thoughts?

Dr. Proctor: Dr. Proctor said that he did blame the government for not standing up more courageously against Big Tobacco. He recalled an old saying that there are two kinds of countries: those where the industry owns the government and those where the government owns the industry – and that we are more like the former than the latter. He also pointed to the enormous power the industry has had over the USDA and Department of Trade. He repeated that there was almost no part of society left uncorrupted by the industry.

Dr. Lynn Haverkos, NIH: Dr. Havercross commented that we haven't heard anyone say that the nicotine refill solutions in e-cigarettes are a potential poison for children.

Dr. Susan Kansagra, NYC Health Department: Dr. Kansagra asked Dr. Proctor what is the historical context for the bans on cigarettes in the 1890s?

Dr. Proctor: Dr. Proctor responded that the rationale was largely health-related – though concerns about corrupting morals were also important. The earliest evidence of tobacco causing cancer was in late 1700s. In the mid-19th century, smokers' cancer was a widely used term, which affected Ulysses S. Grant. Cigarette bans were linked closely with the Prohibition movement. When Prohibition passed in 1919, the slogan was "nicotine next." Bans were partly based on health concerns and partly on the idea of the "temple of the body." Overturns were largely a result that states realized that they could gain enormous tax revenues.

Dr. Tei-wei Hu, University of California, Berkeley: Dr. Hu asked two questions. E-cigarette sales and fast growth—what are CDC's considerations for growth of teenage use? Second, should the e-cigarette be taxed to prevent young people from taking them up?

Dr. McAfee: Dr. McAfee noted that CDC has a number of more than preliminary policy positions based on past experience with cigarettes and what is known about e-cigarettes. In terms of public exposure, our recommendation would be that states and municipalities give consideration to folding them into clean indoor air provisions, with understanding that the rationale is different from secondhand smoke. The rationale for including e-cigarettes is that the standard should be what we have, which is clean indoor air. Functionally speaking in 2014, some of these devices are not designed to be nicotine delivery devices but drug delivery devices, and it is simply not possible to ask a bar or restaurant to police what is in a tank system. We also think we need to be clear with the public that nicotine is itself a psychoactive substance particularly harmful to pregnant women and children. We need to be careful not to accept that the burden of proof is on us to prove the dangers or safety of the products. On the taxation issue, we have had one meeting with health economists to discuss. The challenge is you have two potentially mutually exclusive objectives. First, I think there is no question that taxing e-cigarettes would prevent youth use. The flip side is that we have suggestive evidence from the Swedish snus experience that low price was a driver of adult use.

Break: 11:15 – 11:30.

When the Committee reconvened, conflicts of interest were disclosed. Dr. Deirdre Lawrence Kittner disclosed that she works for Pinney Associates, which does consulting work for Glaxo Smith Kline (maker of nicotine replacement therapies) and e-cigarette maker NJOY. She noted that she is not directly involved with these projects.

At this time, the CDC Tips from Former Smokers ads featuring Terrie Hall were shown.

Impact of 50 Years of Tobacco Control on Cigarette Consumption and on Premature Deaths Averted or Postponed in the United States

Kenneth E. Warner, PhD, Avedis Donabedian Distinguished University Professor of Public Health, Professor, Health Management and Policy, University of Michigan, School of Public Health

Dr. Warner began the presentation by outlining changes in smoking prevalence since 1964 to illustrate the impact of tobacco control on smoking. Dr. Warner defined tobacco control as an aggregate collection of all of the efforts of public and private sectors, and voluntary organizations, to reduce the disease burden produced by tobacco.

Dr. Warner noted that we don't have smoking prevalence estimates from 1963, but that after 1963 cigarette consumption should have continued to climb. Dr. Warner's slide depicted the trend curve that should have happened, which would have been S-shaped rather than bell shaped, rising at accelerating rate, reaching an

inflection point, and then continuing to rise at a decelerating rate until reaching an asymptotic ceiling. If not for tobacco control, cigarette consumption would have been five times higher than it is today.

Since 1964, adult prevalence has decreased by more than half. Among high school seniors, prevalence rose substantially until the late 1990s, when it reached more than a third. Total cigarette consumption has decreased, but peaked in 1981; in 2012 total consumption was under 300 billion.

The likely cause of the continued rise in consumption through 1981 was the tobacco industry's shift toward low-tar/nicotine cigarettes, increasing consumption to compensate for declines in prevalence. Today, cigarettes smoked per smoker per day are now under a pack for the first time in decades.

However, Dr. Warner noted, decreases in smoking have differed by socio-economic status. The rate of smoking decreased 20% for those with 9-11 years of education from 1966 to 2011, but 78% for those with a college education. Today smoking prevalence is 17.9% for those at or above poverty and 29% for those below poverty.

Dr. Warner relayed the findings from a JAMA study he co-authored with Holford and colleagues, which found that tobacco control is responsible for

- 8 million premature deaths avoided (not including secondhand smoke exposure deaths, or 2013-2014 active smoking deaths);
- 157 million years life saved;
- 19.6 years per person; and
- 30% of life expectancy gains from age 40.

Next, Dr. Warner provided a state of the science update on policy inventions that work and do not work.

What works:

- Price increases are the single most important deterrent to smoking; 10% price increase leads to 3-4% decrease in adult consumption and kids are twice as price responsive as adults. These decreases are half from quitting and half from decreasing consumption. The health impact is progressive—proportionally more poor smokers quit than rich smokers. Tax increases also generate a lot of tax revenue, and are politically popular because they tax a "sin" and the majority of the population does not smoke.
    - Cons of tax increases are increased incentive for smuggling, and regressiveness. Most poor smokers will not quit with a tax, so the burden on the remaining smokers is enormous.
- Smokefree workplace laws/policies increase quitting, reduce exposure to SHS 80-95%, don't harm business in the hospitality industry, reduce some business costs, and reduce acute myocardial infarctions, perhaps on the order of 10-15%. Dr. Warner rhetorically asked the group, is there anything that is ever done in medicine that is more effective than smokefree policies?
- Counter-advertising works (e.g., *Truth*, FDA *Real Cost*, CDC *Tips*).
- Bans on advertising and promotion work. Dr. Warner expressed his belief, based on the existing research, that if ads were banned entirely it would reduce smoking by about 6% compared to no bans at all. Partial bans are ineffective due to ability to substitute other forms of promotion.
- New graphic pack warning labels work. Old warning labels were ineffective and almost unreadable, but new Canadian-style labels increase intention to quit and, recent evidence suggests, quitting. The tobacco industry sued FDA over the warning labels because they posed a threat to business. With FDA's proposed deeming regulations, if nobody sues FDA, the regulations are not important.

What doesn't work:

- School health education. Some programs show efficacy (impact with best practice), but none show effectiveness because teachers are not well trained nor interested, schools face competing demands, tobacco education is a low school board priority, few resources are devoted to programs, and booster programs are rare.

The impact of tobacco control has been dramatic, but the problem remains. Nearly a fifth of adults remain smokers, 70% want to quit, 50% try to quit for at least 24 hours each year. Only 2.47% of all smokers succeed in quitting. Today's remaining smokers differ from those of past decades: they are heavily addicted, low SES, close to half have mental illness or substance abuse comorbidity, some (30%) don't want to quit. Surveys ask if smokers want to quit, and smokers may say yes in order to provide a politically correct response. Likely closer to 40% of smokers do not currently want to quit.

Dr. Warner asked, is tobacco control's cup half full or half empty? From the half empty perspective, we are seeing 480,000 tobacco-related deaths per year. But tobacco control is full of surprises. In just one decade we saw the number of smoke-free countries surge from zero to 34, and half of U.S. states are smoke-free. There is a flood of novel tobacco products, FDA regulation, a dramatic decline in cigarettes smoked per day, recognition of disparities, a strong 50th anniversary Surgeon General's Report which focuses on combusted tobacco, and we are having a new conversation regarding the tobacco end game.

Dr. Warner concluded his remarks by noting that ten years from now, we don't know where we'll be, but it will be interesting to find out. He expressed hope that it will be a prettier picture than he expects it will be.

Are We Doing Enough? Current Trends and Modeling the Future

David T. Levy, PhD, Professor, Population Sciences, Department of Oncology, Georgetown University

Dr. Levy began his presentation by introducing the concept of modeling for public health. He noted that modeling is especially useful in dynamic systems with many stages, such as policy changes creating environmental, behavioral, and health outcomes. He then introduced his modeling system, *SimSmoke*, which simulates the dynamics of policy changes on smoking rates and smoking-attributable deaths over time. This model also demonstrates that the effects of tobacco control policies vary depending on:

- The way the policy is implemented
- Demographics
- Dynamic, nonlinear, and interactive effects of policies

Specifically, Dr. Levy's *SimSmoke* work focuses on policy implementation, demographics; and interactive, synergistic, and dynamic effects, especially looking at policy levers such as price, smoke-free air, media campaigns, marketing restrictions, health warnings, cessation treatment (including pharmacotherapy, cessation treatment access in health care settings, and quitlines), and youth access policies (such as enforcement and vending machine bans). This suite of policy levers mirrors both the World Health Organization's Framework Convention on Tobacco Control and MPOWER model, as well as the U.S. *Healthy People 2020* goals.

Dr. Levy then introduced the *SimSmoke* model's policy effect sizes for various policies. He noted that, for instance, the effect size of higher cigarette prices vary, but higher prices have much bigger effects on youth due to their price sensitivity. He also noted that there is more price sensitivity among adults over age 65, due to limited budgets and income. *SimSmoke* also demonstrates that smoke-free air policies have the one of the biggest impacts on health (6% reduction in smoking). Highly publicized media campaigns are also high-performing approaches,

providing a 6% reduction in smoking. He also noted that the most recent studies on health warnings suggest these warnings lead to an approximately 4% increase in cessation—a much larger effect than previously suggested.

Dr. Levy then demonstrated some of the past successes in tobacco control that the United States can learn from going forward. His modeling demonstrates that the United States has seen a 50% reduction in smoking since 1964 due to tobacco control policies implemented after the first Surgeon General's report on smoking and health. Other successes that out-performed the model's predictions include:

- A more than 50% reduction in smoking prevalence in Brazil due to strong cessation treatment, strong health warnings (which were especially effective among youth, leading to a 16% reduction in youth prevalence), a strong media campaign, and large price increases.
- A 50% reduction in smoking prevalence in Great Britain due to very strong, comprehensive cessation treatment policies and targeting low socioeconomic populations, in addition to other strong policies. Smoking rates are currently under 20%.

Based on modeling, Dr. Levy stated that a combination of policies is needed. Specifically, tax increases have been a critical part of all successful policy packages. Other policy changes (e.g., media campaigns, marketing restrictions, smoke-free air policies) create essential social norm change. The policy changes that appear to have the largest immediate impact are higher taxes, improved cessation approaches, and health warnings. Dr. Levy also noted that the United States may see the greatest improvements if it focuses on states with weaker policies, such as those lacking a smoke-free air law, and low socioeconomic populations.

Dr. Levy then introduced some of the limits of traditional tobacco control policies. Specifically, if the United States hopes to reduce smoking by more than 50%, he suggested exploring new policy approaches, such as:

- Raising the minimum purchase age (e.g., 19, 21, or 25 years of age).
    - Age 19 carries through high school, but further research is needed on this effect.
    - Age 21 policies capture ages 18-20, when most of the rest of initiation takes place.
    - Age 25 captures potentially important years for initiation between 21 and 24.
    - Limitations: limited, though important segment of smokers; larger reductions would be seen much later (only after 10-20 years). This approach could also shift initiation to later years.
- Improving cessation treatments (i.e., increasing coverage, integrating services, and improving pharmacotherapies).
    - Dr. Levy noted that the most successful countries in reducing smoking prevalence have had a treatment component.
    - He noted that Great Britain's approach, especially its targeting low socioeconomic populations, is particularly effective.
    - He also pointed out that treatment policies are most effective in synergy with other policies, such as increased taxes, that induce quit attempts.
- Encouraging the use of substitute, reduced harm alternative products, such as snus or e-cigarettes.
    - Although this approach may appeal to lower socioeconomic populations, there is a lack of evidence and may introduce unknown harms (such as dual use instead of quitting, and a potential new source of initiation).
- Altering the content of cigarettes, by either reducing nicotine or other addictive constituents, or both.
    - Specifically, Dr. Levy's prior research has found that banning menthol would reduce smoking rates between 4 and 10%.
    - Reduced nicotine content shows potential.

In summary, Dr. Levy stated that past policies have proven very effective at reducing prevalence, especially in certain states. Future policies have the potential to continue successes, especially if implemented in states with weak policies and if directed at low socioeconomic populations. However, there appear to be limits to what traditional tobacco control policies can do, and, therefore, additional policies may be needed, such as cessation approaches, raising the minimum purchase age, encouraging substitution, and altering product contents of cigarettes.

At this time, DFO Simon McNabb noted that there will be an abbreviated time for questions.

Q and A with the Committee and Presenters

Dr. Lushniak opened the conversation by encouraging attendees to think boldly and aggressively about the tobacco endgame in this discussion.

Dr. Wilson Compton, National Institute on Drug Abuse (NIDA): Dr. Compton noted that he was pleased to see the presentations emphasize the groups that have not been reached as well by tobacco control efforts, especially low socioeconomic status populations, as well as the mentally ill. He noted that the mentally ill have remained nearly untouched by tobacco control efforts over the past 20 years. He asked:

- Do we know the differential impact of these policies in different population groups?
- Have these efforts worked or not worked for low socioeconomic populations and the mentally ill?
- In particular, as the United Kingdom moves to focus on low socioeconomic populations, are we sure these efforts will work for these groups in the United States?

He stated that without answers to these questions, he believes we will not get to an endgame and that there is the perception that we have succeeded when in fact, we have not.

Dr. Warner: Dr. Warned stated that the public believes tobacco is a "done" issue, outside of the public health field. There are differential effects of policy on these populations, and we know some of them—for example, we understand the effect of tobacco pricing on the poor. However, Dr. Warner noted, we do not know much about the differences in smokefree air laws on different groups, and our understanding of the differential effects of media campaigns is limited.

He asked if California knew the effect of their targeted media campaigns, suggesting that the evidence appears poor.

Dr. Warner pointed out that Dr. Levy's presentation demonstrated an important point: if we continue doing what we are doing today (e.g., taxes, smoke-free air), at this rate, we will cut smoking rates in half again in 2050–2060.

For this reason, he stated, we need to do something different, especially if we want to get to 10% smoking rates in 10, 20, or 30 years. He stated that he thinks the odds of us doing that are low.

Dr. Levy: Dr. Levy agreed with Dr. Warner's assessment that we do not know enough about the differential effects of policy and need to learn more. For instance, there is a conundrum: studies find that taxes and higher tobacco prices reduce smoking among low socioeconomic populations, but we have seen the least reduction in smoking rates among that group. We need to find a way to focus on this group and better understand what works for this group. Dr. Levy acknowledged that smokeless tobacco or electronic nicotine delivery systems could play a role and potentially create some health gains.

Dr. Compton, NIDA: Dr. Compton noted that 30% of COPD patients are current smokers. That begs the question, therefore: what would compel someone to continue to smoke without lungs or if they are dying of cancer? We should ask ourselves if we have all the tools. He also noted that we do not understand how to really promote good cessation and tailored to patients. For instance, not all patients are the same (for instance, cancer patients versus adolescents). More research in this field is needed.

Dr. Warner: Dr. Warner noted that we do have some research on those nuances, thanks to FDA. FDA has sponsored cessation research.

He then reiterated that Dr. Proctor's presentation mentioned two ways to make cigarettes very unappealing to the user: non-addictive nicotine levels and raise the pH. Dr. Warner argued that the ultimate solution, then, rests on FDA doing one or both of these policies with regard to combusted tobacco. He also noted that these policies would mean that alternative products, like electronic nicotine delivery systems, can be much more appealing for smokers to quit. Also, he noted, these products will improve, and he would like to see fairly liberal policymaking regarding electronic nicotine delivery systems to allow them to evolve.

Dr. Warner then stated that we need to get rid of the sexy or lifestyle appeal ads for e-cigarettes. Instead, he asked, why not use e-cigarette marketing to target the 50+ population. Our message could be: "okay, cigarettes will kill you. E-cigarettes are far less dangerous. If you can't quit on your own, use this product." This approach, Dr. Warner stated, would address the freedom issue: take the nicotine levels down to non-addictive levels, but respect smokers' desire to smoke to satisfy their nicotine addiction.

Mr. McNabb, CDC: Mr. McNabb noted that the current tools in our toolbox can be very effective. However, geographic disparities remain, creating dramatically different worlds in the United States. He then posed the question to the committee of how we can address these geographic disparities and apply the strategies that work in weak states.

Dr. Michele Bloch, National Cancer Institute (NCI): Dr. Bloch noted that there are some policies the committee has not talked about yet, such as changes in marijuana laws, poverty rate fluctuations, etc. While these are policies outside of tobacco control, they are impacting geographic, poverty, and other factors. A broader discussion of other factors that influence tobacco use rates is needed.

Dr. Hu: Dr. Hu noted that taxes are the most powerful tool in tobacco control, and there are geographic disparities and wide variation in state taxes. We need to consider that our overall retail tax rate is lower than most other countries. Dr. Hu stated that the Federal government should raise taxes further across the board, perhaps to support the Affordable Care Act.

An additional issue with state differences, such as in the tobacco-producing states, is how to incentivize these states to raise taxes. Some options include:

- In addition to minimum purchasing ages, have a minimum state tax rate
- If we can raise the tax, share the additional revenue shared between the federal and states, for instance, Medicaid

Dr. Hu noted that the WHO's focus for this year's "Smokefree Day" is to "Raise the Tax." He argued that we should take advantage of this to promote the concept that we do not have a high enough tax rate at the federal level.

Interagency Committee on Smoking and Health
50 Years of U.S. Tobacco Control
May 13, 2014, 9:00 a.m. - 4:30 p.m.
Ronald Reagan International Trade Center, Polaris Suite
1300 Pennsylvania Avenue, NW, Washington, DC
Meeting Summary

Panel Discussion: Tobacco Endgames: Possible U.S. Scenarios

Kenneth E. Warner, PhD, Avedis Donabedian Distinguished University Professor of Public Health, Professor, Health Management and Policy, University of Michigan School of Public Health

Matthew L. Myers, President of the Campaign for Tobacco-Free Kids

Ruth Malone, PhD, RN, Professor and Chair, Department of Social and Behavioral Sciences, University of California, San Francisco

Simon McNabb introduced the purpose of this panel, which is to continue the conversation of the endgame, including introducing new ideas and pointing the federal government forward.

Question 1: Defining the "endgame": What does that phrase mean to you?

Dr. Malone: The journal *Tobacco Control* was the first to use the phrase "endgame" editorially a few years back, but in the past few years, that phrase has taken off around the world. For instance, in other countries, a report we prepared for Cancer Research UK reviews the literature on endgame and includes discussion of endgame planning in other countries regarded as tobacco control leaders, such as New Zealand and Singapore.

The United Kingdom cancer research report defines "endgame" as "initiatives designed to change or eliminate permanently the structural, political and social dynamics that sustain the tobacco epidemic in order to achieve within a specific timeframe an endpoint" to the tobacco epidemic. Dr. Malone noted that this definition goes beyond simply "reducing the death and disease from tobacco," which can be an endless battle, and which obviously must continue, but addresses the broader issues that continue the epidemic, Therefore, we are not replacing what we are currently doing, but realize we have to go beyond current measures or this will not happen.

Mr. Myers: Mr. Myers noted he may have more concerns on how the endgame conversation has been handled more than others, because there is a failure to articulate what we are talking about. He expressed that people are confusing a discussion of new strategies with setting new goals that define by what we mean as a legitimate endgame. The automatic assumption is that we are talking about new and different strategies in place of existing scientifically proven strategies carried out more completely and more vigorously, This is harmful if it results in the abandonment of basic public health strategies or a failure to recognize that our greatest need is to fully implement the strategies we already know that haven't been fully implemented because of a lack of political will.

In talking about the end game, Robert Proctor speaks about the language we use: abolition versus prohibition. Tobacco Control has been a success in part because the most effective strategies have been consistent with the basic, core values of our society. In talking about new strategies and end goals, we need to be careful that we are not perceived to be prohibitionists and some discussion has crossed over that line We need to be certain that when we talk about the "endgame", we do not cross that line or we could lose public support.

Often, this conversation too quickly turns away from why we have not made more progress. We actually know what works, but we lack the political will. We are not asking the harder question: how do we generate the political will to adopt proven strategies or new strategies? Without generating the political support and political will for decisive action, we will not take the steps that are needed. For Mr. Myers, the most important question is how do we generate the will to take strong action. With political will, dramatic progress is today easy to envision. Without it, we will not succeed.

In conclusion, Mr. Myers noted that we should talk about the goal of eliminating the tobacco burden and how to get there, but we need to be careful on the rhetoric and strategies that hold public support.

Dr. Warner: Dr. Warner opened by noting that he has been struck with the question: what does "endgame" mean? Is it two words? One? Hyphenated?

If it is two words (end game), it is hard to understand what the "game" means and what strategic approach to use.

There are also questions on: what is the end? What are we trying to achieve? He noted that the end, or elimination of death and disease, is rarely talked about in the tobacco control field.

Dr. Warner then proposed some alternatives:

- Health-based: end of disease and death. However, it is unlikely we will get to 100%. Therefore, how much of it is the "end?"
- Product use elimination. Then the question is: what products? Cigarettes? Combustible products? Tobacco? Nicotine products? Nicotine-only products?

Dr. Warner stated he would prefer to focus on eliminating combusted product use.

Dr. Malone: Worldwide, the figure of 5% smoking prevalence is often used to demarcate an endpoint. However, we cannot just look at prevalence. Prevalence also depends on industry behavior and we need to factor that in. Dr. Malone argued that we need to develop a tactical plan for this: we cannot ignore that the industry as a player is constantly changing and working to influence the environment and obstruct all that we do. We need to conceptualize public health as a competitor to the industry, because that is how tobacco companies see us—as more of a competitor than other tobacco companies.

There are other concerns, such as trade issues. We face very important potential obstacles to tobacco control with new international trade agreements, which the United States is pushing hard for. These could also obstruct our ability to reach the endgame.

Dr. Malone noted that the retail sector is also important. For instance, we know that tobacco outlet density increases consumption and reduces successful quits. Having many outlets within walking distance makes it much easier to relapse. We need to look at outlet density to combat the underlying message of retail ubiquity: "it can't be that bad for you or you wouldn't be able to buy it on every street corner."

Dr. Malone also noted that there are brave efforts to begin this conversation in the U.S. military. There is a perception that tobacco use is part of the institution. Dr. Malone noted that research demonstrates that repeatedly, when the military has tried to implement stronger tobacco control measures, the tobacco industry rallied their efforts on the Hill and threatened to weaken their resources. She then stated that these are not just historical but current issues, and that there are very important initiatives that need a lot of public health and public support, but that the tobacco industry is moving to undermine.

Mr. Myers: There is enormous value in establishing the elimination of death and disease from tobacco as the end: this is the harm to people, and a goal that people find very acceptable. It is important to note that 15 years ago, that idea would have been "Pollyanna-ish." But is a measurable goal, just like the elimination of polio, and that does not sidetrack us from the strategies.

Mr. Myers stated that we need to frame this right and address ways to create the political will in both the populous and in decision makers. It is a hard goal to be opposed to, but we need to separate unproductive rhetoric to focus on strategies to get us there. Mr. Myers also noted that we need to hold communities and political figures accountable.

Mr. Myers also noted that this approach allows us to talk about the surrogate voices for the tobacco industry, such as retailers and other businesses, which argue that restricting trade on tobacco is akin to restricting the sale of wheat. There is value is saying it is time to talk about reductions in incremental progress—people then take these efforts seriously. Mr. Myers posed the question of why doesn't anyone care about public officials condemning the children of Kentucky to that kind of risk?

He then pointed out the example of the Philippians, which implemented universal health care with a huge tax on tobacco. He urged the committee to not think less bold and frame the endgame in ways that brings people on-board.

Mr. McNabb: Going back to the idea of traditional tobacco control, talking about the end and the game, we should note that innovative strategies do not mean forgetting about the old stuff. We still need to apply the traditional things where they are not in place yet.

He then pointed the committee back to the international trade discussion, which has been used as a tool against countries that are being more progressive in tobacco control. He then posed the question to the panel: what are these promising practices from other countries that we can adopt?

Dr. Malone: The biggest current example is the use of plain packaging in Australia and soon in the United Kingdom. However, that is probably an impossibility in the United States, given the freedom of corporate speech. In that sense, it is hard to know what we can learn from those examples.

However, in Australia, they are making more effective use of tobacco industry denormalization as a strategy. This approach, she argued, begins to change the dynamic for smokers. Furthermore, public health cannot lose sight of the epidemic, the bigger picture than the individual deaths and disease we see over and over. Instead this is a public health emergency.

She also argued that we need to be thinking not on how to make things worse for other countries on trade policies, but what we can do regarding advertising with our restrictions.

Furthermore, the retail sector is underutilized. For instance, in California, there is universal licensing of retailers, and they are making these licenses more expensive gradually. Some retailers have abandoned tobacco sales. Dr. Malone stated that this traditional alliance between retail and the tobacco industry is starting to fray. Messaging can help advance that fraying and split off some allies.

We need to realize that many retailers are not feeling so good about continuing to sell tobacco. We need to consider ways to incentivize retailers to quit and disincentivize retail sales.

Dr. Warner: Dr. Warner agreed that warning labels and plain packaging are viable tactics.

Russia and Uruguay have also done a lot of things quickly and substantially. However, we cannot. Tobacco control in Canada and France have seen successes, but the French political system is very top-down, whereas the United States is the opposite. The constitutional law framework here is a challenge, and we have a libertarian streak in society that is unseen in other major nations, which makes this much more difficult to do. Dr. Warner noted that it is difficult to learn direct lessons from other countries, given our political systems.

Mr. Myers: There is a quote: "the U.S. produces the science and everyone else uses it." He noted that the cross-fertilization globally is there, potentially. For instance, both the United States and the globe are struggling with non-communicable diseases, and the Philippines are the best example of tackling that problem with taxes.

Mr. Myers then noted that although the United States currently has an anti-tax mentality, he urged the committee not to forget that this is the strongest measure and potential solution. He expressed hope that low- and middle-income countries will address non-communicable diseases using tobacco taxes.

Furthermore, he noted that no one has yet mentioned the second issue of the product itself. The 2014 Surgeon General's Report found that 50 years after we told the tobacco industry they were harming people, they implemented design changes that doubled the risk of their product. What we have learned is that the product is not a side issue. Mr. Myers noted that we see data showing that cigarettes in the United States kill a greater percentage of its users than they did 50 years ago, which is shocking—especially when the products deliver nicotine more powerfully. In this way, Mr. Myers argued, the tobacco industry has spent the last 50 years making the poison go down smoother for kids and women—increasing their tolerance to make the product appeal to a wider audience and increase usage. He noted these product concerns are a particular challenge for FDA and that we should not ignore the product as part of the problem, or the solution.

Mr. Myers asked the committee to consider if we, like Australia, could pursue plain packaging. He noted that part of that country's success is because they have spent decades gradually building support and regardless of the political spectrum, people think alliances with the tobacco industry are inappropriate. He noted that social norm change and bold policies go hand-in-hand.

Dr. Warner: Dr. Warner proposed considering a specific notion in thinking about the product: that the tobacco industry does not like killing their customers—an unfortunate side effect, as it removes customers at their prime smoking ages (as well as legal and public relations costs). The idea is that if they had a product that could do what cigarettes do without killing the user, everyone would be happier. Industry is working on ways to sustain nicotine addiction through true pulmonary inhalation devices. He posed the hypothetical question that if smokers changed their behavior completely, and this increased industry profits, how would the committee feel about this scenario?

Dr. Malone: Dr. Malone noted that the incentive to stop selling combusted cigarettes will only come when these products are not profitable. Right now, they are the perfect product because they are addictive and cheap to produce.

Instead, she argued tobacco companies and retailers may need to be incentivized externally to do something different. FDA regulation has the potential to provide this incentive.

She expressed concerns over the focus on the product itself; after years of litigation and tinkering with individual product components, cigarettes remain a hideously unsafe product, akin to asbestos. She argued that an unsafe product should no longer be for sale.

Dr. Malone then noted that with product innovation, such as e-cigarettes, we could potentially link conversation from the most deadly products to an alternative, if they are considered consumer-acceptable substitutes.

Dr. Warner: Dr. Warner argued that in that scenario, it must be FDA action.

Dr. Malone: Dr. Malone argued that innovation is not happening at the federal level and anything FDA does will be tied up in court appeals for years—we need to start at the state and local level. State and local levels have the legal ability to further restrict retail outlets and sales.

Mr. McNabb, CDC: Mr. McNabb noted that the 2014 Surgeon General's Report mentions these strategies, including product modification using current policy tools, such as reducing the nicotine content, and further bans on sales at the state or local level.

Mr. Myers: Mr. Myers reminded the committee that 9 out of the 10 states with the lowest smoking rates have high taxes and smoke-free air policies. In contrast, 12 out of the 14 states with the highest smoking rates have low taxes and no comprehensive, statewide smoke-free air policies. He argued that one of the quickest ways to address this is look at the "have-not" states and transform what goes on in those states. Some endgame strategies become more realistic once you have low smoking rates. He noted that the disparate smoking rates even within counties within states represent a huge challenge, and addressing these issues is a huge challenge. He also noted that we can learn from countries that have had success because they approach social norm change with something besides gradualism.

Before, when these radical ideas were proposed, we were told that advertising would go out of business in Australia, just like bars will go out of business if they are smoke-free. However, he noted, countries that ban the display of cigarettes have not seen dramatic drops in business. In Australia, young people's attitudes are fundamentally different. We need to seize that opportunity to have that discussion, especially with this generation, which has never seen the Marlboro cowboy.

Dr. Malone: Dr. Malone took the opportunity to add that the reason Australia has seen this success is that someone had the political courage to lead this—then it became un-radical. Industry denormalization has been a theme of California's media campaign, and it is electrifying. Dr. Malone stated she believes industry denormalization and breaking the industry's alliance with politics is key.

Mr. Myers: No one should believe that this is a magic wand. There is no substitute for hard work—in California and other places that move the social norm needle. This is a fundamental lesson for succeeding anywhere.

Dr. Warner: Dr. Warner reiterated that if you want magic wands, we need to look to FDA. FDA is the one place where you can build some of the changes needed to create public support and move toward an endgame notion.

Specifically, he noted that building public support for the end game exists along a spectrum. For instance:

- Harm reduction discussions—the public is much more comfortable with this.
- Nicotine reduction concept—the public is much more comfortable with this.
- Prohibition or abolition, per Dr. Proctor's ideas—the public is decidedly uncomfortable.

We need to acknowledge that the conversation has changed over a short period of time.

Simon McNabb thanked the panel discussants and wrapped up the endgame discussion. After a short break, the committee invited the public members of the audience to make their comments.

Public Comments

Dr. Jeanette Noltenius, National Latino Alliance for Health Equity

Dr. Noltenius opened her comment stating that the conversation has not changed in 20 years. We started this morning by showing once again aggregated data on how well we are doing reducing cigarette smoking. She urged the panel to question: what about disparities? She then noted that smoking prevalence for American Indian/Alaska Native, Asian, and Latino populations have not seen these reductions.

She thanked Dr. Warner for his discussion of low socioeconomic populations and the needs there, especially addressing the retail outlet density issue.

Dr. Noltenius also noted that there some specific product modifications that the committee has failed to address, such as menthol. She argued that menthol encourages these kids to want to start smoking. She reiterated that additives are another key piece. Certainly, she stated, reduce nicotine. However, this will not have the impact we want until we realize very simply that now half the children in this nation are children of color. One of every four newborns is Latino. We have to look at this new population and where they live in communities. We need to incorporate these issues into our discussions of population-based approaches, FDA regulation—what are we doing to reach these communities that are being left behind?

Dr. Noltenius closed by urging the committee not to be afraid of talking about specific product additives and how to address this new "face" of the nation, especially through desegregated data.

Joseph Gitchell, Pinney Associates and Glaxo-Smith Kline

Disclaimer: Mr. Gitchell noted that his companies advise the e-cigarette manufacturer NJOY, although he is not involved in that specific project.

Mr. Gitchell encouraged the committee to focus more on the healthcare system in their considerations, and treat smoking more as we treat other chronic relapsing conditions. For instance, if someone had high blood pressure or high sugar, we wouldn't ask them if they wanted to do something about those issues. In other words, trying to turn a physician into a counselor is ineffective.

Instead, he urged, we should let physicians diagnose and prescribe, turnings offers of help into truly encouraging cessation. This would turbocharge the healthcare system's approach to smoking.

Tom Moriarty, Executive Vice President and General Counsel for CVS Caremark

Mr. Moriarty introduced the justification for CVS to stop selling tobacco. Over the period of time this was in development, the company decided to focus on getting people on the path to better health. The inconsistency of selling tobacco products while simultaneously addressing chronic diseases was not lost on CVS.

We no more expect tobacco products when you go to the doctor's office than when you go to your pharmacist. Ultimately, that is what drove the decision.

Mr. Moriarty stated that this is not a one-time decision, but a guiding company principle. CVS plans to follow that decision with a national smoking cessation program they hope will become the gold standard. All company resources, from the 7,700 pharmacies to the 800 Minute Clinics to the 26,000 pharmacists CVS employs, will reflect this cessation program.

After Mr. Moriarty's remarks, Dr. Lushniak awarded a certificate of achievement to CVS Caremark on behalf of the Surgeon General's office for this corporate decision to stop selling tobacco products.

Member Discussion

Dr. Lushniak: Dr. Lushniak opened the discussion by reminding the Committee that in public health, we have to be optimists. Today's discussion has introduced a lot of new concepts and new partners. We have to remind ourselves that product regulation was once only a dream, but now FDA is an organization empowered to make some of these changes because of the Family Smoking Prevention and Tobacco Control Act. He also urged the Committee to continue to use corporate examples, from CVS and Target, for instance, to remind ourselves that partnerships are needed to achieve our goals. In many ways, these new partners have made decisions to "move ahead" without the government.

He urged the Committee to push ahead with enthusiasm and optimism. Dr. Lushniak then opened the floor for final comments from the Committee.

Lynn Haverkos, NIH: Comment: it is NIH's mission to ensure children are born healthy, wanted, disease-free, and the pregnant women do not suffer. She stressed three key issues for this specific population:

1. Toxicity potential for children in e-cigarette nicotine refills, which is very concerning.
2. Smoking relapse in post-partum women. The data show that smoking rates bump back up after pregnancy, continuing to endanger the mother and her child.
3. Asking the question: how do we truly change behavior? Need for better understanding of the science of behavior change and encourage research and training in behavioral sciences.

Dr. Corinne Huston, FDA: Dr. Huston expressed her gratitude that the Committee had the opportunity to discuss the FDA's new proposed rule for deeming electronic nicotine delivery systems. She reminded the Committee that the rule is now open for public comment and that all stakeholders should send in their comments. She reminded the Committee and the audience that a comment is not a vote, but an opportunity to provide information to support decisions, such as published data, information on new products, unpublished data that reflect issues, and new methodologies. She expressed her hope that this information will produce the best possible final rule.

Dr. Michele Bloch, NCI: Dr. Bloch reiterated that the discussion on the endgame identified political will as a key gap, for existing and future strategies. She urged that endgame approaches align with key societal values:

1. Protection of children. This value sets a very high bar for any strategies that have the potential to increase or lower the rate of products.
2. Protection of innocent bystanders. This is the strongest argument for banning the use of e-cigarettes in public.

3. Fair play. She argued that the industry has never played fair with the American public, which is documented with 50 years of gross deception of the public, as well as sharing the knowledge of how to deceive the public with other industries. This should not be allowed to happen.

1. Population assessment of tobacco and health, in collaboration with FDA. The PATH study and studies of the natural history of tobacco products are especially important in a shifting regulatory environment. PATH baseline data collection for adults and adolescents will be completed in September 2014 and they will work to make that data available as quickly as possible.
2. Genetics research to inform both treatment development and prevention.
3. Development of new treatments, such as vaccines against nicotine addiction.

Dr. Victoria Davey, VA Health Care System: The Veterans Affairs Administration is making strides to reduce tobacco use by veterans in care. Since 1999, the VA has seen a decrease from 33% to under 20% of veterans. This resulted from a combination of resources and policies that improve cessation.

They also have a legislative proposal to make VA medical campuses smokefree. This is a high priority for the agency.

There are special populations to consider as well, such as veterans with mental health or substance abuse disorders. The VA is training physicians to address these populations.

She mentioned that they suspect that tobacco use is a new behavior in deployed veterans to deal with the terror of combat and are picking up smoking as they enter the military in late adolescence. These factors make efforts to prevent tobacco use more difficult.

She also noted concerns with the use of electronic nicotine delivery systems, such as behavior change (e.g., initiation) and their use in healthcare settings.

Dr. Tina Fan, AHRQ: Dr. Fan noted that the U.S. Preventive Services Task Force is updating recommendations on adult tobacco cessation that reflects a systematic review of the evidence. This includes research on e-cigarettes, treatment options for the mentally ill, and newer interventions. Final research and draft recommendation will be available for public comment expected in spring 2015.

Dr. Tei-wei Hu: Dr. Hu expressed three observations:

1. Tobacco control is not only a health issue, but a political issue. We have not done enough—for instance, we have not signed the Framework Convention on Tobacco Control—and when we go to other countries, they cannot listen to our examples. He urged the public to do more work with Congress, to mobilize change drawing on international experiences (including Brazil, Thailand, and the Philippines), including experiences with taxation.
2. We do not have high enough taxes and there is wide state variation in tax rates. The Federal government should take leadership roles to reduce this gap.
3. There needs to be more research on e-cigarettes and whether that is really a substitute, as well as biological effects.

Dr. Helen Meissner, NIH: Dr. Meissner noted that NIH is developing the research needed to inform regulatory authority, including e-cigarettes. The office is especially focusing on the rapidly changing market, as well as

training and building capacity for tobacco regulatory science. She highlighted the uniqueness of these programs in informing national public health policy.

Dr. Antonello Punturieri, NHLBI: Dr. Punturieri noted that more research on electronic nicotine delivery systems is needed, including addressing the nicotine receptors throughout the body (including the immune system). He expressed caution about nicotine exposure: nicotine is a drug and, like any other drug, it has multiple effects—some desired, some undesired.

He also stressed the importance of further research on COPD. When patients come in with COPD, we are trying to patch them when the damage is done. Dr. Punturieri noted that the fastest growing group of COPD patients is white and American Indian women.

In addition to the personal human costs of COPD, there are enormous societal costs, as these patients require several years of medical and surgical care.

Captain Sarah Linde, HRSA: Dr. Linde expressed support for ways to improve health and achieving health equity through access to healthcare and a skilled healthcare workforce to address cessation. This is especially important for vulnerable populations.

She noted that HRSA is partnering with other HHS agencies to spread this message, as networks are great disseminators of information.

Dr. Warren Lockette, Department of Defense: Dr. Lockette expressed his intrigue on a variety of substances used in the military to "enhance performance," including Sudafed and "dip." He also expressed he was surprised by the discussion on nicotine and urged further discussion on nicotine and unique populations. He urged the Committee to consider the effects of different products on nicotine receptors in the body.

Dr. Lockette noted that the Department of Defense is doing a lot on tobacco cessation and have seen a number of successes in this area.

Dr. Susan Kansagra, New York City Department of Health and Mental Hygiene: Dr. Kansagra highlighted the importance of the role of local governments in creating tobacco control change. She noted New York City's success, with 12 years of tremendous political will. She noted they are currently working to protect their high prices, while addressing tax evasion concerns—including new rules to strengthen enforcement—and have submitted a petition for FDA to implement a national track and trace system.

She demonstrated some of the New York City highlights, such as prohibiting discounts, establishing a minimum price for cigarettes and little cigars, and raising the minimum purchase age to 21. These components are being implemented and evaluated for effectiveness.

She also urged the Committee and tobacco control community of the value of local champions to discuss impact of policy change.

Allison Freeman, EPA: Ms. Freeman noted that a number of presentations have under-addressed certain subpopulations, including low socioeconomic, mentally ill, and substance-abusing persons. There are disparities and failures here.

She also noted disparities in post-partum women, as well as parents generally that are modeling smoking behavior, and their children are victims of this exposure. This is EPA's emphasis: the children in Head Start, WIC, and public housing, and their health. She welcomed partners from other agencies on these issues.

Ms. Freeman also urged the public health community to work across issues, such as cancer coalitions, asthma, and diabetes partners.

She expressed appreciation for HHS's leadership on tobacco control strategies, and asked how much the 2014 Surgeon General's Report will inform the HHS Strategy. She also urged continued dialogue on endgame.

Dr. Deirdre Kittner, Pinney Associates: Dr. Kittner noted that taxation efforts also need to include dedicated funding for tobacco control efforts.

She also noted that as we are discussing tobacco control, we do not fully understand how efforts effect certain populations and disparities. For instance, lower socioeconomic status families pay more out of their budget because of taxation. How should we address this?

She stressed the importance of offering cessation services that work. However, much of the challenge is that we do not know what works best for cessation—especially on disparities. There are high rates of smoking by racial/ethnic minorities, the unemployed, nurses, the mentally ill, and the homeless, but we do not have data on what works for these unique populations. We should use resources to understand what works here.

Barbara Vize, IHS: Dr. Vize noted that we can help reduce health disparities by concentrating on people of color, low socioeconomic status, the mentally ill, and those with a combination of all those factors. There are cultural differences in American Indian populations. There are also over 500 tribes served by the Indian Health Services, each with different cultures. We need to denormalize tobacco use for all these groups in culturally appropriate ways. We need more information, research, and better measures.

She also highlighted the *Million Hearts™* campaign, which emphasizes tobacco cessation as part of the ABCS (Aspirin, Blood pressure control, Cholesterol control, and Smoking cessation). There are also a number of key programs in IHS, including health promotion and health education programs focusing on cessation.

Doug Tipperman, SAMSHA: Mr. Tipperman mentioned that the discussion on disparities should also include those with mental and substance abuse disorders. These patients represent about 25% of the overall population, yet smoking about 40% of all cigarettes smoked in the United States.

He acknowledged that mental health care is complicit in this, using tobacco as a reward and incentive for behavior or medication compliance in addiction and treatment settings. We need to change at the local, community, and state level to mobilize partnerships with Medicaid, consumer organizations, and the mental health community to reverse this culture.

Dr. Sara Tamers, NIOSH: Dr. Tamers noted the importance of integrating occupational safety and health promotion. For instance, NIOSH's research has found that a total worker health approach is more successful for long-term cessation, including among blue collar workers. She also noted that many workers are exposed to workplace hazards and have a greater risk of lung cancer and other diseases inherent to those hazards. Many of these are also smokers, putting them at even greater risk.

Dr. Maria Said, Fogarty International Center, NIH: Dr. Said noted that the Fogarty Center has programs in 34 lower and middle income countries, and has trained more than 3,500 people in these countries. The Center has been forced to work broadly to address cross-cutting issues. These lower and middle income countries are recognizing that non-communicable diseases are a growing problem, and cross-cutting issues are becoming key, such as HIV patients and their tobacco use. We need more research and implementation science to see how that research is translated.

Closing

Simon McNabb, DFO, thanked the Committee for their time and comments.

Dr. Lushniak also thanked the Committee for their thoughtful discussion, then commended two retiring Committee members, Dr. Hu and Ms. Mullen of the World Lung Foundation. Finally, Dr. Lushniak dismissed the Committee and the meeting was adjourned.

Interagency Committee on Smoking and Health
50 Years of U.S. Tobacco Control
May 13, 2014, 9:00 a.m. - 4:30 p.m.
Ronald Reagan International Trade Center, Polaris Suite
1300 Pennsylvania Avenue, NW, Washington, DC
Meeting Summary

I certify that this report of the May 13, 2014 meeting of the Interagency Committee on Smoking and Health is an accurate and correct representation of the meeting.

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Chair, ICSH