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Interagency Committee on Smoking and Health (ICSH)
Increasing the Impact of Evidence-Based Tobacco Treatment
U.S. Department of Health and Human Services

Opening announcements/welcome by
Simon McNabb, Designated Federal Official:

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The ICSH is a federal advisory committee and is therefore governed by the Federal Advisory Committee Act or FACA, which means that we have certain guidelines to follow. Today's meeting will focus on increasing the impact of evidence-based tobacco treatment. I believe we have planned a stimulating meeting to help the committee in identifying actions that the federal government can do to increase access, remove barriers, and promote utilization of evidence-based tobacco treatment.

This is a public meeting. We will have members of the public in the hall with us and also on the conference line. The discussion and questions will be confined to the committee and the presenters sitting at this table. We do have time for public comment this afternoon at 2:45 and if people would like to make public comment, those in the hall can sign up at the registration table. Those on the phone can indicate that you want to make a public statement by hitting *1. All public comment is one way. We welcome your comments but we will not be able to respond to your comments or answer your questions during this meeting. We are recording this meeting and we will ultimately come up with a summary of the meeting. In compliance with FACA requirements, we'll publish that on the web.

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Opening statement by
Acting Chair, Dr. Tom Novotny,
Deputy Assistant Secretary for Health (Science and Medicine),
Department of Health and Human Services

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About 32 years ago this federal advisory committee was established under the Comprehensive Smoking Education Act. In the absence of the Surgeon General I had the privilege to chair the last meeting and I'm very pleased to also chair this one focusing on increasing the impact of evidence-based tobacco treatment.

We know that effective cessation really depends on evidence-based tobacco control policies and treatments, but we'll hear more about that later today. However, it also depends on environments in which clinicians deliver such treatments and in which a smoker makes a decision to quit. This means comprehensive statewide local programs as well as federal policies.

At our last meeting of this committee we focused on smoke-free and tobacco-free environments, and we learned about how behavioral health settings, college campuses, multi-unit housing, and other indoor and outdoor spaces benefit from comprehensive tobacco-free policies. These all help reduce exposure to secondhand smoke while they set the stage for successful quitting. Media advocacy, population level policies, and health care setting-based educational efforts are also critically important.

From the federal side, campaigns like Tips From Former Smokers, the Real Cost, and other efforts from partners, fuel the public learning process across the country about how there is no safe exposure to tobacco, whether first-hand, secondhand, or even third-hand. It has been repeatedly demonstrated that even brief educational interventions by health care providers are helpful in moving tobacco users across the spectrum of contemplation to successful quitting.

Everyone in this room knows by now that increasing the cost of tobacco products is one of the most effective strategies to reduce tobacco use. Increases in federal as well as state or local taxes, combined with other aspects of comprehensive tobacco control programs, have helped bring our national adult smoking rate down to just over 15%. Twenty-five years ago, that prevalence was more than 30%. And we thought we had made such significant progress back then. In fact, it was hard to imagine then that smoking would be banned in bars in many big cities, that the cost of a pack of cigarettes would be $13.00 in New York City, and that the FDA could actually regulate tobacco products.

All of these accomplishments are great, but without providing tobacco users the effective and accessible methods with which to quit we can't get to the end game on tobacco. This is why today's discussion on increasing evidence-based tobacco treatment is so critical. Around 70% of smokers report that they want to quit. And we know that nicotine addiction is still the main reason why they do not.

However, we know cessation works, because since 2002 there have been more former smokers than there are current smokers. Today we'll hear more about how individuals are trying to quit, how the public health and medical community is providing cessation support and treatment to smokers, about innovative and exciting interventions for different settings, and about approaches for specific vulnerable populations.

So, the charge to the committee today is to consider how we can increase the impact of tobacco treatment as part of our national goal to reduce tobacco use. I'd like to challenge us all to think innovatively about what is needed to support science-based cessation, especially at the federal level, so that we can reach our shared goal of a tobacco-free generation.

Before we proceed, I'd like to recognize two important historical events. Today, as most of you know, is WHO's World No Tobacco Day. The focus this year is on the economics of tobacco and sustainable development. I'd like everyone to check out the info-graphics and other material on the WHO website. We've also published a blog post on this subject on the HHS website today that will become active at 9:00 a.m. and many other agencies such as CDC, and organizations such as the Association of State and Territorial Health Officers, the Campaign for Tobacco-Free Kids, and others, have recognized this high holy day of tobacco control. So, we want to give that some special attention today during our meeting.

WHO has also published a monograph on the issue of tobacco in the environment. It's a review of the life cycle of tobacco's environmental impacts, starting with tobacco growing, the manufacturing process, distribution, and finally disposal of tobacco product waste, also known as cigarette butts. I'd like you all to take a look at that web resource. It's got some interesting facts and things that you may not have thought about as far as the environmental impacts of tobacco.

For the second historical event, I want to recognize this group of people in this photograph taken during the production of the 25th anniversary report of the Surgeon General. Ken Warner was the Senior Scientific Editor. He's one of those people in the back row there, and Dr. C. Everett Koop was our Surgeon General at the time. You may recognize Ron Davis to the right there, who passed away. Ron was a terrific leader and head of the Office on Smoking and Health at that time. He later became the President of the American Medical Association.

Ken Warner is retiring today from his position as Avedis Donabedian Distinguished University Professor of Public Health at Michigan. He also served as the Dean of Public Health at Michigan in the past and continues as a member of this committee for another two years. But

he is retiring from his academic career and we thought we'd give him little gift that recognizes his service.

I'll read this. "With sincere appreciation and recognition of the years of service that you have devoted to providing advice and counsel to the Interagency Committee on Smoking and Health and serving as Senior Scientific Editor of the 25th anniversary report of the Surgeon General on reducing the health consequence of smoking. We'd like to commend you for the leadership that you've provided for advancing tobacco control science in the Department of Health and Human Services throughout the nation." And that's signed by Don Wright, who's our acting Assistant Secretary of Health.

Finally, I just want to thank all of the speakers today for sharing your work and an enormous thank you to CDC's Office on Smoking and Health for planning this meeting, especially Monica Swann, the Committee Management Specialist, and Simon McNabb, the Designated Federal Official. And thanks to all of the committee members with a special shout-out to our public members, Sue Curry, Steve Schroeder, Ken Warner, Patricia Nez-Henderson, and Denny Henigan. Thank you all and let's have a really great discussion today.

Dr. Corinne Graffunder
Director, Office on Smoking and Health

My presentation this morning will cover what we know about the current trends in tobacco use cessation. I'm going to focus on the progress we're making in helping smokers quit and on trends in smoking cessation behaviors. I'm going to touch on disparities in both smoking and in cessation and then I'm going to talk about leveraging opportunities using CDC's Tips From Former Smokers (Tips) campaign to help support smokers who are trying to quit.

Multiple smoking cessation interventions and innovations since the first Surgeon General's Report in 1964 have resulted in significant reductions in smoking. In the 1990s, we saw a noticeable decline in consumption that corresponded with the release of the Surgeon General's Report on the benefits of cessation. Another decline occurred in the '90s when nicotine replacement therapies were made available over the counter.

Decades of progress reflect the impact of comprehensive evidence-based interventions that motivate tobacco users to quit and make it easier for them to do so. We, in the Office on Smoking and Health, represent this evidence base as our tobacco control vaccine. We know what works to both prevent and reduce tobacco use, but like any other vaccine, a partial dose is far from sufficient.

Cessation access is an important part of the vaccine, because smokers who are motivated to quit by smoke-free policies, tobacco pricing, and hard-hitting ads need to be able to get the help they want when they want it.

Cessation is also critical to the success of the National Tobacco Control Program. CDC's 2014 edition of Best Practices outlines three broad goals for state cessation activities: promoting health systems change, improving cessation insurance coverage, and increasing the use of cessation therapies, treatments, and state quitlines. Each of these goals is ultimately about encouraging and helping smokers who want to quit by increasing their access to proven cessation treatments.

We monitor and track progress in a number of ways, and one important way is to measure changes over time in the proportion of all U.S. adults who have ever smoked and who have quit, also known as the quit ratio. In 2002, more than half of the U.S. adults who had ever smoked had quit. And this trend has continued upward in recent years, reaching 59.1% in 2015. Despite the challenges to quitting smoking, almost three in five American adults who ever smoked have successfully quit.

When we are looking at ways to help smokers quit, it is also helpful to understand their cessation behaviors. The majority of current smokers want to quit and even try to quit. Yet a January 2017 MMWR article found that while over half of U.S. adult smokers attempted to quit in the past year, two-thirds reported not using any evidence-based cessation treatments. Among smokers who did use cessation treatments, far more used medications than counseling. Of concern is the fact that fewer than 5% reported using both counseling and medication, the approach that has been found to give smokers the best chance of quitting. Quitlines were the most common source of counseling, and more smokers used over-the-counter medications than prescription medications.

Another recent study found that smokers who are trying to quit use a wide variety of quit methods, and use more than one quit method during a single quit attempt. For example, smokers give up cigarettes, cut back on the number of cigarettes they smoke, and/or use substitute products including e-cigarettes. A small percentage report using therapeutic approaches such as nicotine replacement therapy, which has been found to significantly increase the likelihood that a smoker will quit for good. What this tells us is that over time, more smokers are trying to quit. They're receiving advice to quit from health professionals. They're using multiple approaches when they're trying to quit. And they are ultimately succeeding in quitting.

While we are making some progress on important indicators in cessation, there are still significant disparities related to both smoking and cessation behaviors. These disparities persist in part because the tobacco control vaccine that I mentioned earlier is not consistently delivered among all populations.

In 2015, the prevalence of cigarette smoking was highest among the following groups: American Indians/Alaska Natives, persons with a GED, persons who live below the poverty line, those who are uninsured or covered by Medicaid, individuals with mental health diagnoses, individuals who have a disability, persons who are LGBT, and persons who live in the Midwest or South. These populations also may have lower quit rates, suggesting that more needs to be done to help them quit smoking.

A recent study found that uninsured smokers are less likely than smokers with private health insurance to receive advice to quit, and are less likely to use counseling and/or medication to quit. The same is true for Hispanics and Asians. Gay, lesbian and bi-sexual smokers are markedly less likely than straight smokers to report using cessation counseling and/or medications. Past-year quit attempts are lower in whites, but cessation generally increases with increasing levels of education attainment.

One especially important disparity that cuts across population groups is persons living with behavioral health conditions. They smoke at much higher rates. They are less likely to quit. They are more likely to be heavy smokers and they have high rates of dual- and poly-use. The evidence shows they want to quit, but they may need more help in quitting.

The data are clear about progress in supporting smokers who want to quit, but that progress is not distributed evenly across all population groups. A major tenet of the 50th

anniversary Surgeon General's Report was the need for sustained implementation of proven evidence-based strategies, especially in underserved populations.

That report also articulates end-game strategies to accelerate declines in the use of cigarettes and other combustible tobacco products. CDC is working on many of these evidence-based strategies, including improving access to barrier-free, proven tobacco cessation treatment, and high-impact mass media campaigns such as Tips From Former Smokers®. This national tobacco education program, which is the first ever to be federally funded, combines high-impact media with access to cessation treatment. Tips® has been shown to increase quit attempts and cessation, and to cost-effectively reduce smoking-attributable morbidity and mortality. This is the sixth year of the Tips campaign and evidence to date shows that the campaign is continuing its record of success.

The Tips campaign leverages two important components of the vaccine that I mentioned. One is the hard-hitting media campaigns. The other is access to cessation resources, including the 1-800-Quit-Now number and the Tips campaign website, which provide evidence-based resources to help support smokers who want to quit. One key early indicator of the impact of Tips is quitline call volume. A majority of Tips TV ads are tagged with that 1-800-Quit-Now number. The Tips campaign has consistently been associated with immediate and dramatic spikes in calls to 1-800-Quit-Now and those increases are sustained throughout the campaign periods.

A study in the Lancet examining the 2012 Tips campaign found that it was associated with 1.64 million additional quit attempts and at least 100,000 sustained quits. Studies assessing the impact of subsequent campaign years resulted in similar findings. From 2012 to 2015, we estimate that millions have attempted to quit because of the Tips campaign and that an estimated half a million smokers have quit for good.

Before closing, I'd like to reinforce a couple of core messages. The first is that we are making progress. More smokers are trying to quit. They're receiving advice to quit from health professionals. They are using multiple approaches when they're trying to quit and they're succeeding. Smoking rates are going down, and most importantly, three in five adults who ever smoked -- more than 52 million Americans -- have quit for good.

However, while we've made encouraging progress, there is still room for improvement. Substantial disparities continue in smoking rates and in cessation behaviors across a number of important populations.

And finally, in order to increase the number of smokers who quit, we need to increase quit attempts as well as quit success. We must remain nimble and explore new opportunities to further promote cessation, including leveraging and modernizing proven strategies to enhance access to and use of evidence-based resources.

At CDC, we are committed to reducing the health and economic burdens that tobacco use imposes on this and future generations. And that commitment includes helping smokers quit.

Dr. Michael Fiore
University of Wisconsin

My talk today is going to focus primarily on the clinical treatment of tobacco dependence and the evidence that supports that, including related evidence-based guidelines. But I also want to talk about context, including population-based strategies to promote cessation, specific

recommendations, and innovations in cessation. Finally, I want to talk a little bit about the concept of reach and its central importance to the effective treatment of tobacco use in terms of its capacity to reduce smoking rates.

The clinical treatment of tobacco use is one of the scientific topics that has the most literature to support it. More than 8,000 articles and 100 meta-analyses serve as the evidence base for the United States Public Health Services (PHS) Clinical Practice Guidelines for Treating Tobacco Use and Dependence. In a Google Scholar Literature search last week, I came up with more than a million scientific publications that mentioned treating tobacco use. This extensive research allows us to make recommendations on which medications, counseling, and system-level changes make a difference and can boost clinical cessation rates.

With that said, there are clearly limitations in these data. One is that much of the research has been done in efficacy environments rather than real-world clinical effectiveness environments. We know when we take those efficacy findings and translate them into clinical settings, quit rates often decrease substantially. Second, many of the articles review a variety of interventions – a package of interventions – so it's often a challenge to discern which components within that packet are most effective. Finally, research typically focuses on quit rates, with less of a focus on reach, utilization, cost or population impact. But, even with those limitations, we have a substantial and powerful body of evidence that can guide physicians and health systems in terms of what clinical interventions make a difference and what clinical interventions could be integrated into health care delivery.

I just want to stop for a moment and emphasize why we focus in particular on health care setting as a unique opportunity. The reason is – that's where the smokers are. A recent survey found that approximately 80% of smokers had visited a health care setting in the last year. Thus, we have a captured audience of smokers, entering and exiting these settings, with an opportunity for clinicians to intervene and provide evidence-based assistance.

In addition, that brings us to the critical importance of population-based strategies. Some of the most powerful evidence regarding what drives smokers to quit relates to population-based strategies. For example, we know that by increasing the price of tobacco products, we can drive down tobacco consumption. Some analysis suggests for every 10% increase in price, there is about a 4% decline, and some studies suggest a 6% decline, in consumption. Clean indoor air ordinances also drive people to make quit attempts and ultimately to successfully quit. In addition, we know that mass media campaigns like the CDC program – TIPS (Tips From Former Smokers), as well as insurance coverage for smoking cessation treatments, are two population-wide strategies that can make a real difference. Finally, comprehensive tobacco control as recommended by the CDC is essential, because it creates a context for quitting.

While data frequently focus on the moment of a quit attempt, quitting needs to be considered in the context of tobacco use as a chronic disease. Many smokers have been smoking 10, 20, 30, 40 or more years – and typically over that time, they have made multiple quit attempts. We need to think about quitting in a broader context of what influences individuals over the chronic course of their smoking history to consider quitting – what is the totality of factors that ultimately led them to take the actions that put this chronic disease of tobacco use into long-term remission. Most smokers who have quit report that they did so on their own, cold turkey. But the context for this cold turkey quit is the sum of all their prior quit experiences – prior quitting that often includes evidence-based experience and information. Thus, if a person successfully quits on his or her own – possibly prompted by a powerful proximal experience – e.g., a brother-in-law who gets diagnosed with lung cancer or a physician personally urging the

smoker to call 1-800-Quit-Now, that proximal attempt is informed by and represents the sum total of all prior quit attempts.

I also want to talk about three important sources for cessation recommendations: the Preventive Services Task Force's updated tobacco use treatment recommendations from 2015, the 2008 PHS guideline, and Cochrane reviews. The consistency of clinical tobacco cessation evidence-based findings over time and across different independent entities is very reassuring – it suggests that the evidence base regarding how to effectively treat tobacco use is solid. So, while the odds, ratios, or quit rates for an evidence-based approach may differ slightly, there is a highly consistent evidence pattern of evidence that counseling, medication, and system-level changes make a difference.

Here's what the Preventive Services Task Force clinical recommendations said in 2015:

1. For non-pregnant adults, physicians and other clinicians should encourage all smokers to quit and offer both counseling and medication. That recommendation received an A-level recommendation. (Editor's note - An A-level recommendation means the USPSTF recommends the service. There is high certainty that the net benefit is substantial.)
2. For pregnant women, all should be urged to quit and be provided counseling. This recommendation also received an A-level recommendation.
3. There were two I-level situations – situations that had insufficient evidence to make a recommendation. One was whether to recommend medication for pregnant women and the second was the potential clinical role in cessation for electronic cigarettes.

These findings of the Preventive Services Task Force are very consistent with the 2008 Public Health Service Clinical Practice Guideline – a Guideline that was independently reviewed by more than 150 reviewers and endorsed by more than 50 medical organizations. That publication recommended three key clinical interventions regarding what constitutes effective clinical treatment:

1. Brief counseling,
2. At least one of the seven FDA-approved medications, and
3. System-level changes that influence what happens when a patient goes into a health care delivery setting – changes that increase the likelihood that the smoker will leave the clinical encounter with some evidence-based treatment.

Regarding counseling, a 7-study meta-analysis examined *Advice to Quit* provided by a physician. This intervention alone boosted quit rates by about 30%. While such a quit rate boost is modest, if applied broadly across the full population of smokers visiting primary care physicians (an estimated 70% of all U.S. smokers, or 25 million smokers), the impact would be enormous. The PHS Guidelines also found that more counseling is more effective, counseling delivered through a variety of venues is effective, and clinician-provided social support and assistance with problem solving and skills training were particularly effective.

Regarding medications, a meta-analysis of more than 80 studies showed that both prescription and NRT medications yielded statistically significant higher quit rates. The highest rates were seen with the use of varenicline, nicotine nasal spray, high-dose nicotine patches, and long-term nicotine gum. The analysis showed all of the seven FDA-approved medications as statistically significantly more effective than a placebo.

System-level strategies refer to changing the architecture of a clinical encounter in ways that boost the likelihood that tobacco use will be systematically identified and action taken.

Having a tobacco user identification system in place - Expanding the Vital Signs to Include Smoking Status – boosts quit rates. Educating providers, dedicating staff people, having hospital-based cessation programs (particularly those that continue post-hospitalization), and covering tobacco dependence treatment as part of an insurance package, boost the likelihood that smokers will take advantage of available treatments. Systematically addressing tobacco use with every patient at every visit results in a key population health outcome – it gives every smoker a dose of tobacco dependence treatment. The intervention algorithm long used in treating tobacco dependence – Ask, Advise, Assess, Assist and Arrange is quite effective in boosting cessation. And if the patient is not ready to quit now, motivational interviewing approaches were shown to be helpful.

I want to turn now to some innovations in tobacco dependence treatment starting with the importance of combining counseling and medicine. Evidence in the 2008 guideline suggests that counseling by itself is effective. Medication by itself is effective. But, importantly, it showed that when you add the two together, you get additive effectiveness. This was seen with a meta-analysis showing that when you add medication to counseling you boost the counseling alone success rate by about 70%. The converse is also true. If you start with medication and you add counseling to that, you boost the success rate by about 40%.

The second innovation is that two medicines were found to be particularly effective in promoting cessation – those two medications were the combination nicotine replacement therapy (the nicotine patch with the lozenge or gum) and varenicline. One of these two medication approaches should be used as the medication of choice absent contraindications.

The quitline is an incredibly important and effective population-wide strategy to promote tobacco cessation and is now available in all 50 states via 1-800-QUIT-NOW. Quitlines are available as a stand-alone approach, but are also available as a *treatment extender* for a clinician-provided intervention. The meta-analysis on quitline counseling for the PHS Guideline showed that it boosted quit rates by about 60% compared to no quitline counseling. Given that a large number of Americans call quitlines every year – approximately 500,000 smokers – they really can have a substantial population-wide impact. The PHS Guideline also found that quitlines boosted the effectiveness of medications - so quitline counseling can be used alone or as a supplement to medication.

I want to talk for a bit about an innovation in treatment that is garnering a larger and larger evidence base. Evidence has documented that if we give FDA-approved medication to smokers who are not yet ready to quit – particularly nicotine replacement therapy, usually the patch – and we talk to them about reducing the number of cigarettes they smoke per day (i.e., reduction counseling), we increase the likelihood that they will make a quit attempt and will successfully quit. A 5-study meta-analysis endorsed this intervention with a very high odds ratio.

We also know that continuing nicotine replacement therapy for a period of time beyond the three months - the current recommendation – boosts quit rates. In fact, evidence is increasing that medication for smoking cessation should be continued for six months, absent contraindications.

I want to take just a few moments to talk about electronic cigarettes. A New England Journal of Medicine article (*Smoke, the Chief Killer – Strategies for Targeting Combustible Tobacco Use* by Fiore, Schroeder, and Baker) in 2014 addressed key points for clinicians when they encounter patients who ask about using e-cigarettes as cessation tools. The article recommended stressing the fact that the burning of tobacco is what causes most of the harm, so completely stopping all use of combustible tobacco products is key. The article also

recommended informing patients about evidence-based treatments, both counseling and medicine, that we know make a difference. Finally, if patients want to use e-cigarettes, the article recommends that clinicians describe what we know and what we don't know about those products (e.g., they appear substantially less dangerous than combustible tobacco products but less dangerous doesn't equal zero risk), but also to emphasize the importance of not using the products along with combustibles. So, the goal is to use them as we use all cessation agents – as a bridge from burning deadly combustibles, to using neither nicotine nor tobacco products.

Lastly, there is a growing body of evidence that we can use financial incentives to drive cessation behavior. The United States Centers for Medicare and Medicaid Services had a series of statewide programs that showed even among low-income smokers, this is helpful. A Cochrane meta-analysis showed that incentives boosted quit rates by 40% and were particularly powerful in boosting quit rates among pregnant women.

I want to turn now to a discussion regarding reach, because a treatment, however successful, is going to have minimal population impact if it doesn't touch enough people. The population impact of a clinical intervention is a product of the effectiveness of the intervention X the reach of the intervention - the number of people that the treatment touches. A 2017 MMWR on cessation practices documented that almost three in six smokers who saw a health care provider in the last year were advised to quit. But, less than a third used one of the evidence-based treatments that we know make a difference to make a quit attempt following the visit and less than 5% left the visit with both evidence-based counseling and medication. While we have a powerful evidence base of what helps smokers quit, we're not connecting most smokers to these treatments.

One way we can increase reach by moving beyond the primary care outpatient setting to different venues, venues often frequented by populations that have high smoking rates and low quit rates. Specialty clinics make a difference and we're going to have a presentation on oncology clinics later today – highlighting how they can be a venue to promote cessation. The in-patient setting is also a particularly powerful way to help smokers to quit. We know that pharmacies can help, and so can behavioral health settings, community settings like the Salvation Army and others where poor and disparate populations frequently congregate. We know that VA and DOD settings are critically important since so many of our military personnel and veterans still use tobacco.

We've made enormous progress, but about 36 million American adults continue to smoke. Thus, our end game needs to come up with a way to bend the curve, to accelerate the decline in smoking rates - because if current trends continue, it'll take until about 2050 to reach a smoking prevalence rate of zero. As part of a comprehensive approach to reduce tobacco use rates, what role can evidence-based smoking cessation clinical interventions play? Clearly, evidence-based clinical intervention has a key role. It is not the end-all by itself. It needs to be viewed in the context of the whole experience of a smoker. But we do have ways that can help the 70% to 80% of smokers who are visiting clinics every year – a total of more than 25 million American smokers. There is a powerful evidence-base for clinical interventions.

Discussion 1

(Novotny) Is there attention being paid now to more personalized medicine approaches to treatment of nicotine dependence? We hear about this in terms of cancer treatment and we're starting to look at in terms of opioid substance abuse disorder treatment. I just wonder if there is a more specific kind of personalized medicine approach, whether it's genomic, whether it's specific interventions where we see disparities that are that need more specific and more targeted kind of approaches than perhaps just a blanket approach.

(Fiore) You highlighted that personalized medicine can be both on the genotypic and phenotypic sides. As it relates to disparate populations, there's a lot of interest in this topic and I would say, looking back at the 2008 guideline, when we examined in detail the literature base supporting specific cessation interventions based on the population, what we found is that the general approach of counseling and medicine in the context of system-level changes actually works for virtually every population that we examined.

There were a couple exceptions. We found, for example, that in pregnant women it's particularly important to have much more intensive interventions. We talked a little bit earlier about venue and I think we need to think about venue when we're thinking about disparate populations. So, absent a powerful evidence base pointing us in one direction on the phenotypic side for disparate populations, I would use the evidence we have to help the general population.

I think it's a really fascinating area and I'm sure not an expert on the genotypic data, but there's increasing evidence that there are certain genotypic signs that are associated with both smoking as well as successfully quitting. A lot of researchers are examining that. And whether we get to a point where we can actually target treatments based on a genotypic profile, and I think we're a little ways from that, a lot of important work is going on in that area.

I want to ask Wilson Compton if he wants to add anything to that, since NIDA has been so central in funding that work.

(Compton) NIDA certainly has supported the genetics research looking at who's at risk for onset of tobacco use disorders. Also, Laura Bierut and colleagues have done some excellent work suggesting that certain of the nicotine receptor variances predict response to treatment. This might be the start of personalized medicine when it comes to tobacco cessation and I don't think it's as far off as we might fear. I think it might be just in the next few years that we have specific markers that would help target interventions to those who may respond particularly well to them or at least identify who doesn't respond too well, so they may need more intense interventions.

(Compton) I have a question for both Mike Fiore and Corinne Graffunder. What do you see as the next major target for cessation? I sort of heard three issues. One is new treatments that might be available. Where might we put our energy in terms of treatment? Two is what are the populations that haven't been reached and how might we do a better job. I have been particularly interested in those with serious mental illness and what a poor job we've been doing in reaching those populations. And third, what about systems-level issues, for example what medications are covered by various insurance programs and do they provide long enough coverage. I'm just curious about what you see as where we ought to put our efforts.

(Graffunder) I think right now the focus in the work we're doing at CDC with a variety of different health systems and partners, particularly partners who are collaborating with their Medicaid programs, their behavioral health colleagues, et cetera, is on access. Are there ways to look at policies and systems interventions to reduce the barriers that exist, whether those are co-pays, or networking and navigating the system for the smoker? How do we make it as easy as possible for smokers who want to quit?

We also know from the Medicaid Massachusetts experience and other work that's being done that you can get the behavioral health population to take advantage of cessation coverage if you promote the coverage to the Medicaid population. If you promote the support for and use of cessation treatment, you do see that you can get a positive response. People want to quit.

Consistently we know populations want to quit and consistently we know they can quit as long as they're provided the right support.

That said, even with our Tips campaign, which is not even a year-long campaign, we're limited by the support that the quitlines are able to provide, because they have a finite amount of support that's available. We're trying to understand how we can get around those limitations with things like m-Health and other things to leverage what is available to the greatest number of populations possible.

The last thing I will say has to do with the issue Mike Fiore raised earlier on the limits on the cessation benefits that are available to chronically addicted people. It's not nearly as common to restrict the availability of medications, for example, with a specific number of opportunities and a set amount of availability for other chronic conditions. It helps to think of tobacco use as a chronic condition that needs to be managed as any other chronic condition is managed. In the same way that we manage hypertension, we should ask ourselves what it would take to manage nicotine addiction and tobacco use as a chronic condition when we have the right tools and resources to do that. Policy barriers need to be figured out.

(Warner) Before I ask my question, I have a data point observation I think it's really important. Mike Fiore, on his last slide, showed 15.2% as the adult smoking prevalence in 2015. NHIS has released the data for 2016 and it's 15.8% I believe.

I was one of many people who got very excited about the 15.2 because that was a gigantic decline. I suspect it's a mistake. And I suspect that the right number was somewhere in between, because if you look at the line of decline that Mike was referring to, we're still on it. So, it's going to be really important to follow up and see whether we have gone up or whether we're simply on a continuing decrease. So, the next couple of years will be very important.

Following up on this idea about treating tobacco use as a chronic condition, Mike showed a slide, "Impact on Cessation," eight versus 26 weeks of nicotine patch. And if I understand it correctly you're showing seven-day point prevalence at week 26 and it was substantially higher if you were on the patch for 26 weeks. It was 27.2% versus 21.7%.

Now the question is this. What happens 26 weeks later when you're off the patch? And I think this relates to the chronic condition treatment, because the people who were on the patch for eight weeks had been off of it for 18 weeks when this was measured. The people on it for 26 weeks haven't been off of it at all. So, you kind of expect them to do better. So, the real question is do they have to keep using the patch? Or if we look 26 weeks later – in other words a year out – is there a fundamental difference between these two?

(Fiore) I believe these are 12-month data, so for both groups, it's six months after the completion of the six-month treatment. But you do raise an important point and that is that irrespective of the cessation treatment, people relapse over time and it does speak to the chronic nature of this disease. And even having a person out two years, there is still going to be some relapse over time. And for many individuals their experience is one of relapse and remission.

(Curry) These are great presentations and it's stunning to me how much evidence we have and how strong it is. We should feel good about that. There are a lot of areas in health where we don't have what we have in cessation data. I know today's conversation about adult cessation is important and makes sense. But I couldn't help but think a little bit upstream when I was looking at some of the slides. Tobacco use is established at fairly young ages, so at some point I think we need to put youth cessation into the mix.

When you look at the declines in smoking prevalence over time, some of them are due to cessation, but some of them are due to lower rates of initiation. And so when you're looking at the vaccine I would hope that there would be some active ingredient in that. I think the use of non-combustible products for cessation is an important one for conversation and consideration. I was struck in the data that were presented on quit methods used by adults in the most recent quit attempt, and a pretty high percentage of folks reported that they used non-combustibles like e-cigarettes to help them quit.

My first thought went back to whether we have comparable data when other new options came into the marketplace because there's clearly going to be some enthusiasm for new options. I think the debate around non-combustible products has been a little bit more robust and contentious than we've had around other options, but I would be interested in seeing comparable data when other options, new medications or therapies came into the mix and what percentage of folks reported using them.

(Schroeder) I want to echo the praise of those two great presentations. I have three questions and a comment. First question is the very figures given on this spontaneous rate of quitting, the unassisted rate. I've seen it as low as 3% and in some presentations as high as 7.9%. How is there a range and how much do we know and what do we see?

Secondly, the tobacco control community is fractious and we sometimes disagree with each other. There is a sub-unit in tobacco control that dismisses focusing on smoking cessation and basically says that it doesn't help very much and look at how many people quit on a cold turkey basis. And I want to emphasize what Mike said that we don't really know that cold turkey quitting is unassisted, because there's a context. They may have been told by their doctor or their pharmacist or their nurse or their dental hygienist or their dentist to quit, and over time that may be an ultimate stimulus.

Something that's very special about this country is our clinicians have extremely low rates of smoking compared to other countries. Doctors 1%, even nurses who just recently were high are down to about maybe 10% now. So that's a contextual figure which we shouldn't forget.

The third question is 2008 was nine years ago. When are we going to update the guideline?

And then the comment is on the mental health/substance abuse issue. We're in the middle of a culture change. This used to be a special isolated culture that felt there would be damage to stopping smoking, damage clinically, damage to the ability to stay sober. But we're in the middle of a culture change and Doug Tipperman has some data to show that actually the smoking cessation rate has fallen faster in this population in the last few years than it had previously. I think part of it is focusing the clinical enterprise on those targets, which has sort of lifted its previous hands- off approach.

(Fiore) I think your first question was the range in self-quitting rates. And if individuals report that they've quit on their own, cold turkey, what can we expect downstream 6 or 12 months in terms of their success rate? We saw some data today that had that number on the higher side, 7.9. I think most analysis reported it in the range of 3 to 6%. So, I think that's a realistic number.

But you picked up on a point that I think is just absolutely critical. This is so much subject to how the question is asked, and also the context of the individual, what that individual is viewing as the method that led them to quitting and often not taking into account some of the contextual factors. I think that a rate of 3 to 7 or 8% is probably realistic.

To the issue of that part of our community that may be less enamored with the importance of cessation support and assistance, that's where we're a robust and independent group, so different people have different perspectives. I guess what I would say is from a purely clinical point of view, how could we raise prices, make indoor environments smoke-free, have ads that tell us we should quit, and not have a clinical approach to assist those who want to use that as an opportunity to quit? To me it's a core issue of what we need to be as a society. If we're pushing people, who often became addicted to this product as children, to quit then we need to provide them with a whole variety of options to allow them to do so and they have to include clinical options, in my view.

To the issue of when the guideline will be updated, that's a question for the Public Health Service. But I know the impact of this panel making such a recommendation would be considered by the Public Health Service. Importantly though, I don't think anyone should wait for an updated guideline to update what they do clinically. The Preventive Services Task Force updated their recommendations less than two years ago. Every month we get new Cochrane Analyses that really help guide us. So, while the guideline has been quite influential and I think important, I don't think anyone should hold back in treating, given all of the new evidence we have coming out in different ways. But I'm sure the Public Health Service would be interested in your recommendation.

(**Henigan**) Thank you. I learned a great deal from those excellent presentations. I wanted to throw one other issue into the hopper. I was struck by the strength of the science indicating that the combination of appropriate counseling and FDA-approved medications can aid significantly in cessation. Also, I was struck by the relatively low rates of use of both the counseling and the FDA medications. I wanted to focus my question on the FDA medications for a moment. I spend most of my time working on FDA related issues.

Clearly, even though the science is strong here, the rate of use of these approved medications for cessation is relatively low even though these medications have been around for quite some time. And Professor Fiore indicated there had been some innovations in terms of medication science indicating that the use of more than one NRT at the same time, or the use of NRTs over a longer period of time might be helpful. But my question is, is there anything that FDA can do to create a greater environment for innovation, both in indicating new uses of the FDA approved medications and also an environment for the development for new innovative medications in the future?

(**Backinger**) I should start out and say that when we went around and did introductions, I made it clear that I was from the Center for Tobacco Products and not the Center for Drug Evaluation and Research. I think everybody knows that CDER is that part of FDA where any drug gets approved. Applications for therapeutic use for whatever condition, not just smoking cessation, go to that part of FDA. So that's not under the purview of the Center for Tobacco Products. I think you already know that, Denny, so I'm just kind of stating the obvious.

I did want to say that our Center Director, Mitch Zeller, has in many public speeches talked about working with CDER and with our Center for Devices and Radiological Health, because of a medical device or drug technologies around having a comprehensive nicotine policy. So, what does that mean? I can't speak directly to all of your points, but I can say that we are working with our other FDA centers to think about nicotine, think about the continuity of risks, and how to work with all of our respective centers for an FDA approach to nicotine.

As you know we also have a new Commissioner and so we're sorting out how that's going to work, but I know that's a priority for us at the Center for Tobacco Products, to think about innovation, about how to think about use of nicotine long term as opposed to smoking the combusted products that are the most harmful.

(Curry) I want to address the question about when the Public Health Service is going to release another guideline. I'm Vice Chair of the Preventive Services Task Force.   The Preventive Services Task Force has an extraordinarily rigorous methodology for evaluating and making evidence-based recommendations for primary care-based preventive services, which tobacco cessation falls under.

In 2009 the task force reaffirmed the 2008 Public Health Service practice guideline. The task force, through the use of, or in partnership with evidence-based practice centers, will conduct rigorous meta-analysis like you would see in a Public Health Service guideline. The Task Force is committed to updating recommendations every five years, and it takes about two years for a recommendation to be updated. So, you know, you're sort of hot off the press and then you're starting the process again.

Here's the part that I think is very encouraging. The 2015 recommendation was actually done in a very unique way, which speaks to the robustness of the evidence. It was conducted as a review of reviews. We did not go into the primary literature like was done in '08 and like was done in the previous recommendations from the Public Health Service Task Force. This is not a statement about the quality of the work that's done under the auspices of a Public Health Service guideline update. I think it just bears consideration of, you know, do you pull that particular topic out, because why have two out of a portfolio that includes a broader range of tobacco-related recommendations?

(Warner) I just want to make two comments that I think are important for context. One is that the number of smokers, their quit rates, are all dependent on how the questions are asked. A number of colleagues led by David Mendez published an article in Nicotine and Tobacco Research this past year that was using a model that takes the numbers of smokers, subtracts out mortality and then looks at numbers of smokers the following year and so on, and looking at initiation. When you do that – and they used separate data sets from NSDUH and NHIS – we ended up with 4.2 to 4.5%. These are essentially permanent quits. This is a permanent quit rate, which is actually up about 50% from at least a decade ago. That's the good news. But when Mike says 3 to 6% I think a narrowed range for what actually happens long term is in the range of 4.2 to 4.5%.

My other comment is that I'm one of the people that Steve and Mike were talking about who likes to focus on the policy stuff rather than the clinical stuff. But I'll say this. First of all, I think with a lot of the policy stuff, we're kind of running out of what we can do unless FDA and CTP end up doing some things that they're not yet doing. On the taxation, that can only go so far, and smoke-free, we've gone pretty far with that.

The important point for this group to understand, if you're not familiar with this, is that the clinical interventions with regard to smoking cessation are among the very most cost-effective things in all of medicine. You look at all these studies, there's almost nothing you can do in the entire field of medicine that is comparably cost effective to smoking cessation treatment. Think about the malpractice accusations for a physician who didn't treat a patient's high blood pressure. That's not nearly as cost effective as treating smoking patients, trying to get them to quit. So, I think that's important context for this.

(Novotny) There's also an article that just got published in the Journal of National Cancer Institute on filters. Mike Cummings and his group have been talking about this for many years. But we haven't mentioned what a tobacco product regulatory approach to somehow supporting cessation might be. And when you think about filters, one of the things that the article did mention is what if we took away the filter? What would cessation look like? I just wondered, from the CTP standpoint, what kinds of considerations on supporting cessation might be possible in terms of product regulation?

(Backinger) When we think about product standards, which is a powerful tool that we have, products have to go through a very prescribed process in order to have notice of rule-making and then have a regulation come out. But we do have the authority to change the product if we feel that it's appropriate, and if we have the scientific evidence that it's appropriate for the protection of public health. So, I think that's the first part. That is within our purview.

And in order to get there, there's a number of hoops that we have to go through and it's kind of like the Schoolhouse Rock video on how a bill is passed. It takes quite a bit of time to do that. And I know that David Ashley, our former Director of the Office of Science, has talked about what kind of scientific evidence we need to have. It's not just that it makes sense to remove filters. It has to be something like it makes sense to reduce nitrosamines because we know that's the constituent in tobacco products that causes lung cancer and other cancers.

It's also at what level, and why that level, and what's the evidence of the health benefit of that? We also have to consider whether the industry can comply. Can they actually do it and what is the cost to do that? So, all these factors have to be taken into account before we can put together the evidence to do a product standard.

Back to Dr. Curry's point, too, it's not just cessation, but it's also preventing an initiation. When we think about what's appropriate for the protection of public health, we have to look at non-users and whether they would likely use and whether current users would then quit, or what former users restart. So, all of those have to be taken into account. As I mentioned before, though, if you want to have a therapeutic indication, that belongs in CDER and not at CTP.

(Punturieri) My comment is about how we can most effectively help people that are making multiple attempts at quitting. And it goes back to the personalized medicine comment. I do think what else can we do is - that's the space for research now. There is a big window that is opening. What other treatments are there? Why do you see the people quitting after two, three attempts, but there are also a lot of people making 30 attempts before they really stop smoking. And it goes back to multiple combination therapy, how long do we need to treat.

The other point that I want to make is there are data that are showing that in the mental health populations, that have some of the highest smoking rates, more people are quitting. But despite those results, another problem is there are still some mental health doctors who continue to believe that nicotine and letting the patient smoke helps with their medication, which, research and study is showing, is going the other way around. It's a little bit like, fighting windmills here. At that point, you need to move to our education of the providers on the real effect of nicotine addiction and nicotine's effect on mental illness medications.

(Corelli) I just wanted to comment on Dr. Compton's statement about policy changes to increase duration of treatment for tobacco cessation medications. I want to first echo what Dr. Warner and Dr. Fiore were saying. It's not just a policy issue. If you change policy and allow for longer treatment durations this alone will not solve the problem. Just a caution that it's also a clinical problem and we need to educate patients and providers.

For example, we conducted a small study analyzing two years of pharmacy claims data for a Medicaid-managed care plan in California, where all first-line recommended smoking cessation options where on the formulary and provided to patients free of charge. Our results demonstrated that was that treatment was grossly underutilized. The average duration of treatment was one prescription fill meaning a month of varenicline, a month of the patch, a month of bupropion SR.

So, if you build it, they won't necessarily come. To echo Dr. Warner's comment, this is a very cost-effective treatment. But underutilization of cessation medications (by patients and providers) is a big problem.

(**Henigan**) There were a couple of comments during the discussion to the effect that we've kind of exhausted use of the various elements of the tobacco control vaccine that were discussed. There is also a different view of that and I just wanted to indicate that in terms of taxation, there are vast areas of this country where tobacco taxes are terribly low and prevalence is very high. Very few states are meeting the CDC-recommended levels for spending on tobacco control. I think 40% of the country is truly smoke-free. There is still a lot that needs to be done to continue to completely enforce the various elements of the vaccine.

Dr. Erik Augustson
National Cancer Institute

Today I'm going to talk about some of the meta concepts associated with smoking cessation delivery. I'm going to talk about the value of quitlines, the potential of mobile health (or mHealth) interventions, and then I'm going to talk a little bit about an mHealth example that is near and dear to my heart, the *smokefree.gov* initiative, which is the federal government's largest m-Health behavioral intervention platform.

It doesn't matter what health behavior intervention you are delivering. Whether it's for depression, whether it's for diet, whether it's for smoking, whether it's for methamphetamine abuse, there are some core concepts related to the structure of that treatment that we need to be aware of. The first of these, because public health is what we do, is reach. Are we reaching a sufficient section of the population of target patients to be making a difference? And how well are we reaching specific sub-populations?

The second is the initial engagement. To what extent are we effectively getting our patients to initiate treatment with us? A third component that's often skipped over is sustained engagement, because it's not just calling a quitline one time or using one nicotine patch. Cessation success depends on sustaining these interventions over a period where a sufficient dose can be delivered. We also need to be sensitive to challenges related to reengagement in treatment, because across behavioral health issues, we have high drop-out rates. That's not unique to tobacco use, but tobacco certainly gives us many shining examples of how that can play out.

We also need to look at meta structures for treatment and ask ourselves how well our traditional treatment approaches are meeting our goals. I'm a Clinical Psychologist, trained that you come and see me in my office, we talk, you feel better, you go away, you come back for more sessions, you make progress. I was quite humbled in about 2003, 2004 to learn that you could do that process over the telephone. I was not a quitline fan until I saw the data. And then a little later on, I was humbled again to realize that you can do the same thing with 165 characters in a series of text messages. Today there are many alternatives to the traditional platforms we

have worked in, and they are successful. Traditional platforms face a number of challenges. First, they cannot match the need. We do not have enough treatment personnel and we lack sufficient infrastructure to really engage patients on a population level. We do not have the money within clinic settings, within health care systems, etc. to address this problem on an individual basis and in small groups, like we used to do in the good old days.

I've already alluded to the expense of these traditional face-to-face programs. There are very well documented clinical realities about trying to intercede with these behaviors within the context of clinic workflow. You know, it's extremely common for us to turn to the physicians and the nurses and say that's where the treatment should be done. But if that's the case, we're dropping responsibility for every single behavior and every single health issue onto the physician and health care team.

Next, there are also long gaps in communication between treatments. You would come and see me in my office or in the clinic. It could be a week. It could be a month. It could be two months before we had contact again. A lot can happen in that time. That's not going to effectively support behavioral change. Lastly, consumers are not using these traditional approaches. Many, many settings have smoking cessation programs that few smokers come to.

So, we have to think of different approaches. There is solid evidence to support the notion that alternative treatment delivery platforms, in particular quitlines and mobile health platforms, can provide us with many of the solutions we need and are good ways to address some of the challenges that we face.

Some of the best evidence on delivery mechanisms is associated with quitlines. We have more than 30 years of clinical research, as well as randomized trials, that have supported the effectiveness of quitlines in delivering smoking cessation support. Quitlines target multiple sub-populations including many of the groups that we're most concerned about, for example pregnant smokers, racial and ethnic minorities, low-income populations, individuals with depression. So we can also tailor interventions based on those kind of features. And in fact, quitlines are a foundational element in state and territorial tobacco control plans.

We have been promoting quitlines since 2004 when the 1-800-Quit-Now number was launched. The reach of quitlines has traditionally been approximately 1% of smokers per year. We're reaching a lot of human beings within these interventions. Although CDC's Tips From Former Smokers national promotion campaign has demonstrated that the value of promotion in driving call volume up, it also appears as if in general the level of call volume has stayed fairly constant for quite some time, and 1% is not great saturation. There are certainly some states that do better than others, some evidence that we may be climbing a little bit, but we clearly have a long way to go to being able to optimize quitline reach. Limited funding of state quitlines has played a substantial role in the failure to optimize reach.

We also have to improve engagement on quitlines. Although quitlines typically have protocols of four calls, six calls, more than that, the vast majority of users do not participate in the multi-call protocol. They'll do a first one, maybe a second one and then they stop answering their phone. It also becomes difficult to schedule staff if you have fluctuations in call volume, so those issues present challenges to us. Many of these core challenges are driven by funding. Despite the outstanding return on investment within quitlines, they can become an easy target for state legislatures looking to reduce state spending.

There are some potential strategies to address these challenges related to quitlines, and one of them is cost sharing. Getting other partners, such as insurers and large employers, to

contribute to the expenses associated with quitlines can help address funding instability. Also, there's been a movement to expand quitline services. Instead of just delivering smoking cessation counseling, we're also seeing quitlines used to triage callers to determine whether they would be better served by the quitline or whether they should be pointed to more intensive therapies or alternative programs. Another innovation that is still in its infancy but has a great deal of promise is the integration of new treatment elements into quitline protocols. These include things like motivational enhancement and acceptance-based treatment, psychotherapeutic approaches.

Finally, what can we do for ambivalent smokers – smokers who are not ready to set a quit date? Fundamental to almost all of our smoking cessation approaches is the idea that you must set a quit date. What if a smoker is not ready to do that? It's not enough to say call us back when you're ready. We need to find ways to keep them engaged, even if they're not ready to commit at this stage.

We also need to be aware that consumers increasingly rely on alternative forms of communication, which is a nice way of saying not as many people talk on the phone any more, especially young people. Anybody in this room who has a family member or a friend who is a teen or young adult knows that you cannot get them to call you. But you can get them to text you.

Some of the gaps that exist in our current capacity can be filled by mobile health approaches. Mobile health is the use of technology to remotely monitor, track, respond and/or deliver an intervention for health-related events. That encompasses a wide range of things that we can do using standard technologies that we all engage with every day.

Some of the potential benefits of mHealth include the number of available communication platforms that work well for public health interventions. There is also strong uptake in target populations. Data last year from Pew Research indicated that 95% of Americans own cell phones; 77% of Americans own Smart Phones; and we had high saturation of these technologies within all of the populations we are concerned with. Even within vulnerable populations, the use of these technologies is extremely high. Another advantage is that platform functionality is consistent with what we want to do in behavioral interventions. These devices can do things that we want to do for successful public health intervention.

We also find that user engagement in the technology matches the treatment needs. Fundamentally, humans have become comfortable with interacting, or having a conversation, with these devices. This opens up the door for us to do an intervention. Although they can be used independently, it's my belief that the true value of mHealth interventions lies in their ability to be integrated into existing, evidence-based treatments. For example, we can integrate mobile health interventions into quitline use, into health system practices, and as resources for treatment extenders that physician and caregivers can use.

One key advantage to these kinds of technologies is that the costs associated with them are even lower than for quitlines. However, I think the real value of these platforms lies in their ability to enhance engagement. We already know a lot about effective interventions, based on PHS guidelines and Preventive Services Task Force recommendations. Now what we're looking to do is design something that uses accessible and familiar technology to host an interaction between the smoker and the intervention that can make it more likely that the smoker will participate in the treatment.

This kind of intervention removes many of the barriers we face in traditional treatment settings. You don't have to make an appointment, you don't have to get a babysitter, you don't have to take time off from work, and you can interact at 2:00 in the morning if you want. That enables these kinds of treatment options to become seamless within people's lives. It decreases the space/time gaps that are the norm for traditional office visits or group sessions. With the mobile technology, we can interact multiple times a day. And we can interact in the real world.

Specifically, these devices give us the ability to be in the space where the behavior is occurring. The people whom we're working with don't engage in the problem behavior when they're standing in front of us. They're not doing meth, they're not smoking, they're not having domestic violence problems. None of these things are happening in the treatment room. But the technology today enables patients to engage with an intervention at the moment they need it most.

Nonetheless, there are a number of challenges inherent in mHealth treatments. First of all, these are a lighter touch intervention. If we think about the intensity, or the dose of the treatment that's being delivered, it's not nearly as intense as being face-to-face with your physician saying, "You have to quit or you will die." But we still have the ability to do multiple interactions which can help to create a sufficient dose.

We also have to think about the type of the device our clients use. Not everybody has the super-cool latest Smart Phone with all of its glorious functionality. So, we have to prepare interventions that can adapt to that. We also have to be aware that just because our patients have a cell phone doesn't mean they always have access to it. A lot of our patients don't have unlimited call/text plans. Some will share a cell phone, or use a family cell phone. That lack of flexibility and accessibility can impact the effectiveness of m-Health interventions.

Let me give you a quick summary of where the research is in terms of common mHealth platforms. There have been a couple of reviews on mobile optimized interactive websites, including a recent one by Dr. Amanda Graham, that indicate there's sufficient evidence to support the use of these as an effective smoking cessation platform. Meta-analysis also indicates that there is sufficient evidence to support the use of text-based interventions. Good work has been done by clinical researchers like Robyn Whittaker in New Zealand, Caroline Free in the United Kingdom, and Lorien Abroms here in the States which strongly supports the use of these. Smart Phone applications have so much potential but we still have yet to figure out how to most effectively use them. We have data that certainly point to their supporting their promise but we do not have a sufficient evidence base at this time to recommend them, even though there is a lot of ongoing data collection.

Social media platforms also have insufficient evidence to support their use although there is growing research in this area, too. As a quick side note, social media platforms can be difficult to get a handle on because they're constantly changing. By the time you get your project into the field and are into recruitment, the social media platform you were planning to use may no longer going to be the coolest platform.

I've been talking about mHealth as a treatment delivery modality, but we can also use mHealth platforms to drive referrals, whether it's to clinic-based interventions or to quitlines or to whatever the intervention is. One example is a live help pop-up on the website. NCI uses this, which is a box that pops up after you've been on the website for a specified period and asks if you want help. You probably encounter them mostly on commercial websites when they ask if they can help you buy something. For NCI, the pop-up asks if it can connect you with a live counselor to chat about smoking. We can also do cross-promotion via multiple health platforms.

That's the ability to push people to other platforms in addition to the one that they're on right now.

One intervention that I'm extremely excited about is the use of Electronic Health Records (EHRs). We're going to be moving to this option quickly in the next couple of years. In collaboration with Epic, a large EHR provider, Dr. Fiore has a very nice research project on this subject that is about to move into the field with a pilot study. The idea is when the patient is identified as a smoker during preliminary triage, the physician sees a "best practice alert" pop up that prompts him or her to offer the patient help in quitting smoking. The physician who accepts the prompt will see a script and links to specific resources. One of the reasons I'm particularly excited about the collaborations we're doing with the University of Wisconsin and the Epic group is that one of the resources that they're going to be pointing to is one of the Smokefree.gov cessation text programs. Physicians will be able to do the ask, advise, assess, assist, and arrange protocol – and they'll be able to refer to SmokefreeText with a single click of a button. So once the patient says yes, the physician clicks a button. The patient's mobile number and some of the basic demographics from the EHR are passed to the smokefree.gov text platform which sends a text message back to the patient right there that verifies that the patient really meant to sign up for this.

The reason we have to verify is a lot of people think it's hilarious to sign their friends up for these kinds of programs. So, we have to confirm it was really the patient. And then assuming it was, at the end of six weeks, the program passes a consult note back to the health record.

I think this has great potential, again, to play a role of integrating mHealth easily into an existing tobacco control treatment program within a health care setting. The electronic health records feature can automatically take care of prescriptions and follow-up appointments. There is a similar program that's been tested that points patients to quitlines.

Before I close, I want to highlight some of the resources that HHS has related to mobile health and tobacco cessation. *Smokefree.gov* is a program that's been running since 2004 at the National Cancer Institute, with partnerships that include FDA, CDC, the VA, DOD, HRSA, SAMHSA, CMS, and other government agencies that have been involved to create this program. It's housed at NCI but it really is a much broader kind of resource.

Smokefree.gov is an evidence-based mHealth behavioral intervention program designed to reach and engage multiple populations. We have expanded substantially beyond tobacco use. We now cover a host of health-risk behaviors, and it's on multiple platforms. Starting in 2004 with a single website, we have now grown to 6 mobile-optimized websites, 15 domestic text message programs, 2 Smart Phone Apps and a presence on about half a dozen social media platforms. This is a population-scale intervention that typically reaches between 3 and 6 million users a year. In fiscal year 2016, we reached 4.5 million users, which represents more than a 10% reach of the smoking population. A variety of research that we have done indicates the efficacy of the program is somewhere between 10 and 30% depending on which element we're talking about and which population.

Paula Keller
Director, Cessations Services; ClearWay Minnesota

Thank you so much for the opportunity to share our story from Minnesota. ClearWay Minnesota is an independent, nonprofit organization. We were established in 1998 with 3% of Minnesota's settlement with the tobacco industry. We were given 25 years to improve the health

of Minnesotans and reduce the harm from tobacco through research, action and collaboration. We work in all elements of comprehensive tobacco control.

In my job, I focus on cessation programs and I'm really excited to share a little bit about what we've been doing over the last few years to try to improve reach, quit attempts and cessation treatment access in our state. Our program has undergone some recent changes so I'll talk about why we decided to make those changes, summarize our planning process, describe in more detail the services that we now offer to Minnesotans, talk a little bit about the changes we've made to our website, describe our "No Judgments. Just Help" media campaign, share some key evaluation results and talk about some lessons learned.

Why did we decide to make changes? We've been lucky to have statewide cessation services for many years. Over time, we saw declining volumes in the inbound calls to the QUITPLAN helpline, our state quitline. And we also saw declines in the number of people who were signing up for our stand-alone online cessation program. We were seeing these declines despite an ongoing statewide paid media campaign promoting our services. We needed better use of technology. When we launched our services in the early 2000s, emails and websites were the tools that most people were using to communicate. We were in no way prepared to respond to the rapidly changing technology and communication environment.

As an organization, we wanted to build stronger consumer demand. Taking a population approach to cessation treatment, we wanted to do a better job of engaging Minnesota tobacco users in the quitting process. We spent some time examining how to meet the needs and wants of tobacco users in the state more effectively, and we looked at quitting from their perspective. We also looked at how we could promote quitting in ways that would reach smokers regardless of where they were in the quitting process. If we wanted to drive down smoking prevalence through cessation treatment, we needed to think about more than just those who were ready to quit in the next 30 days.

We undertook an extensive planning process, reviewing the literature and talking to key stakeholders in this country and in Canada. Most importantly, we talked to tobacco users. We used online bulletin boards as well as focus groups to get their input and to really understand what it was like to be a smoker and what quitting meant to them.

A key insight from our planning process was reaffirming the importance of meeting smokers where they were. We knew from the literature and talking to experts that motivation to quit is very transitory. And we heard that from smokers as well. We heard from them that they wanted help overcoming ambivalence to change. They knew that they should quit but this is really hard and scary. So, what could we do to make quitting easier for them? We heard loud and clear the importance of providing choices. We live in an era of choice for everything else that we do, but we were offering only two programs for smoking cessation. We were strongly encouraged to maintain our helpline, our telephone counseling program, but also to consider other ways that we could offer some free NRT, especially for smokers who are really committed to quitting on their own and would never call a quitline.

We were also encouraged to use technology like text messaging, and to have a much more robust website with online tools and resources that smokers could access without having to sign up for a formal program. We ensured that our clients could sign up for all of our services either online or by phone.

We also heard from smokers about reducing barriers to quitting. They talked about not being comfortable providing a lot of information in order to sign up for a program. And so we

challenged ourselves through this entire process to think about how we could streamline data collection to get smokers to the service they wanted as quickly as possible. We were reminded that product integration is key; that smokers view our services, our website, our promotions as one entire product. It was something that we knew and we operationalized anyway. But hearing that feedback just affirmed how we needed to keep that front and center.

What I plan to do over the next few minutes is describe first our set of QUITPLAN services that we offer in the state today, then talk a little bit about our website redesign and then our media campaign. We launched our new set of services on March 2, 2014. We maintained our telephone counseling program which we call the QUITPLAN helpline. This is a multi-call counseling program. We provide four weeks of Nicotine Replacement Therapy, either patches, gum or lozenges, to all our helpline clients. We also added combination therapy as an option for helpline participants on July 1 of last year. Participants can opt into integrated text messaging and/or email messaging if they find that helpful. And we provide print materials as well.

Minnesota is unique in that we have multiple quitlines in our state. Our major health plans provide quitline services to their members. But since 2001 we have worked in partnership with our health plans. We assess insurance status. It's all self-report but if somebody tells us that they have insurance through one of our health plan partners, we will connect them to their health plan's quitline for service.

So, we serve as that provider of last resort, focusing on the uninsured and the underinsured, whom we define as those who do not have coverage for telephone counseling or Nicotine Replacement Therapy. And in our state the underinsured population includes our Medicaid fee-for-service clients because we do not have telephone counseling specified in our Medicaid benefit.

We ended our stand-alone cessation program and instead offered a set of individual QUITPLAN services. The way to think about these is as an a la carte cessation menu, offering services that tobacco users can pick and choose from to support their quit attempt. We offer two weeks of free patches, gum or lozenges, a stand-alone text messaging program, a stand-alone email program, or a printed Quit Guide. Tobacco users can pick and choose across this menu of options. If they want one, they pick one; if they want multiple options, they can pick multiple options. We provide these services to all adult Minnesotans, including those who do not want to use the helpline. We do not assess insurance coverage for this set of services.

We also offer a mobile App to participants. And we have quit coaches on our Facebook page three times a week, answering questions and providing more information about our services and posing questions to our Facebook community.
We completely revamped our website. Prior to our new set of services, we had two pages on the website – a descriptive page with a little bit of tobacco information that drove people to either call us or to sign up online for the online program. And we had even less information on our Spanish language page.

We redesigned our website to feature more information front and center for all tobacco users, no matter where they were in the quitting process. We wanted to be much more transparent about our services and really help tobacco users understand what they could expect if they decided to sign up for services. We added online sign-up for all of our services and now provide all information in English and Spanish. We made sure through this website redesign process that the entire site links to our online registration platforms and that all of them are fully mobile responsive. I encourage you to visit www.quitplan.com if you'd like to see the types of information, the tools, the calculators, the widgets that we have available for people to use.

Our media campaign is called "No Judgments. Just Help." It follows two smokers, Wendell and Angie, talking about what it's like to be a smoker, that it's really hard. They see all the messaging. They know that it's bad for them. They know that they should quit. But at the same time, it's really difficult. And then we talk about our services, using this positive, blame-free messaging approach. We close with the fact that we're not here to judge, we're just here to provide help.

There are a number of elements to this campaign. We have TV ads featuring both Wendell and Angie. The CDC is piloting those spots in local heavy-up buys as part of the current Tips campaign. We have radio ads, out-of-home ads, and digital advertising as well. Videos of the ads are on our YouTube channel if you'd like to view them.

We did extensive message testing all the way through concepts before we rolled the ads out and found that the tobacco users whom we talked to really could relate to them; 76% said that they could relate to the characters, that this really spoke to them, and 72% found that the ads were encouraging.

We also saw that the ads were spurring people to think about making change; 63% said that they were either very or somewhat motivated to quit or reduce tobacco. And 64% were inclined to give QUITPLAN services a try. We really felt we hit that sweet spot where people understood that we were there to help them.

People liked a lot of the aspects of the ads. The key concept that we were trying to communicate about having free services, that we were there to help them no matter where they were, was really powerful. When we launched our new services, website, and ads in March of 2014 we were really nervous. We had no clue what the impact would be. We had heard from tobacco users that they liked the ads but we didn't actually know if the ads would work – we built it but would they come.

We did a lot of evaluation. We saw tremendous increases in use volume. In calendar year 2013, when the state increased tobacco taxes by $1.60 per pack, we served 5,900 tobacco users, which we were pleased with. Between March 2014 and February 2015, the first full year after we launched our new services, we served 16,000 people.

Looking over three full years, we've served over 49,000 tobacco users. We see that almost 60% are signing up online and 40% by phone, demonstrating to us that adding that online registration for all of our services really helped meet the needs of tobacco users in the state. Among the different services that we've provided over those last three years, our Nicotine Replacement Therapy starter kits are very popular followed by – and I was surprised by this – our printed Quit Guide. We've also maintained about 2000 to 2200 helpline enrollments per year, which is very consistent with where we were prior to launching our new services.

I do want to remind you that we have different eligibility criteria for our helpline versus the individual services, which drives some of the differences in the numbers that we're seeing. We did extensive outcome evaluation. We've looked at quit attempts and saw that well over 83% of participants made a 24-hour quit attempt. We also looked at quit outcomes, using standards established by the North American Quitline Consortium. Overall for our entire set of services, our quit rate was 26.1%. For the helpline, the quit rate was 29.6% and for individual QUITPLAN Services 25.5%. Those rates represent the percent of participants who had been tobacco-free for at least 30 days at the seven-month follow-up point.

We also measured the cost per quit. We do this as a way to track programmatic costs but we also share this information with our Board of Directors who really do a great job of keeping a good eye on our finances and make sure are we using our resources wisely. Overall, the cost per quit for our services was just over $375, for the helpline about $641 and for individual services $329. We're not surprised by the difference in cost because when you think about the helpline program, it is a more intensive intervention. You have people talking to telephone counselors and we do provide more NRT through that program. But overall, we were very pleased at these very modest costs, as was our Board.

We had a few important lessons learned that are relevant to this group. We found that it was critically important for us to talk to tobacco users to get their input throughout this process. We really listened to them and acted on these findings – what they were sharing with us so we could do a better job of meeting their needs. And so, if you all go away with nothing else today, I would just ask that in all of our work, we do a better job of listening to tobacco users and use what they're telling us to guide our program decisions.

We live in an era where choice is the norm. We learned that there is power in offering choices. We had choice before with our helpline and our stand-alone cessation program but we still weren't meeting tobacco users where they were. Adding this set of individual services and providing tobacco users with the opportunity to tailor the types of interventions they're most interested in using was very helpful for us.

We embraced technology. Technology will always change faster than we can keep up, but having all of our websites and our online registration be mobile responsive is very important. We know that 60% of people visit our website on a mobile device. And so, if we did not have the site designed using mobile-responsive technology and online registration, we'd be missing a huge part of our audience.

This work involved a large number of organizations and I want to acknowledge Optum as the provider for QUITPLAN services, Clarity Coverdale Fury our ad agency, Professional Data Analysts our independent evaluator and all of my colleagues at ClearWay Minnesota.

Discussion 2

(**Nez-Henderson**) Paula, this question is for you. I know that Minnesota has a large population of American Indian communities. What was your reach to American Indian smokers? And then a follow-up question is, was your program customized so that the use of tobacco for ceremonial uses was addressed?

(**Keller**) Dr. Henderson is correct, we have a large American Indian population in Minnesota. And our nations do have a tradition of using tobacco for ceremonial and sacred purposes. All of the quit coaches are trained in the traditional use of tobacco within the American Indian population and have that understanding with callers. In fact, one of my colleagues just recently did a presentation for our service provider's staff on the two tobacco ways, to try to improve staff understanding of the difference.

This is why we continue to try to do better. Our reach within the American Indian population historically has been low. We're disappointed by that. We do have some efforts under way with our service provider to both test and pilot a protocol. And we're getting input from the community right now on what that protocol could look like and should look like, to better meet the needs in the community. But we also want to pair that with some tailored promotion and also getting out more, getting into community events to educate the American Indian community

about our services, what we do offer. Honestly, one thing we do hear from the community that is a barrier is the fact that we assess insurance status and triage to health plans. It's a little bit of a conundrum. From a cost-sharing piece, it's really important for state quitlines facing limited budgets. But from a community standpoint, it's not necessarily the optimal.

(Riley) For those of you who don't know me, I'm Rachel Riley. I work in the Healthy Homes office at HUD. I work for Dr. Peter Ashley. I believe he addressed you at the last meeting about our smoke-free rule for public housing.
My question for Paula is whether or not people volunteer information about their residences, where they live, and maybe whether going to a smoke-free policy is encouraging them to quit and that's why they're calling. Do you track the reasons why?

(Keller) We do not ask about how our callers heard about our services nor do we ask about housing status. I mentioned earlier that we're trying to streamline the amount of data that we collect. That was something that was very important to us. We could go back and retrospectively mine some data, try to do some address queries. We do partner very closely with our Public Health Department to promote our services. They are doing a lot of work as the state is working to implement the HUD policy.

(Riley) I understand that. I think that's pretty much indicative of what most of the state quitlines do. But as we break for lunch and then over the course of the afternoon, I'd like to get you all to start thinking about the low-income population that I work with and especially those in public housing, but not just public housing residents. There are a lot of low-income people that are not covered by our regulation, and there is a huge barrier to getting them NRT. There's really no way to supply it. They are, I think, hoping that magically the health departments or local hospitals will come to the fore and help the PHAs implement this new regulation. So, as we go through the afternoon, if you could think about that I would really appreciate it. Maybe we could take that up at a future meeting or even have a little subgroup for it.

(McNabb) Absolutely. And I think we could have a session with people in this room and others about the issue of delivering NRT – what we know worked and the different degrees of services offered by various quitlines. It is a challenge but it's worthwhile also thinking about how we get to these challenging populations. What we just heard is some interventions like m-Health that have the potential and probably already are reaching a lot of people.

(Punturieri) I have two questions, one for each of the speakers. For Dr. Keller, I notice that your cartoon was targeted to a relatively limited group – a person of either sex but no person of color. Did you notice that the response was reflecting that population and was that targeting for a specific reason?

(Keller) The characters were designed to appeal to really either a white or a Hispanic population. When you look at the demographics of Minnesota, we are about 80% white and 20% non-white. It is something that we can do better. We do have other campaigns that target different racial and ethnic communities.

(Punturieri) It goes back to the previous question about tailoring for your target population by gender or racial group but also about the age component of that. It's a relatively young population they're wanting to reach with cessation information, people in their 40s or late-middle 30s.

(Keller) Typically we target our ads to 25- to 54-year olds. But what we've seen is greater numbers of people ages 18 to 24 coming into our services, primarily using the NRT starter kit.

We're really pleased by that given that's not a population that we heavily target in terms of some of our paid ads. I do think this is where some digital ads and Facebook-sponsored posts may be making a difference.

(**Punturieri**) I talked earlier about going to Epic and to medical records with certain populations. I mostly deal with chronic obstructive pulmonary diseases and we have 30, 35% of people that basically are at the end of the rope with their lungs and they're still smoking. So, one of the biggest problems we've found is that these individuals don't want to talk to their doctor and don't want their doctor to talk to them about any smoking cessation intervention. And so, the question is how do you think that could be addressed in that loop?

(**Augustson**) One of the things that I didn't have a chance to really talk about is the script that comes up on the screen. It is something that a lot of thought has been given to. The basic approach for the physician is, "I see that you're smoking and we know that the smoking has significant impact on your health. And so, as part of trying to improve your health, I would like to try to help you quit smoking. I have resources that, if you're interested in using them, can be of help to you. And we can get you started on those right now." So really, what comes from this is the perspective not that you're a bad human being or I'm your doctor, do what I'm telling you, but really more that I really think this is something you need to do if you want to feel better and have better overall health, and I can help.

(**Fiore**) The only thing I'd add, and Paula Keller mentioned this as well, is there's enormous power in being given an invitation, beyond just quitting. We've found that just saying you are interested in hearing about quitting or maybe cutting down opens the invitation up to people who might not otherwise think about it or believe they can do it. The collective work we're doing involves that – a broader invitation, a very soft invitation. And the nice thing about both the test messaging and the quitline is that they're designed to deal with people wherever they are. And that's helpful as well.

(**Schroeder**) I have a couple of questions about folks who are poor and they're disproportionately on a Medicaid program. One is for Erik: are you tracking what proportion of Medicaid callers in the various states are getting vouchers for NRT or other things and how does that work? I know in varies state by state. And then the scary question is if the ACA is repealed or if the Trump budget comes to full fruition, all the resources the CDC has been using now to support state quitlines go away. Paula, you're kind of protected but most of the other states aren't so what are the game plans, what are the backups?

(**Augustson**) So this is my opinion and does not represent the official position of the NCI or HHS. And that is that my team and I are planning a bake sale that we hope will help fill some of the gap. In all seriousness, I think that's a very complicated question. And I think it's a very, very real question. And the people who ponder that, have no interaction with me at any time during their careers. They're way too far up in the stratosphere. So, I honestly don't know. In terms of tracking who's getting vouchers, this is not something that HHS tracks or NCI. However, this is something that's tracked by the North American Quitline Consortium and so they would be more likely to have information that can help to inform how many vouchers are going out. You'd have to do a little bit of synthesizing but that data is probably readily available in their annual reports.

(**Keller**) As I said, we both serve the uninsured and the underinsured. Our uninsured rate is 4.3%. As Dr. Schroeder was saying, about half of the people who we serve are underinsured. And of that group Medicare is the biggest proportion. About 1/3 have some sort of commercial insurance and the rest are – say Medicaid. Our Medicaid fee for service is a small subset. We

also are a heavily Medicaid managed-care state. About 80 – 85% of people are who are enrolled are in Medicaid are in managed care. So, we would be triaging them to their health plan for service.

(Novotny) In terms of reach from the technology standpoint, the train has left the station on this. It feels like we're just sort of dabbling with m-Health at this point. And in the case of smokers, with 70 some percent having Smart Phones and 97% of people having cell phones, do we - have we not reached out to partners in the technology arena to see what we can learn from them? Or perhaps even partner with them. You know, when you talk about a bake sale, this is actually – I'm serious about this because the technology companies have enormous resources.
They have philanthropic arms that they sometimes want to use to provide support. We've been approached by people who say what can we do to tackle this and perhaps look at government partnerships. I don't think it's all just building business. I think there is really a sense of a – there's a public good that can result from all of this technology tweak that we've experienced.

I just wonder if there's been any sort of purposeful thought on that. And just to follow up I think even with our next meeting, we might be able to invite – or some future meetings – some inputs from technology companies to see how this can actually be strengthened.

(Augustson) This is a really, really good question. Even in this day and age, when we have these huge corporations and an international presence, it so often becomes the ability to connect to a single person. I can tell you that we are currently engaged in conversations with an extremely large internet presence who is interested in collaborating with us. If my contact breaks a leg, that can crumble. And of course, it may fall through, too. So, I think what I would say is at this time we do not have an infrastructure that promotes partnerships. And so, this is something, for example, that I'm doing on an individual basis.

That is not to say that we don't have a partnership arm within NIH in particular. However, that's largely focused on partnerships with pharmaceutical companies and medical device companies. It's not really a – in fact we tried a couple of partnerships with behavioral related groups that just got bogged down – it didn't happen. That could be a great topic. It potentially could be convened at an HHS level. And, you know, it's not that far off from some of the things we've been talking about with the pharmaceutical companies, too. So, yes, it's a great idea.

(Christofferson) If I can just comment on some of the VA perspectives...VA has within the past several years pioneered a strategic partnerships office, based on establishing public/private partnerships across the VA system to benefit veterans. One example of the way that VA has partnered with technology companies was last year for Veteran's Day, when VA partnered with Apple. Apple, on their App Store home page, featured a number of VA apps, one of which was the VA state quit coach to help veterans quit smoking. But there were a number of other apps featured as well. And so that was a very nice example of a technology-government partnership that made some of the government resources available to folks.

(Novotny) The other part of this is the use of analytics, big data analytics that can tell us what people are pursuing and especially tailoring that information to either geography or vulnerable populations. You can really make use of that.

(Augustson) I think that is an absolute, fantastic idea. In fact, I would argue that's the cutting edge of where we need to go. And so. The large data engine companies, the Googles, the Apples, etc., those are the people who do that tens of thousands of times a day. An effective partnership with them would be amazing.

Also remember these are corporations that have very sophisticated algorithms that start pushing advertisements to you based on where you've been on the web. If they could start to push health promotion sites or resources, whether it's smoking or drinking or suicide prevention – that would be amazing. And I can also tell you they're pondering that. So, an opportunity is possible.

(**Riley**) This gets back to the NRT Medicaid population conversation that Steve started. And the question's really for you Paula. I'm wondering – given that we know that the optimal dose of NRT is more like six weeks or longer, I'm wondering what the quitline can do or what your program possibly does to follow up after the starter kit provision since it's such an opportunity. I understand the limited resources but am wondering what the protocol is to follow up and maybe get them the full dose.

(**Keller**) It's a great question. Everyone who signs up for a starter kit consents to a follow-up phone call. We place that call about 2-1/2 weeks after the starter kit is sent to them. The purpose is to make sure that they received it and see if they have any questions.   But it's also an opportunity for a soft offer of services. We see that about 25% of people actually pick up the phone when we call. And we haven't gone and looked at whether people are then re-enrolling in other services or are we connecting them to their health plans specifically for the Medicaid population.

We don't assess insurance status for starter kit participants. We would only assess that if, on that follow-up call, they would say yes, I would like telephone counseling. Then we would ask about insurance status so we could find out if they're eligible for our service or if we would send them to their health plans. We were able to pass policy in Minnesota that indicated that for Medicaid enrollees, all USPSTF recommendations graded A and B are covered benefits. We're working on a separate project with our health department to promote that policy.

(**Nez-Henderson**) I know, Paula, that you had mentioned it's been very difficult to reach American Indian communities. And we all know that. Even with the funding support for tobacco control, we still have higher rates of smoking in American Indian communities but lower rates of smoke-free policies or taxation on tobacco products. So not everything that we could use to prevent tobacco use and encourage cessation is being implemented in Indian country. My question is to Ms. Becenti from the Indian Health Service. What innovative ideas are you using to address the high rates of smoking in our communities? I know that a lot has been done so far but certainly more needs to happen.

(**Becenti**) One of the challenges is actually not having enough tobacco cessation services for our population. Cost has been a barrier, and also the high rate of turnover of our personnel.

What has been useful for employees is access to a tobacco cessation training program that is available online and is free. We have done a lot of promotion to encourage our staff to complete that training, to be able to provide tobacco cessation services to our population. As part of that effort we also have reached out to community health workers, public health nurses and dietitians and other professionals, and encouraged the use of the tobacco cessation online training. We want to partner to make cessation services available to our population, and also incorporate the traditional use of tobacco. The other focus is prevention, gearing up to educate our youth. We want to reach them before they even start using tobacco.

(**Henigan**) This question is for Paula. First of all, ClearWay is a terrific organization. On the policy side, we work with them all the time and find them very, very excellent. So, thank you for what you do.

You indicated that as of July 1, 2016 you added a combination NRT option. Does that mean that you actually tell smokers that it may well be more effective to combine NRTs? And I was interested in the history of that. Why did you decide to add that option at that time? Was it because the science reached a point where you felt comfortable with it, or possibly that FDA's change in labeling influenced that decision?

(**Keller**) Whether we were offering single monotherapy or combination therapy, our clients had the chance to go and listen to coaching calls with our service provider and other service providers. The coaches would consistently recommend using combination NRT. We decided to make the change because the science was there, with better outcomes. We also had to assess our budget. We wanted to see what happened if coaches recommended these services, and make sure we had the budget space to do this. While we are lucky in that we have a well-funded service, our resources aren't infinite either. We wanted to make sure that if we were going to add this offer, that we could do so and we could do so consistently.

(**Curry**) My first question deals with other types of mobile platforms and m-Commerce, and goes to reach. Erik, I think you mentioned that quitlines were reaching about 1% of smokers. How can we benefit from the market research that happens outside of the health space to improve our practices and our reach? And that leads me to a second question, which is what is an aspirational but achievable goal for reach? Ken Warner may have a better sense of this from his economics background. But the market share that you aim for when you're going out into the "M" platform can be pretty modest. So, some could argue that if we could get use market research to get from 1% to 5%, we've made an astonishing advance. So, what are we aiming for and how can we get there by standing on the shoulders of not just the health field but the broader m-Commerce platform?

(**Augustson**) I'm going to quickly turn to Corinne and then I'll come back. Corinne, what's the CDC reach recommendation for quitlines?

(**Graffunder**) It's about 7 or 8%. (Editor's Note: State quitlines should seek to reach 8% of their state's tobacco users annually, with a target of 90% of these callers accepting counseling services. Centers for Disease Control and Prevention, *Best Practices for Comprehensive Tobacco Control Programs* — 2014, p. 47.)

(**Augustson**) There are several really good points in there, Dr. Curry. One is that there is this rich knowledge within the marketing world related to the use of mobile resources in terms of marketing and engagement. Unfortunately, a huge chunk of that is hidden from us because it's considered to be proprietary. And it's also what marketing companies make money off of, so they won't share their data with us, they won't tell us. However, it does turn out that Google has a huge amount of data that we can tap into, and most of that is actually free.

Google Analytics is the main driver for all of the metrics that we track within the *smokefree.gov* enterprise. There is a lot of information that can be gleaned there. In fact, there's so much that can be gleaned, the challenge really becomes bandwidth. Do we have enough staff to analyze that data? Related to that, there are a number of increasingly sophisticated analytics packages which help us to begin to try to frame that data in ways that it's useful to us as interventionists. That having been said, there really is so much untapped potential there for us to tap into.

In terms of the reach - so CDC's guidelines I think are very aspirational with the 7 to 8%. But obviously that comes with a price tag. There really is this tension between driving more traffic to quitlines, which we can definitely do, but the quitlines don't have the capacity to really absorb it, which I think is a challenge.

(Keller) And if they're cumulative versus dipstick.

(Augustson) Yes. And we have some wonderful data out of CDC's Tips campaign that shows us that. However, there's also work which looks at what are the ripple effects of any kind of campaign. This data is much more difficult to tease out and I know Tim McAfee's led some of this work. I don't know that data particularly well.

The other thing to note is that within the true mobile platform, for relatively small amounts of money you can have extremely substantial reach. For example, the most money my team has ever had for promotional dollars, paid promotion was $1 million. And we drove an extra 5 million users to our resources with that $1 million. Of course, you can argue that was being driven to mobile health, but what about driving to a quitline, which I believe will be more effective, or to a treatment health care system, which I believe will be more effective. The other factor is that it depends on the population. For example, it's much easier for me to reach relatively well-educated, middle-class white people than it is for me to reach pregnant women who smoke. But which group is a higher priority for me? Well, I love everybody but I would love to be able to intervene more effectively with pregnant women, for example.

(Keller) The other thing to think about when we're talking about reach and what our goals for reach are, is how reach is defined. The North American Quitline Consortium defines treatment reach as receipt of telephone counseling and/or Nicotine Replacement Therapy. So right now, the working definition of treatment reach does not include mHealth interventions.

Dr. Robin Corelli
School of Pharmacy, University of California, San Francisco

My presentation today is about an innovative approach using the community pharmacy as a site for tobacco cessation. As you know, community pharmacies are highly accessible. They offer extended hours, sometimes 24 hours, 365 days a year. Patients don't need an appointment to see a pharmacist. Insurance isn't necessary. There are clinically significant drug/tobacco smoke interactions, so pharmacists have an obvious interest in patient smoking status. The other factor is that cessation medicines are primarily dispensed in pharmacies. Four of the seven FDA labeled first-line cessation drug treatments require a prescription.

For all these reasons, tobacco cessation should be a basic pharmacy care service. When patients are self-treating with over-the-counter cessation medicines, the pharmacist may be the only health care provider they come into contact with prior to or during a quit attempt. So it is logical that pharmacists, who see patients who are trying to quit smoking on a frequent and recurrent basis, should be an important care provider in tobacco cessation. Data published in 2013 on North Carolina's Medicaid population showed that high-risk patients go to the pharmacy 35 times a year in contrast to seeing their primary care provider 3 to 4 times a year. So pharmacists offer a tenfold increase in patient contact, and we could be doing more tobacco control intervention in this venue.

Finally, there are five states that now have legislation allowing pharmacists to furnish or prescribe medications for smoking cessation. This legislation started in New Mexico in 2004, and was passed more recently in California, and we will see more of this in the future. The newer states, Idaho, Colorado and Indiana, learned from California and they are adding varenicline and bupropion to their lists of medications that pharmacists can prescribe.

So how do we know that pharmacists are equipped to do this? Are they capable of providing this service? There have been a number of initiatives over the years in training for pharmacists. Washington State has partnered with GlaxoSmithKline to develop advanced training programs for licensed pharmacists. We've heard of the Rx for Change program mentioned during discussions this morning. That was a program that was specifically designed for training health care professionals and it's a curriculum I'll touch on a little bit later. In 2002 the NIH funded a large grant to disseminate a standardized curriculum into Schools of Pharmacy. We actually trained 89 of the then 91 Schools of Pharmacy in existence.

So what do we know about what's been done in the United States in pharmacy-based tobacco control initiatives, specifically in community pharmacies? We know, through a very large NIH-funded trial that if you try to apply the five A's treatment approach in a busy community pharmacy, it doesn't work. Pharmacists want to do this. They want the training. But when they go back into their work environment, there's no infrastructure that allows them to execute the five A's approach. There's no support for it. So, in pharmacy education, we've moved forward with a more abbreviated version of the approach – one with two A's and an R. And this is certainly not unique to pharmacy; other disciplines are using this as well.

Pharmacists are identifying smokers, or asking; they're advising smokers to quit; and then they're referring them to other resources, including but not limited to telephone quitlines. We know from a variety of research projects over the past decade that this approach is feasible. It can be done. We know that through work we did with a project called LA Quits, as well as through another large study that found this approach can be done in routine practice and that it doubles referrals to quitlines.

So, for the rest of this presentation, I'd like to focus on what happens if we up the ante a bit. We know this ask-advise-refer patient-care model works. But what about establishing a systematic approach to support the ask-advise-refer model instead of relying on the goodness of the pharmacist to execute it? We know that strong systems are necessary. Clinicians want to do the right things but they need a system to support them.

To evaluate the kind of system and the kind of structure we needed, we launched a collaborative effort with a large grocery store chain in California. The project was funded by Safeway to develop a model to engage the pharmacy team in a systematic way to execute the three-step tobacco cessation patient-care model. Safeway had a national presence, even before they merged with Albertsons. And they wanted to develop an organization-wide program that engaged all Safeway pharmacy personnel, not just the pharmacists. We tapped into the support staff who are so critical; the clerks and technicians. Quite honestly, these staff are essential players in community pharmacies, especially within diverse and underserved communities, because they speak the language, they know the culture. They are in the front lines at the in-take window and the check-out window. So, they were, in my opinion, the secret sauce of this project. The goal was to provide brief cessation interventions with patients who were identified as smokers as a standard component of care that would promote referrals to a quitline.

We developed and evaluated two training intervention programs in a proof-of-concept randomized controlled trial. The trial focused on types of training and interventions that would be feasible and acceptable within a large chain, because there's a cost with implementing a cessation program in pharmacies. The trainings included a minimal, written-only training and a more intensive training that included a 4-hour live training session coupled with ongoing monitoring and coaching by management and weekly report cards documenting store performance with smoking cessation counseling activities relative to other stores in the study.

In each community pharmacy, staff including both pharmacists and technicians were trained to ask patients about their smoking status in a sensitive way. This was a challenge for many of the teams. They were not comfortable asking about tobacco use at first because they just weren't used to doing this and some felt they were prying into someone's business. But the coaching and training helped the staff understand how to ask the questions and begin the conversation. We told pharmacy staff that this is no different from asking somebody if they have any drug allergies. For example, once a pharmacy technician or clerk identified an individual as a tobacco user, they moved on to advising him or her to quit. "I see that you're smoking. Have you thought about quitting? Our pharmacists have received training to help people quit smoking, would you like to talk to one of them?"

We gave them the language to be able to respond to patients during the various stages of the conversation. For patients who were NOT ready to quit, the staff would just let them know that the pharmacy has resources and would be able to help them quit whenever they make that decision. For patients who were interested, the staff would activate the rest of the care plan, which included encouraging the use of behavioral counseling as well as pharmacotherapy because these evidence-based tools increase success rates. The pharmacist became involved if a patient indicated an interest in using one of the FDA-approved medications. This phase often involved a phone call to a physician, but many of the cessation products are sold over the counter. In tandem with discussing use of effective medications was a referral to other resources in the community. In this particular study, it was the California Smokers' Helpline and they have been a fantastic partner.

Other key parts of the model included moving nicotine replacement therapy products back to the pharmacy in stores where the products were up front in a locked cabinet, out of the sight of the pharmacist. We also used prominent signage that said talk to our pharmacist if you want to quit smoking.

Another key part was incorporating detailed operational procedures so the cessation intervention was not just something that the staff did when they felt like it or when the pharmacy wasn't busy. This was encouraged to be part of the routine workflow with every patient. It was incorporated into the store's best practices, not only for prescription processing but for immunizations as well. And you can see other things down the road, such as diabetes management, where this would have applicability. The staff also documented patient smoking status in the pharmacy computer system, which automatically performs drug interaction screening. We should be doing that in pharmacies anyway.

Another key part of the model was giving staff prescription credit for the intervention, whether they sold any cessation medications or not. Safeway Corporate aligned the incentives with the team. For those of you not in the pharmacy world – the single most important metric in community pharmacy is number of prescription fills. So, if you're spending time counseling somebody, you're maybe not filling prescriptions and you may not have an incentive to spend time with patients if that slows down the prescription filling process. But the pharmacy staff were given prescription credit for time spent talking to patients, to keep staff incentivized.

Regarding outcomes, I'm giving aggregate outcomes in the interest of time, but we did measure by both minimal and intensive intervention. We measured over 12 weeks in 20 stores throughout the State of California. These pharmacy teams touched almost 45,000 unique patients filling prescriptions during the study period. We included low- and high-volume stores in the study, to see how the model worked in both low- and high-volume settings.

Of those the pharmacy staff served, smoking status was documented in about 15,000. Now that might not sound like great execution. But I will tell you that over 12 weeks, going from zero percent to 34% speaks volumes about the feasibility of this approach. And there may be understandable reasons for those numbers. Children were counted in the 45,000 patients served, so obviously you're not going to execute the cessation model for them. Also, many prescriptions are written for a 90-day supplies so there might only have been one opportunity to provide an intervention during the study

Of those 15,000 patients with smoking status documented in the pharmacy profile, the pharmacy team identified just under 1300 individuals who reported they smoked. That's 9%, which is certainly low, considering that California's overall smoking prevalence is ~12% and ranges from 8-14% depending on the county. Of those 1,300 who said they were smokers, 970 patients received some type of counseling intervention that included ask-advise-refer at a minimum. The intervention had to include a discussion about local cessation resources or referral to the California Smokers' Helpline. So, we observed a 75% execution rate when the pharmacy teams identified smokers. If patients asked for more information, the teams moved forward with a brief scripted smoking cessation intervention.

The model also included passive referrals, which included handing brochures and cards for the quitline to patients. Only the intensive group received training on using the active Web referral to the California Smokers' Helpline. Over the 12 weeks there were a total of 15 web referrals. This is not a huge number, but given the short duration of the study and the fact that most smokers are not ready to quit on the spot, this was not surprising. Interestingly enough, even though there were only 970 smokers who received a counseling intervention, the pharmacy staff gave out about 2,500 of the quitline cards and brochures. We learned anecdotally that nonsmokers were asking about the materials to give to friends and family members who smoked.

Before I wrap up, I'd like to read you a comment from a technician that we received during the evaluation phase. This comment really summed up the model for me. It came from one of our intensive group technicians:

"I asked the patient if he or his wife were tobacco users and he said he's the only smoker in the household. His wife wanted him to stop but he never knew how to start. I referred him to the California Smokers' Helpline and gave him a brochure. I saw that he was really considering quitting so I went on and told him that I can get Medi-Cal (the state Medicaid program) to cover the medication he decided to use. Then he spoke to my pharmacist and they decided on the patches. And we enrolled him on the Web as well."

"We got a prescription from his physician and we arranged for prior authorization, and arranged for payment from the insurance. And he's now tobacco free. Every time he comes to the pharmacy he thanks us for getting him through this hard process. I will always remember him telling me, 'I'm glad I quit smoking. I can live longer to see my grandchildren.' He almost cried as he expressed this to me."

We heard several of these types of stories where the teams felt they were really doing something good here. They felt they were functioning at the top of their training.

So, what we learned from this small proof-of-concept study is that community pharmacies are a logical location for cessation interventions, and it's feasible. A major take-home from this study was that corporate support is critical, and that having strong systems in place that the teams follow is critical. Corporate incentives certainly helped in this setting. And

we found that more intensive training led to increased identification of smokers but it didn't necessarily translate into more cessation interventions.

The study involved 20 stores and the Safeway chain was thrilled with the results. They launched the model nationwide and trained teams in 1000 stores in partnership with 19 different quitlines in the United States. Unfortunately, shortly after the launch, Safeway merged with Albertsons. As often happens when you blend families, the priorities change. The nationwide expansion of smoking cessation services has been put on the back-burner for the time being. The program was expanded in California, though, and it's still going strong with 162 stores providing smoking cessation services. Albertsons plans to prioritize the rollout nationwide to the states that give pharmacists prescriptive authority. So, Colorado and Idaho will be pursued next.

In conclusion, there are approximately 62,000 community pharmacies in the United States. Data show that at least 91% of Americans live within five miles of one of these community pharmacies. If each pharmacy were to successfully help just one tobacco user quit each month, that could translate into an additional 750,000 people in the US who quit smoking annually.

Dr. Kathleen Cartmell
College of Nursing, Medical University of South Carolina

Our project is called South Carolina Can Quit: Facilitating Development of Evidence-based Tobacco Cessation Services in South Carolina Cancer Centers. For people who are diagnosed with cancer, continuing to smoke after diagnosis causes treatment side-effects, secondary cancers, and also an increase in overall mortality. The National Comprehensive Cancer Network developed clinical practice guidelines for smoking cessation in 2014 that encouraged all cancer patients to be screened for tobacco use, advised to quit, and provided with evidence-based cessation services that include counseling, medication support, and follow-up.

Additionally, in early 2017 the National Cancer Institute released a P30 supplement to fund NCI-designated or comprehensive cancer centers to develop tobacco programs. You would think that cancer centers would all have excellent programs in place to counsel patients about smoking. But that's not the case for a number of reasons. First there's the cost of putting a program in place. Secondly, reimbursement rates aren't very high for delivering smoking cessation. Third, for patients who come in with cancer, it's an extremely busy time coordinating everything that needs to be planned for their cancer treatment regimen, leading to time restraints. Fourth, some clinicians are still hesitant to advise a patient to quit smoking because they're under distress having been diagnosed with cancer. Finally, the NCCN Guidelines are only voluntary.

We had a very simple project goal, which was to rapidly diffuse the tobacco treatment guidelines from the NCCN within our state cancer centers. To accomplish this goal, we had three aims; first to develop systematic processes in each of our cancer centers to deliver services. Secondly, we wanted to be able to evaluate project outcomes. For example, we wanted to be able to document the percent of patients who were screened for tobacco use, who were advised to quit, and who were referred for cessation services. Third, we wanted to be able to characterize best practices developed by the cancer centers for delivering tobacco cessation.

So just to give you a little overview of our project, there were 17 Commission on Cancer certified cancer center systems in the state and they were all invited to apply for a grant. We offered $20,000 plus technical support. Three of these centers applied and we funded them all. The centers were asked to first put in place automated e-referrals to the state quitline and also to put in place phone follow-up support using the TelASK platform to basically help with relapse

prevention. We also asked them to put processes in place to "ask, advise, and refer." To give you a little background on TelASK, it's a cloud-based tobacco cessation program platform. It helps to automate delivery of cessation services. It can extract tobacco use screening data from the electronic health record and triage smokers for cessation services. It can also deliver automated calls or emails to patients to give them an opportunity again to be transferred to a state quitline or an in-house cessation service, if preferred.

During the project, the centers used TelASK to re-contact patients by phone at 1, 3, and 6 months to provide follow up cessation support, including an opportunity to be referred back to the state quitline. The interactive voice response calls essentially asked patients if they were still smoking and if so, would they like to be transferred back to the state Quitline for cessation support.

To train cancer center tobacco cessation teams to do this work, we used a structured collaborative learning process. We held three different meetings over the course of the two-year project in which we shared with them information about the rationale for delivery of tobacco cessation services in cancer centers and best practices for delivery of these services. We provided training on quality improvement methods for developing and improving their cessation services. We also built in time during the training for the cancer centers to work through any issues they were having in building their programs and to share best practices with one another.

We used a number of what I think were innovative quality-improvement tools. We worked with all the cancer centers to help them to create process maps. We wanted them all to come up with systematic ways of delivering services so that the effort would be sustainable. We did some quality-improvement work with them to help them test some process changes. And then we had monthly evaluations calls in which we would work with them on any issues that they were having in the course of trying to put their services in place.

I'd now like to share with you an example of one of the three services that was put in place in a cancer center. When the patient checks in, he or she completes an intake form at the front desk and a medical assistant reviews the intake form. Patients who are current smokers are advised to quit smoking and informed that they will be referred to the state quitline. Information is entered at that time into the Electronic Health Record to generate an e-referral to the quitline. Additionally, patients are enrolled in TelASK to receive follow-up support at 1, 3, and 6 months.

During the physical exam, the physician reviews the tobacco information with the patient and formally advises the patient to quit smoking. In a couple of days, patients who are smokers receive a call from the state quitline for cessation support. And then at 1, 3, and 6 months patients receive an automated call from TelASK to evaluate if they are still smoking and receive an option to be automatically transferred back to the state quitline again if they need relapse support.

Now I'll share with you an overview of results from our three participating cancer centers. I want to note that we did not have baseline data, but what we knew up front is that most of the cancer centers in the state were doing pretty well at identifying smokers – but that was about all they were doing. None of the 3 centers had baseline had standard processes in place to deliver tobacco cessation services. The percentage of new cancer patients screened for tobacco use was close to 100% (range: 95%-100%) for each of the three cancer centers. Secondly, we looked to see what percent of screened patients reported tobacco use, which ranged from 15% to 21% across the three centers. Next, we looked to see what percent of tobacco users were advised to quit smoking. Two of our centers were close to 100% but one center was at 26%. This center

had experienced a lot of substantial changes with their cancer center leadership and staffing that affected this result. Finally, we looked at what percent of tobacco users were referred for cessation services. And for two of the cancers it was really good – 79% and 89%. Again, though, we had that one cancer center that was much lower at 33%.

When we did exit interviews with the cancer centers, we found that all of the centers had developed formal systemic processes for tobacco cessation service delivery that each remain in place now. One center had already implemented the automated e-referral and the other two centers were very close to having that done now. All the centers said they plan to continue their programs.

The biggest challenge faced was that two of the centers were experiencing major organizational changes, which was disruptive as they were trying to develop programs. Also, there was a lack of sufficient IT support for program development. At the same time, we gleaned some wonderful best practices for delivering tobacco cessation in a cancer center. First of all the centers found that it was critical to train the entire team on the tobacco cessation program. Secondly, several of the centers reported that having a single point of referral to refer patients to the state quitline helped to make their process more systematic and avoid having patients "fall through the cracks" for referral to services.

The one cancer center that was able to automate e-referral to the state quitline reported that, compared to manually referring patients to the state quitline, the e-referral made this process far more simple and efficient. What was excellent was that the cancer centers reported that they felt like it was critical to reinforce the tobacco cessation message. They noted that the doctors really started talking with patients and engaging them during the visits and that the nurses would find opportunities, such as when the patient was sitting in a chemo chair or when there was down-time, to help reinforce the quitting message and to help overcome barriers to quitting. The last piece here is that we tried to distribute free nicotine gum and patches at the start of the project to each of the centers, and only one of the 3 centers were interested in getting these free medications to give to their patients. What we found though during the exit interviews was that ultimately all of the cancer centers were now using these free medications to help engage patients in quitting. They noted that people really like to get something "free" and that the free medications really helped to get patients thinking about quitting. So, in summary all three of the cancer centers were able to implement comprehensive tobacco cessation programs and plan to continue their programs.

We plan to continue the work at a state level to work with other cancer centers in the state. Finally, and perhaps most important, this was a model that could easily be used in other states to facilitate rapid dissemination of tobacco cessation programs within state cancer centers.

I would like to acknowledge a number of partners on this project that were instrumental in making SC CAN Quit a success. First, Mrs. Sharon Biggers and her team at the SC Department of Environmental and Control Office (DHEC) led the project. Dan Kilpatrick of DHEC was the primary evaluator for the project. Second, Dr. Michael Cummings and Dr. Graham Warren provided expertise in terms of delivering tobacco cessation within cancer centers. Ms. Pam Gillam of the University of South Carolina provided quality improvement support for the project. CVS Pharmacies provided a grant that supported this work. And of course, the state cancer centers were critical partners for this initiative.

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Joy Leuthard
Oklahoma Hospital Association

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I'm going to talk a little bit about the project that we have in Oklahoma. Oklahoma is predominantly a rural state. We have about 3 million residents in the state. About 1 million of those are in the metro area of Oklahoma City. Another million are in the metro area of Tulsa. And then the remainder are dispersed throughout the rural areas of our state.

We have done a lot in the area of tobacco control, though we have a long way to go. One of the things that we struggle with is we have a prevalence that's higher than the national average; 22% of adults are still smoking in our state. And 13% of our high school students are still smoking, 4% of middle school students and overall 31% of youth in our state are still using tobacco of some sort including e-cigarettes. Seventeen percent of male high school students are using smokeless tobacco. So, the cost to our state in health care is $1.6 billion. And according to the SAMHSA data, 54% of that falls within hospital costs.

I want to talk just a moment about the Hospital Association. We were established in 1919. We represent over 135 hospitals in our state and 85% of the hospitals are members of our association. We do advocacy at state and federal levels for the industry itself but we also provide educational opportunities, information and data analysis, and patient quality and safety resources. Our newest component is health improvement for our patients, our hospitals and our communities.

Our motto is to promote health and welfare of all Oklahomans by leading and assisting member organizations to provide high-quality, safe and valued health care services to their communities. We play a vital role in helping to advance the overall state of health. And we are uniquely positioned to promote tobacco treatment, because we have relationships with our hospitals. We work with them every day on many different issues.

Hospitals Helping Patients Quit was developed in the year 2009 through the vision predominantly of two people in our state who were very involved in tobacco control. Some of you know them – Tracy Strader, who is the former, just retired Director of the Tobacco Settlement Endowment Trust, and Sally Carter, who was working at the State Health Department in the Tobacco Use Prevention Service. They came to the Hospital Association asking whether this would be an effective avenue to reach hospitals so that we could work on tobacco cessation. And at that time my boss, LaWanna Halstead, had just been there about 11 months. And she took it on and said sure, why not. And so, at that point Hospitals Helping Patients Quit was born.

When we started I was the only staff but now there are 3-1/2 FTEs: myself, two coordinators and a half-time assistant. And because we are serving our hospital members we have a credible relationship with them. They trust us and that's one of the key elements to allowing us to work effectively with them.

Throughout our project we routinely measure the number of referrals that are sent to our Oklahoma Tobacco Helpline. We look at the acceptance rates of those who are referred and then we look at the percent that are tobacco-free at 7 and 13 months. That evaluation for both the helpline and our project is done through the University of Oklahoma, College of Public Health, along with the Oklahoma Tobacco Research Center.

From October 2010, which is when we launched our very first referrals, through March of this year, we made over 20,000 referrals to our Oklahoma Tobacco Helpline. Those referrals include outpatients; in-patients and some employees. Currently, 50% of those are electronic referrals. We have a 29% acceptance rate for services, which is interesting because when we started with fax referrals, before we had the e-technology, we were running 39% acceptance. But

it's beginning to decline and we're trying to do some research to figure out why that's happening.

We have found that 35% of those who receive counseling and pharmacotherapy through the helpline remain quit at 7 months, which statistically is the same as the 13-month figure. So, our goal is to develop a comprehensive system of change that's the tobacco-free culture within hospitals and health systems. It is policy driven. It includes comprehensive tobacco-free property for each hospital, which means inside and out all the way to the perimeters, and tobacco treatment cessation support for patients, family and employees.

Our goal is to reach sustainable system change and embed it into the medical processes within those systems. So, we have the clinical process to embed in either a paper or an electronic medical process. We have a tobacco cessation protocol based on clinical guidelines, the five A's. And we have a change in the work flow to integrate that clinical protocol into the Electronic Medical Record which includes an e-referral.

We have also worked with a number of hospitals on a fax referral system when they do not have the capability to make electronic referrals, but I'm going to talk mostly about the EMR, or Electronic Medical Record e-referral today. So why hospitals and clinics? Because it is an appropriate time and setting. Others have mentioned that earlier. We're moving from a medical model to a behavioral health model where we need to treat the whole person. This can be a real mind-set change for medical staff. Traditionally they come in, they diagnose, they're going to treat, they want to get them out the door. We're asking them to do one more thing on their list of tasks. It's critical to help them understand that this is one of the most important things they can do for their patients, not just while they're in the hospital but after they leave the hospital.

One of the things that the hospital staff is coming to understand and like is that when they're appropriately dosing Nicotine Replacement Therapy they don't have problems with patients wanting to get up and walk out the door with their I.V. pole outside so they can smoke. Patients are also more manageable because they're not agitated, they're not as irritable. The majority of tobacco users visit a health system annually as Dr. Fiore mentioned. This is a teachable moment motivated because of health concerns that might have triggered their hospitalization. And the tobacco-free campus supports cessation efforts so that patients are getting the message from everyone and not just one professional.

This is also an opportunity for making cessation a more positive experience with adequately dosed medication and supportive treatment. We do training on this, including helping physicians understand how to dose NRT because they traditionally dose it too low. Policy is extremely important and the growing quality measures in the health care sector are helping us with that. The recommendations of the National Quality Forum, the Joint Commission Tobacco Measures, CMS requiring inpatient behavioral health measures, and of course Meaningful Use, all support us in the work that we do.

We now have one system in Oklahoma, Alliance Health, that has fully adopted and required all of their hospitals to employ the Joint Commission Tobacco Measures. But on the one hand while it supports the work we do, on the other hand some hospitals just want to check the box and move on rather than providing the quality kind of intervention that we need.

I want to talk just a little bit about embedding the practice into the clinical work flow. First of all, we do the tobacco use screening but we take it a step further by asking several questions. We not only ask do you use tobacco, but we also ask what kind, what type, how much do you use, how long have you used tobacco, have you made quit attempts and how many? We

ask whether the patients live with someone in the household who uses tobacco, and if they say they've quit we ask them when they quit because sometimes they quit a day or two before they walk into the hospital at admissions. So, we want to know that.

Once that screening takes place, which can be done by an RN or an LPN or a medical assistant, whoever is doing the health history, then we arrange for medication. The physician is alerted and oftentimes the hospital has the medication protocol embedded in the EMR. The physician then can order the Nicotine Replacement Therapy, which is what they usually do. At that point, the EMR prompts a designated staff to complete the cessation intervention. Our responsibility is to bring the hospital the knowledge, the technical guidance, the training and all of those things. But the hospital has to determine how they're going to implement it. So, it's critical that we have an implementation committee, representing clinical, as well as IT, so that the staff can determine how it's going to fit in their system. If it doesn't fit for them, it won't work. The other thing is these responsibilities are sort of dispersed among several people in the hospital so there's not a burden placed on any one person. And that way we have better buy-in.

After the physician prescribes the NRT, then whoever is designated comes in to do the bedside intervention, which is usually three to five minutes. It can last a little longer, but one thing we know is that hospitals are very busy places. Nursing staff has a lot to do. So, we have to give them the skills and the scripting and the words to actually do the intervention. Through motivational interviewing, they assess tobacco users in terms of their readiness or their interest to quit. They assess the desire for helpline support at that point and then they reassess them for comfort with their medication to make sure it's working properly. That can be done by a respiratory therapist, case manager, a social worker, an RN, whoever the hospital designates that they want to do it.

All of these steps are embedded in the EMR and at that point, if the patient wants a referral, the staff sends the electronic referral to our Oklahoma Tobacco Helpline. Our vendor is Optum and that e-referral can be done a number of ways. It can be a direct messaging. It can be HL7 technology. It can be an electronic fax, or it can be batch files. Once patients go through whatever treatment they choose to do through the helpline, outcome reports close the loop and come back into the patient record.

Within our system of hospitals in Oklahoma, the Chickasaw Nation Medical Center has been fabulous to work with. I will say Oklahoma has the second largest Native American population in the country, next to California. We have nearly 300,000 Native Americans in the state. We have over 30 recognized tribes and they comprise 9% of our population. The Chickasaw Nation stepped up. They were the first hospital to implement electronic referrals and they utilized the Indian Health Service EMR, RPMS, which is Resource and Patient Management System. To date, total referrals have been over 2,000, and most of them have been through outpatient clinics. Not only did they implement the protocol at the hospital but they did it in their clinics as well, and they are now expanding it into their dental clinics.

What they did with RPMS is – they did a workaround. They developed a secure file transfer protocol, which includes batching files and we've literally watched how they did this. They have the files literally on the screen and they drag and drop them to the Optum server to make the referral. It has to be manually encrypted. Then it's decrypted, processed by Optum, and then they have to encrypt those files, send them back to the Chickasaw Nation to be decrypted and then they go into the patient file.

This is not the optimal way to do it but it was the only way they could do it at that time. We are having some discussions with them about moving to HL7 technology. One of the things

they did that was unique is that they developed a nicotine replacement therapy to be prescribed at discharge so that patients, for two weeks, would have the NRT until they got the NRT from the helpline. They also embedded the whole process in their EMR. They have the 5As lined out in their EMR. They have scripting available and they actually embedded the FDA protocol according to RX for Change that we use. We also use the protocol from the Mayo Clinic. When physicians do the orders, they have all that information in front of them to know how to or when to prescribe.

Mercy Health System already had an EMR throughout their system, Epic. It took us two and a half years to do a build-around for that EMR and five years to roll it out throughout their health system. It does require one full-time coordinator and a contract with us to help them with that, and they've had 2,400 helpline referrals.

Integris Health was the first system that we did. We began with fax referrals. They did extremely well for about two and a half years and then those referrals began to diminish. They have done a total of over 10,000 referrals but now they're moving over to an e-referral system and so we're trying to troubleshoot that system with them right now.

We are also working with a unique population through the University of Oklahoma Medical Center, Children's Hospital. Their Perinatal – Neonatal Program came to us and said, how can we work with caretakers of NICU babies? What they wanted to do was to eliminate secondhand smoke exposure to improve health outcomes for those babies when they go home. They launched in April of 2016. So, they screened those neonatal parents and caretakers using best practices and they use an e-fax because those babies come from all over the state of Oklahoma and the state of Kansas. And when they're discharged, they're discharged back to their communities. It's also very difficult to get feedback into the patient file because you're treating the family member, you're not treating the patient.

They have screened over 780 caretakers – 85% of their NICU admissions – for tobacco. Of those, 49% received cessation services through their staff and now they're expanding into the Prenatal Diagnostic Center, which is high-risk OB patients. And they're going to be expanding into the pediatric cardiothoracic surgery area and their Infant Transition Center back to the community. They have a national presence now because they've actually presented at conferences and have an abstract that was submitted to the American Academy of Pediatrics in September.

Regarding lessons learned:
- Tobacco treatment in health care settings must be embedded in the electronic medical record. Our experience shows that if they're doing fax referrals, it falls off. So, all of this process needs to be within the system.
- Large system implementation requires internal resources, including oversight, a multidisciplinary committee, a coordinator, and IT support.
- When we go out to work with large systems, sometimes it takes us a year to meet with all of the leadership, from the CEO at the corporate level down through all of the leadership structure within the hospital.
- Permanent changes in health systems require focused effort with dedicated staff. Because we're a provider association, we're credible and a trusted resource.
- Support to health system requires expertise in best practices, it requires technology, and we have to have funding. Resources are essential and in Oklahoma, the funding is through the Oklahoma Tobacco Settlement Endowment

Trust, which are MSA dollars that were put into a trust. We're the only state that has done that and maintained it.

- In fact, the core trust is now $1 billion. All of the earnings from the trust pay for a myriad of tobacco prevention and cessation services throughout the state. Resources are essential.
- The greatest impact is through large multiservice health systems. That's the reach that we're talking about.
- And patience, patience, patience. This is difficult work. This takes a long time and sometimes when we're in the trenches we have to remind ourselves that it takes time.

As for the most important needs:
- The best practice protocol and referral capability really needs to be standardized in electronic health record systems, for example, as we worked with the Chickasaw Nation with RPMS.
- If it was ever possible that that technology could be raised and direct messaging technology could be available throughout the HIS system, that would reach a huge number of high-risk users.
- We'd like to see an update on best practice tobacco research, including e-cigarettes.
- We'd like to find ways to improve tobacco treatment reimbursement through Medicaid and Medicare, to incentivize providers in inpatient settings. We don't get any kind of extra reimbursement, but it could be added through an up-coding system. Right now in the clinics, the staff and the physicians don't bother coding for it because they feel outpatient rates are too low.
- When we're dealing with insurance companies, one of our concerns is that insurance company plans may not pay for all of the medications. They are not able to help with any NRT and their coaching or their counseling programs are not always based on best practices. So, we have concerns about efficacy there.
- Finally, regarding the quality measures, improving those and requiring ease of reporting would increase utilization by the hospitals. IT expertise is needed to help hospitals plan for EMR changes. It costs them money when they have to do work-arounds, provide technical consultation, or do troubleshooting.
- Also, tobacco use best practices need to be a standard part of medical school and allied health curricula.

Dr. Dana Christofferson
Veterans' Health Administration

Today I'll be talking about some of the work in the Veterans Health Administration, implementing change in behavioral health settings. I want to start off with a brief overview of the VA health care system. With over 1,700 health care facilities across all 50 U.S. states and U.S. territories, we are the nation's largest integrated health care system. We serve close to nine million veterans each year within our health care system, out of the approximately 23 million veterans in the United States.

To give you a sense of what our population looks like, our enrollees are largely male. Only 8% of our enrollees are women. This is in large part due to the historical makeup of the military. Many of our patients are older veterans. The largest number is from the Vietnam era. Over three million of these men and women rely on VA for care in rural locations. The largest proportion of our population is lower socioeconomic status. We're also one of the nation's largest

providers of mental health and substance use disorder care. Last fiscal year, 1.6 million of our veteran enrollees received specialized mental health treatment from the VA.

I think this group is probably aware that veterans have historically had higher rates of smoking than civilians and so in order to address that, the VA system has implemented evidence-based policies and programs to support tobacco use screening and treatment within our health care systems. All of our VA medical centers have a smoking cessation specialty clinic. We offer educational materials for patients, and conduct regular training for staff, with continuing education credits for all disciplines. We utilize home tele-health. We have a national tobacco cessation quitline for veterans within the VA and we also have m-Health programs and services available.

What we've seen within our system is a decline in smoking rates at the same time we've seen smoking declines across the adult population in the United States. Many patients who are veterans have benefited from the broader tobacco control and awareness initiatives in this country. We've seen our smoking rates within VA go from a high of 33% in 1999 down to just under 15% as measured in our last survey conducted in 2016.

We also place a priority within our system of providing FDA-approved smoking cessation medications to our patients. They're a very important component of tobacco cessation care. We've conducted a number of initiatives over the years to increase our patients' access to those medications, including policy changes that removed restrictions so that any patient who is interested could receive a smoking cessation medication, whether or not they were interested in attending a group or getting counseling.

We also implemented a national performance measure in 2006, based on the HEDIS measure, which helped to increase the rate of smoking cessation medications that were prescribed to veterans. Our last available data from 2010 indicated that roughly 37% of our veterans who were identified as current smokers had received a smoking cessation medication in the past year. While we've seen these policies implemented system-wide across our system, we know that smoking rates are disproportionately higher among certain sub-populations. We know that in the U.S. adult population, patients with a mental health disorder are two to three times more likely to smoke than patients without a mental health disorder. We also know that individuals with a mental health disorder overall, on average, die several years earlier than individuals without a mental health disorder and this is in large part due to diseases caused by tobacco use.

Within the VA system, this data is no different. Our rates of smoking do vary by psychiatric diagnosis, but in general, among our veterans, those with mental health or substance abuse disorder have smoking rates that are two to three times higher than veterans without mental health or substance abuse disorders. And furthermore, we also know now that in addition to the many, many physical health benefits of quitting smoking, there are mental health benefits to quitting as well. Quitting smoking can decrease feelings of depression, and can reduce stress and anxiety. It can improve patients' moods and their quality of life.

We also know that receiving a smoking cessation intervention is associated with an increased likelihood of long-term abstinence from alcohol and other drugs, and that quitting smoking is associated with a reduction in suicide risk. And so, VA has really prioritized providing tobacco use treatment specifically to patients with mental health disorders. I want to share one example with you today of a study that was conducted by VA researchers with veterans and VA, and how we've worked to implement those findings into our system.

I'm going to describe a trial that we know in VA as CSP 519. This is a randomized controlled trial that tested the integration of tobacco cessation treatment into the mental health care provided for veterans with post-traumatic stress disorder, PTSD. This study recruited 943 veterans who were engaged in outpatient PTSD treatment. These patients were from ten VA medical centers across the country. Those patients who were interested in quitting were randomized to either be referred to their existing smoking cessation clinic at that site or to receive integrated care.

Integrated care was a manualized treatment. It was delivered by the PTSD provider in individual sessions with the patient as part of ongoing PTSD care. There were five core sessions with three follow-up visits. For patients in both treatment groups, whether referred to the smoking cessation clinic or receiving integrated care, they were encouraged to use and were provided with smoking cessation medications if they were interested. And so, what the study found is that overall, participants in the integrated care model, after six months, had 2.26 greater odds of prolonged abstinence compared to those who had received treatment in the smoking cessation clinic. Abstinence after six months was 16.5% for these patients in integrated care compared to 7.2% for patients in usual care. Both sets of patients were followed for 18 months and these significant differences between the two groups persisted. So even after 18 months, patients in integrated care were twofold more likely to quit smoking compared to those in usual care.

The other interesting piece from the study is that among those patients who quit smoking, regardless of their treatment group, they demonstrated an improvement in their PTSD symptoms as well. This study was one of the largest conducted at the time. It was very significant in that it demonstrated that integrated treatment provided to patients in their mental health setting with their existing provider, whom they probably already had an existing relationship with, was successful, and increased their prolonged tobacco abstinence.

Within VA, we looked to see how we could implement this more widely across our system. What we came up with was a learning collaborative methodology. A learning collaborative is a methodology that uses training and consultation along with quality improvement methods and its intent is to support rapid delivery and sustained use of effective treatments within the clinical setting. We did this in two phases, learning collaborative one and learning collaborative two. Each phase included six VA PTSD clinics for a total of 12 across the implementation project. These were geographically diverse clinics found across the country. They served both rural and urban areas and we recruited teams from each clinic. The teams varied in size but were between four and nine members. The teams included a PTSD clinic director, a prescriber, several PTSD treatment providers, and someone from the team who was identified as a clinical champion and would be responsible for helping sustain the program and train other providers at the site.

These teams each participated in several two-day in-person learning sessions that focused on clinical skill building, and how to effectively deliver integrated care in different circumstances, for example in groups or coupled with some of the consultation-based, evidence-based PTSD practices. They also covered planning on how to sustain integrated care after the learning collaborative ended. And the learning sessions were participatory, not just didactic sessions. The groups were working together in their teams, for example, to create action plans, identify and address potential implementation barriers and make plans for moving forward.

We found that in the 12 clinics, almost 400 veterans received integrated care within the first year. Veterans who participated received a median of six sessions of integrated care. And the first learning collaborative group was followed for an additional 12 months, providing

integrated care in total over 24 months to more than 300 patients. Of the six teams that were followed, four continued to deliver care and initiate new patients over a year after the learning collaborative was ended. And three out of those four teams were able to train and add additional providers, demonstrating that it was feasible for them to spread the intervention to some extent at their site.

The two sites that did not continue to provide integrated care and treatment after the 12 months were faced with a number of logistical and staffing issues within their clinics. What we learned from this implementation project, and from surveys completed by participants, was that the majority of the clinicians thought that integrated care was a feasible intervention. It was effective and they also felt that smoking cessation was an important aspect of routine mental health care. We also learned that a number of the sites actually adapted the integrated care model within their clinics. About a third of the providers who delivered the treatment did use some telephone or video tele-health to deliver portions of the integrated care intervention. And about half of all sites used a group format to deliver integrated care to a number of patients at one time.

We also learned about the barriers that sites had identified. Some of the barriers were typical to any site or provider who is working mental health treatment. They have patients who are not interested in receiving care or were not complying with treatment. One of the largest barriers they mentioned was a lack of time. About half of the sites that had participated in the learning collaborative used a consultation-based model, which is a very structured and time-limited PTSD treatment. It was a challenge for some of these sites to incorporate even a few minutes of smoking cessation treatment into those appointments, and required reworking of schedules and more flexibility on their leadership's part.

We also heard that there was difficulty in accessing smoking cessation medication. Most of the providers who were delivering this care and treatment were psychologists or social workers without prescribing authority and we tried to address this from the start by requiring a prescriber to be incorporated with every team, but that still posed some challenges for some sites. That was a definite lesson learned.

This study was just one example of how we worked to implement tobacco cessation treatment into mental health settings in VA. We have a number of ongoing projects and initiatives that I don't intend to talk about today, but more broadly we're focused on raising awareness about the mental health benefits of quitting. There's certainly less knowledge about this among health care providers, among our veteran patients, and among their family members. And so, this is an important initiative for us.

We've also worked to engage a range of mental health and substance use disorder providers with expanded educational opportunities, and to engage them to incorporate tobacco cessation into mental health care. For example, we've been working with our peer specialists within VA, as well as our mental health case managers and others. We see these groups as very important to help encourage a culture of tobacco cessation within these clinic settings.

We've created patient-directed educational materials about the mental health benefits associated with quitting and we've also done specific work on implementing tobacco treatment into substance use disorder settings. This setting, in VA's experience, can be even more challenging in some cases and we have a number of researchers and groups within VA who have implemented quality improvement initiatives in this venue. We've also been piloting more innovative approaches, such as contingency management, in these settings and populations.

Finally, I just want to mention that VA is not treating patients in a vacuum. Our patients are out there in the community with their families. They're being seen in community health care

settings as well as VA. They're going to their community pharmacies and they're influenced by all of the other tobacco control efforts and media campaigns that are out there. And we see partnerships as a really important goal for VA, to help spread this message more broadly across a number of channels about the importance of tobacco cessation for patients with behavioral health conditions.

Discussion 3

(**Curry**) There's an increasing use of pharmacy benefit managers who want to mail you your medications, so I would imagine that there's an increasing population of folks who are not interacting with pharmacists at all. I think there's an opportunity to intervene there as well, though, when you get your little package in the mail with your medications. The other thought that I had with regard to pharmacists is my most recent brain candy, as I call it, has been working in HPV vaccination and looking at community-clinical linkages and at pharmacies as an important linkage for delivering vaccines. And it occurred to me that you have parents and 11- to 13-year old kids interacting with pharmacies or other places. The message framing for HPV vaccination is cancer prevention. This gets to the work in South Carolina. I think there are a lot of opportunities to de-silo some of what we're doing and to take the opportunity to link a cessation message to parents who smoke, as well as a prevention message to kids who are not smoking. I had a whole grant proposal written by the end of that presentation.

(**Corelli**) Can I respond because that's fantastic and is related to another part of the workflow that we're working on? As you know, most flu vaccinations are administered in community pharmacies and a very logical dovetailing of that activity is to ask patients whether or not they have been immunized with the pneumococcal vaccine, a vaccine all smokers should have. So, that is something that we want to begin to integrate into the workflow as well. It starts the dialogue and you have a captive audience, sitting in a chair, waiting for you. I hadn't thought about the HPV but that's a fantastic suggestion.

The mail order pharmacies are a challenge because obviously you're getting your medicines through the mail and not interacting with the pharmacy staff. There's nothing that would prevent some type of cessation message, at least within the packet of materials. The challenge as many of you know when you pick up prescriptions, is that in addition to the medication, you receive about ten other pages of written material. The trashcans outside pharmacies are filled with those. So, that's a challenge, but we do need to work with mail order pharmacies as well because they're an increasingly large distributor for prescription medicines.

(**Punturieri**) In terms of patient outcomes and benefit for the hospitals, did you look at 30-days re-hospitalizations? Going back to the concept of the teachable moment, MIs, COPD, or pneumonia would be affected by smoking. If through smoking cessation, you're increasing patient awareness about benefits of quitting, then you're indirectly leading to prevention of 30-day re-hospitalizations for those causes.

(**Cartmell**) I actually have an R21 study through AHRQ that we have mostly finished and we looked at re-admission rates following implementation of a good evidence-based cessation service. And we found close to a $10,000 difference for patients who were in the group that got the intervention versus those who didn't in terms of their medical costs a year out, looking at statewide utilization. We also found a marginal effect on readmission rates. We're still writing those papers, but I'm really, really excited about the results.

(**Leuthard**) Just to follow up, I'm glad to know you're doing that study because I'd like to see the results. This has been a rather difficult thing for us to approach in Oklahoma because there are so

many varying factors that affect re-hospitalization. At this point, we have not been able to do that research but that's on our radar list to see if we could do that. That's a good question.

(Henigan) I have a question for Dana on the VA presentation. There was a very interesting slide showing the sharp increase in the use of medications among veterans and you said it was due to policy changes. I might have missed it, but what policy was changed that started that increase?

(Christofferson) The VA policy was changed to allow smoking cessation medication for any patient who was interested. Previously, a number of sites used to restrict medications to those people who were willing to come to a smoking cessation group to ensure that they received both counseling and medication. The revised policy was set so that anyone interested could receive a prescription.

(Curry) I just had a question about that slide. You have the U.S. rate at 19.6, which is based on the national adult tobacco survey. What's the data source for the VA?

(Christofferson) The VA data is based on our PBM prescribing data on the number of unique patients receiving medication, as well as the number of smokers identified from our VA enrollee survey, which is conducted annually.

(Hamlett-Berry) In about 2003, 2004, we began to very aggressively do national trainings on how to use medications appropriately. So, we have two clear things that we could point out in terms of a timeline that medication use increased among veterans, one being the change in lifting a previous restriction medication that had been in place for a long time, kind of along the lines of what was done in HMOs. But also, the adoption of national HEDIS-based measures had an effect. Those measures made it standard that every patient in an outpatient mental health clinic and outpatient primary care facility who was currently a tobacco user was asked whether they would like medications to help you with quitting. And that really drove up the numbers because a lot of patients said yes, actually, I would. I didn't know I could get over-the-counter NRT here. So those things, along with a lot more training over the years on how to use medications to improve cessation success, also helped.

(Compton) Thank you all very much for a rich set of presentations. Going back to the pharmacy presentation, NIDA has been working with pharmacies in a couple of areas. We have seen them for a long time as an opportunity for HIV prevention activities, for example, through syringe purchase as an alternative to syringe exchange because that's not possible in many locations. It turns out you don't need a prescription for syringes in many, many states. That's one area.

The other has been very recently, we've been seeing pharmacies as a potential alternative site for methadone distribution because they exist in so many places where we don't have access to medication-assisted treatment for opioid use disorder. But I had a question for you. When we think about the pharmacy's location for tobacco cessation, they're also a site of tobacco sales in many, many states. How do you deal with that in your studies?

(Corelli) I'm really glad you brought that up. In fact, Tom and I were talking about this at lunch. This study pharmacy, Safeway, actually does sell tobacco products with the exception of stores in San Francisco, where it's banned. So full disclosure on that. That was an issue. This was something we talked with Safeway about when we were starting the collaboration.

But we've taken the approach, at least with our pharmacy work, to not throw the baby out with the bathwater on some of these things. We really strive to move the needle and work with pharmacies to have pharmacists at least provide cessation counseling services. Getting tobacco

out of pharmacies will take time because the decision to not sell tobacco is largely out of the hands of pharmacists. In fact, I was just pulling up some of our data that we collected over the years and less than 2% of pharmacists support the sale of tobacco in pharmacies. Independently owned pharmacies by and large don't sell tobacco because the decision-makers in these pharmacies are pharmacists. It's chain pharmacy, which quite honestly is the face of pharmacy in the United States. Generally, the tobacco is sold up at the front of the store in a locked cabinet, not necessarily within the site of the pharmacist. So hopefully that answers your question, but we weren't able to exclude stores that sold tobacco as part of our study.

I can tell you if anyone wants to partner to help get tobacco out of pharmacies, we have an army in the pharmacy profession interested in this because the sale of tobacco is one of the banes of our professional existence, quite honestly.

(Compton) I was in an unnamed pharmacy recently and it surprised me. I had forgotten that they still sell cigarettes and then also, all the NRT products were right next to them. So even if you wanted to quit, you were reminded immediately of all the cues to keep using.

(Corelli) Agree, after you fill your prescriptions, you walk right out past the tobacco. Not ideal. Obviously, CVS got rid of that trigger for relapse when they stopped selling tobacco in all their stores. I would love to see CVS's financial data after they made that decision. To my eye, they're not hurting financially after dropping the sale of tobacco.

(Schroeder) After CVS went smoke free, I bought 100 shares of CVS and watched it soar, but in the last year it has really come down and I'm not quite sure why. Walgreens, now, their stock price, which was lagging, has passed it. So, it's hard to isolate that out. But in the short-term, it was a great financial move. And it's interesting that the CEO of CVS sat in the President's box in the State of the Union speech the year after CVS stopped selling tobacco products.

(Warner) I had some questions for Dr. Christofferson about these really interesting data and specifically, Slides 3 and 4. We were just talking about slide 4 and the apparent very much greater medication-assisted treatment in the VA. This is just an observation. As dramatic as that is, we need to recognize that represents an increase in quitting among the VA population relative to the U.S. population of about 1%. Because you've got almost a 20 percentage point difference in use of medication and you're going to have about a 5% incremental effect on quitting. So as impressive as that looks, it's still not going to be a whole lot towards solving the problem. But what was so interesting to me was looking at the previous slide, two things about it, one of which is the giant decrease in prevalence from 1999 to 2005. One question is to what do you attribute that? It's got nothing to do with medication use since that didn't begin rising until after that.

And the other is am I correct that these data are not age-adjusted? Because I always had the impression that vets smoked at a higher rate than the general population and this suggests they're about comparable. But if, in fact, this is not age-adjusted and we've got many more older people in here, like Vietnam vets, that would account for these two running together. It would actually still be a higher rate of smoking among veterans if the data are age-adjusted.

(Christofferson) This is data from veteran enrollees in VA health care. This is not all veterans within the country. I don't believe this is age-adjusted and you're right, we do have a larger population of older veterans, who do have lower rates of smoking. We also know that a number of the veterans who are coming into our system, veterans of Iraq and Afghanistan, have much higher rates of smoking. Rates are estimated between up to like 35% maybe and so although that's a much smaller portion of our population in terms of total numbers, it's definitely a concern and something that we're looking out for moving forward into the future.

(**Warner**) The other question was how do you account for the huge drop in the difference between general population and VA population smoking rates from 1999-2005, six years, you went from a difference of, what is it, about ten percentage points to less than one, it looks like.

(**Hamlett-Berry**) I don't think we really know. I think part of that is our veterans also benefited from the larger national tobacco control policies that were put into place, whether it be increased taxation, smoke-free work policies and those sorts of things as well. I don't think this is just what's happening in terms of VA care alone.

It's hard to know exactly. I don't think there's one thing that we can tease out. It's like you said, it's not the medication alone. I think our population grew quite a bit in terms of the number of veterans who were being served by the Veterans Health Administration, probably from 1999.

(**Shell**) Dr. Corelli, I have a couple questions on the pharmacy presentation. What were the costs to implement the program in pharmacies? The second question is the amount of time to train the pharmacist, the amount of time that the pharmacist or the staff had to spend with the patients. And then the last question is your thoughts on the potential long-term impact of smoking cessation on patient medications overall. I looked at your drug interaction sheet and am getting the re-awareness of the impact of tobacco use on so many of the medications.

(**Corelli**) The cost was the amount of time that they're spending and I don't have the dollar figure to answer that, but we'll have that for you. The beauty in this particular model is that the pharmacy teams were finding the cessation intervention could be integrated within the routine workflow in the community pharmacy. The vast majority of people that they're interacting with are not smoking, so it's just a simple question to ask, like asking about drug allergies. They're screening, then they're moving on.

Usually, when a clinician identifies a smoker, the person is not ready to quit on the spot. The model within this intervention was not a hard sell to try and convince a patient to quit smoking. The pharmacists were trained to preserve their relationships, serve as a resource in the future by offering to help if and when the patient is ready, then they move on. Anecdotally over the 12 weeks, we found that some patients came back, saying you talked to me about smoking and I'd like to talk again. So, it does take some time, but quite honestly, if you're helping somebody to quit smoking, it's worth the time. These encounters were typically less than two or three minutes. In most of the cases, they were less than 30 seconds. That said, for this to be sustainable, especially with the big chains, there needs to be some financial model for this if you're pulling a provider from medication dispensing activities to provide an intervention.

We did the more labor-intensive training that was four hours. So yes, that was costly. We took pharmacists out of their work environment, brought them to a place for four hours of training and in this particular chain, paid the pharmacists and the technicians to come to the training. So that's a good question to get the actual estimate. We need to include that in our paper. I don't have those figures off the top of my head, but it was a substantial investment. What we're finding (which has been replicated in two different studies) is that even minimal training through written materials leads to increased cessation counseling by pharmacy personnel when compared to intensive in-person training or through academic detailing in community pharmacies.

For the interventions themselves, especially with medication counseling, this is something that pharmacists do behind the counter for prescription medications and in the OTC (over-the-counter) non-prescription aisle all the time. Someone is looking at the cabinet and if they're locked, the pharmacist has to help. This is part of routine practice in pharmacies so I think the

model works and I think that the key to it is that it is brief. If it required a full, comprehensive (5As) intervention with every patient, I don't believe this is feasible in a busy community pharmacy.

As to your next question about impact of cessation on drug interactions, fortunately for the clinicians and the patients, many of the drugs on the drug interaction list are not first-line treatments and we don't use them very much anymore. But with some medications, such as oral contraceptives, the drug interaction between tobacco smoke and estrogen-containing contraceptive can be significant and it is preventable.

(Schroeder) I'm going to give an unpaid commercial. Many people around the table and many people listening in are called upon to give talks on tobacco. And the best repository, the best collection of slides, is found in RX for Change, which Robin Corelli and her two colleagues make available for free. So, go to the website, find them, download them, use them shamelessly, give them credit if you can. If you want to credit your source, you can do that, but they're wonderful resources.

(Corelli) Thank you, Steve and I also want to say because of the collective wisdom in the room, if there's anything that you see that's missing in our materials, that could be improved, we appreciate feedback and might tap into some of the folks in this room for external review again. If you've seen the materials, they're fully annotated for speakers in all disciplines who may not have expertise in tobacco. There are videos, trigger tapes, and they're for all disciplines, respiratory therapy, dentistry, nursing, medicine. Thank you for the shameless plug.

(Curry) Okay, I'm a dog with a bone. I apologize. I'm going to go back to the VA data on medication use and I want to preface this by saying what the VA has done and is doing is amazing. I just have a problem with that slide because we have the U.S. rate set by self-reported use of medication by smokers in a survey and we have the VA data based on prescribing data to a known number of patients. They are apples and oranges.

If you want to compare use of medications between the two populations, either you have to correct your data for how many people actually use the medication when it is prescribed, or find a data source that is equivalent to self-reported, or find a data source for the U.S. population that is similar. These are the kinds of things that take on a life of their own and I think there is a ton of stuff to be proud of, but I don't think these data are accurate.

(Christofferson) I completely agree. It is apples to oranges and a lot of times with our VA data, surveys are conducted with different wording from other data sources and so that is something we struggle with. And I appreciate the feedback and we'll work on that. Thanks.

(Hamlett-Berry) And for the pharmacy data, just the VA pharmacy data, some of this is actually from a tobacco control article that was chaired by Mark Smith, who is an economist who is part of the Health Economics Research Center at Palo Alto VA. He has since gone on to be with Thompson Reuters I think. But he basically started looking at this from CSP 519, looking at all the different sites that were involved in it. His paper was sort of the beginning piece of looking at how medication utilization changed with sort of policy changes in the national system.

The one other thing I did leave out on why cessation medication utilization increased within the VHA was the contributions of Dr. Ken Kaiser who, in 1999 was moving VHA very much away from being a specialty care system to increasing the focus on primary care and health promotion. And I think that's one place that's very difficult to quantify in terms of what changes happened in

the way care was provided. But when I think about that timeframe of 1999 to 2005, that's the other leading change in the national veterans' health care system that may have played a role.

(Warner) My guess is that either, I suspect it's a 1999 number, it's just measured differently and is probably not comparable because that is such a huge difference that there's no way to explain it with better care, better treatment. I think you ought to dig into that and find out what's going just out of curiosity because it's such a huge change.

(Shell) I think VA can also access millennium cohort data, which is our longitudinal data where we do active duty and vets. And so tobacco use is a part of it, under mental health issues. If you want a comparable to a civilian survey, just do Mil Co. Millennium Cohort is both active duty and vets.

(Nez-Henderson) The question is for Joy. I see that there were referrals to the state quitline. Were there increased calls to the state quitline from American Indian population, specifically from the Chickasaw community? And if not, what can we do to increase the calls?

(Leuthard) Yes, we do have an increase. First of all, they were making no referrals before we started working with the Chickasaw Nation on the helpline. So, it's like going from zero to whatever that percent is. So that definitely was an increase. We're also working with the Cherokee Nation. We're beginning to work with the Choctaw Nation and one of the differences is they're much more autonomous and in control of their health systems. As a result, we're able to make changes that we haven't had as much success working through the IHS system in Oklahoma.

Sally Carter, who first started some of this project, also went into a position as the tribal liaison at the Oklahoma state health department and she's worked a lot with the tribes and has a great relationship with many of the tribes. And she's been very helpful and working closely with us on those projects too, so that we have a lot of cultural sensitivity about the specific issues in working with the tribes. I could probably pull those numbers. Laura Beebe, who is with the College of Public Health at the University of Oklahoma, does a lot of research around the helpline but she also has a great interest and has done quite a bit of research with the tribes so we can try to get that information for you.

(Nez-Henderson) The reason I asked is if you look at the Indian Health Service GIFRA, Oklahoma tribes probably have the best rates for the 5As. So, we're just going to try to use you as an example to move forward.

(Leuthard) We worked long and hard. Also, the state health department has worked closely with the Muscogee Creek and developed a whole campaign that was very specific to Native Americans that took into account all of the cultural kinds of issues. So, we can share that with you also.

(Augustson) I had a question for Dr. Cartmell. First of all, thank you very much for talking about your innovative program. Integrating smoking cessation and tobacco cessation within cancer centers has been a long-term interesting challenge for the National Cancer Institute. So, it's very exciting to see this moving forward. In looking at your results, which are extremely impressive, I'm wondering whether it's in exit interviews or follow-up evaluations you folks have been working on, if there are certain key elements of your treatment package that you feel were particularly helpful in getting 100% compliance in advising patients to quit and some of those kinds of numbers?

(Cartmell) Honestly, it had so much to do with the system. Once the centers put the system in place to be able to screen, counsel, refer to the state quitline, etc., they were able to assign staff/clinicians responsibilities for each of these processes and track that they were being done. I think by having that process clearly defined, every time they do it the same way, it really helps. And then we had lots of other lessons learned such as getting the whole team on board, giving out free medications and for several centers having a single point of contact for making the actual quitline referrals.

There were a lot of things that seemed to be effective, but I also felt like the learning collaborative approach was really huge because it's difficult to "reach" all cancer centers to get them on board with delivering evidence-based tobacco cessation services. A statewide learning collaborative approach provides an opportunity to increase the reach beyond what you could possibly do working with cancer centers one, by one, by one.

(Becenti) This question is for Dana. On Page 2 on your presentation, if I'm interpreting the slide correctly, it says that the tobacco screening is at 99%. We hover at a little over 50% so any tips that you can give me would be wonderful. Thank you.

(Christofferson) It's a national performance measure for VA. I guess what we always hear is true – when it gets measured, it gets done and I know our quality managers are all over the screening. I know the clinical reminder is a yearly reminder. It's normally handled in primary care but it also would be handled in mental health care settings.

(Becenti) I just think the use of electronic clinical reminders that can easily be used to capture that information really makes it much easier for the provider. It's not a matter of just doing it. It's a matter of making sure that it's documented in such a way that it can be extracted and to show that it was done.

Public Comment by
Michael Fisher, Altria

Thank you. Good afternoon, everybody. I apologize for talking to the back of your heads. I'm Michael Fisher. I am a scientist with Altria, which is the parent company of Philip Morris USA and the U.S. Smokeless Tobacco Company. I appreciate the opportunity to make a few remarks about the role of smokeless tobacco products in reducing the harm from cigarette smoking.

Public health efforts to prevent smoking initiation and increase smoking cessation have been effective at reducing the adult smoking prevalence from approximately 45% in the 1960s to 15% today, according to the most recent data. Nevertheless, tens of millions of adults continue to smoke. Tobacco harm reduction complements proven prevention and cessation strategies by focusing on reducing morbidity and mortality among adults that continue to use tobacco products, by making available and providing accurate information about tobacco products that are acceptable to adult consumers and proven to be lower risk.

Domestic moist smokeless tobacco products are known to be lower risk compared to cigarettes. We have quantified the risk differential between smokeless tobacco and cigarettes using two largely publicly available, national representative, perspective mortality data sets, the National Longitudinal Mortality Study based on the current population survey, and the National Health Interview Survey Mortality Linkage. We find that current smokeless tobacco users do not have elevated risk for mortality from all causes – all cancers combined, major cardiovascular diseases,

or respiratory diseases. In contrast, smokers had elevated risk for all these outcomes consistent with the well-known health risks associated with cigarette smoking.

These results, based on nationally representative government data, clearly show that smokeless tobacco is vastly lower risk than cigarette smoking. Approximately 40% of smokeless tobacco users also smoke cigarettes. These individuals present an opportunity to reduce smoking-related harm by providing accurate, non-misleading information, about health risks. This is because surveys, including the FDA's population assessment of tobacco and health survey and the National Cancer Institute's health information and national trends survey, show that people are misinformed about the risk differential between cigarettes and smokeless tobacco.

In fact, over 90% of the population believes that smokeless tobacco is as harmful or more harmful than cigarettes. Accurate risk information would provide those who currently smoke and use smokeless tobacco products the opportunity to make informed tobacco product use decisions. Authoritative public health communications currently do not provide information about the risk differential between tobacco product types, including smokeless tobacco and cigarettes. We believe that providing such relative risk information to consumers could lead some of these consumers to become exclusive smokeless tobacco users, thereby reducing their individual risk.

Because the difference in risk between cigarette smoking and using smokeless tobacco is so great, the movement of adult smokers from cigarettes to smokeless tobacco products is likely to have a net public health benefit. Thank you very much.

Public Comment by
Anne DiGiulio, American Lung Association

Hi, thanks so much. I really appreciate the conversation today. My name is Anne DiGiulio. I'm with the American Lung Association. I do our tobacco cessation policy work and I just wanted to let everybody know we've got a couple of great data sources. We've got great funding from CDC and a cooperative agreement. We collect Medicaid coverage data of tobacco cessation treatment. It's published on our website and it's on CDC's STATE system, so you're free to look at it or contact me if you've got any questions about it. But it might be helpful to all of our work here. And then we also had an MMWR that was published back in December that looked at data from about a year ago about cessation coverage in the Medicaid expansion states for those populations. I just wanted to pass this on as an FYI. I hope it's helpful and thanks again. It's a great meeting.

Closing Statements

(**McNabb**) We have determined that there's no one else queued up to make a public comment so that opportunity is closing. I would note to people listening both here in the room or on the phone, if you'd like to submit a written comment on cessation-related content, you can email that to my colleague, Monica Swann, and her email address is mswann -- M-S-W-A-N-N at cdc.gov. For those of you in the room, it's written out at the registration desk and for those of you on the phone, you will find it in the federal register notice of which you found the link to this meeting.

What we're going to do next is I'm going to pose a couple of questions and just ask people to engage. I'm going to ask that public members that are here to absorb what you're hearing both up to this point during the day and in this discussion, and then afterwards, I'm going to ask you to convene and I can help arrange that on the phone or in email, and synthesize what you've heard

and see if you can put it into some suggestive recommendations that would then go to the full committee.

For those of you in the public, what gets suggested will be put up in the ICSH web as required by FACA. Everything we do here is for the public consumption and we're transparent. We don't have to make proposals and have votes or anything like that in this meeting. Let's just have a discussion and then I'm going to trust our public members to use their expertise to bring that together for synthesis.

We started out today hearing the foundation of cessation from Corinne about what the numbers show about who is quitting and how they're quitting. Michael gave us an overview of what the evidence is and some of the challenges. And then the rest of the presentation showed us some innovations of things that are actually working.

One question is what are the things that we can do increase access to evidence- based tobacco treatment, remove barriers for smokers for using that treatment, and to promote utilization of that? We've heard from ClearWay, we heard the research they did to understand the smokers and what would help them find and access these services. And then we heard a number of presentations on what you have to do on the supply side. How do you make it easy for the providers or systematize it so that it's a click of the button and the form comes up or just the right training to say here's the type of words you use if you have apprehension about talking with a patient about cessation? So that's very valuable.

So, the question, for those from federal agencies is, from what you've heard today, what can your agency or perhaps other agencies do more of or differently to help achieve that threefold goal of increasing access, removing barriers, and promoting utilization? And for those who are not federal agencies, from what you've heard, what could you suggest? Certainly, the focus is on federal agencies but we know that those federal agencies don't exist in a vacuum. So, if there are things in larger society that could help as well, we'd love to hear that. I'm going to toss it to Steve to respond first.

(Schroeder) My crystal ball is somewhat cloudy, but it seems to me in the next few years the action is going to shift increasingly to the states. That tells me that CMS, NCI, NHLBI, SAMHSA, HRSA, all will be key. To the extent that you can influence state behavior by setting guidelines, influencing fund flow, giving report cards, keeping the pressure on, praising the good performers, shaming the ones who aren't doing so well, that would seem to me a very worthy question. That, I think, is where the action is going to be. That's where the comprehensive budgets get set. That's where quitline budgets get set. There's where promotional materials get set. So, I'd be interested to hear from those agencies now or later, what levers they think they have to influence state actions.

(McNabb) That is also going to apply to tribal communities. And that's great because we know that within tobacco control already, so much work is done at the state level. CDC's program is, in fact, to support and provide resources to states, tribes, and territories. We know that we're all going to be facing challenges as far as resources go.

I also want to say that people shouldn't feel constrained to respond only to the question I asked. If they have other questions, feel free.

(Curry) I think the operative word that I would put out is partnership. I think linking with other areas that also have resources is going to be incredibly important because there just aren't going to be enough of them go around. We heard some great examples of linking with PTSD treatment

programs, linking community-clinical community partnerships in the realm of pharmacies, the idea of looking at other cancer prevention initiatives, and certainly chronic disease initiatives.

You get more by sharing and a lot of what we want to have happen on the ground involves similar skills and opportunities, and people do not come in sliced and diced to these opportunities in the way that we often think about them.

(Grana) In order to facilitate the adoption of existing tobacco cessation treatment programs within the health care systems in comprehensive cancer centers, the supplement opportunity that was mentioned, it's a really significant thing that's happening now. We've received the applications. They're being reviewed but the whole goal of that is to enhance the capacity. The goal is not necessarily focused on research yet, but instead to make sure the initiatives are developed and developed with the best practices, integrating EMR systems, and really making sure that the institutions have sustainable commitment to those programs.

I think that's very significant for recognizing what Dr. Fiori mentioned this morning about increasing venues and focusing on the venues where we can really have a lot of impact being one way to target populations. It's not precision medicine from the genetic standpoint, but sort of more precision medicine where you're going to have a big impact.

Some of the other things, and this is in our briefing book for this meeting, also increase the capacity. There are really excellent treatments that are going to be happening with the lung cancer screening community, which I think is very significant for expanding cessation where we're providing treatment, making sure it's systemized and getting people at high risk into the treatment.

I also want to mention the FOA, the funding opportunity announcement, around socioeconomically disadvantaged populations that really focuses on delivery and scalable interventions, not just figuring out what works with low SES populations, but making sure that it is scalable and can have high reach.

(Punturieri) We have already acted at NHLBI and at CDC because just in the last two weeks, during the American Thoracic Society Conference that was held here in DC, we launched the first comprehensive national plan for COPD. And of course, since we know that at least 75% of COPD is caused directly by cigarette smoking, cigarette smoking is a strong component of the action plan.

It involves a little bit of the themes that were recurrent here, especially participation and dialogue among diverse components. That plan is not only a federal product but actually more than that, it's a patient-driven product and all the stakeholders contributed to it. There was an open request for information and refinement of the plan along its course. Patients, their caregivers, health care providers, industry, and yes, government, we all participated in making this final product. So, we think it's one of those things that it's possible to realize only if everybody contributes to it. ALA is one of the entities that participated to the plan and each one of us occupies a different niche but all the niches together make the final result.

As another side, I mentioned research earlier this morning. Research is fundamental, just to establish risks of new emerging products, for example. There are things that FDA does but there are things that we can do at a more basic level, understand mechanisms of harm, for example. And my colleague there in the back, Lisa Postow and the institute, were gracious enough to put money into it so that we could study the direct effect of nicotine on the lung and cardiovascular system, things that were not done in detail before. We have six applications we're going to be

funding. And we have a new RFA on the street that is asking to study the effects of e-cigarettes on those same systems.

(McNabb) Thank you, Tony. You raise a broader question on research, especially for our NIH colleagues here. What are some of the areas of research that you think we need to develop in order to achieve our goal? And if there are things that are ongoing, that's great but are there other areas that are underutilized?

(Compton) There are multiple areas that I would suggest that need research. One that's a little bit beyond what we're framing today, which is very much in the clinical realm, is to continue to invest in an understanding of the basic pharmacology of nicotine and how that interacts with reward circuitry and decision making. There's very interesting work just published about how nicotine replacement may have some unexpected effects on decision-making processes.

I wouldn't underestimate the value of these long-term strategies to discover new ways to provide cessation aids for the populations that need them. As much as we're excited by the current technology, really, the effect sizes aren't quite as good as we might like. So, I think we need to continue to invest in long-term strategies as well as the obvious tremendous importance of the implementation work that was the emphasis today. I would highlight our collaborative work that, as I look down the table, we have the leader of our Tobacco Regulatory Science Program at NIH and the leading agency that's providing the funding for that collaborative work between FDA and NIH to fund an awful lot of the science that we hope will inform the regulatory world that Cathy Backinger represents here today. I'd ask them to comment on what research they see as the most promising that we can help them conduct.

(Meissner) Our program really covers a huge spectrum of research, from basic to applied science to informed tobacco regulation. We have a number of large initiatives out right now for centers for tobacco regulatory science. The major scientific domains include behavioral research, addiction, toxicity, health effects, communications, marketing, economics, and policy. So, I think all of those areas are really important for further investigation and a large focus is on new and emerging tobacco products.

(Backinger) The FDA is interested in the impact of tobacco products. When you think about potentially lower risk, it's around modified risk tobacco products. When you think of the continuum of risk, we want to understand how that affects youth initiation, how that affects adults that are smoking cigarettes or other combustive products, whether they move to those products. And we want to understand issues around dual use as well as former smokers that would then take up a tobacco products. So those are all areas that we're interested in and I think that's covered, as Helen said. We will have a new set of TCORS that we hope to be funding in FY 2018, next summer. And we're working with NIH on other funding opportunities. But as you know, we're not the only game in town. NIH has lots of other research so what we do is not taking away tobacco research from what NIH funds. We're supplementing and complementing what NIH funds because we can't fund everything that NIH can fund.

(Meissner) I would just add on something that Tony mentioned, that as a complement to the research and tobacco regulation we're supporting through FDA, NIH can complement that by focusing on mechanisms of disease and treatment in a way that the FDA Center for Tobacco Products cannot do. The Office of Disease Prevention is leading an effort right now, which I can't elaborate on at this point in the development. Working across the NIH institutes to try to address some of the research areas would be complementary to FDA regulatory science.

(Compton) I would like to mention one specific topic that has been implicit in some of the discussions related to e-cigarettes. NIDA is very pleased to have launched a research e-cigarette device, which we hope will provide some standards that can be used to compare to other products and might begin to help us develop a research into e-cigarettes as a tobacco cessation aid. We have so little information about that. People are using them to help themselves quit smoking. We're not sure how well that works. As we saw from the U.S. Preventive Services Task Force, the research rates e-cigarettes an I for effectiveness, an indeterminate level of knowledge. We don't know whether e-cigarette use helps cessation, or doesn't help cessation. We think having a specific product with known pharmacology could be a major step in the right direction, and we're open for your research applications using that.

(Backinger) Keeping up with the changing landscape of tobacco products has been a real challenge for the research. You start a project with, say, one e-cigarette and a year later, there's something else on the market that people are using. Having NIDA develop the standardized e-cigarette will be a real boost to research.

(Augustson) Just two comments. I want to mention a resource that I don't think we've brought up today that is funded by FDA CTP but is under the leadership of NIDA and this is the PATH study. It's a detailed, large cohort that's following these individuals over an extended period of time. I think there's a great deal of information to be gleaned from that. Is it the first two rounds of data that are available or only the first?

(Compton) The first two rounds are now available for researchers and the public use data file on the second round will be available very soon.

(Backinger) They're in the field now on wave four. Wave three data will be coming soon. Researchers are talking to both youth and adults, asking whether they have made a quit attempt and what specific cessation aids have they used. Because it's a longitudinal study, we'll be able to track people over time. At SRNT in Italy recently and the National Conference on Tobacco or Health, data were presented from wave one to wave two. So, we'll be able to see if people are quitting, how they're quitting, what they're quitting with and whether that's going to be sustained over time, or are they going back to combustibles or dual use and all those combinations.

(Augustson) Some information not related to PATH has been briefed to senior leadership at HHS and I'm looking forward to more of those presentations. Not that I'm senior leadership at HHS. The second thing I want to highlight is an effort that Michael Fiori and Robin Mermelstein were the co-chairs on. And this is that NCI did a soul-searching exercise about two years ago now in which we identified what the top research priorities for the Institute were going to be over the next ten years. This document is available on the NCI Tobacco Control Research Branch website. For researchers who are interested, and really for the public health community at large, I'd encourage you to find that document.

(Warner) I think Mike, at the very beginning of the day, gave us a wonderful setup for what we're talking about here today. We're talking about a slice of what produces cessation. And what we all care about is cessation and not starting. But for cessation, the question is how to get there. And I think we all are in agreement, this meeting I think has demonstrated that we can get there faster if we're doing much better at the clinical level than we are. And we're not doing terribly well.

I also heard, and I think this is a correct statement, that it is unlikely that the clinical route is going to produce very large increases in the number of quits at least in the foreseeable future. You'd have to have everybody on board, be very serious about it, have a lot of resources. So, I

think this issue of e-cigarettes is particularly important because we've got data from other countries, specifically England, where there were two studies, Robert West and Emma Beard and their colleagues, very respected scientists who both found an increase of about 8% in the long-term quit rate associated with the use of e-cigarettes in England.

There's nothing we're talking about here today that could do that so far. We don't know whether that's real. It's coming out of two studies, with different methodologies, in two different years, but they both came up with about 8%. They are in a country where e-cigarettes have been encouraged as a means of quitting. We are in a country where we're doing exactly the opposite. We're not trying to discourage people to use them for quitting, but we sure are trying to make them look terrible, with all the evidence that's presented with the fears with regard to kids. I would strongly encourage, and I know, Cathy, that you all are doing this, but I think the more research we can do on this, and the more international research, looking at the environment for e-cigarettes and what seems to be happening as a consequence, would be terribly important. We know from the study presented here that it's the single most used product in quit attempts, according to CDC, but we don't know how effective it is at aiding quitting.

I'm delighted that NIDA has now produced the new NJOY standardized e-cigarette, but I was speaking with one of your colleagues the other day about it and there's a big problem with it. It's tobacco flavored and I understand for financial reasons that they limited the product to tobacco flavor. Adults who are successfully quitting with e-cigarettes don't like tobacco flavor. They like flavors, maybe not bubblegum and all those candy flavors, the kid ones, but they like flavors. So, I would strongly encourage you to try to make another version in a flavor that is appealing to as many such people as possible.

The other thing that's tough here, when you start thinking about experiments, it appears from what we have seen to date that the people who are successfully quitting are using these products, the tanks and mod systems, intensively. The people who are using them a little bit are not having success. So this whole notion of how you would use them has got to be defined and it's going to be a very difficult thing to do. It may be different strokes for different folks. But I do think that this is an enormously important area. It could become much more important with IQOS and the other heat-not-burn products as that gets through the FDA, because that's going to be a different game, folks. Everybody needs to be aware of that. Everybody familiar with the heat-not-burn? Okay, that's going to be a very different game because those products are produced pretty much exclusively by the major tobacco companies. They're going to be sold with very sophisticated marketing, trying to get people to use these products instead of cigarettes forever.

Right now, the major manufacturers of tanks, and mods, and e-cigarettes, they can't do that. They're little squirts. They may get bought out eventually but right now, they'd be thrilled if they could get a year or two's worth of customers substituting them for cigarettes and then getting off of them. So, we've got some very different products coming forward unless, of course, the deeming regulation shuts everything down, which is a very real possibility, except for the major company products.

(Stockmann) At CMS, and I'm speaking for the Medicaid side, we're looking forward to continuing our collaborations with CDC and certainly other partners to really better understand what drives utilization as cessation services are available to people in Medicaid and CHIP. And I think Anne spoke a little bit about the great and very helpful work that the Lung Association does to help us know what is available because there are a lot of states and there's a lot of variation. There have been improvements in coverage, but we still, just like everyone else, see very low utilization of those services, understanding that it's a small slice of what's going to help people quit. But I think there's still a lot that we could learn, particularly with the Medicaid

population and what kinds of partnerships, partnerships with pharmacies, partnerships with public health or public housing facilities, partnerships with FQHCs, what kinds of relationships and systems changes, and quality improvement, actually work.

That micro level drives up utilization of cessation services by people enrolled in Medicaid, because states are asking for that information, state Medicaid agencies. Not every single one but many of them really want to know what's working in other states. We have these services. They're not being used. Can you point me to some examples? And so, we've heard some great, really helpful things today and I appreciate all the presentations. And we're looking forward to doing more work on that in the future.

(Shell) Just a quick question or comment. For all of the studies and projects that have research aspects that are funded, it would be helpful for us at DOD if you potentially could identify active duty status, reserve, guard, and even veteran status. DOD sponsors a lot of research but that's not our primary role. But anything you have, population based surveillance, that you had a question for active duty status, would be helpful for us to compare to the general population.

(Stockmann) The same goes for enrollment in Medicaid.

(Henigan) I just wanted to underscore the importance of something that Cathy talked about earlier and that is that now, the FDA actually does have jurisdiction between, CEDR and CTP, over the full range of nicotine products. It is the deeming rule that gives it that full range of jurisdiction and authority, which has enormous potential, I think, to increase rates of cessation without creating adverse impacts from some of these new and innovative products that we see on the market.

From our perspective, one of the fundamental problems is that the way regulation works now, there isn't a sufficient incentive to develop products that truly help people quit. And the products that are on the market now are falling short, both in terms of utilization and effectiveness. However, because of so many years of no regulation of e-cigarettes, you had incentives develop to produce products without regard for whether they help people quit, but to develop enormous profitability in marketing these products that are in kid-friendly flavors with marketing that appeals to young people, mimicking many of the same strategies that big tobacco used for years to attract young people. So that's where the incentives were and that's where the profitability was. Now, the FDA really between the two centers, if they effectively work together, can develop, as Cathy said, a comprehensive policy that reorders the incentives in a way that actually produces products and maybe some of those products are going to be e-cigarettes that actually help people quit.

My perspective on the deeming rule is very different from Ken's. I think it is the deeming rule itself that actually gives FDA the capability to properly evaluate these e-cigarettes and other innovative products to see if they actually do serve public health.

(Fiore) Deidra, correct me if I'm wrong, but I believe in 2010, CMS awarded large grants to ten states, each of about $10 million, to see if financial incentives could drive healthier behaviors among Medicaid recipients. And of these ten states, I think six of them targeted tobacco cessation solely or in combination with other behaviors. I mention it only because in the next year or two, we should have the results of this information that is going to target both a key population, and that is the poor who smoke at a high rate, with the value and potential of financial incentives. I know we all will await that because I can envision that that could have an impact on how we think about particularly high smoking rates among low-income individuals.

(Stockmann) For those who are keeping score, it's the Medicaid Incentives for the Prevention of Chronic Disease grant. It was a five-year grant that ran from 2010 to 2015. Most of the projects concluded in 2015, 2016. Many of them extended a little bit longer and so last I heard, it was April 2017 for the final report. That has now come and gone so hopefully within the year, we will have the final report and know a little bit more. But maybe not a ton more.

(Curry) I just want to review a little bit where we are and then I have a suggestion for where to go. We have the benefit in smoking cessation of a very robust research portfolio. The field came together, developed common measures or standard measures, and defined intervention components in relatively consistent ways. There have been rigorous longitudinal randomized controlled trials. We've been able to aggregate to meta analyses.

When we stop and think about where we need to go in the future, we have to be sure that we pull through that foundation. So, I'll put on my Preventive Services Task Force hat again and say that every recommendation that we publish – and we have several in tobacco and tobacco cessation – has a section on research gaps. In every recommendation that we make, there is a published research plan for the evidence-based practice centers that has something in it called PICOTS – Population Intervention and then COTS. I can't remember what it all means. If this is a quiz, I would have just failed. But those are very important resources as funders think about the kind of studies that they are funding. And as advocates for pulling new products or innovations into the cessation realm want to advocate for having new innovations brought in, they should have to get over the same bar that our research now gets over. And we know what those bars are, so I just would encourage at the research end that we think about those things.

(Meissner) The Office of Disease Prevention has been going through all of the I statements – maybe you're aware of this, Sue, the I statements in the U.S. Preventive Services Task Force and asking the Institutes periodically how they are addressing those research gaps.

(Keller) I was thinking about something that Dr. Schroeder said at the start of this discussion about innovation really occurring at the state level over the next few years. But I still think federal agencies have a great opportunity with respect structuring funding announcements. And I'm thinking along health care reform initiatives and value-based insurance design, and as announcements are structured, how can tobacco cessation be elevated as a priority within these types of health care reform initiatives?

The value-based insurance design is to really move toward more of a preventive- care focus, giving people incentives to adopt healthier behaviors and prevent higher costs for services that provide less value. We've got, as we've been talking about today, we've got such a great body of knowledge demonstrating that addressing tobacco cessation is clinically effective and cost effective. So, I think there's a great opportunity for agencies to take that information, integrate it into the funding announcements, and layer in the quality measures and the promotional expectations to really help move the needle.

(McNabb) Thank you. All right, on that I'm going to give the last word to our acting chair, Dr. Novotny. Tom, take us away.

(Novotny) Thank you and thanks to you all for this really stimulating and scientifically informative discussion about cessation science and how it fits into our larger objectives on tobacco control. There are plenty of things to summarize from this meeting and I just want to point out a couple of things. One, as Ken pointed out, this is a slice of what happens for a comprehensive tobacco control process but it's a necessary one. One might consider it low-hanging fruit, but it's not that easy a low-hanging fruit you just pull down off the tree.

What that means is that we need to continue to think in terms of innovations, and we had several ideas here, starting with things like automating identification of smokers within a health system. The VA has done a really great job at that, and now at the state level or system level that's also important. And integrating cessation into treatment centers for certain disease conditions, such as in cancer centers; that's a no brainer. It should have been done decades ago. And that could be extended to other kinds of identification processes. I worked recently on TB and smoking interactions. We don't have that much TB in this country, but TB is complicated by smoking for sure, and identifying those patients with respiratory diseases, such as COPD that we mentioned earlier would also be, it seems, a no brainer. It should be automatic for identifiable conditions that would have a set protocol to identify tobacco use and get after it.

As Ken also pointed out, if someone has hypertension or diabetes and is not screened for smoking status when they have these risk factors, the medical system would be held accountable for not picking up on that. And I think there perhaps might be opportunities for accountability in terms of identification and pursuit of tobacco cessation among patients in the health care system. Dr. Price has really pointed out the importance of patient-centered care and I think that's really what we're talking about throughout this discussion here. And I think the mention of precision medicine and targeting, and really trying to understand the patient, reinforces that notion in the context of smoking cessation. I think it will help fuel what we can do here in the department going forward.

I want to continue to encourage product regulatory science, not only for regulations on existing products, but on the new products as well, to make sure that they meet the rigor for safety and efficacy that we've been accustomed to expect. Even with the products that are on the market now, we can look at whether there's something that could be done to regulate them so that they can be more amenable, or useful, or supportive of smoking cessation.

I also think that the partnership perspectives are really important, especially with technology, and big data, and the people who do those things so much better than we do, to bring them into this activity as a public good. And I think it would be very positively accepted.

I really think that the issue of tobacco sales in pharmacies is something we can deal with. It's another low-hanging fruit. We can discuss that and figure out ways of supporting pharmacies as a tobacco-free environment that is a health care delivery system rather than just a retail store that sells both drugs to stop smoking and cigarettes that support smoking. I think it's a possibility and that we should use what we know, based on what CVS and others have done, to support that effort. The leveraging of state activities by the Feds is something that needs to be considered. What things can we do at the federal level that can help support the states, because that's increasingly where the action on health care and public health policy, of course, has always been? Maybe there's something we can do in terms of pharmacy sales to help states go after that goal.

This cessation slice of tobacco control is extraordinarily important. It is cost effective and so necessary for us to continue to understand in terms of our health care financing and whether or not Medicaid can be, again, encouraged, at the state level and with federal encouragement, to support those clinically demonstrated effective cessation programs in a comprehensive way, not just piecemeal.

I just want to, again, thank you all for this. I've had a really great educational opportunity here again and look forward to the next meeting. And again, I want to thank Simon and the rest of the staff from CDC for their great organizational work and sustained support for this activity.

(McNabb) Thank you, Tom and on that note, this meeting of the Interagency Committee on Smoking and Health is adjourned. Thank you all. Until next time when we will talk about tobacco use and behavioral health.

I certify that this report of the May 31, 2017 meeting of the Interagency Committee on Smoking and Health is an accurate and correct representation of the meeting.

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Chair, ICSH

Interagency Committee on Smoking and Health
Increasing the Impact of Evidence-Based Tobacco Treatment
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May 31, 2017

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