

UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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CENTER FOR TOBACCO PRODUCTS

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WATERPIPES: A PUBLIC WORKSHOP

+ + +

March 17, 2016
8:30 a.m.

Food and Drug Administration
Building 31, Room 1503
10903 New Hampshire Avenue
Silver Spring, M.D. 20993

FDA:

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SESSION 1: GENERAL REVIEW, WATERPIPE TOBACCO PREVALENCE AND USE IN THE US

WASIM MAZIAK, M.D., Ph.D.
Florida International University

BRIAN KING, Ph.D., M.P.H.
Centers for Disease Control and Prevention

KENNETH D. WARD, Ph.D.
University of Memphis School of Public Health

ERIN L. SUTFIN, Ph.D.
Wake Forest School of Medicine

SESSION 2: WATERPIPE TOBACCO TOXIC EMISSIONS AND HPHC EXPOSURES

ALAN SHIHADDEH, Sc.D.
American University of Beirut

MARIELLE C. BRINKMAN
Senior Research Scientist
Battelle Public Health Center for Tobacco Research

SESSION 3: DESIGN PARAMETERS, SECONDHAND EXPOSURES, ENVIRONMENTAL CONCERNS AND MATRIX FOR REFERENCE PRODUCTS

RONALD EDWARDS, M.Sc.
Biologist
FDA Center for Tobacco Products

MARIELLE C. BRINKMAN
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Johns Hopkins Bloomberg School of Public Health

SESSION 4: WATERPIPE TOBACCO PERCEPTIONS AND POPULATION HEALTH

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ISAAC LIPKUS, Ph.D.
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M E E T I N G

(8:30 a.m.)

DR. DRESLER: Good morning. It is 8:30 according to my atomic time clock, and I would like to welcome everyone to the FDA Center for Tobacco Products workshop. And as some of you may have noticed, I am attired in green. But this is not a menthol workshop, as some of you may be thinking. But I am half-Irish, so I'm unabashedly wearing one of my favorite colors. And I won't wear the hat the whole time, but I couldn't resist because it just went with everything else.

So again, welcome to these 2 days for the waterpipe workshop. We're really excited about it because personally it's a topic that I don't think gets as much airtime as some of the other tobacco products that are out there, yet we know it is increasing, as we'll be hearing. So, much interesting science around waterpipes, which again I am eager to hear. So welcome to it. I think it's a very exciting 2 days. And we'll move forward.

A couple of things I went over with the speakers before, just to say how we kind of do it. We have up here green and yellow and red lights, which are controls. Because all the speakers know how long that they've been given to speak, and in

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order that we can get all of the speakers done, we will try and run it on time, which is kind of why I think that they're having me do this, because I'm, you know, shy and retiring for getting people to stay right on their time. So that's what the lights are for, and the speakers will all be following that.

We have a kiosk that is around the corner that you might want to think -- if it's working how it usually does, if you go out at the coffee break and order what lunch that you would like to have and pay for it, then there's a shorter line when you go out there at lunch. And I think since most of our participants on this workshop are online, it won't be such a long line here. But that's at the coffee break, if you would like to be able to do that.

What we will do is we'll have a couple of introductory speakers, and then we'll have the first session, and then we'll have a panel discussion where we will take questions from the audience that will pass in their cards with their questions on them. And we will also take questions from people that are online.

So with that I would like to introduce Rear Admiral Dr. David Ashley, who is our Office Director of the Office of Science within the Center for Tobacco Products, with an

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unparalleled knowledge of tobacco products, who will be giving us introductory remarks.

David?

(Applause.)

DR. ASHLEY: Thanks, Carolyn. And good morning, everybody. On behalf of FDA Center for Tobacco Products, I want to welcome everybody who is here in the auditorium and those folks that are watching online. We are very excited about having this. This is our first workshop on waterpipes or waterpipe tobacco, hookah -- it goes by lots of different names. But this is the first of those. And as Carolyn said, this is a subject that doesn't seem to get as much press. It doesn't seem to get as much discussion. But it is of very much interest to us. This is another in the series of products that if the deeming rule goes forward, it is included in the definition of tobacco products and would be deemed under our authority. So we're very interested in information around this product.

We have held in the past -- we will continue to hold -- workshops on the science of tobacco products. It's an opportunity for us to gather scientific information. So we are looking at lots of different ways. We go out and read the

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peer-reviewed literature. We go out and talk to experts. And we also hold these workshops to gather information together for us to make good scientific decisions as we go forward with regulations.

Over the past 5 years, we've held really quite a wide variety of workshops. We've held workshops on modified risk tobacco products. We've held workshops on analytical methods for measuring HPHCs. We've held workshops on e-cigarettes. So we've held lots of different workshops, and those are just an opportunity for us to gather information in. We've also got, for a little plug, another workshop that's scheduled for next month on biomarkers of harm. That will be our second in a series of biomarker workshops, again for us to gather scientific information for us to know better.

We have found these to be very informative, very helpful. The speakers have brought in new information and things we were not aware of in the past. They have been really, really helpful to us.

Now, today's workshop focuses, as I said, on waterpipes and waterpipe tobacco. As you'll hear in the presentations as they go forward, the prevalence of waterpipe use is particularly high among adolescents and young adults. We have

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seen similar changes as we have seen with e-cigarettes in waterpipe use over the past few years. And we want to ensure that progress that's made in reducing cigarette use does not translate over into increased use in other products like waterpipes.

There is lots of aspects of waterpipe use we really don't fully understand -- things that are questions to us that we want to know more about, including how people use waterpipes. Waterpipes generally aren't used like cigarettes. We're trying to understand more about how they're used, the behavior and the factors that go into people's decision about using waterpipes. We also want to look at the levels of potentially harmful constituents in waterpipes, and what does that mean in terms of regulatory decisions that we will be making? We're also interested in long-term and short-term health effects of waterpipe use. All those factors are important for us to understand more and to be able to make the right decisions.

So there is going to be a real range of topics discussed over the next 2 days, including product design, smoke constituents and emissions, of HPHCs, exposures to users and nonusers, the environmental impact of waterpipe use, prevalence, patterns of use, people's perceptions of waterpipe

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use, addiction and the impact of marketing of these products on population health. Although we don't currently regulate waterpipes, as I said, they are included in the proposed rule for deeming. And so the information we are gathering today would be information we would use as we move forward with making decisions later, if those products do end up being included in the deeming rule.

Last month, in February, we published a *Federal Register* notice of this public workshop, requesting information on waterpipes and waterpipe tobacco. So information that others have outside of what's being presented today can also be submitted to that docket so we can gather information from those people who don't get the opportunity to present here.

So that's it for me. Thank you all for coming. I think this is going to be a very interesting 2 days. I do have to apologize myself. I'm not going to be able to stay as long as I'd like to. You might not be surprised; there's a lot of things going on, and I've got to deal with a lot of those. I will stay as long as I can, but then I will have to get up and leave. But we have plenty of folks from the Office of Science here in the room, and also folks that are watching online. So everything that the panelists and the presenters say, we will

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be taking note of and really appreciate your participation in being here. So thank you very much.

(Applause.)

DR. DRESLER: Thank you. And I'll also add that this is being recorded. So not only is it webinared, but it's being recorded, and there will be a transcript that will be available afterwards.

Our next presenter will be the scientific lead for this workshop, Dr. Baoguang -- I always call her Baoguang. I'm sorry. Baoguang Wang. So please come on up. She is the one who has actually done the hard work for putting this together and working with the scientists for this. So Baoguang.

DR. WANG: All right. Thank you, Carolyn. I think I'm going to hide behind the podium. But it's important that you can hear me. And good morning, everyone. My name is Baoguang Wang, and I am an epidemiologist at the Office of Science Center for Tobacco Products here at the FDA. I'm also scientific lead for this waterpipe workshop. I too would like to welcome everyone, both people in this room and those who are attending this workshop online.

Before I begin my presentation, I'd like to make it clear that the information in this presentation is not a formal

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dissemination of information by the FDA and does not represent Agency position or policy. In the next 10 minutes, I will give you some background information about this workshop, its purpose and scope, and I will also briefly discuss or describe the topics that are going to be covered today and tomorrow.

Many of you are aware that the Family Smoking Prevention and Tobacco Control Act, or TCA, signed into law in 2009, granted the FDA immediate authority to regulate the manufacture, marketing, and distribution of cigarette, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. TCA also gave the Agency the authority to deem other products that meet the statutory definition of a tobacco product as subjected to regulation under the TCA.

In April 2014 FDA issued the deeming proposed rule over other products that meet the statutory definition of a tobacco product, such as waterpipes, electronic cigarettes, cigars, and certain dissolvable tobacco products that are not smokeless tobacco, and gels. As a reminder, the comment period for the deeming rule ended on August 8, 2014, after a 30-day extension. Should the Agency move forward to regulate waterpipe tobacco as proposed, additional information about the product will assist the Agency in carrying out its responsibilities under the law.

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And this workshop is a platform to obtain additional information. So the purpose of this workshop is to gather scientific information and stimulate discussion among scientists and the other interested parties about waterpipes and waterpipe tobacco.

This workshop is intended to address a wide range of information on waterpipes and waterpipe tobacco smoking. We will be hearing presentations and panel discussion about the current state of the science. We will also focus on the waterpipe tobacco toxicity and toxic emissions, exposure to harmful and potentially harmful constituents, or HPHCs, including secondhand exposure, design and environmental concerns, prevalence, perception, use patterns and addiction, and the individual and population health. This workshop is intended to better inform the FDA about the products through an open exchange of scientific information but is not intended to seek advice or consensus.

Here, I would like to point out that there are going to be FDA presentations during this workshop. So there are going to be FDA presentations during the workshop. I would like to make it clear that information in the FDA presentation is from public sources and is not information from industry under the

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FDA regulatory authorities.

We have a packed agenda and very interesting topics today and tomorrow. We will hear presentations from speakers from academia, government, private organizations, and the general public. We will also embrace technology and have speakers presenting remotely during this workshop. This morning, we will begin our Session 1 presentation with a general review of waterpipe and waterpipe tobacco, including history, culture, changes over time, when and how these products spread to the United States.

After that, we're going to hear a presentation on prevalence and use patterns of waterpipes and waterpipe tobacco. We also have a topic covering trajectory of waterpipe use, and the last presentation for the first session will be a topic on prevalence and correlates among college students. At the end of this first session, we are going to have a 30-minute panel discussion when our speakers will have the opportunity to answer questions from our audience.

After a short break, we are coming back here to have a discussion or hear presentations on Session 2, Waterpipe Tobacco Toxic Emissions and Toxic Exposures. There are two topics under this session. The first one is the toxicity: what

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is in the waterpipe and waterpipe tobacco smoke. And the second topic is going to be about a tool for testing waterpipe components and toxicants. And then we have a panel discussion for Session 2 combined with Session 3.

So basically after the two presentations for Session 2, we take a lunch break. And then after lunch break we come back for Session 3 presentation, Design Parameters, Secondhand Exposure, and Environmental Concerns. Under this session, we're going to be covering topics on considerations of an environmental impact analysis of waterpipes, the influence of testing protocols and waterpipe designs and toxic emissions from waterpipe tobacco smoking. And we will also cover a topic on secondhand smoke, environmental concerns and the health effects. At the end of this session, Session 3, we will have a panel discussion covering or addressing the questions from the audience for both Session 2 and Session 3. We combined the panel discussion for Session 2 and Session 3, then. This is different from Session 1.

Then after a short break, we come back for Session 4, Waterpipe Tobacco Perception. We are going to be covering the topics of perception, susceptibility, flavor, appeal, and marketing.

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We will begin our Day 2 presentation for Session 5 -- actually, we are going to have a general public session before our Session 5, and so following the public session we will have discussions and presentations under Session 5, Waterpipe Tobacco Dependence, Topography, Use Behavior, and Systemic Exposures and Responses. The topics under this session include dependency in waterpipe smokers, waterpipe topography and exposure, and the clinical pharmacology research for waterpipe use.

Finally, we're going to be talking about Acute and Long-Term Health Effects under Session 6. The topics are cardiovascular and pulmonary health effects among waterpipe users and waterpipe use. And we are going to also have a topic on cancer risk and waterpipe use and the mortality. Finally, we are going to be talking about infectious disease transmission risks in waterpipe use.

I'm very excited about this workshop and the opportunity to learn more about waterpipes and waterpipe tobacco from our distinguished speakers around the world. I'm glad you are here, and thank you for participating in this workshop.

(Applause.)

DR. DRESLER: Okay. With that, let's move on to our first

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session in the session General Review, Waterpipe Tobacco Prevalence and Use in the US. And our first speaker is Dr. Wasim Maziak from Florida International University, speaking on The Waterpipe: Beginning, Spread, Health Effects, Dependence, and Policy/Regulation.

Wasim?

DR. MAZIAK: Good morning, everybody, and thank you very much Carolyn and Baoguang and Caryn for organizing this important workshop and inviting us to it. I could have ended up in another place today because I went to the shuttle and asked the shuttle driver is this the FDA shuttle. He said yes. And I sat, and then people start giving me weird looks. So I went back to the driver and said is this the FDA shuttle. He said no, no, no, this is the SDA shuttle. And that was the Seventh Day Adventist shuttle. So I might have ended up, one can argue, in a better place. But who knows.

(Laughter.)

DR. MAZIAK: So I'm going to provide an overview of the waterpipe. It's a very huge problem. It has many aspects and many particularities, and the first message that I want to convey to you -- the waterpipe is not a cigarette with a water bowl. It's totally different. The context, the use, the

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experience, the dependence, and even the financial interests behind it does not follow the classical cigarette tobacco industry model. So keep that in mind, please.

I want to give acknowledgement to my team that I've been work with on the waterpipe for more than a decade, and my funding through Fogarty and NIDA in particular.

So what is the waterpipe? This is -- the figure up actually describes the way most commonly waterpipe is used nowadays. As you can see, the coal usually is put on top of aluminum foil that is perforated, and below it is a bowl that has the mixed tobacco product. So when the smoker inhales from the mouthpiece, a negative pressure is created, and air comes through the wall, gets heated, heats the tobacco mixtures, produces the flavored smoke that bubbles through the water and gets to the smoker. And that kind of mechanism underlies much of the harm-reduced perception among waterpipe smokers, because they think the tobacco or the smoke is filtered somehow through the water. But we know now that that is not the case.

The origin of the waterpipe or, as it's known in many cultures under different names, which is shisha, narghile, hubble-bubble, or a hookah here in the U.S., is very vague. We know that the first mentioning of the waterpipe was in a

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Persian poem from the middle of the 16th century, but we think the habit was there during that time, but it was not probably with tobacco, because tobacco was introduced to that region in the 17th century. So it probably started with something else and then morphed into tobacco.

It has been part of the culture of the Middle East and Far East societies, and as you see this, the public exhibition of waterpipe use was mainly in a form of older men smoking the waterpipe. But we think that there is also considerable historical use of waterpipe by women, because it's frequently depicted in the art, although not publicly exhibited.

So what happened? I mean, up until the '90s there is nothing -- nobody in public health would have thought of the waterpipe. It was a declining practice among older men, mostly in the Middle East. But something happened in the early 1990s that kind of catastrophically led to an increase in waterpipe use in that region and into broadening the spectrum of who uses it, and that then got transferred to all other parts of the world. So this is where we started before the 1990s, where older men would be the typical smokers of waterpipe, whereas recently it's youth mostly, and it's girls and boys and women and men equally.

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So what are the main factors behind the recent explosion in waterpipe use all over the world? We think that there are several main factors. The most important of them, we think, is the introduction of flavored manufactured tobacco, which is called maassel. Maassel is from honey, so it's a sweet and flavored tobacco that was introduced in the early '90s. The Internet and other social and multimedia helped to actually transfer the habit all over the world and particularly probably in the U.S. There is also the reduced harm perception that encourages young people to use the waterpipe, and the thriving café culture and the allure of social environment of waterpipe smoking in a café setting is also very powerful for youth. And, of course, we don't have much policies or regulation to limit that kind of free spread, and that probably was a contributing factor to the waterpipe epidemic.

I want to focus a little bit on the flavored waterpipe tobacco, because we think it's a cardinal factor behind the spread of waterpipe, and also it's one of the factors that can be brought under regulation. So what happens -- I always kind of make similarities between the introduction of flavored waterpipe tobacco and the Bonsack machine, the introduction of the machine that rolled cigarettes, how it industrialized and

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commercialized and allowed mass production of essential waterpipe component and helped kind of spread it globally. Also, we know flavoring is very appealing to youth, and you can have any flavor that you can think of, from bubblegum to Coke to coffee to soda, in waterpipe tobacco.

It made also the smoke milder and smoother. The way originally waterpipe was smoked was with raw tobacco that was mixed with a little bit of water, then pressed and put so that it produced really very harsh smoke. The sweetened and flavored tobacco, according to smokers and according to personal experience, produces way less harsh and really a smooth tobacco with aromatic kind of scent. It is kind of way more pleasant to begin with. Also, the flavored tobacco allowed the mass marketing and sales through the Internet, which is the medium most favorable to youth.

This is a study that Dr. Ramzi Salloum will talk more about, but we looked at some kind of hypothetical scenarios and we presented to smokers and looked at their choices whether to smoke the waterpipe or not, and as you see here to the left, no matter who are these smokers, they were way more favorable of the flavored variant rather than the unflavored. So the unflavored tobacco product -- when we presented that scenario,

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very few actually thought that they want to smoke the waterpipe with that kind of tobacco, just showing empirical evidence of the importance of flavored tobacco for waterpipe smoking.

So why the waterpipe is an emerging public health problem? I think there are three essential factors that we need to be alert to, the spread, the harmful effects, and the addictive properties. That kind of makes sort of a perfect storm for any public health problem.

Let's talk about the spread. Brian, I think, will do more due to epidemiology of waterpipe smoking, but I picked some examples that show the global spread of waterpipe smoking. The figure to the left is from the Global Youth Tobacco Survey in the Middle East, and the dark columns represent the waterpipe and the gray columns represent cigarettes. And as you see in most countries in the Middle East, actually waterpipe use among 13 to 15 years old is becoming the number one tobacco use method.

The figure to the right is from the Global Adult Tobacco Survey, and you can see consistent and significant spread among adults in countries actually that have not much Middle Eastern communities or even connection to the Middle East. So that kind of shows the global appeal of this tobacco use method.

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The trends are very alarming, especially in the United States. This is a very simple picture that shows the dynamics of epidemiology between waterpipe and cigarettes among high school students in the U.S. from 2011 to 2014, and it is based on the National Youth Tobacco Survey. So starting from about less than a third of the level of cigarette smoking in 2011, it more than doubled and became on par of cigarette smoking in 2014. This is current tobacco use these past 30 days.

The view among adults is not less dangerous, and this is data we published recently based on the National Adult Tobacco Survey, looking at 18-to-24 age group, which is the prime group for smoking. And as we see, the same kind of picture -- waterpipe is now on par of cigarettes in terms of spread, and it's affecting about one-fifth of that population.

This is a kind of overcrowded a little bit slide, but it's based on surveillance data from around the world, and the simple message that I want to convey in this slide is that intermittent use actually is the most predominant use pattern among waterpipe smokers, which is very unlike what we see in cigarettes, where most use is daily.

But intermittent tobacco use method can be as harmful as cigarettes because the length of smoking bout, which always or

usually averages an hour, is way longer than with cigarettes. And the charcoal adds another dimension of harm that we don't see with cigarettes. So let me briefly speak about the harmful effects of waterpipe use.

Three lines of evidence show how serious this is, from the public health perspective. The first line of evidence comes from machine-smoked waterpipe and cigarettes comparison, allowing to look for toxicants and carcinogens in the smoke and compare waterpipe with cigarettes. So this very simple basic table shows how enormous the exposure to tar, with one waterpipe session compared to one cigarette, and a significantly larger amount of CO, probably coming mostly from the charcoal, and also considerable exposure to nicotine. But these are machine studies. So what about human exposure studies?

Here we come to the second converging line of evidence, when we see that the figure on the left is a study we did. Very simply, we measured breath CO before and after waterpipe use and compared it to breath CO before and after cigarette use. And you can see a way larger exposure to CO for the waterpipe session compared to the cigarette. For this study to the right, we looked at urinary tobacco-specific nitrosamines

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in exclusive waterpipe smokers compared to exclusive cigarette smokers compared to nonsmokers. And we see more nitrosamine exposure with waterpipe smokers compared to nonsmokers, and the difference between active cigarette and waterpipe, although it looks kind of significant, is not significant.

The third line of evidence about the health effects come from association study with health effects. And there is plenty of them, and probably Dr. Ward will talk about that -- and others -- in later sessions. But we still actually lack the type of studies to show the long-term heart effects or clinical effects of waterpipe smoking. One factor that is probably contributing to that is the recency of the epidemic. For those kind of long-term effects, you need probably a couple of decades to start having significant amount of significant numbers of those people to be able to detect, in the way we did with the 1950s first studies that showed the cancer potential and cardiovascular potential of cigarette smoking.

How about harm to others? This is a study done in Germany, and the blue line is CO exposure anchored on the right axis, and the dotted line is particulate matter anchored on the left y-axis. And you can see when you have waterpipe smoke in the room, you have a large increase in particulate matter and

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CO in indoor air. To give you some perspective, the arrow actually shows what is allowed under the current guidelines for exposure to be, particulate matter 2.5. So you see -- like, in a multi kind of -- I mean, way larger emissions of particulate matter and CO than what is allowed. And that poses potential harm to nonsmokers, considerably.

Let me talk about the third component of why this is a public health problem, about waterpipe dependence. I'll go in more details tomorrow about these questions, but there are several key questions to answer to characterize dependence of waterpipe smokers: Does it deliver nicotine? Is it associated with common craving withdrawal symptoms? And the other factor that is important for designing tailored interventions, what are the differences between nicotine dependence in waterpipe and in cigarette smokers?

This is a simple study. We did two studies actually. One, we measured plasma nicotine before and after waterpipe smoking and compared it to cigarette. As you see, the blue column shows higher nicotine exposure after a session of waterpipe smoking compared to a session of cigarette smoking. The figure to the right shows the pharmacodynamics of exposure to nicotine among waterpipe smokers compared to cigarette

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smokers. So this line is waterpipe smoking, and this is cigarette smoking, and the scale is 5 minutes time here in the bottom. So you see gradual less acute increase in nicotine level in plasma levels in waterpipe smokers, that reaches actually higher accumulated exposure compared to cigarette. In cigarette, there is a more acute increase in the first 5 minutes because it actually takes only 5 minutes compared to waterpipe.

How about abstinence-induced withdrawal or craving? We did a very simple study where we brought people who were overnight abstinent waterpipe smokers and asked them to rate their urges to smoke, restlessness, craving -- these are common symptoms that people feel, what we know from the cigarette literature when they abstain from smoking. And sure enough, we saw a high level before they smoked the waterpipe, and these high levels of urges and craving were ameliorated after smoking a single session of waterpipe.

How about whether it's different in some aspect than dependence in waterpipe smokers compared to cigarettes? We think this is a very important factor because it's mostly intermittent use. It's a prolonged tobacco use method. Accessibility is not as easy as with cigarettes, so that has

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also kind of influenced how craving and withdrawal and all these manifest. And it has a very, very strong social component. And we think this can be an essential part of the dependence complex, as we say, for waterpipe smokers. I'm only listing some qualitative evidence about that kind of difference that we think from a study we did several years ago.

So this is one waterpipe smoker's kind of testimony. "I usually smoke narghile" -- narghile is the local name of waterpipe in the Middle East -- "once a day, but sometimes I smoke more, because even when I have already smoked it, seeing or smelling narghile makes me feel that I need to smoke again. And I usually do smoke."

What are the policy and regulatory implications of the waterpipe epidemic? The first, that we need to establish surveillance that is waterpipe specific, using instruments that are waterpipe specific. The second important aspect, clean indoor policies need to include waterpipe venues, because they pose significant exposure, as we see, to particulate matter and so forth. And warning labels and content descriptors should be an essential part also of the policy of waterpipe smoking. And we need to start the same counter-advertisement that was done with the cigarette, with negative health effects and limit

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marketing of waterpipe through the Internet mainly using deceptive descriptors.

Thank you. I'll stop here.

(Applause.)

DR. DRESLER: I do feel bad because, Wasim, I have so many questions that I don't even know we'll have time in the panel. So that was a fascinating start. So thank you very much.

Our next speaker is Dr. Brian King from the Centers for Disease Control and Prevention, speaking on Prevalence, Use Patterns, and Waterpipe in Special Populations, such as Youth, Young Adults, Pregnant Women, and Women of Reproductive Age.

DR. KING: Great. Well, thank you for the opportunity to speak today. I am Brian King with the U.S. Centers for Disease Control and Prevention. I am the Deputy Director for Research Translation in the agency's Office on Smoking and Health.

First, I'd really like to commend FDA for convening this workshop. I can tell you, in my capacity I do hundreds of talks on tobacco, and I can probably count on one hand the ones that are exclusively on the issue of hookah. So it's certainly an increasingly important and frequently overlooked topic in the field of tobacco control. So I think that's quite nice that we're convening today to really do a deeper dive on this

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topic.

So for my part in today's session, I'll be speaking on some patterns and correlates of waterpipe and hookah use among U.S. adults and youth. Again, I'm specifically focusing on the domestic scenario using some major surveillance tools. And just for some funding and disclosure statements, I have no conflicts of interest for funding sources to declare, although I will say that I am an employee of the Federal Government. So depending on who you ask, that could be a conflict of interest. And also what I'm about to say to you is not the official position of the U.S. Centers for Disease Control and Prevention.

Okay, so in terms of an overview, this is where we're going to go today. Four major buckets of demographic groups that I'll be presenting some patterns of use to you: We'll start with U.S. adults more generally, then do a deeper dive into younger adults and women of reproductive age, and then finally youth. So you've seen a brief snapshot of patterns of use from the previous presenter, but we'll go in a little deeper dive for this particular session.

So before I get into the slides of the actual estimates, I'm just going to explain the data sources that I'll be using

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today. The first is the National Adult Tobacco Survey, and this is going to be the estimates we present among adults. This is a random digit dial survey of U.S. adults 18 years and older. It's a telephone survey, and it's both landline and cellular, in 50 U.S. states and D.C. It was first fielded in 2009 to 2010 by CDC. There was national and state representative estimates. Hookah use was asked. It was a past 30-day measure. Then, beginning 2012 to 2013, CDC partnered with the FDA to conduct the survey, and it was only nationally representative. And then in 2013 and 2014 we repeated that survey.

Today, I am going to be presenting you estimates for 2012-2013. The '13-14 data just came in. We're in the process of cleaning those, and those should be publicly released later this year. But currently the publicly available data is what I'll be presenting, which is 2012-13. And those are available on CDC's website.

In terms of the youth data, those will come from the National Youth Tobacco Survey, which is middle and high school students. That's grades 6 through 12. It's a school-based pencil and paper survey in 50 U.S. states and D.C. It started back in 1999. We've used this as a standard since then for

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measuring youth tobacco use. Beginning in 2011, CDC and FDA began partnering to conduct this survey annually. And 2011 was also the year that we added estimates of hookah use among youth, and that was in a "list all" response option, among other different tobacco products.

Okay, so without further ado, I will start with some estimates among adults. So in the National Adult Tobacco Survey, we did something interesting in 2012-13, and we added a "rarely" response. So, many of you who are familiar with tobacco surveillance know that for years, since back in 1965, the National Health Interview Survey has assessed cigarette smoking using every day and some days. So there's 100 lifetime threshold. You have to use cigarettes at least 100 times, and then do you use it every day or some days.

Beginning in the NATS survey for 2012-13, we added that "rarely" option. And that was particularly important for emerging products, and I use that term "emerging" to describe hookah, even though we know it's been around for years, to really articulate the type of users. And as you can see from this slide, it's really quite important when you're assessing this product, because when you account for rarely users, you'll see exponentially higher rates of use.

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So the dark bar on this slide and the ensuing slides is going to be every day or some day use, and then the light one is going to be every day, some days, or rarely. And the addition of rarely considerably increases the use patterns. So you see overall in 2012-2013 about 4% -- 3.9% of U.S. adults currently used waterpipe or hookah every day, some days, or rarely.

Now, in the 2009-2010 survey, we didn't use the same metric. It was a past 30-day measure, but it was about 1.5%. So we can't make a direct apples-to-apples comparison, but gleaning from those older data, we can see that there have been increases in hookah over time. But we'll know better once we repeat this measure in future years, to really glean what the patterns of use are temporally among adults. And as you can see from this slide, prevalence is higher among men than women, particularly when you count for that rarely use.

So here is some variation by age. And I've included some icons up in the top right, just to give you a feeler for what demographic factor we're assessing. And it's also highlighted at the top because these are all very similar. So just so you can follow, this is age. And it's no surprise here that use is considerably higher among younger adults. So age 18 to 24 you

see 18.2% currently use hookah every day, some days, or rarely, and you see declines as the individuals get older. About 4% of 25 to 44 years old, which is fairly comparable with the general adult prevalence, and then even lower, at .4%, for 45 to 64. And the greater than 65 was so low that we couldn't even produce a statistically stable estimate among this group.

So here is some variation by race/ethnicity. Again, some variability. It's higher among those who are other non-Hispanic race ethnicities and Asian non-Hispanics. That does include individuals of Middle Eastern descent, where we typically see high prevalence of use. It's lower among non-Hispanic black individuals and among non-Hispanic whites, about 3.6%. And among Hispanics, it's around the middle -- around 4.6% overall for that every day, some day, or rarely use.

Here's some differences by education, and this is really interesting. Because for conventional tobacco products, like cigarettes, we've always seen a longstanding gradient where the higher the education of the individual, the lower the prevalence of use. And we don't actually see that with waterpipe. You see that it bounces around a bit. And we actually see the highest prevalence of use among those with some college but no diploma and those with high school diploma

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and GED. But then on either end of the spectrum, it's fairly low and comparable. So those with 0 to 12 years of education and no diploma about 2%, which is similar to what you see with those with a graduate degree. So this is really distinct for this tobacco product. And you don't see this for other conventionals. It's normally that standard gradient. So there is some marked variability by education.

The same follows for income. It's actually a reversing trend. So with conventional tobacco products like cigarettes, you'd typically see lower prevalence of use as individuals have higher income. In this case, you actually see increases. So people who make more money have higher prevalence of use. It's about 3.4% among those lower than \$20,000 per annum for household income, and around 4% for those making 50,000 or more, and then 100,000 or more.

Here's some estimates by region. Not much variability by region. It's fairly comparable: slightly lower in the South, about 3.5%, in contrast for other conventional tobacco products. We typically see higher prevalence of use in the South and Midwest. So again, hookah is an interesting entity because you're seeing reverse patterns of tobacco use than what you see for other conventionals. In the West is the highest,

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at 3.4% for every day, some day, rarely use.

So sexual orientation is an important variable to include. We first started including it in the 2009-2010 tobacco survey, and there's an increasing body of evidence demonstrating that those in the lesbian, gay, or bisexual, and transgendered individuals have a higher prevalence of tobacco use, and hookah and waterpipe is no exception. These data present variation by heterosexual/straight individuals and lesbian, gay, or bisexual. You'll note that the T for transgender is not there because this variable did not include transgendered individuals. So it's not generalizable to the entire LGBT population. However, you can see a marked disparity and prevalence of use, particularly that every day, some day, rarely: 3.5% in heterosexual/straight adults and nearly threefold higher among lesbian, gay, and bisexual adults. And those with unspecified sexual orientation, it was about 5%.

Okay, so in terms of frequency of use, this is a figure from *Morbidity and Mortality Weekly Report* that was released by FDA and CDC in 2014, and this really gets at the frequency of use of those who have ever used hookah. So that bar in the middle with the orange around it is waterpipe hookah, and you can see that among those who have ever used hookah, about 70%

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currently use it not at all. So there's a lot of people that are trying it and then they don't try it again. In contrast, a lot of the rarely use is -- 25, 30% is those who have ever used it and then they now use it rarely. So you're seeing a lot of intermittent casual use among users. And, in contrast, you have about 5% of some days, and then a very small proportion of individuals are using the product every day. So there is large variability.

And that rarely use is actually fairly pronounced, comparable to what we see with cigars and considerably lower than what we see for some of the other tobacco products, as you can see on this particular figure. So again, reinforcing that issue and that rarely and intermittent use is particularly pertinent to capture among adult waterpipe hookah users in the U.S.

So now let's move on to young adults. So we've already seen from that previous slide that young adults have particularly high prevalence of hookah waterpipe use. And so we're just going to do a little deeper dive. These ensuing slides are going to compare 18 to 24 to adults 25 or older. So the adult 18 to 24, which is our high burden group here, is going to be the lighter color shade. And this is every day,

some day, or rarely use. So we've removed out that every day, some day that we saw in the previous slides. This is going to be all three, just because that's the higher prevalence of use. And so here you can see that, again, adults 18 to 24 have considerably higher prevalence of use. And the variation that we saw overall holds when you stratify by age. So younger males have higher prevalence of use than younger females. That's 21.5% for males and about 14.5% for females.

Similar patterns that we're seeing by race/ethnicity -- you see the highest prevalence among non-Hispanic white younger adults compared to the other categories of younger adults. As we saw before, lower prevalence among young adult black non-Hispanic, at about 8%, which is the lowest of any race/ethnicity for the young adults.

And here is the data by education. Again, similar patterns among the young adult demographic, just keeping in mind that some of them aren't yet old enough to achieve graduate degrees. So the pattern is slightly different here. But you do see a lot of variability, with the highest prevalence of use among those with some college.

And here's the data by income. And this is particularly pronounced. So before we had a slight gradient for income.

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But here you have marked increase in young adults who are coming from highly affluent households. So those from households that have over \$100,000 per annum in income, 30% -- which is nearly twofold higher than the young adults from the longer income households. And so this is particularly important to consider, given that you don't see this marked disparity when you just look at all adults overall. And then here is the variability by region. Slightly more pronounced -- a lower prevalence among younger adults in the South, at about 15%, compared to a higher prevalence in the Northeast and the West, at around 20%.

And then here is by sexual orientation. Again, similar patterns. Among LGBT young adults, close to one-third currently use hookah. This is a very marked disparity that we don't see for some of the other tobacco productions. When you see that heterosexual/straight, it's about 17.2% of young adults use these products and similar variability when you look at adults 25 or older. But again, this variation between young adults and adults persists and is even more pronounced by sexual orientation.

Okay, so women of reproductive age. So we have started to expand our surveillance systems across the U.S. to capture

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pregnant women. This is really our target demographic, so we have the PRAM survey, which is the Pregnancy Risk Assessment Monitoring survey. I believe I got that acronym correct. And we have added questions on hookah beginning in 2016. So we don't yet have those for public release. We don't even have the data yet because they have not been fielded. But in the interim, our best proxy is really women of reproductive age.

So the ensuing slides that I'm going to present for you are women of reproductive age, and particularly 18 to 44. And that's going to be used as a proxy for pregnant women for these slides. So as you can see here, women age 18 to 44, women of reproductive age, are going to be the light bar. And then women of 45-plus are going to be the comparator, which are the darker bar. And so, here again, we see a lot of racial/ethnic variability in use, particularly high among other non-Hispanics and Asian non-Hispanics as well as white non-Hispanics. So about 6.5% of white women of reproductive age reported currently using hookah every day, some days, or rarely.

Again, similar patterns by education among women of reproductive age. You tend to see the highest prevalence of use with those with a GED or some college, and then a lower prevalence on either end of the education spectrum,

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particularly those with a graduate degree, about 4%.

And then here is by household income, again similar patterns of use that we're seeing, not quite as pronounced. They're the same trajectories as we saw for adults overall or young adults, but about 5% across the board of women of reproductive age are using hookah, irrespective of their annual household income.

And then finally here is by region, again similar variation. Women of reproductive age in the Northeast, about 6%, 6.9% in the Midwest, and then lowest in the South at 5%.

And then finally sexual orientation, similar patterns, but not as pronounced as we saw for the younger adults. So you remember when we looked at younger adults overall. It was a higher, about 30%. It's about 13.7% among women aged 18 to 44, compared to about 5.4% among heterosexual/straight women age 18 to 44.

Okay, so now we'll move on to youth. And this is really where we have some fairly robust surveillance data, and we've really seen some dynamic changes in recent years. These are data from the National Youth Tobacco Survey, which you already saw some of those. And this is really a marked increase for a tobacco product and unprecedented as well. Between 2013 and

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2014, we saw a near doubling of use, and this is past 30-day use of waterpipe hookah among high school students and middle school students. And we saw declines in conventional tobacco products during this time, but e-cigarettes and hookah increased. So this really underscores the public health importance of dealing with the diversity of tobacco products among youth. We don't want to get into a habit of playing public health whack-a-mole, if you will, where we're seeing certain products decline and others escalate.

And right now, based on these surveillance data through 2014, hookah use is on the rise among the middle and high school demographic. The middle school demographic is particularly important, and NYTS is the only national survey that captures national use. So seeing that marked increase under those very young youth -- 12, 13 years old -- is particularly concerning from a broader public health standpoint.

So here is some variations by school level and sex. And so here you see -- favorably comparable, this isn't statistically significant between males and females -- for high school and middle school. But you see that there is markedly higher prevalence of hookah use among high school students

compared to middle school students. So the older students are the ones that are using these products, nearly threefold higher among high school compared to middle school.

Here is also some variations by race/ethnicity. These are also stratified by school level. You see the highest prevalence of use is among Hispanic students, at about 13%. Then white non-Hispanics are around 9.4%, which is fairly comparable to the overall prevalence for all U.S. middle and high school students across the country. And then lowest among non-Hispanic blacks and those of non-Hispanic other race/ethnicities.

So fairly simple patterns by race/ethnicity that we see among adults, and these hold true with middle and high school students. But it's also important to note the magnitude of these estimates. So hookah became the second most prevalent tobacco product used among U.S. youth in 2014, behind e-cigarettes. So higher than conventional cigarettes, which is something that a lot of people don't know or you don't necessarily see in the reports that come out. Even among middle school students, hookah are tied with cigarettes for the second most prevalent tobacco product behind e-cigarettes. So it is not only increasing, but it's a highly prevalent form of

tobacco that we need to keep our pulse on in terms of tobacco control policy, planning, and practice in the context of youth prevention.

Okay, so here is the summary. If you fell asleep, you can arise from your slumber and get the CliffsNotes version on this slide: everything you need to know.

So waterpipe hookah use is common among U.S. adults and youth, with use increasing considerably among youth in recent years. Particularly between 2013 and 2014 we saw a doubling in use among U.S. middle and high school students, making it the second most prevalent tobacco product among youth.

Among adults, variation in current waterpipe use exists by sex, age, race/ethnicity, education, annual household income, and sexual orientation, as well as U.S. region. And these disparities are not necessarily consistent with what we see with conventional tobacco products, such as cigarettes.

Among youth, we also see variations by school level, sex, and race/ethnicity, particularly by school level, where the older students in high school have higher prevalence of use compared to their middle school counterparts.

Also, from a surveillance standpoint, accounting for occasional or rarely use is going to significantly impact

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estimates of current use. And so there is momentum across federal surveys, as well as nonfederal surveys, to really best capture the use patterns of hookah and waterpipe users to ensure that you're actually capturing those rarely and intermittent users, which appear to comprise the preponderance of user profiles.

Also, moving forward, it's really important to have advanced surveillance of waterpipe hookah use, particularly among these high-burden populations: young adults and pregnant women. Currently, we don't have very good standards for assessing pregnant women in terms of national surveillance data. There's certainly other people doing it. But it's important to incorporate these into surveys. And we have considerable efforts underway at the federal level to add it to PRAMS, as well as some state-based surveys, such as the BRFSS and other surveillance efforts, so that we can also get, in addition to the broader demographic disparities, also subnational regional disparities by state, which is, again, particularly important for informing policy and practice.

So with that, I will end with the CDC contact information, cdc.gov/tobacco, where you can get access to all of the data sets for the data I've presented today, for both the National

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Adult Tobacco Survey as well as the National Youth Tobacco Survey, including methods, reports, and data sets to replicate these data or do more nuanced analyses at will or desire on hookah use among youth and adults.

So thank you very much.

(Applause.)

DR. DRESLER: I did say that it would be an exciting workshop, but I didn't say it might be a distressing one too. So thank you very much for that, Brian.

Now we are going to test our technological expertise, and we are going to have a speaker from Dublin. Dr. Kenneth Ward is from the University of Memphis School of Public Health, but I believe he currently is in Dublin and has agreed to help us out remotely.

DR. WARD: Good morning.

DR. DRESLER: Good morning.

DR. WARD: I'm glad I was able to participate in this. When I agreed to participate, I had forgotten that today was a national holiday in Ireland. As Carolyn mentioned earlier, it's St. Patrick's Day. So the good news is I have my entire office building to myself. The bad news is that there's a half million people right outside my window for a huge St. Patrick's

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Day parade. So I hope it's not too noisy for you.

Okay, can we have the next slide, please? And the next one. Okay.

So I'm going to be discussing trajectories of waterpipe use or the changes over time in individual users. And trajectories have implications for both the health consequences of waterpipe use as well as dependence. So I want to address three questions that are relevant to the issue of trajectories in waterpipe use.

The first one is whether waterpipe use is sustained over time. We heard from Dr. King that most use, at least in the United States, is very occasional. But we want to look at whether it is more sustained in some users. Second, if sizable numbers of people do sustain their waterpipe use over time, it's of interest to know whether use escalates, which might increase the risk of health effects and dependence. Lastly, a related issue related to dependence potential is whether waterpipe users are at risk of transitioning to cigarette use. I'll spend a little time on that too. I'll just briefly discuss dependence, but we'll defer that topic until tomorrow, when Dr. Maziak will discuss it. Next slide, please.

So we are developing better and better surveillance data,

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but there is still rather limited longitudinal data. So I am going to spend most of my time discussing the longitudinal data that we do have.

So this first slide shows data from a longitudinal study of college women; 343 college women when they entered college were surveyed, and they were surveyed every month during their first year of college. Thirty-four percent of them used waterpipe over the course of that year. Half of them, 49%, used waterpipe on at least four occasions, and 20% of them used waterpipe at least 10 times. So at least in this fairly small sample, there is a high level of sustained use over the course of a year. Next slide, please.

Similar findings come from a large study of U.S. high school seniors. This study was conducted by Brian Primack and his colleagues, and they used data from the Monitoring the Future study. They looked at four waves of data from 2010 to 2013. They were interested in sustained waterpipe use, and they defined that as six or more sessions of use in the past year. And they found that nearly 20% of these high school seniors -- 18.8% to be precise -- had used waterpipe in the past year. And of those, 38% did so on at least six occasions in the past year. Males were more likely than females to have

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sustained use, and other correlates included a higher level of parental education, having lower grades and history of truancy, being less religious, spending more evenings out, and dating. So again, we're seeing a fairly high level of sustained use. Next slide, please.

This figure is from the same study by Primack and colleagues, and they examined time trends and the prevalence of sustained use of waterpipe over the 4 years of the study. They compared these to changes in the prevalence of past year waterpipe use, past year small cigar use, and past month cigarette use. And the trends are shown in the panel on the left. On the right you can see the linear regression coefficients for those trends. So while use of both small cigars and cigarettes seem to be trending downward, both past year, sustained waterpipe use are trending upward over time, suggesting that at the same time that these other tobacco products are declining, use of waterpipe in general, and worryingly more frequent or sustained use, may be increasing. Next slide.

So, in sum on this issue, a sizable percentage of youth and young adults smoke waterpipe in the United States and in Canada, do report sustained use over time, and the prevalence

of sustained use may be increasing over time relative to other tobacco products. Next slide.

Okay, so given that use is sustained over time in some waterpipe smokers, the next question to address is whether use escalates over time. There is only a few longitudinal studies that have assessed that. One from Canada tracked 777 young adults in Montreal over 4 years. They were surveyed when they were 20 years old in 2007 to 2008, and then they were resurveyed at age 24, in 2011 and 2012. And half of waterpipe users, 51% at age 20, were using waterpipe 4 years later. However, only 8% of them had increased their frequency of use, and 16% had actually decreased. The rest, 76%, reported no change in the frequency of use. So while sustained use is common, the vast majority of waterpipe smokers didn't increase the frequency of use over time. Next slide.

So that's the data from North America. That's really the entirety of the longitudinal data we have. We do have some longitudinal studies from the Middle East, though. This slide shows data from a longitudinal study in Iran that surveyed a representative sample of about 5,200 tenth graders, and they were surveyed three times over a 1-year period in 2010 and 2011. And at baseline, 52% of the boys and 37% of the girls

were experimental waterpipe users, meaning that they used it but it was no more than occasionally. And 10% of the boys and slightly more than 1% of the girls were regular waterpipe users, and that was defined as at least one time per month.

The table shows the percentage of students who transitioned in waterpipe use over the year. So over the course of the 1-year follow-up, 18.5% of students transitioned from being never smokers to experimental; 1.5% transitioned from being never smokers to regular smokers. So 20% of the students initiated waterpipe use over the year. In addition, about 7.8% of the students transitioned from experimental use to regular use. So in total we have 28% of students showing progression in waterpipe use, either initiating it or escalating use over the course of 1 year. Across these three transition categories, predictors of progression included being male, being a regular cigarette smoker, and having positive attitudes towards tobacco use in general. Next slide.

Lastly, we have longitudinal data that our team at the Syrian Center collected in Jordan, which was part of the Irbid Longitudinal Study of smoking behavior. In this study, nearly 1,800 seventh graders in Irbid in northern Jordan were enrolled in 2008. They were recruited from a representative sample of

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19 public and private schools, and they were followed up in grades 8, 9, and 10. This particular analysis from that data set included 864 students who had ever smoked waterpipe during any of the first three assessments, and they weren't daily users at baseline so that progression over time could be evaluated. Over the 3-year follow-up period, nearly 30% -- 29.6 -- progressed to higher frequency of use.

We examined the predictors of escalation separately for boys and girls. For boys, the predictors of escalation included a higher level of education from the mother, attending a public school, frequent physical activity, being less confident that one could refuse an offer to smoke waterpipe, and a low awareness of the harms of waterpipe use. For girls, predictors were having ever smoked cigarettes, having friends or siblings who smoked waterpipe, and not being exposed to the health warning labels on waterpipe paraphernalia. So giving us a little bit of insight in what may help in terms of intervention to prevent use. Next slide.

These are data from another analysis from the same study. So while nearly a third of the waterpipe smokers in those cohort increased the frequency of their use over time, as I just told you, another analysis suggests that frequent

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waterpipe use may not be increasing over time. So on the right, if you'll look at the bottom panel, it shows the frequent waterpipe use, which is waterpipe use weekly or more. You can see that there are significant negative time trends for both boys and girls. So the prevalence of frequent use over the 4-year period is declining for waterpipe use. And if you look at the top panel in the cigarette comparison, this shows that the prevalence of heavy cigarette smoking -- this is daily over 4 years in the cohort -- increased for boys but trended downward for girls. So the data suggests that while waterpipe use is escalating in Jordanian youth over time, it may not be escalating to very high levels. The caveat, of course, in these trend data is that they are prevalence estimates, and these are not within subject estimates. Next slide.

So, in sum, we still have limited longitudinal data that assess change over time in waterpipe use. But in North America, the available evidence suggests that relatively few waterpipe users are progressing to more frequent use. But we're seeing a different pattern in the Middle East, where waterpipe has a longer history and use in general is higher. So in the Middle East, upwards of a third of youth and young adults do seem to increase the frequency of use over relatively

short periods of time, raising concerns about health effects as well as dependence. However, it is unclear if substantial numbers of these young users are progressing to very frequent use. And we need larger and longer prospective studies to determine that. We do know, however, that progression is more likely to occur in males, and it's associated with cigarette smoking, higher parental education, positive attitudes towards tobacco, and less exposure to health warning labels. Next slide.

Okay, so the final trajectory-related issue I want to address is whether waterpipe smoking predicts cigarette smoking. Waterpipe smokers are much more likely than nonsmokers to use other tobacco products. In the United States, about 60% of young adult waterpipe smokers also smoke cigarettes or cigars. And there's many reasons for that association, or many potential reasons at any rate. It may be due to a general tendency or disposition to experiment with tobacco or to experiment with substances in general, for example, due to proneness for risk taking or sensation seeking. But it also may reflect a more specific relationship between waterpipe and cigarettes. And as Dr. Maziak alluded to, there is growing evidence that some waterpipe users become dependent.

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Waterpipe use, though, compared to cigarette smoking, is not very easy to engage in. It is stationary. It's a time-consuming practice. It's not usually readily available. So some users may become dependent and transition to cigarettes, which are easy to use. There's now a handful of longitudinal studies that have evaluated whether waterpipe use predicts initiation and escalation of cigarette use. And that may help to shed some light on potential mechanisms for this association. Next slide.

So these are data from the same longitudinal study that I showed you previously in the United States, where 343 entering college women were interviewed monthly during their first year. So those students who had used waterpipe before entering college were more likely than those who hadn't smoked waterpipe to initiate use of cigarettes in college. The adjusted odds ratio, as you can see, is 1.08. These models adjusted for several risk factors for tobacco use, including impulsivity, sensation seeking, binge drinking, and use of other substances. So similar to pre-college use of waterpipe, having used marijuana before college also was associated with greater likelihood of waterpipe smoking during the first year of college. In contrast, though, having smoked cigarettes before

college did not predict college use of waterpipe. Next slide, please.

These are data from another longitudinal study in the United States, and the data are from a cohort of 15- to 23-year-olds who are part of a national household survey. So they were surveyed first in 2010 and 2011 and then resurveyed 2 years later in 2012 and 2013. The sample included nearly 1,600 individuals, and of those 1,048 had never smoked cigarettes at baseline. They were included in this analysis.

So at baseline, 20% of the sample had smoked waterpipe. The waterpipe smokers were twice as likely as non-waterpipe smokers to initiate cigarette smoking over the 2-year follow-up. So 39% of the baseline waterpipe users started smoking cigarettes, compared to 20% of the never smokers. And the table shows the result of multivariable models that are adjusted for several determinants of cigarette use. And you can see that the odds of initiating cigarette use were two and a half times greater for those who had ever smoked waterpipe at baseline. Similarly, the odds of current cigarette smoking at baseline were two and a half times greater among the waterpipe users.

Likewise, use of snus also predicted by initiation and

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current use of cigarettes, but neither waterpipe use nor snus predicted binge drinking. So these associations are independent of the effective use of other substances at baseline, and the fact that these are independent associations, along with the finding that waterpipe and snus didn't predict binge drinking, indicate that the associations may not be due to a higher propensity, in general, for risk-taking behavior but may be more specific to tobacco use. Next slide.

This is another analysis from the Irbid Longitudinal Study. This is from Rana Jaber and her colleagues, and this sample includes 1,454 participants who at baseline in the study had never smoked cigarettes. So 1,100 never smokers but 300 people who had smoked waterpipe only at baseline but not cigarettes. And the study examined the risk of initiation of cigarette smoking among waterpipe smokers compared to waterpipe never smokers. And they also examined whether this association was dose dependent according to the frequency of waterpipe use. So smoking waterpipe at baseline predicted initiation of cigarette smoking in this cohort across 3 years of follow-up, with an adjusted hazard ratio of 1.66. Next slide.

The data also indicated that the risk of initiating cigarette smoking increased with the frequency of waterpipe

smoking. So as shown in this figure, there's a significant linear trend for an increasing probability of initiating cigarette smoking as a function of waterpipe use, going from having never used waterpipe, to formerly but not currently waterpipe, to currently smoking waterpipe less than once a week, and finally to currently smoking waterpipe more than once a week. And we see a positive linear trend across those categories. Next slide.

So there's consistent evidence that waterpipe use predicts the initiation of cigarette smoking. The data, though, are more mixed regarding whether waterpipe use predicts escalation of cigarette smoking. So we might expect to see such a relationship if the association is being driven by waterpipe users developing dependence. So this first study comes from Denmark, and Jensen and colleagues surveyed 762 eighth to tenth graders who at baseline were intermittent cigarette smokers, defined as having tried cigarettes but never smoking at least one cigarette per week. They were then resurveyed 8 months later, and the authors examined the association between frequency of baseline waterpipe use and the odds of progressing from intermittent to regular cigarette smoking. Now, as you can see, the odds of progressing from intermittent to regular

cigarette smoking increased as a function of waterpipe use. The adjusted odds of progressing for those who tried waterpipe just once was 1.1, compared to 2.4 for those who smoked waterpipe occasionally and 2.5 for those who smoked waterpipe regularly. And the data show a significant linear trend. Next slide.

And a longitudinal study in the U.S. also provides some evidence that waterpipe predicts escalation of cigarette use. This is analysis from Doran and colleagues, and they interviewed 246 college students who were current cigarette smokers, and then they reinterviewed them 3 and 6 months later. And at baseline, 34% of the sample were current waterpipe users, last month users. And as shown in this table, having smoked waterpipe in the past month was associated with an increase over the 6-month interval in the total number of cigarettes smoked and the number of days on which they smoked cigarettes. And the data translate into waterpipe users smoking approximately 32 more cigarettes over the 6-month follow-up period than the baseline non-waterpipe users.

Also interesting, from this paper, though not shown in my slide, is that baseline waterpipe users compared to the nonusers were younger, and they smoked fewer cigarettes per day

at baseline, indicating that they were in the earlier uptake process for cigarette smoking, but they were nonetheless more likely to increase their cigarette smoking follow-up. The authors speculated that one potential mechanism might be increased nicotine exposure from waterpipe that accelerates development of tolerance and dependence, leading to increased cigarette consumption. It also may be the case that waterpipe use increases opportunities for cigarette smoking at social functions. Next slide.

So we have two longitudinal studies that indicate waterpipe use predicts escalation of cigarette use, but a recent analysis from the Irbid Longitudinal Study didn't find such an association. So this analysis included 669 participations who had ever smoked a cigarette at baseline when they were in seventh grade or during follow-up. A large proportion of the students increased the frequency of cigarette smoking during follow-up, including 43% of the boys and 32% of the girls. However, baseline waterpipe use did not predict cigarette-smoking progression for either boys or girls. Next slide.

Okay, lastly, there's evidence from one study that waterpipe use is associated with a reduced likelihood of

quitting cigarette smoking. This analysis is from more than 1,200 students from 17 universities in the U.S. who were enrolled in a Quit and Win cessation OSCE. It's an OSCE that provided financial incentives for college students to quit smoking. And at baseline, 22% of the enrollees were current waterpipe smokers. Waterpipe smokers were younger, they had smoked fewer cigarettes per day, and they were less nicotine dependent, suggesting that they'd have an easier time quitting cigarette smoking. But the opposite was true; 8% of the waterpipe users achieved biochemically verified abstinence from cigarette smoking at 6 months, compared to 14% of the non-waterpipe smokers, which was a statistically significant difference. Next slide.

So, in summary, regarding whether waterpipe use predicts cigarette smoking, there is strong evidence that waterpipe users are at increased risk of initiating and escalating cigarette smoking. There is some evidence, though it's not entirely consistent, that waterpipe use predicts escalation and may also make it more difficult to quit smoking. There's a graded association such that the risk of initiating cigarette smoking increases as a function of the frequency of waterpipe use. And this dose-response association, along with other

evidence that waterpipe can produce dependence and the fact that waterpipe seems to predict cigarette initiation more consistently than cigarettes predict waterpipe initiation, suggests that some waterpipe users may become dependent and transition to cigarette smoking. That hypothesis is tentative and needs to be tested directly in longitudinal studies of waterpipe dependence development specifically. Next slide.

So finally just a few overall conclusions. A sizable minority of waterpipe users in North America appear to sustain their use over time. But most don't progress to greater use. In contrast, in the Middle East, which has a longer history of waterpipe use among youth, the likelihood of escalating use is much greater. And waterpipe use increases the risk of initiating cigarette smoking and may increase the risk of progression and failure to quit smoking cigarettes. Next slide.

And that's the end. Thank you.

(Applause.)

DR. DRESLER: Thank you, Dr. Ward. I appreciate how hard that can be from a distance and not seeing the audience. That was excellent. Thank you.

Our next speaker is Dr. Erin Sutfin from the Wake Forest

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School of Medicine, speaking on Prevalence and Correlates of Waterpipe Tobacco Use Among College Students.

DR. SUTFIN: Thanks. Good morning. I want to thank the Center for Tobacco Products for this opportunity to present my research today. Today I will be presenting data from three different studies that were funded by two different NIH grants that are listed here, and neither I nor my co-authors have any conflicts of interest to disclose.

You've already heard excellent talks today describing waterpipe use, including use by some special populations. And I'm going to expand upon this discussion by focusing on college students, who I'm going to argue are another priority population.

So first I'll provide a rationale for this focus, and then I'll describe findings from three studies addressing the following research questions: What is the prevalence and what are the correlates associated with waterpipe tobacco smoking among college students? What substances are college students smoking in their waterpipes? And finally, what proportion of college students report waterpipes were their first tobacco product that they tried? Then I'll end with some thoughts on future research and regulatory needs.

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So perhaps due to demand, commercial waterpipe establishments tend to cluster near college campuses. If you Google where to open a waterpipe café, you'll likely find several articles including quotes similar to these, highlighting the profitability of college towns for these businesses and noting that college towns are an ideal business location because of the constant flow of students from semester to semester.

Additionally, many of these commercial venues offer specials specifically for college students, like this one that offers 50% off a waterpipe with a valid college ID, and this one that offers both free drinks and half off with a college ID. While not all waterpipe smoking occurs in these commercial venues, a substantial amount does. I'll show you data on that shortly.

So here I have included data on annual prevalence of waterpipe tobacco smoking from the 2014 Monitoring the Future study. The red bars indicate twelfth graders, the green bars are young adults age 19 to 28, the purple bar is a subset of the young adults who are currently in college, and the blue bar is also a subset of young adults who are currently not in college. So what these data show are that college students

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have the highest annual prevalence among these age groups. As you saw from Dr. King's presentation earlier, rates of use drop off considerably with age. So it's unclear whether supply preceded the demand or vice versa. It is clear that college students are both an important market for the industry as well as a priority population for research.

So turning now to the research that colleagues and I have conducted, I'm going to start by describing a study assessing waterpipe tobacco smoking, prevalence and correlates among a large multi-institution random sample of college students. This study was conducted in the context of a larger trial, the Study to Prevent Alcohol-Related Consequences, funded by NIAAA. Now, we conducted annual cross-sectional surveys of students at eight participating colleges in North Carolina, and data were collected in the fall of each year. I'll be sharing data from 2008, which was relatively early in the history of waterpipe tobacco smoking in the U.S. We used a stratified random sampling design stratified by class year to ensure approximately equal representation across the college years. Our sample included 3,770 participants; 63% were female, and 80% were white. As designed, they were equally distributed across class year. Fourteen percent were members or pledges of

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Greek letter organizations.

So these are the data for lifetime on the left, and current or past month waterpipe smoking on the right. As you can see, 40% of our sample reported ever smoking tobacco in a waterpipe, and about 17% reported past month use. So for comparison, I have included data for cigarette smoking in the blue; 47% of our sample had ever smoked a cigarette in their lifetime, and just under 25% had smoked in the past month. And while cigarette smoking was more common in this sample, the rates of use were surprisingly similar.

There was also considerable variation in waterpipe smoking across our eight campuses, with rates ranging from 6 to 30%. We also identified whether each campus had a commercial waterpipe smoking venue within a 10-mile radius of the campus, and three of the eight schools did. As you can see here, in three out of the four schools where rates of use were the highest, there was at least one commercial venue nearby. Now, school number 3, they had a high rate of use despite the fact that at the time the data collected there was not a commercial venue nearby. Shortly after our study, we learned that one opened. So in that case, demand may have preceded supply.

Current users were also asked about where their waterpipe

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smoking occurred in the past month, and they were able to select more than one response. So 63% reported at a friend's house, which included either their house or dorm; 39% their own residence; 34% at a party; 32% said at a café or restaurant; and 9% indicated some other location.

In the three schools that had at least one commercial venue nearby, 65% of waterpipe users reported smoking in a commercial venue in the past month. So as I mentioned earlier, a substantial amount of waterpipe smoking occurs in commercial venues, especially when there is one located near campus.

Age of waterpipe initiation was about 18 years old, and this may reflect a cohort effect given the recency of this form of tobacco in the U.S. We also asked current users whether they thought they could quit anytime they wanted, and not surprisingly they were very confident in their ability to quit; 97% indicated they can quit anytime they wanted.

We also asked if they intended to quit, and 53% indicated that they did intend to quit at some time. Among those, 18% said they planned to quit in the next month, 2% reported they planned to quit in the next 6 months, and 33% indicated that they planned to quit at some time in the future.

We also assessed whether participants believed waterpipe

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tobacco smoking was less harmful, as harmful, or more harmful than a regular cigarette. Among our full sample, 32% of students reported waterpipe smoking as less harmful than cigarettes, which is shown in the green bar; 51% said that it was as harmful as cigarettes, in the blue; and 17% said more harmful than cigarettes, in the red.

Now, when we look just at current waterpipe users, the picture looks very different: 55% of current waterpipe users indicated that waterpipe smoking is less harmful than a regular cigarette; 33% said it was as harmful; and 12% said more harmful. So clearly perceptions differ among current waterpipe users, and they incorrectly underestimate the harms associated with waterpipe smoking. These misperceptions of reduced harm may make waterpipe smoking an attractive alternative to cigarettes.

We also conducted multivariable logistic regression, adjusting for within-school clustering. We found that compared to females, males were more likely to be current users. Compared to first year students, all other classes were less likely to be current users. It may be that waterpipe smoking is an attractive alternative for younger students who are not able to get into traditional bars and clubs.

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Not surprisingly, compared to never smokers, those who smoked in their lifetime and current smokers were more likely to be current waterpipe users. Current marijuana users were also more likely to be current waterpipe users. Whether this strong association is due to using the waterpipe to smoke both substances is unclear.

Those with a history of lifetime other illicit drug use and current drinkers were more likely to be current waterpipe smokers, and as we saw in the last graph, those who perceived waterpipe smoking to be less harmful than a regular cigarette were more likely to be current waterpipe users. Finally, those who are on campuses with a commercial venue nearby were more likely to be current users.

Now, we also assessed other predictors and didn't find significant relationships with race and gender, on or off campus residence, Greek membership, monthly spending money, parental education, and whether or not the school was public or private.

So given that marijuana and cigarette smoking were strong predictors in the multivariable model, we wanted to quantify the overlap. So what you see here is that 66% of current waterpipe tobacco smokers were also current marijuana users,

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and 55% of current waterpipe smokers were also cigarette smokers. However, it's important to note that 22% of current waterpipe tobacco smokers had never tried a cigarette. So for some, waterpipes may have been their first introduction to nicotine.

So, in conclusion, college students have high rates of lifetime and current use, and rates are almost as high as cigarette smoking. I do want to just mention here that because this study, and the others I'll describe today, were conducted in the Southeast, our ability to generalize to college students nationally is limited. However, our findings are very similar to other studies that have been conducted across the U.S.

Results also highlighted that commercial venues are an important context for this priority population. However, we know very little about these environments. Misperceptions about the reduced harm of waterpipe tobacco smoking compared with cigarettes was an independent predictor of use. The origins of these misperceptions is unclear, although there is some evidence that waterpipe marketing often includes reduced harm messages.

Additionally, we found overlap with marijuana use. It is perhaps due to use of the same device to smoke a variety of

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substances. Finally, there was also substantial overlap with cigarette smoking. However, it's important to note that just under half of the sample were not current cigarette smokers, and 22% had never smoked a cigarette, suggesting that waterpipe smoking may be appealing to those who are not interested in cigarette smoking.

So turning now to the second study, given the overlap in waterpipe and marijuana smoking, we were interested in assessing the types of substances that college students smoked in their waterpipes in describing classes of users based on their patterns of different substances smoked. So again, we capitalized on our NIAAA-funded study, this time using data from 2010. Our sample included 3,447 students, of whom 44% were lifetime users and made up the analytic sample for this study. So just over half were females, and the majority were white. Again, we had fairly even distribution across the college years. And 18% were members or pledges of Greek letter organizations.

So we assessed whether participants had ever used a waterpipe to smoke flavored tobacco, herbal or non-tobacco shisha, marijuana, and hashish. And again, these were not mutually exclusive categories. So we found that the vast

majority, 90% of students, reported smoking flavored tobacco; just under half smoked marijuana; 37% smoked herbal or non-tobacco shisha; and 18% smoked hashish from a waterpipe.

We conducted a latent class analysis to derive subtext of waterpipe users based on their patterns of use of different substances, and the analysis resulted in two classes: Class 1, in the blue line, included 77% of the sample, and those in Class 1 reported mainly smoking flavored tobacco with minimal use of herbal shisha and marijuana and virtually no use of hashish. Class 2, in the red line, was 23% of the sample and included those who smoked all substances, notably flavored tobacco and marijuana. Members of this poly-substance class were more likely to be males, have mothers with a college degree or higher, be current cigarette smokers, and have used illicit drugs in their lifetime.

So the results from the study suggest that students do smoke multiple substances from their waterpipes, not just tobacco. This has important implications for measurement. So when assessing waterpipe tobacco-smoking prevalence, researchers need to be clear that they're interested in tobacco. Otherwise, they may inadvertently overestimate rates.

Flavored tobacco use was by far the most commonly smoked

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substance. However, we did not assess the use of unflavored or just tobacco-flavored shisha. So we cannot compare flavored versus unflavored from this study. Among lifetime waterpipe tobacco smokers, 23% were in the poly-substance use class and may be a priority subgroup of waterpipe users, with co-occurring substance use.

So finally I'll turn to our third study. Now, historically the tobacco products available for initiation included cigarettes, cigars, chewing tobacco, and dip. However, with the proliferation of new tobacco products, youth have the opportunity to be introduced to nicotine in a variety of ways. This study aimed to determine product choice for initiation. The study was part of a larger longitudinal cohort study of college students from 11 colleges in North Carolina and Virginia and was focused on smokeless tobacco use.

To form the cohort, we conducted a brief screener survey of all about 30,000 first-year, first-semester college students from the 11 schools in the fall of 2010. Students who had ever used smokeless tobacco, current cigarette smokers, and males were oversampled for inclusion in the cohort, where all other students were randomly selected. This resulted in a sample size of 3,146 who completed the baseline survey in fall of

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2010, and the weighted prevalence of lifetime tobacco use was 48.6%, and those 1,656 students made up the analytic sample for the study. Again, our sample was just over half female, mostly white and non-Hispanic.

Among ever tobacco users, about 38% reported their first products were cigarettes; 29% reported cigars; just about 25% reported waterpipes; 6% reported smokeless; 2% reported bidis or kreteks. And although we did assess it, we had no students tell us the e-cigarettes were their first product. And this may again be a cohort effect, given that the products had only recently been introduced into the U.S. market.

Reports of first product trial varied by gender. Males were more likely to report cigars and smokeless tobacco as their first products, while females were more likely to report cigarettes and waterpipes as their first products. We also assessed first product trial among the 743 current cigarette smokers in our sample, and not surprisingly 65% reported cigarettes were their first product, but 35% reported starting with a non-cigarette product, including 11% who reported starting with waterpipes.

We conducted a multivariable model, comparing those who reported initiating with waterpipes versus all other products.

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We found that females were more likely than males to have initiated with waterpipes. Those who had mothers with higher levels of education were more likely to have initiated with waterpipes. Current cigarette smokers were less likely to report waterpipes as their first product, but current dual or poly-tobacco users were more likely to have started with waterpipes. Those with younger ages of initiation were less likely to have reported waterpipes for their first product, and this is likely because those products weren't as widely available at the time of tobacco product initiation, which for 61% of our sample was between the ages of 14 and 17 years of age. Finally, those whose parents smoke cigarettes were less likely to report waterpipes as their first product.

So, in conclusion, the study showed that a quarter of college freshman tobacco users reported waterpipes were their first tobacco products, and this number could be rising as younger children now have the opportunity to initiate with waterpipes. Females, those with more highly educated mothers, and current dual or poly-tobacco users were more likely to start with waterpipes. The appeal for females and those with more highly educated mothers may reflect reduced perceptions of harm.

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Additionally, over 1 in 10 current cigarette smokers reported waterpipes were their first tobacco products. However, because these data are cross-sectional, we can't be sure of the temporality, but it does certainly suggest that at least for some cigarette smokers, smoking tobacco from a waterpipe may have been their introduction to nicotine. However, we need more longitudinal studies to determine the sequence of product trial.

So these three studies highlight the need for continued surveillance among college students who represent a priority population. The research points to the need for further longitudinal studies to assess trajectories over time. In particular, it is important to understand whether those youth who have largely rejected tobacco but are open to waterpipe trial are so because they believe it to be less harmful, or perhaps they don't even realize it's a tobacco product. We also need to determine whether they are then going on to more readily accessible tobacco products, like cigarettes, as you heard about in the last presentation.

Our findings also point to the importance of commercial waterpipe venues for college students, and we really know very little about these environments and if and how they communicate

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the risks associated with these products. Do they clearly indicate that the products are tobacco and have nicotine? Do they suggest waterpipe smoking is safer than cigarettes? So although waterpipe smoking isn't exclusive to these venues, these venues may represent an opportunity for policy interventions. We need to understand how to best communicate risks through campaigns, warning labels, and other things to inform the FDA's rulemaking process. And this is some of the work that our team is doing for our Tobacco Center of Regulatory Science.

Finally, I want to acknowledge my co-authors, our funding agencies, and CTP. Thank you.

(Applause.)

DR. DRESLER: Thank you very much. It's raised, again, several questions. So it's time for the panel. So if Drs. King and Maziak -- and Dr. Ward, are you still on the telephone? Dr. Ward?

DR. WARD: Yes. I'm here.

DR. DRESLER: Okay. Okay.

DR. WARD: Can you hear me? Okay. Great.

DR. DRESLER: So what we'll do is we'll -- I have a couple of questions that I'll start off with. But if you have

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questions, we have cards that we will share with you. You can write the cards. And Asia has them. So just kind of lift your hand a little bit, and you write your card, pass it over, and she'll get those questions in for me. And so we'll go through and ask questions. Yes. Okay.

The first question I have is what's going on with well-educated mothers? Push the red button, yes.

DR. SUTFIN: I think that's a great question. We don't full know what's going on with the well-educated mothers. You know, as Dr. King pointed out, this is really a different pattern than we've seen for the other tobacco products where we see uses higher among low income. In this case, this seems to be more appealing, at least from the data we have, among more affluent families. I don't think we really fully understand why that it.

DR. DRESLER: It wasn't just in the U.S., though, because we -- one of the other presenters had that too. Dr. Ward, was that in your presentation?

DR. WARD: Yes. We see the same in the Middle East. And similarly, it's not clear why. You know, it may indicate that there is -- you know, they have more disposable income to use waterpipe. Or it could indicate that parents are more

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permissive about using it. But it's not clear.

DR. DRESLER: Well, the other question that I had was perhaps analogous to this, is that you had said in the 1990s was when it really started to expand up. And in the picture you showed, it had both genders in that picture, women as much as men. And I'm wondering -- and that wasn't in the U.S. that picture, I don't think. Is either -- so did this have something to do -- women picking up more? It used to be just men.

DR. MAZIAK: Well, in that context, I think cigarettes is looked at as a Western thing. So it's not really very acceptable for women to smoke cigarettes, while the waterpipe is looked at as more germane to the culture and the region. So that's why it's enjoyed an explosion among girls and women, particularly to that region.

But generally about the pattern of who is smoking now the waterpipe, I could kind of make a 50 years back with the cigarette epidemic, where actually the educated -- the physicians and the high income -- were the smokers. And perhaps we're seeing the same kind of thing, because this is a new epidemic, and the knowledge about the harmful effects and all other issues are not widespread. So it's just kind of the

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same pattern. I would expect we will have a shift towards lower income, unless price is a factor. But I would expect that would -- more knowledge about the harmful effect, that we would see a transition as we saw with cigarettes.

DR. DRESLER: This also goes for a historic question. So in the 16th century they were using waterpipes, you said, on certain -- could it have been opium? Is that what they were -- you think they were probably doing?

DR. MAZIAK: I would expect -- yes, I would expect that would be the most likely --

DR. DRESLER: In that area?

DR. MAZIAK: Yes. Some kind of product that they used.

DR. DRESLER: And then tobacco. Okay.

So, Dr. Ward, this one is for you. What are the criteria used in defining sustained waterpipe use as six times in the past 12 months?

DR. WARD: You're asking what's the rationale for defining it that way?

DR. DRESLER: Yes.

DR. WARD: Well, you know, one issue is that sustained use hasn't been defined consistently across these different studies. I think Brian Primack's group did that because they

could parcel out the data that way, from Monitoring the Future, and also they had calculated that that amount of use was equivalent to a fairly high toxicant exposure dose. And I can't remember what the rates are, but that would -- using it at least six times over the course of a year would give users quite a bit of sustained exposure to nicotine, to carbon monoxide, and to other toxicants. So that was the rationale used in that paper.

DR. DRESLER: Okay. Dr. Sutfin or panel, did you assess the use of hashish used as waterpipe tobacco? In qualitative research, college students indicate that they typically mix the two because hashish burns too rapidly.

DR. SUTFIN: So we did ask about use of hashish in a waterpipe. We did not -- and we did see some, although it was the least used of the products that we assessed. We did not assess any mixing in our studies. So we don't have those data. But they are certainly using -- college students are using waterpipes to smoke a variety of substances, including hashish.

DR. DRESLER: And when you say a variety of products, are you saying they're like mixing them? Some might mix marijuana in with your tobacco, with your --

DR. SUTFIN: It could be. We don't know if they're mixing

them or they're using them -- they're using it at separate occasions, where sometimes they just using tobacco, other times they're using marijuana, or if they're doing mixing. From our study, we can't tell that.

DR. DRESLER: So a question on -- so I will confess I have admired the beauty of some waterpipes, but I've not used one. But how long -- when you set up a waterpipe, so the average use is around an hour? So when you set it up, does the tobacco or the coal that you put in it, does it last an hour? Or can you just be sitting there for an hour and keep going through your variety of products? Which usually happens?

DR. MAZIAK: Well, mainly, it's very different in terms of the context of the smoking from cigarettes, which is a prolonged and seated kind of behavior. And also preparation time, it depends whether you prepare it for yourself at home or whether you're in the café setting. But it takes a longer time, and usually in the café setting is a usual pattern that the hostess or steward or whoever there will come and refill the coal. Usually when you smoke the tobacco, it's kind of -- it's not very common for people to smoke multiple heads because the CO, I think, uptake is huge. They cannot. But usually it's the charcoal get exchanged, because it extinguishes. So

you have multiple -- even in lab studies, we use multiple kind of refilling of the charcoal to keep it going.

DR. DRESLER: Okay. Yes. Dr. Maziak, this is for you. Please elaborate on the ease of in-house preparation of flavors used in narghile.

DR. MAZIAK: Well, the introduction of maassel is one of the main factors that we think has actually made -- simplified a lot the processing of waterpipe, because before, as I said, it was raw tobacco. So you have to kind of crush it and put it in a piece of tissue, add water to it, and then squeeze and stuff. So it kind of was a little bit elaborate process. With the flavored and sweetened tobacco, the maassel is just a ready product for you. You just pack the head, cover it with aluminum foil, and that's it. You're ready to go with the charcoal. So it's become a lot easier with the novel introduction of the maassel, of the flavored tobacco.

DR. DRESLER: Okay. And, Dr. Ward, I can't see you so much. So don't hesitate to speak up if you want to address.

DR. WARD: Sure.

DR. DRESLER: Okay. What are some factors that speak to the higher prevalence of waterpipe use in the American West? Dr. King, this was --

DR. KING: Yes. So I think it's ultimately multi-factorial. I think one high influencer of use among the broader population, particularly those in the West, is flavors. And if you look at the youth issue, some data that CDC and FDA put out showed that about 60% of youth hookah users were using flavored varieties. So it's about, you know, a million middle and high school students across the country. So there is definitely momentum in terms of the availability of flavored products. It's also a highly social issue, which is not necessarily what you see with conventional cigarettes, where there is a broader stigma of using the products. And then you also have, you know, lack of knowledge combined with advertising for these products as, you know, social mechanisms that are available on flavors and potentially, you know, less harmful than conventional cigarettes. So it's really a multifactorial issue that are probably influencing this, but I think that -- definitely the tops are the flavors, the lack of knowledge, and then the social desirability around the use of the products, among other factors.

DR. DRESLER: So going back to a question that raised, but also from earlier, you said the -- it's usually around an hour, and at around the hour, the carbon monoxide is getting too

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high. And the social impact of it -- you're in a café. What makes it one hour? You know, we know why you smoke a cigarette for, you know, however many puffs. That's how long it is.

DR. MAZIAK: Well, again, it's a very social tobacco use behavior. So the social context -- and usually it's not only smoking. Usually it's associated with food and beverage consumption. And it's not like an impulsive intense smoking behavior, compared to cigarettes. It's a relaxed intermittent puffs and over a long period of time, because the waterpipe keeps conversation, keeps kind of the ambience, people say. But that -- it's a very different kind of context.

But the CO uptake is huge, and we're seeing multiple reported emergency room admissions because of CO intoxication with waterpipe smoking. We have not seen much of that in the cigarette literature. Very rarely. We've seen already multiple -- and carboxyhemoglobin levels in those people are up the roof. It's really over 30, which is very rare that you see with other -- any tobacco use product.

DR. DRESLER: So to go with that, you had said that it may be accompanied with food. And then you had commented, Dr. Sutfin, that the freshmen may be doing it because they can't get into the alcohol bars. But how much of waterpipe is

co-consumed with alcohol? Not alcohol in the waterpipe, but --

DR. SUTFIN: Right. I don't think we have a great answer to that. I don't think we know yet. We hear anecdotally from college students that when they go to a party, there is always a waterpipe there. It's sort of a -- there's the keg, there's the waterpipe. I mean, it just sort of -- it's seeming to go along now with this culture. Some cafés serve alcohol and some don't. It varies. It may vary by state.

So in North Carolina, for example, our state smoke-free air law is specific to restaurants and bars. So you cannot smoke inside if you have a permit to sell alcohol or food prepared on site. So there's less of that in these commercial places in North Carolina. However, if you're outside -- and we have great weather in North Carolina, so there's lots of patios -- you can smoke waterpipe outside and enjoy an alcoholic beverage.

So I do think there is a fair amount of mixing -- of course, not in the same device, although sometimes people do fill the bowl of the waterpipe with wine and other juices to enhance the flavor. But consuming alcohol while also using a waterpipe, I think, is fairly common. I don't know that we actually have data on that, per se, but I do think it's common.

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DR. MAZIAK: Well, there are several studies showing association between alcohol and waterpipe. And also the other element interesting related to the waterpipe and food is that we're seeing actually more weight gain among waterpipe smokers with smoking, compared to what you would see with cigarettes. So the whole context and then kind of relation is unique. And yes, I've seen some reports that people have added alcohol to enhance the effect of nicotine to the -- in the bowl itself.

DR. DRESLER: Any difference that you know of between in the U.S. and ex-U.S. on the consumption of alcohol? And perhaps not so much in the waterpipe, but in co-consumption? Or is it mostly food ex-U.S.?

DR. MAZIAK: I'm not sure. I'm not sure about this issue. The manufactured maassel actually unified this practice all over the world. It used to be different in different parts of the world. In China or India, they use it differently. They have a different product. In the Middle East differently. But with the manufacture maassel and how it's used with it, it's now you see that same instrument, same kind of context of smoking it all over the world. So it's kind of an overwhelming method of use now. The variability that was before is not that much anymore.

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DR. DRESLER: Okay.

DR. WARD: So going on this -- the alcohol issue, too, I think it's important to note that there's a lot of municipalities across the country where a hookah bar is the only place where you can smoke inside and also consume alcohol. And so there's a lot of municipalities -- particularly ones that have been particularly vanguards of tobacco control, like New York City, where there are specific exemptions in the state and local legislature that allows people to smoke indoors with hookah. And frequently those also allow the drinking of alcohol. So that's something important to consider, that it's almost an influencer in that it's the only place where you can smoke indoors. And it's the last bastion of smoking for a lot of municipalities that have otherwise had comprehensive smoke-free laws prohibiting smoking for a decade or more.

DR. DRESLER: Dr. Maziak, given the Western uptake of waterpipe use, are there data speaking to whether or not the social aspects of waterpipe use have changed in the Middle East?

DR. MAZIAK: Oh, because the U.S. now is -- it's a U.S. phenomenon, so they will be antagonistic to that? No, actually no, I don't think so. I think it's they're proud that they

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infected the whole world with the waterpipe, especially the U.S. I don't think -- no, I don't think. It's a joke.

DR. DRESLER: Well, I was just wondering if it changes, because how cultural norms change -- what's happening in the U.S. and perhaps the youth. And so you were saying in other cultures it was more men. Now more women are -- so, is --

DR. MAZIAK: I think the pattern among youth is kind of also showing some universal trends, with both boys and girls, and kind of -- there's a little bit predominance of male in the U.S., but not that much. And you can see ample girls, boys, women, men. Among older population, I think you get that more male, even in the Middle East, predominance. But among youth, it's kind of really -- it reigns supreme regardless of gender.

DR. DRESLER: So Dr. Ward had had some Danish data. What about from Africa, Australia, South America? Do we have any data for what's happening in those other consumption markets?

DR. MAZIAK: So there are data from Australia, from Canada, Latin America. I mean, basically there are some hotspots, but basically you can see it now in every society. Whether they have, again, large Middle Eastern communities or not is not a factor. It's just becoming -- the marketing over the Internet is the crucial factor because that's the youth

market. So the social media, the Internet, and the youth are just a very suitable combination for the spread worldwide. So I think that's now the most important factor, and you can see it everywhere.

In Australia, it's about 8%, the number, but there was no youth surveillance for it. And smoking is generally very low in Australia. But I haven't heard of a country that was not witnessing an increase in waterpipe smoking. That was very clearly documented with the Global Youth Tobacco Survey.

DR. DRESLER: Okay. For the panel, any thoughts as to why we are seeing higher prevalence in Hispanic young adults of waterpipe? It's a good question. Okay. Well, good.

DR. MAZIAK: Well, I think we don't know. But I think it's -- those of collective cultures probably are more prone to that social tobacco use method. I'm not sure because the data is still a cross-sectional and we don't know what's underlying that. But my kind of hunch is that this might be an issue because these are like larger families, larger kind of collective cultures that will be more conducive to that kind of smoking rather than cigarettes.

DR. DRESLER: Okay.

DR. KING: And I would agree with that. I think that it's

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the social structure, and also the fact that these are relatively emerging product. And we're seeing higher rates of things like e-cigarettes for Hispanic youth as well. So it's probably a combination of multiple things.

And, you know, in the research and surveillance realm, we've stratified things up the wazoo in terms of trying to articulate who we're seeing increases in and why, but I don't think we have a definitive answer of why it's occurring at this point. We'll have to see the trajectory over time. But I think it's definitely, again, on these issues multiple influencers. But the social aspect and emerging nature and others are probably influencing it, as well as some geographic variation that we're seeing across the country as well.

DR. DRESLER: That brings me to one of the questions I had on your slides, Brian. You had other non-Hispanic and Asian was to the right. So is that Native Americans? So what is in that category?

DR. KING: Yes. So a lot of -- it's whoever doesn't identify within any of the other groups. So if they do a write-in -- we have that option for some of the adults. It has a lot of Middle Eastern individuals who don't necessarily identify with some of the other demographics. But it also

includes American Indian, as well as people of multiple races who would not necessarily fit within a mutually exclusive other category. But I can tell you that, you know, based on the write-ins, it's primarily people who identify as Middle Eastern and don't consider themselves, you know, to fall within any of the other identified categories.

DR. DRESLER: Consistent with that higher percentage, too, that they had there.

DR. KING: Yes. Yes.

DR. DRESLER: Okay. Dr. Maziak, for the study evaluating if people smoked unflavored tobacco, was the unflavored tobacco, maassel, meaning was it sweetened, or was it tombac?

DR. MAZIAK: Well, the study I presented is based on hypothetical choice options. So we did not even provide an unflavored versions of flavored tobacco. So it's just an option put on a menu: Would you smoke if you have an unflavored tobacco versus an apple-flavored tobacco, and people did not choose the unflavored option. So it's not an actual study. But I'm proposing to study that. So if I'm funded by the FDA and, you know, we'll -- I'll be able to do that.

DR. DRESLER: Okay.

DR. MAZIAK: Again, it's a joke.

DR. DRESLER: I know. So, well, to follow up on that -- and I know I'm wearing green -- where does menthol play in these flavors in waterpipe?

DR. MAZIAK: Not very popular. It's one of the hundreds of flavors out there. The most popular, the double apple, double cherry, those kind of flavors. But not really the menthol. In cigarettes, it's more kind of predominant because it's one of the only flavors. But with the waterpipe, there's any flavor. So I haven't seen any specific inclination or predominance or any, even, specific level of menthol waterpipe smoking. I don't see it as a big issue at all.

DR. DRESLER: Okay. Dr. Sutfin briefly mentioned younger adults less than 18 congregating in hookah bars because they are not allowed in other bars. Has this been further studied? It certainly was the excuse my kids gave.

DR. SUTFIN: So we hear that in qualitative. So that's something that we do hear. We have not done a systematic study of that, so I can't speak to that. But in qualitative studies, when we asked students about their use of these products, they do sometimes say it's -- you know, they go to these places. It represents an opportunity for them to go out and still sort of have their night out, yet they're not of legal age to get into

bars. I don't know if anybody has any -- yes.

DR. DRESLER: If after a period of time someone is classified as a rarely using, is this significant as a public health issue? So if somebody is rarely using, is it a public health issue?

DR. KING: The short answer is yes. I mean, in the context of youth, they shouldn't be using any form of tobacco, whether it's a combustible like hookah, noncombustible, or an e-cigarette, you know. So we know that there are detrimental health effects from tobacco use. So from a broader public health context, yes.

But it's important to understand the dichotomy between adults and youth, and among youth the issue is of particular concern because we know that most tobacco users begin before the age of 18. So if you have initiation of a tobacco product, particularly hookah, as we saw with Dr. Sutfin's analysis, there's potential for a lifetime of tobacco use and nicotine addiction. So if you can prevent them from the onset from starting, then you're potentially preventing another generation of tobacco users, whether it be hookah or other products.

DR. MAZIAK: I agree. And we don't know actually what are the percentage or proportion of very rare versus -- because

they have a group where they lumped on some days or -- so, we don't know whether -- and we're actually proposing to use waterpipe-sensitive instrument for waterpipe surveillance that covers that range of intermittent use, because if you lump, as with cigarettes, intermittent and daily, for waterpipe you can kind of hide a lot of variability of use that is very important to addiction and health effects with just intermittent use. We're proposing daily, weekly, kind of monthly type of differentiation. And as Brian said, it's an addictive product. We know that. You start with rarely, and I have some evidence that I'm going to present tomorrow as to how people very, very quickly actually develop dependence on waterpipe, using longitudinal data.

DR. DRESLER: I think that's going to come with this next part of the question. All studies seem to use last 30-day use, but would this include all of those that are experimenting? Especially with waterpipe and -- I think it's e-cigarettes and other products. Should scientists set a mark that makes someone -- so I believe what the question is, should it be 5 times, 10 times, or et cetera. So I think it's going to that variability of better defining what is actually the use. And I think that's what you were saying. Right?

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That was one of the comments, you know, when I said I forgot to do that at this workshop. If I can't read the question, you got to go with what my interpretation is.

Okay. Dr. King, when comparing different groups and usage for every day, some day group, or not rarely, were the differences statistically different?

DR. KING: Yes. So it varied depending on the different demographic. But for the most part, the variations were statistically significant when assessed by age and sex. But when you started to parse down with smaller sample size, it was not. But the slides got so incredibly dense that it would have been non-understandable.

But there are large variations that you see by demographics. So we have significantly higher among males compared to females, higher among the higher economic groups, as well as higher among LGBT compared to heterosexual/straight. Those were statistically significant. But some of the others were just trending towards significance, not necessarily statistically significant.

DR. DRESLER: Okay. I think you touched on this a little bit before. Why did your presentation focus on the total groups, including rarely used, rather than an every day, some

day usage, which appears to be more of a public health risk?

DR. KING: So I would argue that it's not more of a public health risk. I think that rarely use, as we've already covered, is a public health problem, and we'd be masking the situation if we didn't. And I think that the large intermittent use is particularly a concern because a lot of people start as intermittent users, and then they continue more routine for different tobacco product use.

So, you know, outside of the public health importance of presenting that way, there's also the statistical importance in that if you assess only every day, some day, you're not going to have a stable sample to present estimates or make comparisons. So for the bulk of those we present some day, every day, and rarely so that we could make some meaningful comparisons, but also to capture the demographic of the people who were actually using the products.

DR. DRESLER: Okay. Are the waterpipe flavors similar to other tobacco product flavors that have some mentholated flavoring? So I -- we sort of touched on this. To support the cooling sensation experienced during the smoking of traditional hookah products. So I guess two questions within that. Are waterpipe flavors that we're seeing similar to other flavored

tobacco products, which in the U.S. those currently would be the little cigars, or are they different flavors? And then do the tobacco product flavors have any level of mentholated ones to have a cooling sensation?

DR. MAZIAK: Yes. I think they're totally different, and I don't know they're perceived by smokers because the tobacco mixture for waterpipe is a complex mixture. It's not only flavors. There's flavors, there's glycerin, there's other substances, and it's a very yucky and sticky product. Even if you touch it, you cannot even wash it out with soap. The smell will continue for days on the hands.

And molasses is a big part of it, and a lot of actually produces -- not only influences the smoke smoothness or flavor, but it produces additional toxicants, such as aldehyde and stuff. And some of it comes from the molasses and from the other ingredient that they use with the mixture. Dr. Shihadeh is going to present later on. He's an expert on that.

DR. DRESLER: This was one of the other questions that you sort of brought up. Do people who smoke waterpipes consider themselves tobacco smokers?

DR. SUTFIN: So I don't know. My hunch is that they probably don't. We hear a lot about -- my concern is do they

ever realize it's tobacco? Do they know that there's nicotine in it? Because some don't. When you talk to them -- when we do qualitative studies, we realize that they know very little about these products. They also tend to believe that because they use it so intermittently there are no health effects. They're mitigating the health effects because they use it so intermittently.

So I think there's a lot of education that really needs to happen. The misperceptions among youth are huge. We've done a really good job of educating youth about the risks of cigarette smoking, but for whatever reasons they are seeing this as a totally different product, and they believe the risks should be totally different. And because they use intermittently, they actually feel that they are at a much lower risk.

And I think, you know, the question about does intermittent risk -- is it a public health threat, I agree completely with what the other panelists say. It absolutely is, and part of it is just the amount of carbon -- the amount of CO that they're getting from the charcoal in any one session. So even one session, you know, they can have CO poisoning. I mean, and you heard about -- Dr. Maziak talked about the reports that we're seeing with hospital -- with ER

admissions. So I think there's a lot of education that needs to happen, just so that they understand the basics of the products that they're using.

DR. KING: And I would just concur, wholeheartedly. And we've done some focus group testing on this, and with most, you know, novel emerging products, there is a lack of understanding of the health risks of the products. You know, we've done for the past 50 years to educate the public on the adverse effects of cigarette smoking. But these emerging products necessarily haven't had that luxury. And so there's a large profound, knowledge gap, particularly around the health effects and among youth.

And the bottom line is whenever you ignite something to the point of inhaling it, there's going to be a health risk. And that's something to -- that needs to be translated to the public, to underscore that less harmful is not necessarily the same as no harm. And educating people on the health effects, particularly youth, is a growing issue for emerging products, such as hookah, but also e-cigarettes and other products that contain nicotine.

DR. MAZIAK: If I can comment, this issue also relates to some very kind of important regulatory issues, which is what

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they write on the product. If you look at the waterpipe tobacco, the nicotine content and tar content, you'll see 0.05 for nicotine and 0 for tar, of course, because it's not combusted. If you combust it, that's how you will produce the tar. And, in fact, Drs. Eissenberg and Shihadeh did investigate different tobacco products and their nicotine yield based on what is written on the package, and there is no association whatsoever. So that deceptive labeling of the product is also one of the factors that probably leading a lot of people to think, okay, it's not tobacco -- look, there's 0 here and 0.005 nicotine. This is nothing. And this is all out of own heads. There is no scientific basis for whatever they write on their tobacco in terms of yield.

DR. DRESLER: Okay. And you all saw, we had that red light, which means if I don't let you go, you're getting your shorter break. So I do have a few more questions, but we can ask them in following sessions. So what happens if we do that? Okay. But excellent. Fascinating. Thank you very much, Dr. Ward. Thank you for being present for us.

(Applause.)

DR. DRESLER: So we have a 15-minute break. There is a kiosk that's outside. If you came in late, I believe they are

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doing what we have done previously: If you order your lunch and pay for it, you won't have to stay in as long a line. And we'll be back here in 15 minutes. Thank you.

(Off the record at 10:47 a.m.)

(On the record at 11:02 a.m.)

DR. DRESLER: It looks like we still have some people out for coffee. So I'm sure they'll be coming in as they hear how quiet it's getting in the room.

So our second session is Waterpipe Tobacco Toxic Emissions and Hazardous and Potential Hazardous Constituents -- that is HPHC. So if you're cool, you don't say hazardous and potentially hazardous constituents; you say HPHC.

So our first speaker again is remote. Dr. Alan Shihadeh is presenting from the American University of Beirut. I think actually he might be at home because it's significantly later in the day there. Speaking on Waterpipe Tobacco Smoke Toxicant Yields, Determinants, and Human Exposure.

Dr. Shihadeh?

DR. SHIHADDEH: Yes. I'm here. Thank you very much.

DR. DRESLER: Excellent.

DR. SHIHADDEH: Thank you for inviting me to talk to the workshop, and I'm very happy to be part of it. I'm glad that

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the FDA is conducting it. As mentioned, I'll be talking today about waterpipe tobacco smoke constituents, their determinants, and some human exposure. I won't have time to talk about a lot, but I'll do my best. Next slide, please.

All right. Before I begin, I should acknowledge that I have no conflicts of interest to report. And also that -- I'd like to acknowledge Tom Eissenberg, Wasim Maziak, Marwan Sabban, and Najat Saliba for their collaboration over the past years. They've been instrumental in a lot of the work I'm going to be presenting today. Also, I'd like to acknowledge the funding by NIH and the Center for Tobacco Products, as presented here, as well as funding from the International Development Research Center of Canada. And finally I'd like to say that the contents that I'm presenting is solely my responsibility and is not meant to speak on behalf of any of the other institutions that have funded this work.

I'll also start by summarizing the whole presentation, and that is -- next slide, please. Sorry. Summary. I'll start by summarizing the presentation, and that is that waterpipe smoke, whether or not tobacco is involved, it derives from charcoal and a maassel -- and you've heard what a maassel is -- and the interaction of these two. It also contains and delivers a

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large dose of toxicants in a single use session. The smoke elicits inflammatory responses and dysfunctions in human cells. It emits large quantities of toxicants into the surrounding environment, and it's affected by waterpipe design and operating conditions. Next slide.

All right. So this is an image of a waterpipe. Its hardware consists of a head, body, water bowl, and hose. It is loaded by the user with a heavily flavored tobacco product known as maassel, which is about one-third to one-half tobacco by weight. The maassel is covered by an aluminum foil sheet and perforated. Because the tobacco cannot sustain combustion, lit charcoal is placed on top of the foil to provide the heat source. We have found that by mass, more charcoal is consumed than is the maassel in a typical use session. You can think of waterpipe smoke as charcoal fumes flavored by flavored tobacco.

And the long path between the hot head and the point of inhalation at the mouthpiece, at the end of the hose gearing in the figure, allows for a lot of cooling and humidification of the smoke as the smoke passes through the water bowl, resulting in a cool moist aerosol that can be inhaled deeply and with little resistance. And, in fact, waterpipe smoking involves puff velocities and volumes an order of magnitude greater than

are found in other tobacco use methods, like cigarettes. Next slide, please.

All right. So before I go too much further -- and given that this is a diverse audience, I just thought I would say a little bit about the tobacco smoke constituents and toxicants. Tobacco smoke, including waterpipe smoke, is an aerosol, which just means that it has a gas phase and a particle phase. The gas phase is about 90% of the mass of the smoke, and it's invisible to the naked eye. We don't see that part. And it contains things like nitrogen and oxygen and carbon dioxide, but it also contains some bad things like carbon monoxide, which causes heart disease. It has benzene and other hydrocarbons, aldehydes, which cause COPD, and other constituents, other toxicants that are in the gas phase.

The particle phase, on the other hand, reflects light or refracts light, and so it's visible to the naked eye. It's the part of the smoke that we can actually see. And it consists of condensed water, nicotine, and everything else. And everything else is 4,000-plus compounds that we collectively have historically called tar. And those contained the majority of the PAHs, nitrosamines, metal, and the most important carcinogens. I'll also mention that the particulate matter is

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well -- seems to penetrate deeply into our lungs. It's of a size range that our lungs are poor at filtering prior to getting deep into the alveolar region. So tobacco smoke is concentrated with many toxic chemicals, but it comes in a package which is the right size to penetrate into the lung. Next slide, please.

All right. If we look at the waterpipe more specifically, there are three sources of toxicants that one can talk about. One is tobacco obviously, and it's where the nicotine, the tobacco, specific nitrosamines, and metal from other things comes from. The second source of toxicants in the waterpipe is the charcoal, and that's where the preponderance of the carbon monoxide, the polyaromatic hydrocarbons, which are lung cancer-causing materials, nanoparticles and so on, all that comes from the charcoal. And then there's the interface, where the hot charcoal is meeting the tobacco. And in that zone, we can produce things like aldehydes and furans and phenolic compounds. So the toxicant emission sources are diverse, and all of them are important with respect to what humans are exposed to. Next slide.

Now, once the smoke leaves the head, many things can happen to it before it gets to the user. And so the first

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thing that I'm illustrating here is condensation on the inner walls. So you have relatively hot smoke coming down a relatively cool metal pipe. So some of the material that's in the aerosol will condense on the inner walls of the pipe. And that's a function of the length of the pipe, the size of the pipe, and the temperature difference between the smoke and the pipe walls.

As we continue down into the bubbler, as the smoke passes, it bubbles through the water that's at the bottom of the bowl. Some of the species that are water-soluble can be absorbed into the water, to some extent, or dissolved into the water. And some smoke can also deposit on the inner walls of the head space above the water in the bowl.

Then, as it continues through the hose -- the hose is typically constructed of a porous material; it's typically leather. So that means when someone is sucking on the mouthpiece, fresh air is coming in and diluting the smoke that's in the hose, and it can account for a third or more of the actual volume that's inhaled. And also, because the hose is porous, small molecules like carbon monoxide can diffuse outward from the hose. And so the hose can act as a way of reducing the amount of CO that's actually received by the user.

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Next slide.

All right. So to summarize this section briefly, waterpipe emissions are influenced by combinations of products. They're not really intrinsic to any one product or any one component of the waterpipe, so the hose affects emissions, the charcoal affects it, the tobacco affects it, and the waterpipe design itself also affects the waterpipe emissions. Next slide.

So the first question is do waterpipes emit toxicants. And if we -- next slide, please. If we read the packaging, we might be led to think that, all right, the waterpipe tobacco has nicotine in it, but it's a 0% tar. And that's almost a universal label you'll find. At least in many parts of the world, waterpipe tobacco products would be labeled this way. And, of course, the label is rather meaningless. The nicotine says 0.05%, and it says that practically across the board. It doesn't say whether that's by weight or by volume. And it says 0% tar, which is technically correct in the sense that there is no tar unless that stuff has been burned. There's no tar in that package. But that's also not very useful. So if you don't want to depend on the labels, we need some information ourselves. Next slide.

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So finding out what is in the smoke involves three basic steps. First of all, we have to find out how people smoke waterpipes; the second step is to program a robot to smoke the same way in the analytical lab; and three, analyze the smoke for toxicants. And that in a nutshell is a lot of what we've been doing over the past 15 years. Next slide.

So finding out how people smoke involves using a puff topography instrument. And because waterpipes involve such higher flow rates, and also because the signal is noisy due to the bubbling, we had to develop our own puff topography instrument. And this has been more than 10 years ago. And when you talk about puff topography, we're really just talking about the flow rate versus time. What is the volume flow rate of smoke versus time while the person is using the waterpipe. And so there you see below a puff topography record of four individual puffs that happened to be drawn by a particular user. Next slide, please.

If we average the data over many use sessions, we can get some kind of representative puff topography. And that would normally be characterized by the volume per puff, the puff duration, the frequency -- like how many puffs per minute are taken and the total number of puffs. One thing to note is

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that, you know, unlike the cigarette, which has a very definite end point -- so someone can't smoke past the filter, for example -- the waterpipe doesn't really have a well-defined end point. So we normally talk about the use session in terms of either the total time or the total number of puffs that were drawn. Next slide.

So we deployed that device in Beirut, in cafés in Beirut. We asked people at the time they ordered a waterpipe from the food server if they would mind participating in a study, and we would attach our topography device to their waterpipe, and we would just let it record for their entire smoking session. And for these 52 smokers that were sampled in Beirut, we found that they smoked on average -- they puffed 171 times on the waterpipe. Total session time would be about an hour. Each puff would displace about 530 mL of smoke. Average puff duration was about 2.6 seconds, which is similar to a cigarette; 17 seconds interpuff interval; and total volume of 90 L of smoke. Next slide, please.

So if you compared that to a cigarette, it's obviously much greater than a single cigarette. Of course, it takes much more time. But what we found astounding was the volume per puff. I mean, it turns out that every puff of the waterpipe

displaces about as much smoke as an entire cigarette does.

Next slide, please.

So other than finding out how they puff, we also needed for the analytical lab to specify other parameters related to generating the smoke. So we developed a protocol which has become known as the Beirut method, and it involved loading 10 grams of maassel into the head of the waterpipe.

And also, I should mention that the charcoal that's been used in this method is a standard manufactured charcoal. It comes as a briquette, as a round disk. And that's used instead of using what are normally used in cafés, which are lump charcoal produced through traditional kilns. And they come in various sizes and shapes, and there's no standardization of them. So it's very difficult to do reproducible experiments in the lab using the natural -- what we call natural -- charcoal. So this is a manufactured charcoal that is an easy light. In other words, you just have to hold a lighter to it and it ignites.

And then we developed a protocol based on the total particulate matter being produced per puff. We wanted to make sure that we had a roughly constant particulate matter per puff throughout this smoking session. So there's a lot of work that

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went into developing this, from that perspective.

Then there was the aluminum foil. We perforated it in a consistent fashion, this pattern shown here. Next slide, please.

Okay. Now that we have a method, we can program our robot to smoke or to produce the puff topography that's desired. Our robot -- this is a schematic of it here, but the main things I'll say are that the robot is digitally controlled. So we can either program it to produce average puff topography, or we can actually play back individual participants' puff topography on a moment-by-moment detail. The machine draws smoke through a series of particulate filters to trap the aerosol phase. And the gas phase either goes into real-time online monitors, or goes into a bag that can be sampled later for various constituents. Shown here is carbon monoxide, but it can also be done for other things. Next slide.

So waterpipe smoke does contain toxicants. Next slide.

And this is just a selection of some of them. There a lot more. There are about 300 chemicals that have been identified in waterpipe smoke, 27 of which are known or suspected carcinogens. And those are detailed more in a special supplement to tobacco controls, which I've listed up here on

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the slides. But I'll say in brief that waterpipe smoke has -- so what you're seeing in this slide in red is waterpipe toxicant yields in a single smoking session, one hour, versus in black the yields from a single cigarette, which would take typically say 5 minutes. And you can see that there is much more tar and nicotine and carbon monoxide in a single use session of the waterpipe. There's also much greater polyaromatic hydrocarbon content, much greater volatile aldehydes, much greater heavy metals, and actually lower quantities of tobacco-specific nitrosamines. Next slide, please.

We have taken these waterpipe smoke samples, and we've done work on them in the biology labs, and we found that the condensates are biologically active. They cause oxidative stress, inflammation, cell cycle arrest, and impaired cell functions. And we've identified plausible cellular mechanisms for vascular disease and COPD from waterpipe smoke exposure in human endothelial cells. And this work is mainly done by my collaborator, I should say, Marwan Sabban, in American University in Beirut. Next slide.

Okay, so is waterpipe smoke generated in the analytical lab relevant to real-world conditions in the first place? So

we've got a lot of questions about that. When you're using this smoking machine, does it really represent what people do? So next slide.

One reason why that question comes up is charcoal. We found that, of course, as I mentioned, more charcoal than maassel is consumed during a typical use session, and users continually tune it while they smoke. So they're constantly fiddling with the charcoal. They pick it up. They add more charcoal. They remove charcoal. They pick it up and blow on it to remove the ashes, put it back on the head. It's very difficult to standard those acts, and we may have been missing something. Next slide.

So one of the things we did is we tried to, early on -- this is back in 2007 and '08, we tried to figure out what portion of the toxicants are actually coming from the charcoal in the first place. And we did that by developing an electrical analog to the charcoal -- so a device that heats the head in a manner that produces similar temporal and spatial patterns as charcoal does. And then we smoked waterpipe using that electrical analog. Next slide.

And so what we found is that the charcoal -- when we compared the carbon monoxide and PAHs in the regular smoke,

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which is generated using charcoal, to that which is generated using electricity, we found that charcoal is responsible for 90% of the CO, more than 95% of benzo(a)pyrene, and the preponderance of all the PAHs. So charcoal turned out to be a very important part of the picture when we're thinking about toxicants. That gave us pause because, as I mentioned before, we were using a particular brand of charcoal in all of our analytical lab studies, and we know that other kinds of charcoal and other patterns are used in the real world. Next slide.

Furthermore, when we sampled the tobacco, we looked at lump charcoal that's used in cafés. We looked at the charcoal that we were using, which is a Three Kings brand, and we looked at another brand of charcoal that's advertised as being eco-friendly and healthier. And we found that actually the PAH content of the charcoal, even before you burn it, varies quite significantly across different types of charcoal. Next slide.

So all of that gave us the impetus to develop a different approach to measure toxicants in the environment. And that approach involved sampling smoke off of the waterpipes as they were being smoked by human participants in the café. Next slide.

So this is a schematic of that device. It's called REALTIME. And basically it has a smoke sampling unit attached to the mouthpiece of the hose. So every time a person draws a puff, about 2 to 5%, depending on what we need, is automatically sampled onto a filter and into a bag in the carrying case. It's all portable and battery-powered. So we can deploy this in people's homes, in cafés, and elsewhere. Next slide.

So when we compared the toxicant yields measured in the real world to that measured in the analytical lab, you see these plots here. We have nicotine, tar, the nicotine-to-tar ratio, and carbon monoxide. And the red triangle represents our analytical lab method using a single type of charcoal and a single product of maassel. And the circles represent individual smoking sessions by different people, adlibbed, using whatever products they happened to be smoking in the café at the time. And what you can see is that the Beirut method -- it represents -- you know, it's in the cluster of reasonable points that are measured with real people. Next slide.

All right. And then another question that comes up is, well, how important is the tobacco? We know the charcoal is important. Was tobacco actually even important? We know it's

the source of nicotine, but what else? Next slide.

DR. DRESLER: Alan, do you know -- I know you're only halfway through your slides, but we're actually at time.

DR. SHIHADDEH: Okay. Well, I -- can finish with this one actually. I don't have to go through the rest of the slides.

This is a product that's typically sold in the U.S. and elsewhere. One of the quotations would be the it "provides the same flavorful smoke found in other shisha but without the harmful effect of tobacco." And on the package you'll see that it says free of nicotine, free of tobacco, and free of tar. Next slide.

And this will be my last slide. And what we've found is that except for nicotine, toxicant profiles of tobacco and tobacco-free toxicant yields are the same. So you can see there on the slide that there were no significant differences. We gave 31 human participants in the clinical lab the opportunity to smoke their own product and then a flavor-matched placebo, which was the SoeX product, and we found that when we played back to our smoking machine their puff topographies, when they used each of those kinds of products, there were actually no differences in any of the toxicant yields. And then we further analyzed that smoke for biological

activity, and we found again that they essentially had the same biological activity as the tobacco-containing product, except for nicotine, of course.

And I will stop there. Thank you.

(Applause.)

DR. DRESLER: It just is so striking to me how much we need to know and the information that's out there. So I am sorry to sew that up, because it was excellent.

DR. SHIHADDEH: Thank you.

DR. DRESLER: Our next speaker is Marielle Brinkman, who is a senior research scientist at the Battelle Public Health Center for Tobacco Products, and she will be speaking on Research-Grade Waterpipe: a Tool for Testing How Waterpipe Components Influence Puffing Behavior and Resulting Hazardous and Potentially Hazardous Constituent Exposures.

MS. BRINKMAN: I would like to thank FDA and Dr. Baoguang Wang for inviting me to speak. It is an honor to talk at this important workshop. Today I'll be talking about a tool that we developed, the research-grade waterpipe. I'll give a brief summary of what went into the design. I'll talk about how we validated it for use with machine smoking and then also in a cohort of waterpipe smokers. And next I'll give some

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highlights of a clinical research study that we conducted to evaluate two accessories that manufacturers claim reduce the harm of waterpipe smoking. Then lastly I will show you some machine smoking mainstream emissions data for the research-grade waterpipe, and we'll compare it with some of the biomarker data and see what conclusions we can draw.

So all waterpipes contain essentially the same primary components, and Dr. Maziak walked us through those: the head, the body, the hose, the bowl that contains the water, and the mouthpiece that people puff on. But commercially available waterpipes around the world run the gamut with respect to size, design, materials, and leakiness. And these differences introduced quite a bit of variability in terms of things like heat transfer, flow dynamics, and so on. This makes it difficult to achieve the precision that's needed to compare emissions and human exposures from different waterpipe tobaccos and coals and draw valid conclusions.

These types of studies are important because under the current draft deeming rule, you heard David Ashley talk this morning, waterpipes will hope to be covered under FDA's authority. So we'll need to understand how toxic emissions, both for waterpipe users and nonusers that are passively

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exposed, are affected by different tobaccos and charcoals.

So in order to conduct the systematic studies that will be needed to generate the evidence for FDA's decision making, we needed a waterpipe that was made of inert materials so that the chemicals that we're measuring don't absorb or desorb from the waterpipe, which would confound our measurements. We also needed to have a low resistance to draw, which is one of the most important ways waterpipe smoking is very different from cigarette smoking. All the fittings have to be secure and leak-tight. Otherwise, we may be underestimating exposures because of ambient air that's infiltrating the system. It has to be easy to clean so that there are no memory effects or background contamination that would prevent reproducible results. And it has to have interchangeable parts so that we can test things like the length of the body and how that affects the emissions, both to users and nonusers. And then we need the ability to measure and record human puffing behavior, and we'll integrate that into the waterpipe so that it can take place without any intervention needed from the smoker.

So the picture on the right shows the result of our thinking. It's actually the fifth prototype, so it took us a while to get everything right. A smoker's puffing behavior or

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topography data can be reduced to give each puff's volume, duration, mean and peak flow, and the intervals in between puffs. So let's move on to some highlights of the validation of the research-grade waterpipe.

We determined the precision and accuracy of the research-grade waterpipe using machine smoking. Here you see some of the data that's describing the precision. This is a graph of coal, which is shown in the black triangles, and tobacco, which is shown in the red circles. And it's the consumption during a 1-hour machine smoking session. You can see that the variability across the 24 sessions generally falls within two standard deviations of the mean.

So once we optimized the precision and accuracy of the research-grade waterpipe, we invited 35 experienced waterpipe smokers into the lab and had them smoke the research-grade waterpipe in a controlled environmental chamber. We asked them to smoke until they were satisfied, but we did limit them to one quick-light charcoal. So this slide shows the puffing profile for one of our participants. Each peak is a puff on the waterpipe. So looking at the data, we found a similar pattern to what's been reported by Maziak, Shihadeh, and Eissenberg, and that is that waterpipe smoking behavior is not

homogenous throughout the session. Participants smoke more intensely in the first third of the session, and you can see that here in the first 10 minutes. Then they settle in to take smaller and less frequent and intense puffs in the last two-thirds of the session.

So some facts that might explain this behavior: why do they do this? Hookah tobacco is composed of up to 50% by weight humectant. It's almost gel-like in appearance because of this humectant. And typically the humectants is glycerin, which is a very sweet and viscous substance. And this high level actually has the effect of cooling the tobacco, and this lower temperature can actually limit the amount of nicotine that is aerosolized. So for waterpipe smoking, the temperature of the tobacco surface rarely exceeds 350 degrees Celsius, and the temperature of the coal is about 500 degrees.

So in the beginning of the session, the subject is drawing very strongly on the waterpipe in an attempt to transfer the heat from the charcoal to the tobacco in order to aerosolize the chemicals that they want, which would be nicotine and the flavors. So once the tobacco heats up, they don't have to work as hard to get what they want, and so puff volumes, flow rates, and puffing frequency generally declines.

So we took all of the topography that we collected for the 35 participants, and we cut each smoking session into thirds. Here you see the average values. So going from left to right across the first row, for the first 10.6 minutes, our smokers took an average of 27 puffs. They were 0.86 liters in volume and 5.3 seconds in duration, at a rate of about 3 puffs per minute. So take a look at that puff column. And we've already talked about it a little bit; 0.86 liters, that's incredible. And Alan already mentioned that a single puff from a waterpipe actually is equivalent to the entire volume of smoke that's drawn from a typical cigarette.

So why do waterpipe smokers take such huge puffs? Largely because the resistance to draw is much lower for waterpipe smokers, which results in about 16 times the flow rate of a cigarette. And waterpipe smokers are also humidifying -- excuse me, they're inhaling a humidified smoke sample, which is about the same humidity as exhaled breath. So it's much easier on the throat and the lungs.

So going back to the table, looking at segments 2 and 3, we see that over the last two-thirds of the session, the puffing rate slows down, and the total volume of smoke inhaled from the waterpipe is roughly half of what was taken in at the

beginning of the smoking session.

So we can compare the average puffing parameters that we got with the research-grade waterpipe to Dr. Shihadeh's Beirut regime, which he was just previously discussing. And that's here shown in the slide in orange. Our research-grade waterpipe smokers took fewer puffs, but they were much longer and larger at a slower frequency. Overall, our laboratory smokers took in roughly half the total puffing volume, as compared to Shihadeh's café smokers: 45 liters versus 91 liters.

So why is our data so different? We think it's because our smokers were restricted to a single coal. They were also smoking in a laboratory environment, which is very different than social smoking in a café. Also, the research-grade waterpipe's plastic hose may be playing a role, since unlike leather hoses it does not allow air infiltration. The lack of air infiltration makes the smoke sample more concentrated, and smokers may not feel the need to take as intense or as frequent puffs.

So next we examined how well the participants accepted or liked the research-grade waterpipe smoking experience, and here we're looking at select responses from two subjective effects

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questionnaires, the Hughes-Hatsukami Withdrawal Scale and the Direct Effects of Tobacco Scale. So our participant data is shown in red. So looking at the top four items, we see that our subjects' average responses, in terms of was the waterpipe satisfying, was it pleasant, did it taste good, did it taste bad, these data are similar to those reported by Dr. Maziak for his cohort of 61 waterpipe smokers. Our participants also responded that smoking the research-grade waterpipe did reduce their craving of waterpipe or nicotine, and it reduced their urge to smoke a waterpipe. You can see our levels were similar to those reported by Dr. Blank in her cohort of 37 waterpipe smokers.

So once we were comfortable with how the research-grade waterpipe performed, in terms of accuracy and precision of machine smoking and its acceptance among waterpipe smokers, we then used it as a tool to evaluate manufacturers' claims of reduced harm. And this is for two accessories that were promoted by the manufacturers as reducing the harm of waterpipe smoking. We used the same cohort of 35 experienced waterpipe tobacco smokers, and a crossover or longitudinal study design, so that each subject served as their own control.

So participants came into the lab. They were randomly

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assigned to one of the three configurations: charcoal, charcoal with bubble diffuser, and electric coal. And they came back to the lab two more times. Each visit was separated by a week -- to smoke the remaining configurations. During each smoking session, the pipe was hidden from the subject so that they were blinded to which configuration they were actually smoking.

So here's some pictures of the different accessories. The two different heating sources are shown at the top, charcoal and electric coal, and the bubble diffuser is shown installed in a commercial waterpipe on the bottom. And you can see it in action when a puff is being taken.

Here's the manufacturer's claims: "A must for the healthy hookah smoker. It is smokeless, odorless. There's no FIRE" -- in all caps -- "no carbon monoxide." And then the bubble diffuser: "These water diffusers work by breaking your hookah smoke into tiny bubbles for increased water filtration." It sounds very promising.

We evaluated the two harm reduction accessories as compared to the standard charcoal configuration on the research-grade waterpipe by measuring exhaled carbon monoxide, environmental carbon monoxide, the exhaled volatile HPHCs -- so these are in the breath -- plasma nicotine, puffing topography,

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heart rate, and then subjective effects.

So we'll just talk about a few of these here. So here's the average exhaled CO boost. These are averaged across 35 participants. We defined boost as the increase from the pre-smoking carbon monoxide breath concentration. Right away, we see there's no difference between the standard and the bubble diffuser configuration. So is the bubble diffuser filtering out toxicants? Not carbon monoxide.

But look at the electric coal. You actually can't see the electric coal because there was no detectible change in exhaled carbon monoxide. When someone smokes a cigarette, we see carbon monoxide boosts that ranges from 6 to 35 parts per million. The charcoal heated waterpipe levels shown here are roughly double that. Carbon monoxide is highly toxic to humans. We've already heard about some of the emergency room visits that have been reported in the literature. It's also a developmental toxicant, and it is classified by the FDA as one of the 93 harmful and potentially harmful constituents in tobacco products.

So looking at the levels of carbon monoxide in the environmental chamber -- these are environmental levels -- we see, in fact, the quick-light charcoal is the primary source of

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carbon monoxide. And so, you know, this has been said previously. You can just barely see the green line for the electric coal because it's hugging the x-axis there. So the levels for the charcoal heating configuration are quite high, roughly 100 times higher than you would expect for a cigarette, even though the air exchange rate of the chamber is set at two and a half air changes per hour.

So just to put that ventilation rate into perspective, the air change exchange rate typical of a home built prior to 1970 is about three air changes per hour. Now, for homes built after the energy crisis in the '70s, you can expect about one air change per hour. So previously -- I think it was -- I'm not sure who showed the data, but much of hookah smoking is going on in residences. So you can see we're roughly in that two and a half air changes per hour.

So this finding that the coal is responsible for just about all of the mainstream and sidestream carbon monoxide agrees with Dr. Manser's findings. And Alan went through those earlier, with his electric coal that he constructed in his laboratory.

So here we see the average level of benzene boost in participants' breath after smoking. So remember boost is

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defined as the increase in breath from baseline pre-smoking levels. For volatile chemicals such as benzene, concentrations in a person's breath can actually reflect the levels in their blood. That's why the device known as the breathalyzer can be used to estimate a person's blood alcohol content. So it's the same theory. Again, we see no difference between the research-grade waterpipe with and without the bubble diffuser. So is the bubble diffuser filtering out toxicants? Not benzene.

But so far, things are looking pretty good for the electric coal as a harm reduction device. We can see from these data that the quick-light charcoal is also the primary driver for benzene exposure, and this conclusion agrees well with Schubert's findings when he used machine smoking of the waterpipe to look at mainstream smoke benzene levels. These findings are also consistent with Dr. Kassem's biomarker data, which showed a fourfold increase in benzene urinary metabolite levels the morning after waterpipe smokers participated in an evening of social hookah smoking. Benzene is a human carcinogen, and in the U.S., the National Institute of Occupational Safety and Health limits benzene exposures in the workplace to less than 1 ppm in the air for a 15-minute time period. That's 1 ppm in air. Our participants had 8 ppm in

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their breath. So benzene is also on FDA's HPHC list.

We also looked at the change or boost in our participant's plasma nicotine as a result of smoking. Again, we see no real difference between the standard and bubble diffuser. It's not filtering out nicotine either. Looking at the electric coals shown in red, nicotine boost was only about half of what we measured for charcoal heating. So for cigarette smokers, we see plasma nicotine concentrations ranging from 20 to 55 ng/mL, and this is roughly half for waterpipe smoking. Nicotine is also classified by the FDA as an HPHC because it's an addictive chemical.

So now let's move from human smoking back to machine smoking. This shows the average nicotine levels measured in mainstream smoke that was generated using a smoking machine and a standard waterpipe puffing regime. The black bar shows the nicotine emitted when the research-grade waterpipe has a quick-light charcoal, and the red bar shows the same waterpipe using an electric coal. And we see that the electric coal results in much less mainstream nicotine delivery, about one-fifth the amount.

But wait a minute. When we look at the participants' plasma nicotine levels, we see that they do have lower plasma

nicotine when using the electric coal, but the disparity is much less. They have about half. So these ratios aren't quite jiving. On the left, plasma nicotine for electric coal is roughly half that for the quick-light charcoal. But if the electric coal is only delivering about one-fifth the level of mainstream nicotine shown on the right, how do the participants get all that nicotine in their bloodstream? Where is the nicotine coming from?

The answer lies in the participants' puffing behaviors. This slide shows the average total puffing volume participants inhaled each session. Again, there was no significant difference between the standard and the bubble diffuser, but look at the electric coal in red. Subjects took in over one and a half times the volume of smoke from the research-grade waterpipe when using the electric coal. So much for harm reduction.

So taking all this into consideration, we're seeing evidence of waterpipe smoker compensation here. And it's very important, especially from a product regulation standpoint, that we remember the hard lessons we learned with light and ultra-light cigarettes. Humans don't smoke like machines. In fact, humans titrate their nicotine dose through compensation,

by taking larger and more frequent puffs. This is well established for cigarettes, and the data presented here provide evidence that this can also happen with waterpipe smoking.

This finding highlights the limitations of evaluating tobacco products based on machine smoking alone. We know from Benowitz's work in the late 1990s that cigarette smokers seek to take in a constant level of nicotine each day and will change their puffing behavior in order to get that nicotine. This is why human studies are so important to understanding a tobacco product's harm. Had we stopped at just the machine smoking data, we would have concluded that the electric coil delivers one-fifth the nicotine of charcoal. But our participants almost doubled the volume of smoke that they inhaled when using that so-called harm reduction device.

So keep in mind that half of our waterpipe smokers said that they didn't even smoke cigarettes, and the ones that did smoke cigarettes said they smoked less than half a pack a day. Yet, we see evidence here that suggests these waterpipe smokers are in fact addicted to nicotine.

So, in summary, the research-grade waterpipe is a tool with known precision and accuracy, and it's well accepted by smokers. Waterpipe accessories can be associated with changes

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in puffing behaviors and subsequent user exposures. Manufacturers' reduced harm claims need to be supported by sufficient peer-reviewed evidence. And smoker and environmental exposures from waterpipe exceed those from cigarette smoking.

I'd like to thank the National Cancer Institute and the FDA Center for Tobacco Products for the funding that made this work possible. And I would also like to recognize all my hardworking collaborators for their contribution to this work.

(Applause.)

DR. DRESLER: Another excellent presentation. Thank you so much.

So right now what we're planning on doing is putting our Session 2 and 3 together. So after lunch we'll do the Session 3, and then we'll have the panel crossing both of those.

So right now it is lunchtime, and it is 10 to 12. So we had planned for an hour for lunch. Let's do an hour and 5 minutes. Is that okay? All right. Because then maybe we finish a little bit earlier instead of -- 4:55 instead of 5:00. So anyway, please come back, and we'll start at 5 to 1.

Okay. Thank you so much. As I had said before, there is the kiosk that's out there.

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(Whereupon, at 11:49 a.m., a lunch recess was taken.)

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A F T E R N O O N S E S S I O N

(12:55 p.m.)

DR. DRESLER: Shall we gather and get started, please? I see our first speaker walking up.

So this Session 3 is on Design Parameters, Secondhand Exposures, Environmental Concerns and Matrix for Reference Products. And our first speaker is one of our scientists from our Office of Science, Ron Edwards, who is a biologist. And he's going to be speaking on Considerations of an Environmental Impact Analysis for Waterpipes, and I've had the opportunity to actually hear him practice this. I'm not sure if everybody in the world knows or the U.S. knows that a key part of our regulatory aspect is to look at this environmental aspect. So I think you'll find his presentation very informative.

Ron?

MR. EDWARDS: All right. Thank you, Carolyn. Again, I'm Ronald Edwards. I'm a biologist with FDA for Center for Tobacco Products. And I'm with the Environmental Science Group. Today I'm going to present considerations of an environmental impact analysis of waterpipes.

But first, I would like to state that waterpipe tobacco is currently not subject to the FD&C Act's tobacco product

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authorities, specifically deeming authority. In April 2014, FDA issued the deeming proposed rule. Comment period ended in August 8, 2014. And specifically, should the Agency deem waterpipe tobacco as subject to Chapter IX of the FD&C Act, as proposed, additional information about the products would assist the Agency in carrying out its responsibilities under the law. However, this workshop is not intended to inform the Agency's proposed deeming rule or seek advice of consensus. Lastly, if waterpipe tobacco is deemed subject to Chapter IX of the FD&C Act, NEPA provisions would apply.

My talk today will specifically go over the National Environmental Policy Act and FDA, potential waterpipe environmental impacts, and specifically the environmental impacts of waterpipe tobacco cultivation, imports and exports domestically for waterpipe tobacco, environmental impacts of waterpipe tobacco manufacturing, and waterpipe use and disposal after use and their impacts for the environment.

So, first, National Environmental Policy Act and FDA. I want to go over what is NEPA, the purpose of NEPA, and FDA's decisions subject to NEPA.

So, first, what is NEPA? "An Act to establish a national policy for the environment, to provide for the establishment of

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a Council on Environmental Quality, and for other purposes."

So what is the purpose of NEPA?

- "To declare a national policy which will encourage productive and enjoyable harmony between man and his environment"
- "to promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man"
- "to enrich the understanding of the ecological systems and natural resources important to the Nation"
- and lastly "To establish a council on environmental quality"

So FDA's decisions are subject to NEPA. Specifically, for the formation of new regulations, request for private action, and specifically market authorizations for certain product applications.

So what are some of the potential waterpipe environment impacts? Environmental effects as a result of waterpipe manufacturing: we have to consider tobacco cultivation; also, impacts due to manufacturing. Environmental effects as a result of waterpipe use: we have to consider tobacco imports

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and exports domestically; also, we have to consider secondhand and thirdhand smoke. Secondhand smoke is not on my slide. I'm not going to cover that today. That will be covered and has been covered in other talks. And lastly, environmental effects as a result of waterpipe disposal after use.

This is a flow diagram, specifically an overview of potential environmental impact considerations. And we start with natural resource use, and then we move up to environment effects as a result of manufacturing waterpipes and tobacco itself. Then we move over to actual use of the waterpipe. Lastly, we consider disposal after waterpipe use.

And now to specifically go over the flow diagram. Land use, we have to consider, again, cultivation of tobacco itself, the trees used for charcoal, and then we move over to the left where we consider mined materials, the use of wood and synthetic products, manmade products, for the actual unit.

Then we move up to the actual manufacturing of the units and also the tobacco manufacturing, and specifically mass production and manual production. There's obviously differences between -- mass production is mass production in respect to more automated/less human involvement, whereas manual production would be human involvement, single unit

construction. But more importantly with us with the Environmental Science Group, we look at TRI data, which is reported information of waste by manufacturers on the larger scale of mass production.

Then we move over to environmental effects as a result of the use of the waterpipe, and we consider secondhand and thirdhand smoke.

Then lastly we move over to disposal after use, specifically waterpipe recycling. What happens to the unit when it's reached its life expectancy? The wastewater disposal from the bowl of the waterpipe, what happens to that water? What's in that water, does it go down the sink; is it thrown out onto the ground as waste? Also, we consider waterpipe ash and tobacco disposal. Again, is that thrown out as trash onto the ground, or is it thrown into the municipal solid waste stream. Lastly, we consider human excretion. Does it end up into our wastewater treatment, or does it go onto onsite septic systems. We have to consider that.

So, first, specifically, the environmental impacts of waterpipe tobacco cultivation are not fully understood. Specifically, we would like to know pollutant machinery emissions: again, tractors, other farm machinery. Change of

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land use due to potential increased use of waterpipe tobacco: Will there be more acreage or more land used with trends? And lastly, we need to consider pesticides, fertilizers, water use, nutrients, and chemical runoff from those farms.

Next, we need to consider waterpipe tobacco manufacturing, and also the manufacturing of the units, again, are not fully understood. We need to consider pollutant emissions from factories, their effect on greenhouse gases, solid and liquid waste from factories, nonrenewable resources used for the production of the units themselves, and construction of new waterpipe factories is an increased trend, meaning more construction domestically of waterpipe factories to produce the units.

So I said I would cover imports and exports, first here being imports. This is USDA's data. The reason why there is just from 2012 data is the metric tons did not hit on USDA's blip for enough product coming into the United States. It just started doing that in 2012. And as you can see, that there's an increased trend of waterpipe tobacco coming in domestically into the United States from foreign lands. And just a little disclaimer on this. This data does not represent domestic use as it is just showing imports, not actual sale and use of

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waterpipe tobacco. So again, it's just showing a trend that we're actually bringing in waterpipe tobacco.

Here is exports, and you can see an increase from 2012 to 2013, but it's plateaued. And the difference between the two, as you can tell, there's significantly more coming in domestically from foreign lands than we actually exporting in waterpipe tobacco.

I said I would cover thirdhand smoke. Again, secondhand smoke will be covered in other presentations and have been. I found one study that specifically stated greater than 47 times the amount of nicotine in thirdhand smoke detected in hookah-smoking households than in non-hookah smoking households. To define thirdhand smoke, thirdhand smoke is after the use of the waterpipe, the smoke that adheres to inanimate objects. We need to consider that in the Environmental Science Group.

We also need to consider disposal after use, again not fully understood. We need to consider waterpipe bowl water disposal. We need to consider wastewater dumped on the ground, sewer, or septic system, again the wastewater from the bowl after the waterpipe has been smoked. We need to consider used tobacco and the charcoal disposal, effects on municipal solid waste systems, again with these products being disposed of or

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the unit itself. And finally recycling of the waterpipe unit itself: So when it's reached its life expectancy, what happens to the unit? Is it recycled? Does it hit our mainstream waste?

To continue, again, disposal after use, I have two studies here, the first being a study conducted found that the distribution of heavy metals, including the ones listed here -- chromium, iron, manganese, again, nickel, lead -- throughout the compartments of a waterpipe, and as you can see to the right, that ash residue has 40% of those metals left in it after the use of the waterpipe. Another 3% is in the wastewater. So again, we have to consider where these are going to. Are they going in our mainstream solid waste? Are they being thrown onto the ground?

Lastly, the second study shows that arsenic remained in the ashes after use, again leading us to understand what happens to that ash, if it has arsenic in it and where it goes.

So to bring up some research gaps -- there's many, specifically emissions due to cultivating, manufacturing, and use; disposal of tobacco, ash, and wastewater after the use of the pipe; energy used due to manufacturing of the waterpipe units themselves; raw materials used to manufacture waterpipes;

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the composition of a typical waterpipe's wastewater after a smoking session, again, if we know what's in it, and then also, as I said before, where it's going; and lastly there, secondhand and thirdhand smoke, their effects from using the waterpipe.

These are my citations. And I would like to thank you for my presentation today.

(Applause.)

DR. DRESLER: Until I learned more about this topic, I had not thought about, you know, those hookah cafés and where all that water is going from there. It brings up some pictures to mind.

All right. Our next speaker is going to be Marielle Brinkman, again from the Battelle Public Health Center for Tobacco Research, and she is speaking on The Influence of Testing Protocols and Waterpipe Design on HPHC Emissions from Waterpipe Tobacco Smoking.

MS. BRINKMAN: Okay. Thank you again, FDA, for inviting me to speak. The first part of this talk is actually a little bit of fiction because you don't yet have a final rule that deems waterpipe products under FDA's regulatory authority. However, FDA has put forth a draft deeming rule, and we heard a

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little bit about that in the previous talk. And I will highlight parts of that draft rule that apply to the talk I'm going to be giving. And I will talk about the need for standardized emissions testing for waterpipe products and why we can't just use the existing cigarette methods because there are so many more variables to waterpipe testing. And then finally I'll review some of the findings from our laboratory and other laboratories in terms of understanding how waterpipe components, parts, and accessories affect smokers and nonsmokers' exposures.

So on April 24 FDA published the rule to extend the Agency's authorities to all of the products that meet the statutory definition of a tobacco product, and this would include waterpipe tobacco. Currently, only cigarettes, cigarette tobacco, roll your own, and smokeless tobacco are subject to the Family Smoking Prevention and Tobacco Control Act.

So if the current deeming rule was accepted, what would be covered in terms of FDA's regulatory authority? Obviously, waterpipe tobacco would be covered. Not as obvious, waterpipe components and parts. And these are defined in the draft rule as part of a finished tobacco product or intended for consumer

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use in the consumption of a tobacco product. So examples of these for waterpipe are filtration devices and flavored waterpipe charcoal that would be used during the smoking of waterpipe tobacco.

So what about waterpipe accessories? These are defined in the draft rule as items that may be used in the storage or personal possession of a waterpipe, such as tongs, charcoal burners and cases, and these accessories would not be subject to FDA's regulatory authorities.

So once the rule is finalized and waterpipe falls under FDA's authority, what does that mean? Essentially, all of the same Food, Drug and Cosmetic Act provisions that cigarettes, roll your own, and smokeless tobacco are subject to would be applied to waterpipes. So I've listed the provisions that are important to what I'll be talking about. So manufacturers must submit a list of ingredients for the brands and sub-brands. They must also report harmful and potentially harmful constituents in the mainstream smoke for all products. No more false claims regarding reduced harm. And no new products without FDA review.

These provisions are designed to improve the public health by providing FDA critical information regarding the health

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risks of waterpipe products. They're also designed to prevent new products from entering the market if they're not appropriate for the protection of public health, and they reduce the use of misleading claims that might lead consumers to initiate or continue to use waterpipe products when they would otherwise quit. The provisions listed here also have something else in common, and that is that they all require chemical testing in order to generate the necessary data.

So before we get into the waterpipe emissions, let's just take a quick look at ingredients. Waterpipe tobacco and coal has essentially all of the same harmful and potentially harmful constituents as cigarette tobacco. Although characterizing flavors have been banned in cigarette tobacco, waterpipe tobacco and coal offers many sweet and candy-like flavors, and the current evidence shows that these flavors are very attractive to adolescents and young adults, and they may actually play an important role in tobacco initiation.

In addition to flavors, up to half of the weight of waterpipe tobacco is due to humectants. Glycerin, which is the most widely used humectants in waterpipe tobacco, is a very viscous liquid that makes the tobacco more like a gel. And you can see how shiny it is in the upper left there on the slide,

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as compared to cigarette tobacco. Glycerin is also sweet, almost as sweet as table sugar, which may serve to enhance the appeal of waterpipe tobacco smoking. Cigarettes also have glycerin in them but at much lower levels 20 to 50 times lower than what you would find in waterpipe tobacco. So other harmful and potentially harmful ingredients include, as already discussed, heavy metals, nicotine, PAHs, and TSNAs, and all of these have been reported in waterpipe tobacco and charcoal products.

So the rest of my talk will primarily focus on the testing of waterpipe emissions. Waterpipe smoking normally uses burning coal as the heat source, and Alan went over this this morning; the smoke includes toxicants that are emitted both from the charcoal and from the tobacco product itself. Waterpipe smoke includes constituents that are simply transferred from the raw material to the smoke. Those would include heavy metals, humectants, nicotine, and tobacco-specific nitrosamines. It also includes constituents that are chemically synthesized during the smoking, and this would include carbon monoxide, ultrafine particles, and volatile harmful and potentially harmful constituents. And then in the case of PAHs, they are both transferred from the coal as well

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as synthesized by the burning of the coal.

So there are many cigarette emissions testing protocols that have been established and used for years. And ISO 3308 is one example. Here you can see from Figure 4 of ISO 3308 the kind of specific detail that these protocols describe. This is schematic of a suitable holder for the glass fiber filter that would be needed to collect particulate matter or tar from a cigarette.

There are no standardized waterpipe testing protocols. So why can't we just use the ones that have already been established for cigarettes? Simply put, waterpipe smoking is much more complex than cigarette smoking. It involves a lot of human involvement, things like loading the head with tobacco, covering the head with foil, poking holes in the foil for proper airflow, lighting and moving the coal around. All of these activities introduce a wide array of variables that need to be specified and controlled for waterpipe emissions testing in the laboratory.

So this slide shows some of our recommendations for the testing protocols that would need to be developed. Tobacco sampling and waterpipe preparation: That protocol would answer questions like how do you homogenize the tobacco, is it

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meaningful to condition a tobacco that has such high levels of humectants in it, how much tobacco do you put in the head, do you pack it loosely or do you pack it tightly, how should the smoking apparatus be cleaned, how often?

And the smoke generation protocol: Should the puffing regime be based on real-world smoking behaviors, should it use playback or steady periodic puffing, or should there be more intense puffing in the beginning to model human behavior? What type of charcoal should be used? Should the smoking machine have syringe-based puffs that model the human diaphragm or just a mechanical pump?

Sample collection: How many filters should be used to avoid breakthrough or mechanical losses of the particulate phase since there is so much more particulate in waterpipe smoke? How should the gas phases be collected?

And then finally toxicant quantitation: How should toxicants be chemically extracted? Does the sample need cleanup to remove interferences? And what instrumental methods of analysis should we use for the specific toxicants?

So moving on to the equipment that's needed, one of the advantages to testing cigarettes is that they're already manufactured to be quite uniform in size, and a lot of them can

be smoked simultaneously in a machine, just like the one that's pictured in this slide.

But even though all waterpipes contain essentially the same primary components -- the head, the body, the hose, the water bowl, and the mouthpiece -- commercially available waterpipes run the gamut with respect to size, design, materials, and leakiness. And I covered this earlier today.

You can even see this variety within the public health tobacco research community. Here you see the commercially available waterpipe that was used for Alan Shihadeh's earliest mainstream smoke study. And here's another commercially available waterpipe that was modified with the addition of a mobile puff topography collection, and this has been used by both Shihadeh and Eissenberg's groups for human and machine smoking studies. And here is the shisha smoker with waterpipe that was designed by Borgwaldt. This apparatus was used extensively by Shudark (ph.) and colleagues for waterpipe emissions testing of inorganic and volatile and semivolatile organic compounds. Then there is Battelle's research-grade waterpipe, connected to the Borgwaldt shisha-smoking machine here in this slide. The research-grade waterpipe also includes puffing topography collection, and we have used it to measure

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puffing behaviors in human exposure studies and with the smoking machine to conduct emission testing. For those that just tuned in, I talked quite a bit more about this device this morning.

So this table shows waterpipe puffing behavior from three different research groups, each collected with their own specially designed topography devices. On the right-hand side is cigarette puffing behavior for comparison purposes. So waterpipe puffing is very different from cigarette puffing, and we've covered this quite a bit today. The average puff volume is roughly 20 times that for cigarettes. This is quite amazing when you consider smokers can take up to 171 puffs in a single waterpipe session.

How does this variability in puffing parameters translate to establishing a single puffing regime for waterpipe emissions testing? This is an important question because there's plenty of evidence to support the fact that toxicant emissions are strongly influenced by the puffing parameters that are used to generate them.

So besides puffing regime, what are some of the other important variables in waterpipe emissions testing? How does the design of the waterpipe affect the emissions? What about

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the smoking machine? What heat source should be used among the many combustible and electric coals that are available? What materials should the head be made out of? How should it seal to the body? Should the bowl be made of glass or plastic? How much water should be put into it? Should we use traditional leather hoses or the newer plastic ones? How do we collect our smoke sample, given how much more material we'll be collecting compared to what is collected for cigarettes?

So in the absence of standard waterpipe emissions testing protocols, public health researchers have used a wide variety of equipment and procedures to study waterpipe emissions. And you've seen some of those data here today. Because of this variety, rigorous comparisons of measured toxicants across research groups isn't possible. However, machine smoking emissions data collected within research groups are available to estimate the influence of a single variable on emissions. These include looking at the heat source, the material used to separate the coal from the tobacco, the water in the bowl, and the hose material.

So heat source and the material used to separate the coal from the tobacco. We used the research-grade waterpipe to perform a systematic evaluation of the effect that different

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waterpipe components have on constituent yields. I'm going to be showing you data from two different heat sources, the quick-light charcoal versus the electrical, and two different ways of separating the coal from the tobacco, using foil versus a tray.

So here is our set-up. Our smoking room is shown in the blue box on the right. It is a room that is isolated from the rest of the laboratory. The smoking room is well mixed and has a separate ventilation system that can be precisely controlled. The coal is weighed, lit, and placed on the research-grade waterpipe using a glove box that is built into the wall of the chamber. And this prevents our laboratory staff from being exposed to toxicants. The smoking machine, which is controlled using our human-topography-based puffing parameters, is located outside of the chamber. It takes a puff, and the resulting mainstream smoke is sent to the particle monitor, which not only continuously records the size distribution of the particles, it collects them for later size-specific chemical analysis. Then looking at the pink and gray boxes, we also continuously monitor the room for volatile toxicants, including carbon monoxide.

So here is some of the data that we collected for the mainstream smoke. We're looking at semivolatiles now. These

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measurements were done in replicates of 12 or more. Right away, we see dramatic reductions in emissions when using the electric coal, which is shown in bright green. We also see reductions in everything but nicotine when using the tray, which is shown in orange, instead of the foil, which is shown in brown. So looking now at sidestream smoke and looking at volatiles, because we made these measurements simultaneously, we again see significant reductions for the electric coal, this time for acetaldehyde, 1,3-butadiene, benzene, and isoprene. But look at the charcoal with the tray in comparison to the foil. Now, we see increases in acetaldehyde, benzene, 1,3-butadiene, and isoprene.

So this table summarizes the findings I just discussed. In general, mainstream and sidestream levels of harmful and potentially harmful constituents were much lower when using the electric coal. But, and this is a very, very big but -- I can't believe I said that. Sorry.

(Laughter.)

MS. BRINKMAN: One very important thing to note here is that machine smoking yields do not, do not provide valid estimates of human exposure because human puffing can vary dramatically by product. And I hate to keep banging the same

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drum -- if you saw my earlier talk, then you've seen this slide -- but I want to draw your attention to it again to back up my statement that machine smoking does not provide valid estimates of human exposures to toxicants. So this slide shows the average total puffing volume that human participants inhaled when they smoked the research-grade waterpipe using charcoal heating, which is shown in the black and the white, versus electric heating, which is shown in the red.

Participants took in over one and a half times the volume of smoke from the research-grade waterpipe when using the electric coal. And they also smoked the waterpipe for a longer period of time. Machine smoking using a single puffing regime does not account for this type of compensation via puffing behavior.

All right. So there's been a lot of talk about the water. Does it filter out the toxicants? Waterpipe use is increasing in the U.S., and the one of the reasons may be that it is frequently inaccurately perceived by adolescents and young adults as being a less harmful alternative to cigarette smoking. And one of the rationales that's often given for this mistaken perception is that the water in the bowl filters out the toxins.

This table shows evidence from two groups that have

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conducted testing with and without the presence of water in the bowl. So if you look at the left-hand column, you can see some of the harmful and potentially harmful constituents that are partially removed from the smoke because they're dissolved and retained in the water. However, if you look at the right-hand column, that even with the losses to the water taken into account, the levels in waterpipe are much higher than those in cigarettes. So although the water does filter out some of the toxicants, the levels that everybody has been talking about today, the ones that are inhaled by the smoker, are still so high that they exceed levels in cigarette smoke. And we know, of course, that none of the reductions would apply to sidestream smoke because that does not bubble through the water.

So the last question we'll look at is whether the construction of the hose has an effect on mainstream smoke emissions. So although leather hoses are more traditional, plastic hoses are becoming more and more popular in the U.S. because they can be more easily cleaned. However, because plastic hoses do not allow air to infiltrate the hose and dilute the smoke sample, mainstream tar and carbon monoxide emissions are much higher. Again, the results shown in this

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slide are from machine smoke data. So it is not clear whether smokers will adjust their puffing volume to a lower intensity to account for this more heavily concentrated smoke. Plastic hoses are more reproducible from a standardized machine testing standpoint because they produce a leak-tight system that behaves consistently at different puffing flow rates.

So, in summary, standardized methods are needed for waterpipe tobacco, coal, and emissions testing. Standardized tools are needed to inform our understanding of the important variables and in order to develop these methods. And that is one of the reasons why we designed and built the research-grade waterpipe. Waterpipe components and parts can be associated with changes in emissions, smokers' puffing behaviors, and overall smokers' exposures as well as nonsmokers' exposures.

So I would like to thank the National Cancer Institute, the FDA Center for Tobacco Products, and the World Health Organization for the funding that made this work possible. And again, I'd like to thank the hardworking collaborators for their contributions to this work. Thank you.

(Applause.)

DR. DRESLER: Okay. And our third speaker is Dr. Ana Rule from the Johns Hopkins Bloomberg School of Public Health, and

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she will be speaking on Secondhand Hookah Smoke: Health and Environmental Concerns.

DR. RULE: Thank you very much. And thank you for the invitation to the FDA. And I will be talking about some studies that we have done about secondhand smoke and health and environmental concerns. Fortunately for this audience, everybody is aware of the Tobacco Control Treaty that was adopted in 2003 and entered into force in 2005 and, of course, has been ratified by 180 countries by last year. The reason I wanted to set it up is because of these three clauses that are very relevant for hookah.

There is no safe level of exposure to secondhand smoke. It has been shown that effective measure -- the only effective measure is total elimination of the smoking in the indoor environments, that ventilation, air filtration, and designated smoking areas are ineffective measures. Second, that all people should be protected; therefore, all indoor workplaces should be smoke free. And, third, that the legislation is necessary because it has been shown that voluntary policies are ineffective, and legislation should be simple, clear, and enforceable.

And you've all seen many variations of the theme. But I

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just wanted to highlight that the users and bystander both inhale the charcoal -- I mean, inhale both the charcoal and the tobacco smoke, which is why we see these really high levels, and that many national and international policies that apply to cigarette smoking do not apply to hookah smoke or waterpipe.

This has also been pointed out before, that somehow it went from being a traditional Middle Eastern culture into college bars where our children are being exposed now.

At the time when we started this study, there were really few real-world evaluations of what was happening in the environment. So we first conducted a relatively small -- basically a pilot study, where we visited 7 hookah bars, 12 total sampling visits. So a couple of the same bars were visited a couple of times. And the mean sampling time was around 3 hours. This was mostly done by students in our group, so we didn't want to expose them too much, although it was voluntary, they were already doing it.

So we observed the smoking activity within the rooms, the number of patrons, the facility characteristics, like was there cooking, the ventilation, open windows, things like that. And then we really wanted to develop methods that were easy to use to evaluate the main or some easy to measure pollutants.

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So we sampled PM2.5 in two ways. We have a real-time monitor that measures once a minute, and then a gravimetric integrated monitor that requires a pump. We have a real-time carbon monoxide monitor, and then we used air nicotine monitors that integrate the exposure over the sampling time, so the 2 hours.

So to get promptly to my results, the PM2.5, even though it varied greatly by establishment, as is, you know, understandable because of the different characteristics, were really very high. And we were surprised at how high they were, although maybe we shouldn't have been surprised when we went into one of these establishments. You can barely see. But so, as has been pointed out, the WHO guideline of 25 $\mu\text{g}/\text{m}^3$ for 24 hours is way down here, as is the EPA 24-hour guideline. Our overall mean of 712 is still above the guidelines, and many of these greatly exceed, by 20 to 30 times.

So CO, as has already been pointed out, is also very, very high and a great concern. Both exceed the WHO and EPA guidelines.

Then, we also found airborne nicotine concentrations. They were not as high as we expected they would be. But also it was a very short period of time. So it's hard to -- we were

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bumping on the limit of detection of our method. But they were definitely higher than smoke-free bars and restaurants.

So we did find indoor concentrations of PM2.5 and carbon monoxide exceeded the health-based exposure standards. They were both markedly greater than the venues allowing cigarette smoking. Measurable airborne nicotine concentrations showed that there was secondhand and potentially thirdhand exposure. And waterpipe smoking was likely the major source of these because they had no alternate source of combustion, such as cooking, open fires, or cigarette smoking. This is published a couple of years ago.

So the second study that I wanted to talk about just came out in January and was led by Terry Gordon and colleagues in New York City, and we collaborated with some of the logistics and lab analysis. So it was 10 workers recruited in New York City from 4 of the 14 targeted hookah bars. The inclusion criteria was you had to be older than 20 and excluded pregnant or current cigarette smokers. Again, the area environmental sampling was for 1 to 2 hours and measured total particulate matter, fine black carbon, carbon monoxide, and nicotine integrated samples.

They also measured biomarkers in workers immediately

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before and immediately after their work shift. Work shifts varied between 10 and 12 hours. So they measured blood pressure and heart rate, exhaled carbon monoxide, and saliva cotinine levels, which have been shown to be markers of active smoking and secondhand smoke exposure, and some selected inflammatory cytokines in blood, like IL-1b, IL-6, IL-8, interferon gamma, and tumor necrosis factor alpha.

So the results for air pollution, I put the table from the paper here. The mean PM2.5 was 363 $\mu\text{g}/\text{m}^3$, again an order of magnitude at least higher than the guidelines. Mean carbon monoxide was around 13 parts per million. Mean black carbon 2.5 was 2.2 $\mu\text{g}/\text{m}^3$, and airborne nicotine was found in all establishments, despite the ban on tobacco-use-based shisha in waterpipes in New York City.

For the cardiac biomarkers, they found heart rate very similar, not statistically significant, but slightly elevated post-shift compared to pre-shift. Exhaled carbon monoxide was through the roof, like has been pointed out before. And keep in mind these are nonsmoking workers. But the rest of the biomarkers were non-significant. And I wanted to point out that even though this is not significant, the salivary cotinine before and after the shift, they were both elevated. So that

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indicates that these workers are being exposed. This just shows the half-life of nicotine, and there might be other exposures.

Regarding the markers of inflammation, the only one that was statistically significant was interferon gamma. But the others, even though not significant, you can see a trend. They were all slightly elevated post-shift than pre-shift, and we think that's not -- we didn't achieve significance because of the small sample size and huge variability.

But this is important because these markers of inflammation have been shown as a risk factor for cardiovascular and pulmonary disease, such as atherosclerosis, ischemic heart diseases, stroke, and COPD. IL-6, TNF alpha have been specifically implicated in the progression of atherosclerosis. IL-1, TNF alpha and interferon gamma are believed to be involved in ischemic heart disease. And IL-8 is postulated to possible genesis for COPD.

So indoor concentrations of PM2.5 exceed standards and guidelines. CO exceed EPA standards and potentially also occupational standards. Worker biomarkers indicate some effects caused by exposure to secondhand hookah smoke during their work shift. And the long-term consequences of these

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exposures are not well known.

So these findings contribute to the understanding of hookah smoke as a hazardous indoor air pollutant, as has been shown before, of course. And it is at least as toxic as cigarette smoke. Our findings also suggest that a large number of workers in these venues will be adversely affected. And there is need to address these regulatory gaps that allows indoor smoking.

And I know I don't have a lot of time, but I just wanted to briefly mention that we wrapped up an international hookah study that was done in Istanbul, Moscow, and Cairo, where we enrolled some hookah bar employees, and we did very similar to what I've been talking about. We took air samples, and then we also collected biomarkers. So we collected hair, urine, and saliva. And we've been analyzing them for nicotine, cotinine, NNAL, hydroxypryene, trace metals, and carbon monoxide. So you have to stay tuned because those are in the works.

But I would like to acknowledge all the hard work of many, many people involved in these studies, and most of the funding was obtained through the Institute for Global Tobacco Control at Johns Hopkins University. Thank you.

(Applause.)

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DR. DRESLER: So what we'll do is a panel and questions. So again, as you're thinking of your questions, to write them on the cards that are available and pass them over, and we'll ask. And then we're getting Dr. Shihadeh on the phone. And thank you, Marielle, for coming up.

I have a question. In your slide, you said that there should be policy recommendations for indoor smoking. So I was thinking secondhand smoke law, which is not under FDA jurisdiction. So that's why I'll ask it before he comes on. And why are you saying indoor smoking versus say on the cafés, because some places in the U.S. are going for banning that even out on the patios? And I'm wondering if you had any thoughts about measuring that.

DR. RULE: So yes, of course. The ban should, you know, include also outdoor smoking. But just wanted to make -- emphasize the indoor smoking because of the exposures, especially to workers. The occupational exposure is something that we think helped drive the bans on tobacco cigarette. And so if we focus on that one, we could maybe give it that extra push.

DR. DRESLER: All right. And, Dr. Shihadeh, you're on the phone, I believe now? Alan? Can you --

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DR. SHIHADDEH: Yes. I'm here.

DR. DRESLER: Good.

DR. SHIHADDEH: I was just having a hard time understanding what was being said just now.

MS. BRINKMAN: He said he's having a hard time understanding.

DR. DRESLER: Huh?

MS. BRINKMAN: He said he's having a hard time understanding.

DR. DRESLER: Oh, he's having a hard time. Yeah, I was having a hard time understanding you. So one, sometimes I speak too fast. So I'll go slower. And so my microphone is on. So Alan, we'll see as we go, as we're asking questions. So here's one. Have you looked at carbon monoxide and other HPHCs' contents using different types of charcoal?

DR. SHIHADDEH: That's a question for me, or --

DR. DRESLER: Sure, you can -- Alan, well, I'll tell you what. Since you spoke up, yes, you go first. And then we'll have Marielle.

DR. SHIHADDEH: Well, my answer is really simple. The answer is no, I have not. But I could say -- I would say that when we looked at CO content in waterpipe smokers in actual

cafés, it was very close to what we were measuring between the CO using the charcoal that we used in the laboratory. So they're going to be close, but I wouldn't be able to say if one type of charcoal had higher or lower CO than another type. All I can say is that they seem to be similar.

DR. DRESLER: Marielle, do you want to?

MS. BRINKMAN: We have not looked at specifically carbon monoxide emanating from the different charcoals, but we have looked at some of the volatile HPHCs, and actually those data are being worked up right now. So I think Alan might have shown some of the different charcoals in a previous slide. We included Coco Nara and the quick-light charcoal, and some of the -- what's referred to as the natural charcoal. But I'm sorry, I don't have any results just yet.

DR. DRESLER: Well, you know, one of those questions that it had quick-light charcoal, and my experience with that is with my charcoal grill. And so they put chemicals in that to quick light, don't they? Am I not mistaken? That there's other stuff in there besides just charcoal?

MS. BRINKMAN: It's not clear to me what exactly is causing -- we don't think it's a volatile because these charcoals are stored -- we've been testing charcoals for

several years now, and there doesn't seem to be any type of degradation. So we don't think it's a volatile chemical that's causing them to act in this quick-light manner. But it's some type of propellant. Alan might have more. I don't know if he has more insight into that.

DR. DRESLER: Alan, there's a question. If you could mute your speakers because it's giving feedback. I'm sorry?

(Off microphone comment.)

DR. DRESLER: Talk into the headset is the suggestion. If that's possible, please.

DR. SHIHADDEH: I guess I accidentally put the headset on, and it's been muted all along. I'm sorry for the feedback. I'm not sure where that's coming from.

DR. DRESLER: So we're not hearing you as well this time as we did this morning. And you said you were speaking into your headset, if I understood what you were saying.

DR. SHIHADDEH: Yes. That's correct. I was -- I am speaking into my headset.

DR. DRESLER: There we go. I don't know -- whatever just happened, that was working. Okay.

DR. SHIHADDEH: Okay. Good.

DR. DRESLER: So, Dr. Rule, typically in hookah bars,

workers prime the pipe. Did you ensure the nonsmoking workers with high levels of CO were not those workers?

DR. RULE: So not on the study that I showed. But we are looking into that for the international hookah study, and we had to generate another variable or segregate by -- not every worker is the same. And so the workers that were priming, we had to separate them because the exposures are so different. But the results are just coming out soon.

DR. DRESLER: You can add in, if you'd like.

MS. BRINKMAN: I have seen the activity that you're referring to, and just in case there are others in the audience that aren't aware of what she's talking about, the worker will come with a -- like a basket of coal -- a metal basket of coals. They'll put the coal on top of the foil, and then they will take the pipe itself and draw heavily to try and transfer that heat into the tobacco. So that's what I'm assuming you're referring to as priming.

DR. DRESLER: Yes. Given the diversity of tobacco products and the complex nature of waterpipe tobacco use, i.e., intermittent but with long session links, should we be moving away from simple prevalence measures and instead think about developing a common unit of tobacco as is done with measuring

alcohol-related harm? So that goes across both this morning and this afternoon.

MS. BRINKMAN: Well, I think one of the concerns that hasn't been brought up yet about this intermittent use is that adolescents -- it has been shown, there have been animal studies that show that adolescents can develop dependence at very low nicotine levels. So the concern is that any use can actually develop into dependence. So I think that's very important. And once a dependence -- once nicotine dependence is established, then some of the data shown this morning indicates that there's a higher likelihood that adolescents will then transfer to combustible cigarette smoke, which is a much more portable, easier habit to have. So I have to disagree, that I think any use is something to be concerned about, even if it's just infrequent.

DR. DRESLER: Okay.

DR. RULE: And that's just considering the nicotine, but if you consider the mix -- you know, the soup that goes in there, there's, just like in cigarette smoke, 400-plus carcinogens. So we don't know yet. For what we know, this is not a harmless mixture. So the person gets the full effect of the whole component. So separating just by one, I don't think,

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would be fair.

DR. DRESLER: Okay.

DR. RULE: I don't know if that addresses the question.

DR. DRESLER: I think this next question sort of follows on from that. Since maassel is highly flavored, how much impact would particular flavors have on either emissions or exposure?

MS. BRINKMAN: So we know that -- about flavors, that some of the same flavors that are showing up in electronic cigarettes, as well as smokeless tobacco, are some of the same flavors that are being used in waterpipe tobacco. Flavors can be separated into -- you can think of them in two ways. Flavors are tastants, where you can actually -- they impact on the throat, and they provide a taste in your mouth. Or they're volatile. And so when you inhale them, you experience, you know, either a sweet sensation or, you know, something that tastes like apple or something like that. We know that with some of these, when you burn them, they become carcinogens. And the levels -- the concentrations in waterpipe tobacco are quite high. So with some of these flavors like cinnamaldehyde -- there's another flavor, and I'm sorry I'm blanking on the name, that mimics buttered popcorn.

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(Off microphone comment.)

MS. BRINKMAN: Diacetyl. These are potent carcinogens and can cause lung disease. It's been shown for workers' exposures. So I think that flavors contribute to the harm of tobacco products and specifically waterpipe products in several ways, not just from a toxicity standpoint but also from increasing the appeal. You know, this idea that somehow something that tastes like a cherry is harmless -- I think, you know, the perception of adolescents is that waterpipe tobacco smoking is a less harmful alternative to cigarette smoking. In fact, many of them respond that they are not smokers, even if they are waterpipe smokers. That's how firmly cemented in their minds that it is. So I think one of the -- you know, in addition to being -- some of them being quite toxic and carcinogenic, I think the fact that they enhance the appeal of tobacco products and thus make it easier for adolescents and young adults to initiate is probably one of the greatest factors of their harm.

DR. DRESLER: And probably just to look at it, the diacetyl and the cinnamaldehyde probably more into the inflammatory markers, with bronchiolitis obliterans or something like that, than a malignancy.

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Okay, so regarding environmental hazards, has anyone assessed air environment or workers in stores adjacent to these hookah bars?

DR. RULE: Next project.

DR. DRESLER: Somebody who is asking that question is aware of the research that started off with secondhand smoke too. But back on the flavors one, is it possible that -- say there is a ban on flavored maassel; can you flavor charcoal somehow? And then by drawing down, that you still get the -- so it's not just the flavor in the maassel, but you could have other flavored charcoal. And can you inhale it that way?

MS. BRINKMAN: Yes. I think this is really important, and I'm not sure that my talk did the best job it could highlighting it. But there are flavored coals already out on the marketplace. And that is why I think it's very important -- and I think this is FDA's intent -- to not just look at, not just regulate the tobacco, but also coal and other -- there are items called hookah creams that are actually -- you can mix them with your tobacco, or you can just put that cream in the bowl and smoke that. I think all of these things have the potential to transfer nicotine at levels that are high enough that people can become addicted, in

addition to -- you know, a lot of these flavors they are -- some of them are considered to be safe, but that's only from ingestion standpoint. It's a very different toxicological profile when you're inhaling something, and especially something that's being heated before you inhale it. So even though some of these flavors are considered -- are generally regarded as safe, we are using them in a way or they're being used in a way in waterpipe tobacco smoking that was never intended when that safety label was established for them.

DR. DRESLER: So generally recognized as safe for oral ingestion into the GI tract, not into the pulmonary tract. If that's what you're -- and, Alan, I'm conscious how hard this is for you at a distance. Did you want to pop in and comment on anything we've been talking about?

DR. SHIHADDEH: Well, I think Marielle is doing quite capably over there. I'm listening to her answers and pretty much nodding my head. I think that, you know, the flavor is important. I think it is actually a quite complex one because sometimes, for example, adding more humectant can increase aldehyde -- the compounds in the smoke -- but at the same time decrease furans. So the question becomes, well, what's the relative harm of furans versus aldehydes. I think, you know,

we can really get stuck in a cycle of questioning what chemical gets produced from which additives, and probably the larger question is not carcinogens as much as it is just the impact on the uptake of the practice and what's the impact on how often people smoke. And I think those are more addressable questions than getting into the nitty-gritty of what chemicals are caused by which constituents in the products.

DR. DRESLER: Okay. Can you speak to any data that ties popcorn lung, which is that bronchiolitis obliterans, to waterpipe use as ENDS have been?

MS. BRINKMAN: So I don't know of any data that shows that particular flavorant in waterpipe tobacco.

DR. DRESLER: Okay.

MS. BRINKMAN: But I do know that some of the flavors that are added to waterpipe tobacco include characteristics like that diacetyl that has that sort of creamy, almost buttery flavor to it.

DR. DRESLER: Okay.

MS. BRINKMAN: And there's really only one paper that I'm aware of, which is Jens Schubert out of Germany, where he did, you know, a very -- non-target analysis is what we call it. It's when you don't know what you're looking for, so you just

kind of shoot it on the gas chromatograph, and you compare the spectra with the available library spectra, and you make tentative identities to the various chemicals. That's really the only published work that I know on flavorings in waterpipe tobacco. Alan might know of something more.

DR. SHIHADDEH: We've done something similar. We found vanillin and other compounds, and I don't remember them now. It's been about 10 years ago. But I think, yes, there is -- the field is not -- the products are not well characterized in terms of the actual flavorants that are added. I think also there's a study that might have shown pyrazines in waterpipe tobacco products. But off the top of my head, I can't give you those references right now.

DR. DRESLER: What are your thoughts about a definition for thirdhand smoke vis-à-vis waterpipes? Define thirdhand smoke for waterpipe.

DR. RULE: Well, I would say similarly that you define for, you know, cigarettes. It's whatever is left over in the carpets, the walls. So you could touch it and have, you know, like a dermal exposure. A different rule that is not just the air and just not through the direct contact with the -- either sidestream smoke or direct smoke.

MS. BRINKMAN: Yes. These semivolatile particles that are generated in the air, and we know that Nancy Daher has shown that there's plenty of ultrafine particles that are generated during waterpipe smoking. Some of these you can't even see they are so fine. They settle out onto exactly what Ana has just described, upholstery, carpeting, and then they get resuspended when people enter the environment. So actually I don't know that it would be a different definition for waterpipe than it is for cigarette smoking. It's just the same type of phenomenon.

Now, the degradation products may be different. You know, some of these chemicals actually change just from being in the environment, whether there is microbial changes going on or something like that. So they may be different than what they are for cigarette smoke. But that's just not known that I'm aware of.

DR. RULE: No, no. Me either.

DR. DRESLER: But you did bring up something, another estimate. What's -- talk about the microbiology of maassel. We looked at that. It's a interesting mixture of things. The question is what's in, say, smokeless tobacco, which has some similar sort of humectants and et cetera. Anybody looked at

the microbiology or what happens when you heat it?

MS. BRINKMAN: So we have not looked at the microbiology, but that high level of humectants also serves to try and kind of keep the microbial growth rate down. I can't remember, but I think Alan may have something to say about what actually survives in the various pipes.

DR. SHIHADDEH: Oh, we have done some work on fungi that are in the smoke, and they're in the maassel, and they survive into the smoke because a lot of the tobacco actually, you know, devolatilizes. It doesn't get heated to very high temperatures during smoking. A lot of the bacterial compounds that are in the maassel are different but intact in the smoke. So there is -- there are parts in the smoke. They were, you know, comparable to what you might find in cigarettes but not a lot more than that. There is one paper on that. It was done by a group from Sweden.

DR. DRESLER: Okay. I think I heard fungal, though, as one of -- perhaps more than bacterial, there is more fungal. So can you speak to the toxicologic hazards from different device characteristics, say between plastic hose, plastic mouthpiece, and the leather? So you said that the plastic tubing isn't permeable to air to dilute. But are there other

toxicants that one would be worried about, whether it's a rubber tubing, a plastic tubing, leather -- any work done on what that looks like?

MS. BRINKMAN: Well, when we were designing the research-grade waterpipe, we tried multiple different types of Tygon tubing. And what we were looking for was something that would -- that chemicals would not absorb or desorb onto the tubing so that it was -- we didn't want to the tubing to actually scavenge the toxicants and the mainstream smoke and have them played out on the tubing and thus we would essentially be underestimating users' exposures. We did not test rubber tubing. We mostly evaluated Tygon tubing, and we ended up using a tubing that was designed specifically to allow particles to pass through without sticking to the surfaces.

DR. DRESLER: Tygon, is that PVC?

MS. BRINKMAN: Tygon is a type of plastic. And it's very tightly controlled. It is a laboratory-grade type plastic so that, you know, when you order a specific grade of Tygon tubing -- if I order it 2 years ago and then today I turn around and order it, it's going to be the same Tygon tubing. Each one is enumerated with a number, and it has specific properties associated with it.

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DR. DRESLER: And it doesn't spall off. So sometimes with the PVC tubing, you can have the spalling of it.

MS. BRINKMAN: No. It does not. It's flexible, similar to, you know, leather hoses. But it stays intact. Also, the tubing that we selected was also designed for corrosive environments because -- for that very reason. We didn't want things to actually be coming off of the tube that had nothing to do with waterpipe smoking and everything to do with the tube.

DR. DRESLER: Okay. When you're looking -- yes, Alan?

DR. SHIHADDEH: Yes. Hi, can I just jump in for a second to that question?

DR. DRESLER: Yes.

DR. SHIHADDEH: What we found is that the hose -- the physical, it affects the particle size distribution quite a bit. So when the particles come in through the plastic hose, they don't see additional air. They tend not to evaporate, and they pretty much stay the same size distribution. When smoked particles go into the leather hose, they lose a large fraction of their mass, and they become much smaller as a result of going through the leather hose. So there's some physical changes that just have to do with evaporation in the leather

hose that don't happen in the plastic hose. So that's a factor.

And then, of course, the other factor being the changing CO concentration. We found that, you know, if we actually put an analyst around the leather hose and we measure CO concentration continuously in air flowing over the hose, we see that a significant amount of CO escapes through the surface of the hose, CO and water vapor. So the plastic hose doesn't have that. You can pretty much consider the same amount of CO that goes in on one end comes out the other. With the leather hose, you might lose 30% of it or more.

DR. DRESLER: So when you look at the products that are on the market in the U.S., what proportion of them are leather tubing versus other? Are most of them leather tubing that are, you know, out to --

DR. SHIHADDEH: It's both. You can buy both, and the funny thing is that the plastic ones are often called the healthy hose. And they consider them healthier, I guess, because you can wash them and disinfect them better than you can the leather hose. But they're both available in any store that sells supplies. So they'll gladly sell you either one. I don't know in terms of surveys which is more commonly used, but

they're both commonly available.

DR. DRESLER: And just one other question: What kind of leather? Which -- you know, are we talking cattle leather? Sheep leather?

DR. SHIHADDEH: Yes. As far as I know, it's cattle leather.

DR. DRESLER: I was just wondering. Okay, so back on the maassel, do they alter the pH, you know? So pH is important for looking at nicotine delivery. As this is becoming a more manufactured product, you're saying that it's increasingly manufactured, able to do something about the contents of it -- are they looking at the pH of maassel, and how is that then impacted by the heating and inhalation?

MS. BRINKMAN: So I think we know from Dr. Watson's work from the CDC that it's really the pH of the smoke that we're interested in. And although that's been very well characterized in cigarettes, and also Dr. Pankow's work from Oregon State University, both of these scientists have looked at cigarette smoke pH, and the reason being that nicotine, when it's in its unprotonated form, is in more of a gas phase and it's much more readily bioavailable. And so the speculation is that it's more addictive in that form. And so the way that

cigarettes have manipulated the form that nicotine is delivered to the smoker in has been by using reconstituted tobacco that is very basic in nature, and that base, using things like ammonia, actually drives the nicotine into the unprotonated or freebase form and makes cigarettes more addictive. So then it begs the question is that happening with waterpipe tobacco? So we know that taking the pH of the tobacco doesn't necessarily predict the pH of the smoke. And that's what we were most concerned with, the pH of the smoke.

There are no measurements to date that I know of looking at the pH of waterpipe smoke. Keep in mind that waterpipe tobacco is very different from cigarette tobacco in that high humectants content is, I think, somewhat of a game changer when it comes to how nicotine -- what form nicotine will actually take. So I guess that's a non-answer. I'm not aware of any pH data.

DR. DRESLER: Can you put bicarbonate soda in the water? Anybody doing that? I'm just thinking if I was increasing my nicotine delivery, what I would be thinking about? So I was just -- has any of that happened?

MS. BRINKMAN: I mean, that's certainly -- from a theoretical standpoint is a very interesting idea because we

know that the mainstream waterpipe smoke that people inhale is 90% humidity because it's being bubbled through the water like that. So we would expect bicarbonate of soda to stay in solution and be delivered.

DR. DRESLER: I was just wondering.

MS. BRINKMAN: So I don't know.

DR. DRESLER: Just wondering.

MS. BRINKMAN: Yes.

DR. DRESLER: One other question. What type of tobacco is being used in the maassel? We have different types of tobacco. Does it matter which country you're -- you know, we saw how much more tobacco is being imported into the U.S. from the different countries. What type of tobacco is typically used in maassel? Anybody have an idea? Is it cured? Air-cured? Burley? Oriental? What -- does it matter? We don't -- haven't looked at that? Don't know? Because it would have some different characteristics too.

What is the particle size distribution in waterpipe smoke? So, you know, we're starting to look at this, certainly for electronic cigarettes. Has anybody been looking at that for waterpipes?

MS. BRINKMAN: I know that there are substantial levels of

ultrafine particles, very similar --

DR. DRESLER: Ultrafine being less than?

MS. BRINKMAN: Ultrafine being less than 0.1 micron.

DR. DRESLER: Okay.

MS. BRINKMAN: So in what was -- what is referred to as the nanoparticle range. And actually waterpipe tobacco is very similar to electronic cigarettes in the fact that they both have these high levels of glycerin in there as well as propylene glycol. Both of these chemicals are considered humectants, both are used in waterpipe tobaccos, and both are the primary solvents for electronic cigarettes. So our laboratory has shown high levels of ultrafine particles in electronic cigarettes, and I know Alan can probably speak about Nancy Daher's measurements made in waterpipe tobacco. So I'm going to shut up and let him do that.

DR. DRESLER: Alan? I'm not sure that he heard.

DR. SHIHADDEH: Oh, hi. Sorry. My mute button was on. I was talking, and I just realized my mute button was on. Yes, we've done measurements -- quite a few measurements of particle size distribution, and what we found is that when you do head-to-head comparison with cigarette smoke, using the same setup, it gets quite similar particle size distributions with

waterpipe as you do with cigarette smoke. So these are, you know, particles that would peak around -- the count, maybe, in diameter would be around 150, 170 nm, quite similar to cigarette smoke. So I wouldn't expect the deposition patterns -- to the extent the deposition patterns are affected by particle size distribution, I wouldn't expect them to be very different for waterpipe smoke as compared to cigarette smoke.

DR. DRESLER: So your voice goes in and out. But if what I heard was correct, that the waterpipe and electronic cigarettes and cigarette smoke will have similar size particles that would have the same deposition patterns? No?

Marielle?

MS. BRINKMAN: I think he's talking about the deposition patterns --

DR. SHIHADDEH: Yes. That's exactly right.

DR. DRESLER: Okay. All right. Do we have other --

DR. MAZIAK: One of the important differences in the waterpipe from cigarettes and let's say cigars, where you can actually mouth-smoke and you have mouth deposition for particulate matter and also for nicotine, is that because of the size of the tubing, the volume, you cannot get the

waterpipe going without deep inhaling, having a full inhalation. So even though we've not done much research, probably most of the deposition of this harmful substance as particulate matter is going deep down. It's unavoidable because if you puff from your mouth, it's not going to go. You don't hear the bubbling, and there's no volume -- enough volume in the mouth to get the waterpipe going. You have to have it deep, and that's why the volume of each puff is way above what you -- it's like a whole package. So I'm thinking in terms of harmful effects, although it's an intermittent tobacco use by that, but you have that basic difference that have a lot of these toxicants going directly to the deep lungs.

DR. DRESLER: So that's a prelude to tomorrow's presentation on health impact that we can bring back and talk about that. That's interesting.

Are there any other questions? No other questions. And look it, we're on time basically.

So okay. Let me check my notes because I think we have a break time. Yes, indeed. Break time, 15 minutes. Okay, so yes. We're actually right on time. So 2:30. Okay, so a 15-minute break. We'll see you back.

(Off the record at 2:14 p.m.)

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(On the record at 2:31 p.m.)

DR. DRESLER: Okay. Let's come back together, please. Or I'll use my outside voice. Thank you.

Well, so far, I have just like completely loved this, so let's get onto our next session. And our next session is entitled Waterpipe Tobacco Perceptions and Population Health, and our first speaker is Dr. Tracey Barnett from the University of Florida, speaking on Harm Perceptions of Waterpipe Use and Perceived Personal Risk.

So Tracey? And also I'm wondering, what's going on in Florida that there's so many waterpipe -- just wondering there.

DR. BARNETT: I can't answer that. I have no conflicts of interest. We can smoke outside, right. All right. Thank you. All right. And I didn't put a slide, but I have no conflicts of interest to report either.

Okay, so again, I am going to talk about harm perceptions. And I will show you that actually some of the early work started well over 10 years ago. In 2004 Smith-Simone, as part of her dissertation work, was already looking at waterpipe. And she showed in 2004 that among young adults, it was the most socially acceptable form of tobacco use among the peers and that their peers defined it as looking cooler when they used

waterpipes -- not cool as in temperature, but cool as in popular -- when compared to smoking cigarettes or cigars. She continued some of that work a few years later, and again looking at just users themselves.

So the 2006 data showed that most users did believe that waterpipe tobacco smoking was less harmful, less addictive, and did deliver less nicotine than cigarettes. The commonly perceived positive attributes for the smokers included the taste. We've been hearing a little bit about that, as far as the flavors and what they do. So sure enough, they were reporting that taste was important for them; smell, which is also going to come off the flavors, depending on what flavor has been added; and, of course, they also mentioned relaxing effects; and then the opportunity to socialize with friends.

Eissenberg did a comparison a little later and showed that the positive beliefs were actually associated with being a user as well. So those who were users reported a greater likelihood of believing that waterpipe made them look cool, an odds ratio of nearly two and a half, and the belief that the waterpipe use is, again, socially acceptable among peers. So this was some of our early work that we were seeing.

We've seen a lot from the National Youth Tobacco Survey,

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but we've also -- Florida Youth Tobacco -- there are several state tobacco surveillance systems as well, but Florida was one of the first ones to go ahead and add a question about waterpipe, as early as 2007. So they were catching some of those early preliminary numbers. Unfortunately, all they asked was prevalence: Have you used it ever or current? So we were only able at that point to associate what beliefs they might have about it. And sure enough, at that point cigarette questions were being asked. So we looked at those who endorsed cigarettes for things like relieving stress and making social situations more comfortable, and those were also predictive and associated with being a hookah user for adolescents.

More recently, the Legacy Young Adult Cohort Study, which covers 18 to 34 years old, of a probability sample, again they looked at harm perceptions as well. And notice they broke it down by never, ever, and current users, and then went ahead and used that five-point scale. And we tend to ask harm perceptions merely in comparison to cigarettes. That's really how far we've gotten with this question. So just how is it in comparison to cigarettes? As you can see, really the one that gets the most, frankly, regardless of use, is that middle one, about the same. That's the -- you know, I don't really know

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the answer, so I'm going to tell you I think they're similar. But, of course, you can see along the current users, you're going to see that they said that they obviously believed it was a lot less harmful, at that 26%, versus a never user who would not really endorse that it was a lot less harmful.

As I mentioned, even though Florida added the question about prevalence in 2007, we couldn't get them to add any belief questions until more recently. So in 2015 we finally got them to ask a few belief questions. So this was their most recent -- and this is of all; this is not just users. So they asked all adolescents in the state, a probability sample in the state of Florida, basically again in comparison to cigarettes, how harmful is hookah. You can see in the high school students, more than half tell us that it's less harmful, and the rest say either more or equally harmful. So not a lot of difference there. The middle school students did have a little higher rating of harm.

So we were fortunate to have some funding from the National Cancer Institute, and one of the things we argued through a lot of that grant was that most of the questions that had been developed so far really came from experts. While it's good, and I've used these questions as well, we were the ones

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developing things like is it socially acceptable, is it cool? Those were words that were driven by experts and not by users themselves.

So we were able to conduct qualitative study using focus groups. So we conducted six focus groups with young adult hookah smokers. We did try to get non-college students as well. Unfortunately, we're a little bit gridlocked in a very college student area, so only two of our six focus groups were non-college students, and the other four were college students. We asked them a very open-ended question. We did this using both outcome expectancy theory, and this was also used by Brandon et al. in around 2005, when they were looking at reasons why people might use cigarettes. So this was grounded in current research on cigarettes, and we were trying to apply it to hookah. And we asked a very open-ended question. We basically just opened with "Hookah smoking is" -- and again this was among users -- and you were looking for just kind of words and phrases that would describe why they were engaging in this use.

We had 40 participants. Average age -- the inclusion criteria was they needed to be between 18 and 24 and to have had some experience with hookah within the past 3 months. We

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had just over half female. It is Florida. We did have a slightly higher people who identified as Hispanic as participants; 72% white. This actually is pretty reflective of the University of Florida student population.

You haven't seen a ton of publications yet because in six focus groups with 40 people, we managed to generate 277 words to fill in the blank, "Hookah smoking is." So we're still trying to make sense of what they told us. After the exercise within each focus group, though, we spent time with them asking them to talk to us about -- okay, once you've given us this word, so why? We asked them to categorize these words. Is this a positive, is it a negative, and put that into perspective for us.

So of the 277 words that they gave us, over three-quarters of them, they told us, were positive or at least positive and negative reasons for use. And again, that makes sense. I mean, remember, we are talking to users. They're going to need to have a positive association to want to engage in a particular behavior. But again, we were trying to understand really a little more in depth what that was.

I don't always love reading their quotes because they put in a lot of fun things. I'm going to read the quote first, and

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then explain what I mean by the top bullet. "Well that's like, one thing with hookah is, you know, I love it, but you give me like a cigar or something, and I can't stand it cause it's hot smoke. It's like, I don't like the taste of hot smoke, but there is something about the hookah when you get the flavored tobacco and it's been cooled through the water, it's...smooth."

So that was what we found repeatedly. They liked to talk about the smoke, and they liked to talk about the cooling effect of that smoke and that it was a much less harsh experience. If some of the users has had any kind of past experience with other products, they would talk about that being a harsh experience, maybe promoting a cough or an unpleasant experience when they started. But when you got them to talk about the hookah use, it was not described as something that was unpleasant. It was very much described as a positive aspect of the hookah, the volume of smoke, the less harsh smoke, and the coolness of the smoke was really something that came through all of the focus groups as a tremendous theme for why they're interested in using.

Again, one of my students took a different take on our qualitative data, and she actually -- when she went through it on her own, not being part from the beginning, which is always

nice sometimes, with qualitative data, when you can get an outside perspective -- and she was able to identify really a lot of generational reasons as well, things that we hear the Millennials saying kind of coming through as also related to why they might use hookah.

But sure enough, she also identified many of these commonly held beliefs that we have heard today, just reinforcing here that they were very much said from our users. And that included they told us that hookah is not addictive, and they especially talked about the reason behind that being what we've talked about already in that it's this transient behavior. They believe it's not addictive because they only do it sometimes. So here's an interesting quote. One student told us: "Sometimes I will smoke hookah a couple days a week, and then other times I'll go several weeks or several days without doing it or considering it. I wouldn't say hookah is addictive." So again, they really talked about that transient, intermittent, non-daily use as one of the biggest reasons that they believed hookah was a non-addictive product.

As I mentioned, they're very aware of both the negative and the positive consequences that stemmed from their use. But again, they quickly turn most of these into all positives. So

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their behavioral beliefs were, again, primarily positive. They even used words like "healthy." They described it as a healthier alternative. They used words we might have expected a scientist to use. They talked about the toxins. But they told us that it had less toxins, and that's why they believed that it was a healthy product and healthier. And again, remember, we had a very open-ended -- we were not really guiding the focus group too much. But they, too, did compare it a little bit to cigarette smoking and kind of frame it for us like that, and why they believed it was a better product in comparison to cigarettes.

As I mentioned, we had them go through and identify for us what was positive and what was negative. Some of these came through as both. And I think it's important to talk about what did that mean. Why would it be both?

One was about it being a stress reliever. So they like that it's a stress reliever, but interestingly they could still kind of identify that maybe that was not such a great reason to use. So some could talk through that that really was a positive and a negative for them. They're going to turn to it, but they know that maybe that's not the best solution when they're stressed out.

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Similarly, they talked about escaping from other parts of the party. So it became maybe something that was just being done in one room. So they might describe this large party, but apparently the hookah room was a little bit of an offshoot or a different part of the party, and then smaller groups would gather there. So again, that was something they discussed, though, as a positive -- that they could have that connection and move away, but that also maybe it was a negative because it did pull them away from the party.

They talked about the volume of smoke as both positive and negative. They very much liked to tell you about the smoke tricks that they do. So it is true, they're doing a lot of them. And they like that. They like the volume of smoke. They think that really adds to the ambience. They talk about the ambience of these cafés, the "mystiqueness" of it was another word we heard. But they also were in some ways able to still identify that maybe that wasn't a good thing for them and wasn't good.

Most of these conversations, where they would give us the positives and the negatives, it was interesting to watch them kind of explain it away. So there was the yes, maybe that's not so great, but here's why it is better.

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Lightheaded became an interesting -- I'm going to talk about that on this slide and in a few slides as well.

Lightheaded was definitely an interesting one that ended up on both sides of the spectrum. They pretty much described wanting to reach that point of being lightheaded, and that was their way of defining it as a very positive experience. They were defining that as something they wanted to accomplish. But again, recognizing a little bit that that could kind of tip too far, and sometimes they didn't necessarily feel good if they got too lightheaded.

Finally, the other one that they talked about as being kind of dual, both positive and negative, was that it was complementary with other substances. So other use, including marijuana, that we've heard a little bit about, and alcohol, which I'm going to be able to delve into a little more.

So I had the benefit that there was already a morning session, and I got a little cheat sheet that we're a little interested in this alcohol association, right? So we also have an article, it was written by Eric Soule et al., and it's in the *American Journal of Health Behavior*. And he did show us, this is using the same data that we had, that nearly half of the participants actually told us they preferred to drink while

smoking hookah, and the reasons they like this is they said that there were enhanced physical and social effects that come about combining these two behaviors; 70% of them actually told us that they liked to drink -- they tend to drink alcohol sometimes, most, or always while drinking/smoking. So 70% told us they're always combining these two behaviors.

We also broke that down and asked them kind of where it fit into their night. In Gainesville, in addition, we have the rule that bars that serve alcohol must close at 2 a.m. But in Gainesville alone, many of the hookah bars have started to stay open until 4 a.m. because they don't have any restrictions. So there's also a little bit of a scene where they apparently all leave -- I'm home at this point. They all leave at 2 a.m. and then head over to the hookah bar.

So we asked them kind of where it fit in their night as well, as far as drinking. We know that many of them are saying they're drinking while doing it. But we also were asking about, okay, are you drinking before, during, or after. So again, over two-thirds of the participants who were over the age of 21 also told us that they either drink prior to coming to the hookah bar or that's where they're headed after. So it's kind of in their night or part of their tradition.

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But we also looked at those who were under 21. We do know that at least the few times we've been in our bars, we do see that they do card the students. So those who are under 21, a quarter of them told us that they drink prior to going to the hookah bar. And then more than half told us, of the ones who are under 21, that they plan to drink after leaving the hookah bar. So it's really just part of their evening. It's not necessarily their whole evening.

And again, I think the point here is they talked especially about how it enhanced their buzz and became more important to combine these two behaviors. We did have one woman tell us this story, and the quote is in this paper, and she talked about the first time she used hookah, she was actually quite nervous, and then ended up telling us that the alcohol that she was using helped alleviate her nervousness about smoking for the first time and maybe embarrassed if she didn't puff right, and that the alcohol was what ended up being the relaxer for her to then try hookah for the first time.

So really hookah use was perceived to be social and result in these positive physical effects. But they really talked extensively about how that could be enhanced or modified by this alcohol use.

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Interestingly, as I mentioned, the word "buzz" -- so when we said "hookah smoking is" they got to the word "buzz" as well. So the word "buzz" was associated with being a very positive aspect of why they would smoke hookah. Remember, in the last slide, that they were talking about how it enhanced if they did it with alcohol as well. I would argue that what they described, lightheadedness, buzzed feelings, was really probably some early signs of some carbon monoxide poisoning. It's also possible that's coming from the nicotine as well, but I think I would argue that there's a better chance it's coming more from the carbon monoxide.

But they could also describe this as a bit of a continuum. So the lightheaded and the buzz they were okay with keeping in the positive category, but then when they started talking about things like nausea or feeling like they might actually pass out, well, then they were able to identify those as negative feelings. So they kind of seemed to have this sweet spot for where they were trying to achieve their high and the physical effects they could get, and they kind of needed to keep that balance so that it didn't tip into being an unpleasant experience. So I just think it's important to note that similar negative themes for CO poisoning do include feelings of

dizziness or nausea.

So, in conclusion, I purposely started with how long -- I mean, we really have been studying the beliefs of hookah users for well over a decade. Mostly we talk about is it addictive or is it harmful in comparison to cigarettes.

Most of the negative physical experiences that the users talked about, they tend to interpret those, though, as a positive experience, as what they're trying to achieve. So we know as scientists that really that physical experience is not good for their body, but they'll tell you that that's their goal and that's the high that they're looking to achieve when they're using hookah.

Frankly, I set out when charged with this topic to look for harm perceptions, and my conclusion really is that there are very few harm perceptions for either adolescents or young adult users. And as I mentioned, the negative things that they do experience, they quickly interpret and change their perceptions such that that is actually a positive experience for them.

(Applause.)

DR. DRESLER: Thank you.

Okay. Our next presenter is Dr. Isaac Lipkus, from Duke

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University School of Nursing, speaking on the Characterizing Individuals Susceptible to Waterpipe Use and their Reactions to Messages of Harm. Dr. Lipkus?

DR. LIPKUS: Well, first of all, I'd like to thank the FDA for inviting me here. What I want to do today is to give you some insights into some of the characteristics of a population that hasn't been really studied very much at all, and that is young adults who are susceptible to waterpipe use, which I'll define shortly, and also present for you fresh data of the first study that I know of that tries to present harm messages to this population to see how they actually react to it, and in particular in relationship to people who are not susceptible.

So we've talked today about various factors that may contribute to why waterpipe tobacco use is spreading. I'm not going to go through each of these details. But the general idea is if you look at all these various factors, what it does, in part, is it makes people more vulnerable to the use of waterpipe tobacco. In other words, it creates a sense of susceptibility to using this particular product.

So what does it then mean to be susceptible? Basically, what it means these are individuals who do not adamantly oppose the future use of waterpipe tobacco smoking. So they're

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basically saying to you, well, there's a chance in the future that I would actually maybe try waterpipe. And the reason this is particularly important is because if you think about stages or phases in tobacco use, susceptibility might be one of the very earliest stages that puts people at risk because basically what it is saying is if I'm open to the topic of maybe trying waterpipe use, then the next phase is, what, actually experimenting with it. And depending on what their experiences are with experimentation of the product, it actually leads to maybe the formulation of a "regular user."

So one of the questions, then, is of course how do we assess susceptibility. So my colleagues -- which Erin Sutfin, one of the colleagues here in the audience, actually wanted to investigate this to note that the measurement of susceptibility in the past, and it hasn't been done very much at all, has been using single item measures. And what we wanted to do is to go ahead and use a multi-item measure, developed after some of the work that Pierce has done in the area of adolescents and susceptibility to cigarette use. So what we wanted to do is look at how young adults, here defined pretty much as college age populations, actually responded to this four-item scale, and importantly to what extent did it actually predict future

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waterpipe use among people who didn't actually ever try the product?

So just in terms of way of methodology, what we did is to use a cohort of college students from a variety of different colleges, both in Virginia and in North Carolina, and the important thing is that there was a heterogeneity in this composition of the universities. Some of them were public. Some of them were private. Some of them were from rural communities. Some of them were from suburban communities, et cetera. So it hopefully represented a gamut of the characteristics of what those college students might be. What we did is we went ahead and gave these four questions to these students in the fall of their junior and senior years. So we gave them in the fall of 2012, and then we followed them up in 2013.

Here is the number of participants who completed both of the surveys, and the final sample size that I'll be reporting on is a sample size of 964. So here are the characteristics of the population: about an even distribution in terms of gender; the majority were white; the majority were non-Hispanic; very little use of cigarette use in the past 30 days, or tobacco use; about a third of them did binge drink in the last 30 days;

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about 8% used marijuana in the last 30 days; and about average on sensation-seeking, which is to seek novel experiences.

So here are the four items themselves. Do you think you'll smoke tobacco from a waterpipe soon, all the way down. And what these numbers represent is the number of people who gave an answer other than definitely no. All right. So it was pretty similar across both years, 2012 and 2013. And overall, when you look at the bottom row, what you find is that approximately close to 28% of the sample were susceptible to waterpipe tobacco use, which is not a trivial number when you think about it.

So here are the statistics of how well this particular scale actually predicts waterpipe use in 2013, when you look at what they said in 2012. So you have here the univariate analysis, and you also look at the multivariate analysis in terms of the univariate analysis. Not surprisingly, susceptibility in 2012 in and of itself almost tripled the odds of you smoking or reporting smoking when you took the survey in 2013. And the other items that you see here in bold were also individually predictors of susceptibility. So, for example, people who used other tobacco products within the last 30 days were about 4.4 times more likely to be saying that they've used

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waterpipe within the last year, between 2012 and 2013, all the way down to sensation-seeking, et cetera.

The thing that is important is really the highlight that I have here in the upper right-hand corner, which is if you compare and put all of these variables in the model that were significant, did susceptibility in 2012 actually predict that they used, based on self-report, waterpipe in the following year? What we find is the odds were about 2.5. And what does that mean in terms of concrete terms? Well, this means that among those people who were found susceptible in 2012, approximately 20% of those people actually went on to try waterpipe tobacco, compared to 7% of those people who reported not being susceptible. So it did seem to do a fairly decent job of predicting future use of waterpipe tobacco.

All right. So the question is now -- now that we've got a sample of people that could be accurately predicted by this four-item measure -- how do we go ahead and think about what this measure actually does in discriminating among people who are susceptible or not on a variety of different characteristics? And these are the characteristics that I have here in terms of variables of interest that have been shown to be reported to people who are actually waterpipe tobacco users.

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So, for example, we know now that people who smoke waterpipe tobacco perceive themselves at lower risk for getting harmed. They have more positive attitudes towards waterpipe use. They tend to see it as more socially acceptable. They tend to see more of their peers actually using waterpipe. And the one measure that we created which is very similar to susceptibility is asking the question how much interest or curiosity do you have in actually using waterpipe? And then what we wanted to see among these susceptible groups is to what extent do they actually react differently than people who are not susceptible to messages about harm.

So what we did in this particular study is we went ahead and recruited young adults through this online system called Mturk who were between the ages of 18 to 30. And what we did is we gave them the four-item scale. They could have never used waterpipe, by the way. So these are all nonusers. Never tried it before. We used the four-item scale to divide them into being susceptible or not, and then based on that distinction, we stratified on that distinction, and we randomized them into a control group that didn't get any information at all about waterpipe at all, about the harms, or we went ahead and gave them information that we used in the

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prior study that's now impressed with the actual waterpipe users, that has actually been shown to affect perceptions of risk.

So what I want you to do for the following slides is ask yourself the following questions: If I were to get the information that's going to be presented, how would I feel towards waterpipe use? All right. So this is some of the information we actually presented to them.

So the main message here is that waterpipe tobacco use is related to a variety of different diseases. It's not related to just one or two common diseases, of which, by the way, many of them think is diseases related to respiratory disorders as well as to cancers and sometimes heart disease.

Here's the other thing we gave them. So in this particular slide, the concept that we were trying to get across is if you look at these chemicals, they are much more likely to be found in waterpipe tobacco smoke than in cigarettes. And the reason we put these commonly found things in there is because a lot of them may not know what in the world these chemicals are. I know when I initially looked at these chemicals, I said I have no clue what in the world they are, right. And then when they said something like, well, these are

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what you find in mothballs, I said, oh, well, that makes a big difference, at least in my understanding. And clearly I'm pretty naive then in some ways.

All right. Then here's some information we gave them on nicotine dependence. So here's some stuff that you could read. Clearly, the idea that there is some relationship between smoking waterpipe and nicotine addiction. And if you go to the next slide, it just tries to quantify that a little bit more in terms of how much of an intake can actually be related to becoming addicted.

So given these four slides, which is what they actually looked at, the whole gist of this is this is not a trivial habit. You know, if you were to actually take on this product and use it consistently, it actually does have some adverse effects. They read that, if they were in the experimental group, and again if they were in the control group, they didn't read any of those materials.

Here were some of the measures that we assessed in both groups, the experimental and control group. We assessed risk appraisals, which meant we captured their perceptions of risk and worry about both the harms and of becoming addicted.

Some of the other variables that we captured, again

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variables of interest in terms of their overall attitudes. This issue of ambivalence, which, by the way, I think is a really important concept, which is how conflicted/torn they were about actually using the product, and it's been shown to be pretty well associated with a variety of different tobacco use products, especially cigarette use. Social acceptability and peer use are common metrics looking at the social dimensions of the product. And this willingness/curiosity item is what we wanted to do is to create a measure that as closely as we can taps into this notion, again, of susceptibility. Here are just a couple of little examples: How tempted are you to try waterpipe smoke in the next year, and how curious are you about trying? I think the topic of curiosity is an incredibly important one that I think has not been studied sufficiently in this particular area.

All right. So what are the characteristics? Well, first of all, out of about 4,400 people who went online, we finally got a sample of 508 who met our criterion. Again, the age is 25 all the way down. Most of these individuals were well educated, mostly Caucasian, and about half of them were college educated, which is important, which means some of our results don't just apply to college populations or people outside the

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college population. And you find the majority of these people were nonsmokers and not a lot in terms of past tobacco use for the last 30 days.

So here's what I'm going to present in terms of what characterized the people who are susceptible. All these are in bold, which means all of these were statistically significant, and the basic idea is that people who were susceptible viewed their risk as less than people who were not susceptible. These people had less negative attitudes towards using waterpipe. They felt less conflicted about using waterpipe. They viewed it as more socially acceptable. They thought that more peers used the product. And they experienced a greater sense of willingness or curiosity to try the product. And the biggest effect size, or the things that susceptibility seemed to matter the most is this notion of felt ambivalence and willingness and curiosity.

What about the study condition? How did presenting these materials actually affect their perceptions on these variables, compared to the controlled group? Those that are in bold are statistically significant. And what we found is that the experimental materials actually increased perceptions of risk, made people feel that tobacco use from a waterpipe is actually

less positive. In other words, we increase their negativity towards the product. And we decreased their sense of ambivalence towards this product use. But the overall effective sizes are small, and that's important to keep in mind.

Okay. Well, what about the interaction between these conditions and susceptibility status? Well, here we found something which is really important. We didn't have any interactions with any of the other variables, but we did get an interaction for one, which it was the one that we think was most important, which is to what extent are you willing to try the product, and how curious are you about trying the product?

What we found was no effect at all for the control. It didn't matter whether you got materials or not. Your overall evaluations on willingness to try the product stayed the same. But for people who were susceptible, our treatment actually made a difference, such that if you were susceptible and you read the materials, it made you less willing and curious about trying the product.

So, in summary, what are some of the main take-home messages that I want to convey here? Well, one of them is that there are a variety of different things out there in terms of

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marketing, peer use, et cetera, that makes people more susceptible to waterpipe tobacco smoking, and we need to be very conscious about these factors because it could increase their vulnerability of becoming susceptible.

The other idea that I think is very important is there are scales that measure susceptibility. Ours is a four-item scale, and we believe it shows promise in being used in future research and being able to categorize people in their susceptibility status and therefore being able to target interventions to that particular group.

The other thing that I think is very important, based on our data, is that if you look at these various attributes, such as attitudes, risk perceptions, perceived peer use, social acceptability, et cetera, that these profiles among people who are susceptible all increase their risk for uptake of waterpipe tobacco. If you look at people who are actually waterpipe tobacco smokers, they all exhibit these kinds of characteristics: more positive, more socially acceptable, lower perceptions of risk, and et cetera.

And the thing -- the last one, which I think is a very important one, is that giving brief messages of harm and addiction is actually useful, even though you get a small

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effect, per se, in lowering their willingness and curiosity to try waterpipe tobacco smoking among those who are susceptible. So this now replicates some of the effects, per se, in terms of decreasing desire to use among people who are actually waterpipe tobacco smokers themselves. So we're finding some generalizability of the effects of showing these messages to now populations who are susceptible and those who are actually users.

In terms of future directions, I think there's various things that we could explore. One of them is to actually refine the susceptibility construct. One of the things we did is we grouped people into being susceptible or not, but you could actually think about gradients of susceptibility, whether you're highly susceptible, moderately or less susceptible, or not susceptible. In fact, there's just been one recent paper that came out that actually did that and shows that gradients of susceptibility predicting cigarette use is actually useful in adolescents, to see who experiments with the product.

The other thing that we should be attentive to is what are some of the factors that actually predict which of those people who are susceptible go on to actually experimenting and then becoming an established user, versus those who claim to be

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susceptible but stop right there; they don't go to any experimentation. As some of the earlier research shows, there are people who go ahead and say they have ever tried it but then don't go on to use. So now, go and think of that parallel idea with susceptible groups. Who are the people who actually go on to experiment with the product versus those who say, well, I'm open to it but then decide that they don't even want to try it.

The other thing which I feel is very important is to actually try to get people very early on to not even consider trying the product. So what kinds of interventions do we want to explore that prevents people who are susceptible from actually taking up the product. We just did something very simple, but naturally this is probably going to be a much more complex undertaking. So what are the effective interventions? What kinds of effect size do we want to ultimately achieve?

And then finally, the one area that I think is really important is how do messaging about waterpipe tobacco in general, but maybe in particular in this group, differ from the other kinds of messaging that we have for the other tobacco products? In fact, I would gather to say that a lot of the way we do tobacco research is we tend to focus on single products

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-- cigarettes, e-cigarettes, cigarillos, et cetera -- but more and more we're finding that people are poly-tobacco users. So what are the kinds of messages that we need to do to intervene upon people who are actually poly-tobacco users, which is not a simple issue because if you think of people who use waterpipe, a lot of them use other tobacco products? So what are the messaging strategies that we need to use in terms of people who just smoke waterpipe alone versus other tobacco products as well?

And with that, I just want to acknowledge some of the people who helped me and reviewed some of these presentations, as well as the grant support that my colleagues have done to collect these data. Thank you.

(Applause.)

DR. DRESLER: I did not plan that cutout of the microphone at the end. That wasn't me. So, but I do know that they're aware of it, but I don't know what's causing it either.

Okay. Our next speaker is Dr. Ramzi Salloum from University of Florida College of Medicine, and speaking on Flavors and the Demand for Waterpipe. And, you know, so we had an earlier slide today that showed that waterpipe use was the lowest in the Southeast. Didn't we? Isn't that what we heard?

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But we have the highest proportion of investigators.

(Off microphone comment.)

DR. DRESLER: It's -- there's no effect. Okay.

DR. SALLOUM: We have a recent study actually that I won't be talking about today that shows that we have the third largest number of waterpipe tobacco cafés in the country. So those estimates are probably changing.

So, first off, I'd like to thank the Center for Tobacco Products for giving me the opportunity to present on this important topic of flavors and how they influence the demand for waterpipe smoking. I'd like to acknowledge my funding sources, and I have no conflicts of interest to declare.

What I'd like to accomplish in today's talk is really introduce the topic of flavors in the context of waterpipe tobacco regulations, and its history in addition to how the demand for waterpipe smoking has evolved. And then I'd like to talk a little bit about the recent findings that were released from the PATH study, which is a national study on tobacco in the U.S. And finally I'd like to discuss findings from a discrete choice experiment that my colleagues and I have conducted to ascertain the role of flavors and other components of the waterpipe smoking experience on the demand for smoking

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among young people.

So we all know that the 2009 Tobacco Control Act was a landmark act in terms of regulating tobacco products. It banned flavored cigarettes, with the exception of menthol. However, this flavor ban did not extend to waterpipe tobacco, along with some other tobacco products. And I know that the issue of pricing and taxation is not under the jurisdiction of the FDA, but as an economist I have to point out that the taxation for waterpipe tobacco is relatively low. It's considered pipe tobacco, and the federal tax rate is \$2.83 per pound, which is approximately \$20 less than cigarette tobacco per pound. And another important issue that speaks to the harm perception among youth is that there are currently no required health warnings on waterpipe tobacco, whereas federal law requires warning labels for cigarettes and smokeless tobacco.

In terms of the history of flavors, Dr. Maziak gave us a fascinating talk this morning on the history of waterpipe. So I won't torture you through that again. But we've had at least five centuries of waterpipe smoking that was confined to certain parts of the world but no flavors. And then in the 1990s we saw the commercialization of waterpipe tobacco, with the introduction of maassel and some basic flavors that were

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attracting especially young people. And this has evolved over time to include much more sophisticated waterpipe flavors and the introduction of U.S.-based suppliers into the market, where we saw earlier today that the U.S. is exporting waterpipe tobacco now in addition to importing it.

So with the development of these sophisticated flavors, we're seeing a more targeted approach to specific demographic groups. There are, for example, brands that target specifically women and have flavors that are designed for women. And then it's not surprising to see in the recent PATH data that waterpipe was the only tobacco product in the U.S. where the prevalence was higher among females than males, specifically in the young adult age group. We also see a huge target in young people with flavors like candy and gummy bear, and so many other flavors that depict energy drinks and alcohol products and cocktails and so on.

We also wanted to -- given the increasing profile of waterpipe smoking in the U.S., we wanted to characterize the trends, and in the absence of temporal surveillance data in the United States, and we saw presentations mainly on cross-sectional data this morning from Dr. King, we ended up going to Google Trends to look at the popularity of waterpipe-related

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searches. We thought that was appropriate because of the concentration of waterpipe smoking mainly among adolescents and young adults who also use the Internet. And what we found is that the searches for waterpipe smoking preceded tracking by Google Trends, which started in January of 2004, and since then they have steadily increased over at least this 10-year time period that we saw.

In terms of what the literature says about waterpipe and how it drives demand, there was a recent review of articles looking at this topic that was published in *Tobacco Control*, and what it found is that flavors encourage young people to smoke waterpipe tobacco. The perceived positive experience was also attributable to flavors engaging the senses, including the taste and smell. And most importantly fruit flavors contributed to the perception of lower harms among young people.

So we also wanted to look a little bit at recent evidence from the PATH study, which is a nationally representative study in the United States of smokers and nonsmokers -- or tobacco users and non-tobacco users. And they've actually asked some questions related specifically to flavors. So in the adolescent group, among those who had previously used waterpipe

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tobacco, 89% of them reported that the first product they used was a flavored variety. And also, among users in the past 30 days of waterpipe, there was almost the same percentage reported using flavored tobacco.

PATH also asked respondents about the leading reasons for waterpipe use. And among the primary reasons that were endorsed in PATH for that, adolescents like socializing using waterpipe. But a close second was that they smoked waterpipe tobacco because of the flavors. And that was at almost 79%. The number three reason was that waterpipe may be less harmful than cigarettes, which could also be related to the fact that it comes in flavors.

In terms of perceptions that were asked of adults in the sample, 17.8% of adults in the sample perceived waterpipe as less harmful than cigarettes. And this was actually among all tobacco products, it was ranked second only after e-cigarettes. We've heard several presentations today reminding us that waterpipe is a combustible tobacco product and explaining the harms that we are aware of thus far from smoking waterpipe. And it was really striking that in terms of relative harm to cigarette, waterpipe was perceived as less harmful than many noncombustible tobacco products in the PATH study.

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Now, the PATH study did not go into the variety of waterpipe flavors that were used. But I know you're all curious. So I have some information here from a survey that we conducted about what flavors were actually used by youth in a single college survey that we did. We had almost 300 students declare that they used a flavored tobacco in their last experience, and out of those 289 students, we had 68 distinct flavors, and we used those flavors to generate this word cloud based on popularity of the flavors that were selected. So I'll leave that up for a few seconds so you can admire the variety of flavors.

What I would like to spend the rest of my time talking about is this discrete choice experiment that we conducted to elicit preferences for waterpipe smoking and understand what is driving demand. We conducted this study at a large university in the southeastern U.S. in 2014 and included adults in the sample who were currently attending college or just about to and who had previously tried waterpipe tobacco. Participants were asked about past tobacco product use, all different kinds of tobacco, and we elicited their preferences using hypothetical waterpipe café menus, and we chose those menus to emulate the experience that these students would get by

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visiting a waterpipe café, which is a common place for them to experience waterpipe smoking. And we also tested in the study the impact of waterpipe-specific health warnings. I will not be presenting those results in this talk, but we did have an article that was published this week on the topic that I'd be happy to share information about.

So the reason why we chose a discrete choice experiment is that it's commonly used in marketing research to test the influence of individual product attributes simultaneously in the decision-making process for consumers. It's well suited for measuring each product's influence, each product's characteristic's influence on consumer choice, and it basically gives us estimates specific to that attribute that we're interested in. And in addition to that, discrete choice experiments have been increasingly used in health research settings, including in the tobacco control arena.

And during the planning stages for this meeting, there was a lot of interest in the methodology for a discrete choice experiment. I won't go into a whole lot of detail here, but I'm happy to elaborate about that later. But briefly I'll say that we tested four different product characteristics that are typically addressed by tobacco control regulations globally,

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and those -- the attributes that we tested were flavor, nicotine content, price, and health warnings. We chose these attributes specifically because we thought that they would affect the respondents' choice and these attributes were also policy relevant. Our design was a fractional factorial design. It included 18 distinct choice sets that were divided into two blocks of 9 choice sets. One block had warning labels, and another one did not have warning labels on the menus. We randomized participants to either be exposed to the health warnings or not. Then we tested the effect of that.

So in terms of the details of the experimental design, we had four flavors that we tested. Three of them were fruit flavors, and one of them was the non-flavored tobacco option.

The second attribute was nicotine content. We were interested in testing the effect of that, even though that's usually not something that's on the menu. And we chose levels that were documented in the literature based on nicotine content rates on the packaging of hookah tobacco. And then we finally chose three price levels. We also provided respondents with an opt-out option in case they wanted to refrain from choosing a waterpipe product.

I'll quickly mention some limitations. This was a

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convenience sample, and findings may not be generalizable to the entire population. We also did not include nonsmokers in the sample. As with every discrete choice experiment, these are based on hypothetical scenarios.

Our sample included an almost equal number of males and females, and the average age was almost 22 years old. We had a mixture of undergraduate and graduate students, and we had almost one-third racial/ethnic minority representation in our sample, and 23% were concurrent cigarette smokers.

So here is what our menus looked like. This is an example here that includes the three different fruit flavors. We tried to make this look like an actual café menu. We had the non-flavored option, and then we had price on the right-hand side along with the nicotine content labeling under each of the products. This particular example did have an actual warning on the menu. Then participants were asked to choose one of the four options, or the fifth one was to choose none of the above.

And this is what we found. We ran two sets of models. The first one was a multinomial logit model, to examine the impact of the different attributes in the waterpipe smoking alternatives on the consumer's choice. So these are all predicting choice. And we found essentially that flavored

options were more likely to be selected if they were part of the product, whereas the tobacco flavor was significantly less likely to be chosen. The 0% nicotine content option was more likely to be chosen over the higher nicotine content options, and lower price was more likely to be chosen.

We then were interested in looking at individual specific determinants. So we used a nested logit model, which is basically a two-step model. The first step of the model examines the decision to either smoke or not smoke. So essentially we looked at the opt-out option this way. And then the second step would -- conditional on choosing a waterpipe product, then it would compare the different options available to the individual. So we saw consistent estimates here, as with the other model, of flavors being more likely to be chosen. A higher nicotine content was sort of a deterrent. And so was higher price. And we saw significant effect of health exposure; being randomly exposed to health warnings was significantly predictive of choosing the opt-out option.

We then looked at how the different attributes in the decision-making process influenced choice when compared to each other, and essentially these rectangles show the relative importance of each of the attributes. We found that flavor was

the most influential attribute on the decision-making process.

We also observed some differences by gender in decision making. So in this case we have -- females were represented with the solid line and males with the dotted line. We saw that females were more averse to the non-flavored option. They were also less likely to choose the highest nicotine content option when compared to males.

We also compared those who were cigarette smokers to nonsmokers, and we essentially found a similar effect. Nonsmokers were more likely to prefer the flavored options and less likely to prefer the non-flavored option over cigarette smokers. And interestingly enough, we saw with the nicotine component here that then the nonsmokers preferred the 0 nicotine option, whereas the preference for cigarette smokers went up as we increased the nicotine content labeling on the menus.

So, to summarize, we tested this discrete choice experiment, which had the potential to help us understand consumer preferences in waterpipe smoking. Health warnings were a significant deterrent when used on the menus. We found that not all young people were similar in their preferences, and these differed by gender and cigarette smoking status.

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Most importantly, we found that fruit-flavored tobacco significantly increased demand, and so did lower nicotine content.

And I'd like to leave you with some of the knowledge gaps and further research in this area. We obviously need to consider other components of waterpipe smoking, such as charcoal and other components that were discussed earlier this morning and how they affect the demand, and further understand waterpipe-specific health warning labels, and expand the inquiry into the demand for waterpipe smoking into a national sample that includes smokers as well as nonsmokers and non-college students of that age. Thank you.

(Applause.)

DR. DRESLER: What percent of the waterpipe cafés are in the Southeast?

DR. SALLOUM: I'm sorry?

DR. DRESLER: You said that two-thirds of the waterpipe cafés are in the Southeast?

DR. SALLOUM: No, I said that we had the third largest number in Florida.

DR. DRESLER: The third largest. The third largest in Florida. Okay.

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DR. SALLOUM: California and Texas.

DR. DRESLER: Because our next speaker is also from the Southeast. So that's why.

So our next speaker is Dr. Merlyn Griffiths from the University of North Carolina at Greensboro, and she will be speaking on Hookah Culture: The Marketing and Appeal of Waterpipe Smoking.

DR. GRIFFITHS: Just want to say thank you to the FDA for this invitation. It is a great pleasure to come and speak with you today.

So based on the content of my presentation, I have to make this disclosure. So I want to make sure that it's clear. I have no financial relationships or any conflict of interest at all with -- and have no connection at all -- with any organization that manufactures, markets, or sells hookah products. I have no affiliation or endorse any of the brands or any of the accessories or ancillary products that are sold. The images and videos that are in this presentation are strictly demonstrative examples and are used only for educational purposes. Okay.

Now, this work is extending two prior pieces that were published, one in the *Journal of Public Policy & Marketing* and

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the other in *Social Work in Public Health*, and also some ongoing work that has yet to be published.

So why is marketing an important factor in our understanding of the proliferation of waterpipe smoking? If we consider what we know about, for example, cigarette smoking, we know that it is definitely socially destructible, right. We do know that it is associated with significant levels of negative health effects and consequential lifetime impact. So what we're seeing, however, is that hookah has created a separation of what we traditionally have thought of as smoking. So, in essence, what we're seeing is that hookah is crossing the chasm of the mainstream, and it's being embraced as something that is definitely acceptable and even culturally appropriate. So along these lines, it is being marketed as being -- and some of these terms you've heard all day -- it's cool, it's fun, it's socially pleasurable. It is perceived as not the same as smoking. So smoking has a whole different meaning when it comes to hookah smoking. And as a result, we're seeing that -- and we've heard this ongoing -- young adults are adopting the practice. They're being enticed by the myths about hookah smoking and also being enticed by the images of their peers and similar others having a very enjoyable experience. So if we

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think about the marketing aspect of it in this light, I would venture to say that marketing is actually fueling the practice. It's fueling the adoption, and it's actually fueling the creation of the hookah culture.

So along those lines, what I want to focus on is I first want to distinguish the different types of entities along the lines of the retail side and also the entertainment/service marketing side. Okay. Then I'm going to talk a little bit about some of the normative depictions of hookah culture, different marketing mediums that are being used to actually build a proliferation of hookah, this whole culture of hookah smoking, some of the growth trends, and then implications for hookah culture.

So let me start first by just walking through -- okay, and I have a lot of moving parts. I'll just say, I have a lot of moving parts. I'll try to hit my 20 minutes. Okay, so on the commercial side, the retail side, it's important to understand exactly what these entities are. So they're hookah shops. Okay, so hookah shops basically are those that offer a wide range within the context of everything hookah, from the tobacco to the replacement parts, the charcoal, the tongs, the vaporizers, the grinders, the pollen boxes, the scales, the

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stems, the vases -- okay, and I know these are terminology that some of you may not understand. But trust me, it's all a part of the hookah experience, right. The apparatus, replacement parts, and so on. So that's hookah shops.

And then there are tobacco shops. These shops may sell the pipes, but they may not carry any of the accessories, or they may carry very few of the accessory or ancillary products. Then there are combination shops. Now, this one is a little bit more difficult to classify, and it's harder to identify these types of entities because combination shops can be cafés and lounges with perhaps a grocery component to it, selling hookah.

So, for example, this is one of my favorite spots to go and sit on a Saturday and watch. I'm a qualitative researcher. I observe everybody and everything. And so this place is called Al Baraka. It's in Raleigh, North Carolina. So this is inside of the store. And I don't know if you can actually see this, but it's an Eastern Mediterranean grocery store. They carry a wide range of products and food items specifically from different regions of that area of the globe. In addition to that, they have a full-service restaurant. So the offerings include a wide range of halal meats and products and food items

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that's actually cooked and served. Now, in addition to the restaurant and the grocery store aspect of it, they actually sell hookah, shisha, charcoal, and all of these pieces to it.

So this is what's classified as a combination shop. It's very difficult to identify them because, first of all, their DBAs don't necessarily indicate that they sell anything that's in the category of tobacco. There's nothing that necessarily identifies them as a smoking environment, or even an environment where the sale of these items is contributory to their significant stream of revenue. So they're harder to actually classify.

All right. Now, let's talk a little bit about the retail side. One of the gentlemen in one of my studies, he made this point, and I thought it was very telling. He says, "I know 16-year-olds can't buy cigarettes, but they can buy hookah." And that is very much true. You really don't need to have a whole lot of anything to get access to hookah. It is widely available. And so these online retailers and also wholesalers, they do sell what we call everything hookah. Several studies have actually identified well over 1,200 brands of the shisha or the shisha tobacco. A lot of these sites offer what we call gateway hookah starters, hookah starter packs for first-time

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users. And they carry a wide range for those who are very experienced or the connoisseurs. And you'll find a lot of the how-tos -- how to light it, how to set it up, how to pack it, how to do it yourself. All of these things you can find on these sites.

So in terms of the wide range of products, I'm showing you a set here. And notice, one of the things that we should understand, too, the typical or the traditional looking hookah apparatus is something like this. But they're also like this. It looks like a glass bubble. And throughout you're going to see some different examples of items that are sold that you would not think that they're hookah equipment, but they are.

Now, in terms of the pricing, believe it or not, we can see prices as low as \$20. But if you're definitely one of those who wants to spend the money to show that you're definitely on the high status of the hookah line, you can actually spend \$1,099.99 to get the Z1 glass hookah. So if you have that kind of money, you can definitely "roll like that."

Okay. Now, one of the ways that we're seeing that this is continuously keeping the attraction of our young consumers are new and innovative types of products. So one of the newest ones that's actually caught my attention is ice drops. And

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what makes ice drops very much so appealing is that the smoke comes out in colors. So the image that you see here -- that's actually real. That's actually someone smoking, and the tricks that they actually play would be in color. So the smoking tricks -- so you can actually -- if you take a look at some of the video, you'll see some of these tricks. But using ice drops, the smoke comes out in a myriad of different colors, and it waves, and they do all kinds of funky, wonderful things.

So, in essence, this happens on the retail and wholesale side in terms of accessibility. There's several of these entities online that actually operate in the B2B and B2C markets, meaning that they sell directly to consumers and they also sell directly to businesses that actually are selling these products. And so one of the examples that I brought that I'm showing you here is Sahara hookah. Lots of discounts, volume discounts, different kinds of sales. For example, yearend New Year clearance event. Okay. A wide range of incentives and awards and rewards are offered, along the lines of also trying to normalize the typical buying behavior. So, for example, Black Friday -- a Black Friday sale on hookah, birthday sale on hookah, back to school shopping for hookah. Students can get 15% off at any time. You have free things.

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The more you buy, you get free items. So there are a lot of different incentives to get you to become a customer, to become a reoccurring customer, and to become even what may be classified as a "loyal customer." Okay. All right.

So let's talk now about -- I'm shifting gears. Let's talk about hookah establishments from the entertainment and service side. Now, back in 2011, my colleagues and I, Dr. Mary Gilly and Dr. Tracy Harmon, we did a study looking at some of these establishments. And we were able to identify over 700 hookah bars, lounges, and cafés in the United States, with one being in at least 43 states, including D.C. Now, that was 2012. Now, I would venture to say 5 years later, though I don't have current information, that that number has significantly increased. So it became very important to us to try to understand exactly how do we categorize the entertainment side of hookah. So one side of it is the retail, which I just showed you. But there is an entire world out there which is actually on the entertainment and service side. So wonderful studies that we've heard about today, if you put it in the context of how it's actually practiced, this is what I'm going to show you. Okay. All right.

So if you look at my first example here, Pimp my Hookah.

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This is truly an actual place. It is called Pimp my Hookah. So you'll see a listing of the different offerings there. In terms of this typology of these establishments, they're categorized based on exactly what they offer and also the types of environments that they are. So, for example, the first typology are clubs, and these clubs are characteristically nightclub venues. They offer a range of different activities, including alcohol, a DJ, dancing, happy hour, specialty bottle service, VIP service, specialty drinks. So you walk into a nightclub, and it sounds and looks like the typical nightclub. Okay.

And then there are hookah loungers and bars. Now, these are different because they do offer both day and nighttime activities. They may or may not serve alcohol. They may have a DJ and entertainment. That might include something as exotic as belly dancing, poetry slams, spoken word, billiards, tastings, of course, happy hour, and specialty drinks.

And then there are what I'm calling transformational places, and transformational places are an interesting mix because they actually serve food within the lunch and dinner day parts. But then at night, they become an actual hookah bar or a hookah lounge or a hookah club. Okay.

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Then finally, one of the others that we're seeing that's emerging are gentlemen's clubs, gentlemen hookah clubs. And I'm not calling -- they're not strip clubs. I didn't say that. Can you erase that from the video? But, in essence, they do reflect that category, right. You do have women servers and dancers that are scantily clad and so on. And so, in essence, what we're seeing is that hookah smoking is very much sexualized in this environment. So it's all about the hookah and the sexual components of it that's embedded.

Okay, so if we think about just what has been done surrounding just trying to understand characteristically what some of these entities are, Primack, one of Dr. Barnett's colleagues, and several others did quite a bit of work back in 2012 and, looking at about 144 of these establishments, was able to actually identify some of these same characteristics. Interestingly enough, one of the things they found is that very few of them actually promote tobacco-free products. So even though there might be tobacco-free shisha, very few of them actually promote it, which does indicate that there is a possibility that they want you to become addicted in some way, shape, or form so that you can become a repeat customer. That's my opinion. Okay.

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They also found that from some of these websites you typically find images of hookah pipe or different aspects that is significant to the culture or the origination of the culture or images of people having fun and images that actually are very sexually suggestive. And so these are some of the classifications that I just talked about.

So now let's just turn the tables here for a second and look at exactly who is this target audience. So we've heard a lot today about the target audience being young adults. And I would venture to say what is advertised is that the target audience are 18 and older. The advertised age is 18 and older. However, that's not the case in terms of in actuality what actually walks in the door. If you take a look at my graphic here, from the 40 Thieves Hookah Lounge, this is a red circle over here, and I don't know if you can actually see it, but basically says "Under 18, no tobacco. We card." So what does mean? That means that if you're under 18, you can actually get in. Now, if you're in a group and one of us are older than 18, I get to order the hookah. Guess who gets to consume it with me? Everybody who is with me. So while the advertised age is 18 and older, that does not necessarily mean that the people that are in these establishments are only 18 or older. Okay.

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Arthur said this about this age context. He said, "It's kind of a social activity, and you feel like you going out to a bar, and you get a drink, it's kind of like going to a bar especially if you are under 21. People under 21 see it like going to a bar. They can't get into a bar to drink, but they can go to a hookah place and smoke." Okay. All right.

Now, there's a heavy amount of emphasis on college students as well. And so you'll find a myriad of activities targeting college students. A lot of these entities surround college campuses. The price points that you'll see there are definitely in the context of what college students can afford, very low cost in terms of beers and so on and so forth. There's also a focus on trying to get them to come into these places and stay as long as possible.

So here is an example where this hookah lounge, called Hookah Hookup in Lake Forest, is inviting you to bring your books and study for the night. Okay, so if you can actually imagine. So this is, again, a completely different world in terms of what's actually happening out there.

Now, in terms of actually normalizing it to attract other groups, like young professionals, we're seeing that a lot of these entities are creating means to continually get a group of

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consumers into the space. So, for example, Cloud 9 is out of Alpharetta, Georgia. And actually this is a chain. They have Mix It Up Mondays every other Monday night. And so the invitation goes out to people who are business professionals, entrepreneurs, music artists, models -- those who are opportunity seekers. They want you to come out, pass out your business cards, make connections, and create a profile. How is that for smoking hookah?

Okay, so that's, in essence, just a snip on the target audience. Now, I'm going to talk a little bit about just the normative depictions of hookah, because this is actually a culture. It's greater than just smoking. There's more to it than just smoking, and the users don't necessarily, as you've heard before, do not necessarily consider themselves as smokers.

And so this quote I found on Instagram I think sort of embodies what I'm about to talk about in terms of what they believe the culture really is. It says, "Smoking hookah is nothing like smoking cigarette. Cigarettes are for nervous people, competitive people, people on the run. When you smoke a hookah, you have time to think. It teaches you patience and tolerance, and it gives you an appreciation for good company."

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So along those lines, I'm got talk about four normative depictions: social depictions, occasion, lifestyle, and high life.

So I think you just heard Dr. Ramzi just talk about the length of opening. So hookah, the depiction in terms of the social aspect of it is an everyday access. Okay. There are themes to entice. You have VIP service, valet parking, and in a lot of respects, because a lot of them are open for extended periods of time, they become these after-hours joint, and definitely a nightlife destination.

So, for example, on Sundays you can go and you can have \$12 hookah all night. Or you can decide to have a moonlight on Monday. You can get tempted on Tuesday, with free drinks and free all night hookahs. Or you can decide to have a sip and smoke on Wednesday. You definitely might want to try Hookah and Heels on Thursday night. And for this, you might actually hear it advertised on the radio, Hot 107.9. If that wasn't enough, you can have a very flirtatious Friday. And as you can see, in terms of what's represented here, that combination, the association of hookah smoking with also the consumption of alcohol, so a very interesting looking martini there. And if that wasn't enough, well, you might as well just go out and

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have a very seductive Saturday. All of this, everyday access with hookah. So that's an indication of just some of the social depictions of making hookah a normative part of lifestyle.

Okay. Now, in terms of occasions, we're seeing that hookah is something that is being integrated into just what is considered normal life. Okay, so Pedro actually says one of his friends had a birthday party, and they rented out a place. It was in Tampico, Mexico. They had about 25 people there, and his friend had his birthday party there. All they did was dance and smoke hookah, and that was a birthday party.

Now, if you're into the zodiac, you can definitely go in for the competition and have a Capricorn versus Aquarius takeover smoking hookah. It's competition, okay. You can take your sweetheart there for Valentine's Day and have a very romantic package. If you want to be scared, you can get dressed up and go to a hookah lounge for Halloween. Or you can actually have a nice Christmas party at a hookah lounge. Or ring in the New Year's at a hookah lounge. And if that wasn't enough, if you really, really, really want to get somebody really excited, take your mom out for mango madness on Mother's Day.

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So, in essence, we're seeing that this is definitely more normalized, right. It's actually being integrated into different occasion or rituals that are typical in our normal operating life.

Now, let's talk a little bit about normative depictions. And I see my time here. I'm going to move fast. So normative depictions of nightlife -- and I do have a video here, but I don't think I have time to actually show it. Part of the lifestyle depiction is the authenticity of hookah. And when we talk about the authenticity, I'm saying in essence that the authenticity is actually staged. So think about the images that I just showed you. The objective is to make consumers feel as if they are actually having an authentic experience, but in actuality they are not. It's actually very much so staged. And actually the lifestyle is enveloped in terms of experiential activities, self-expression, and even the freedom to experiment and actually share those experiments, post those experiments, and encourage others to actually do some of the things that you do -- substitute the different things in the bowl, put ice in the base, which is another dimension that we're seeing as well, to cool it off.

Then there are high life depictions, for example, the

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hookah connoisseur. And so in the top there, you see Mike Tyson with his hookah, different images -- so that high life lifestyle, carefree living. We also see that there are associations that are being leveraged. For example, handbags and hookah, and in this case, hookah with Louis Vuitton. So designer high fashion, so the objective here is to associate hookah with pulling on those associations, those positive associations that consumers have with these brands. Okay.

Now, marketing mediums -- many. They're all being used from billboards to websites, a heavy amount of web presence. Social media is also being used in a wide array. So some of the work that has been done is listed on the side. Just to summarize, basically, all of the posts -- the pages, the profiles are created by creators and sharers. The objective is they want everyone to understand and see their experiences; they want to share these experiences as well. Across the globe, because social media is so pervasive, you can actually tap in from wherever you are. So wherever you are, you can actually see some of the normative components of how hookah is being used in life. So here is a wedding picture where the groom is actually enjoying hookah while his bride sits there. She looks upset.

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And additional mediums -- so apps. There are many different apps that have been created. So if you want to find a hookah lounge, there's an app for that. There are apps that actually tell you about the different types of products. You can actually order your hookah well in advance. There are hookah meet-ups. And then there are also apps for tutorials that will teach you how to do different things.

So, in essence, it is accessible. You don't necessarily need a lounge to actually smoke it. So here, for example, you can sit in the park, you could be on the beach, or you and your friends can sit on the floor in the parking lot and smoke. So it's widely accessible anywhere.

In terms of growing trends, we're seeing franchising. So you can actually have your own hookah franchise. You can actually become a hookah consultant. Or you can cater.

Okay, so just to wrap this up in -- no more minute, that's it.

(Applause.)

DR. DRESLER: Thank you very much. There is always so much information. So our next speaker and our last one for this session is Dr. Mohammed Jawad from Imperial College of London, School for Public Health. So wins the prize for the

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furthest distance away. But you are here for SRNT, or --

DR. JAWAD: Yes.

DR. DRESLER: Yes. Okay. Waterpipe Tobacco Products and Marketing Messages: Findings from the International Trade Exhibition.

DR. JAWAD: Good afternoon, everybody, and thank you to the FDA for having me here to speak about waterpipe tobacco products and marketing messages. I hope it will follow on nicely from Dr. Griffiths. It's a fascinating talk, and I'm going to present some findings from a trade exhibition that I went to.

This work was done in collaboration with American University of Beirut, and so I am presenting on behalf of both institutions. I don't have any conflicts of interest to declare, but can I just ask the audience, is anyone here from the waterpipe tobacco industry? Anyone retail, manufacturers? Yes. Can you just -- which company or business?

(Off microphone response.)

DR. JAWAD: Social -- is that a waterpipe retail company?

(Off microphone response.)

DR. JAWAD: You manufacture as well?

(Off microphone response.)

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DR. JAWAD: So you manufacture tobacco, apparatuses -- what do you manufacture?

(Off microphone response.)

DR. JAWAD: Both. Okay. Anyone else? No? Okay, so the background to this is that understanding tobacco products and marketing helps to develop effective tobacco control policy. And we know this very well from the cigarette industry. We certainly have access to internal documents of the industry and have a really good idea of the way in which they developed their products and market them to increase market share.

However, we do have very little understanding of the waterpipe tobacco industry. That's concerning, given the proliferation in what I calling waterpipe-serving premises in Western countries. I know in London alone we have at least 400 known waterpipe cafés, and I think Dr. Salloum was telling me they have about 1,500 now in the U.S., which is slightly increased on the 700 Dr. Griffiths estimated a few years back.

In the United Kingdom, we actually have quite good legislation, but we do have poor compliance with that legislation. So I know in the U.S. there are a few exemptions for smoke-free laws and so on, but in the U.K. that's not the case. However, lots of anecdotal evidence showing recurrent

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and deliberate breaches of the smoke-free law, even when it's legislated.

So I have three aims with regards to my research. That's to describe the products of the waterpipe tobacco industry, it's to evaluate some marketing messages, and to assess packaging and labeling compliance of waterpipe tobacco products. I appreciate every country has their own way of regulating packaging and labeling, but I'm going to do that with regards to the World Health Organization suggestions in the Framework Convention on Tobacco Control. The first two aims, I should mention, are available in a peer-reviewed publication, and the third aim that I'm going to be talking about is currently unpublished but should be published shortly.

So I attended what we call the International Hookah Fair, which is an annual event in its now fourth iteration this year. I went to the second and third in 2014 and 2015, and I was one of approximately 7,000 delegates in 2014. And I brought two other researchers with me the year after, and we were three of 11,000 delegates the year after. Although the hookah fair was called an international hookah fair and therefore had an element of global representation of the industry, I would say that most of the companies were European. There were certainly

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a few U.S. companies there and from other continents. It was a fair that was completely open to the public and occurred over 2 days.

So what did we do at this fair? We sequentially attended every exhibition that was there. We engaged in discussions with the representatives of the exhibitors about what products were on display and how they worked. We then asked for and collected marketing material from every exhibitor. The first two of those were done in 2014, and in 2015 we went around and specifically asked for any free product samples as well in order to engage in analysis of the health warnings and packaging compliance. The study was approved by Imperial College Research Ethics Committee.

So what did we find? I was slightly disappointed actually because in 2014 there were nearly 100 exhibitors, but only 55 of them actually displayed products related to waterpipe tobacco, that being the tobacco or the charcoal or the apparatus. And 2015, similar thing: about less than 50% actually presented anything to do with waterpipe tobacco. The remainder were electronic cigarette companies. So while I was disheartened, actually this is quite an important finding because it shows that the waterpipe tobacco companies are

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certainly sharing marketing platforms with electronic cigarette companies. This picture here, you can see it's called Skinny Shisha, which is an electronic cigarette just given the name of a waterpipe synonym, which makes you think why is this occurring, why are electronic cigarettes being marketed as waterpipe? We'll come into that later.

I found three broad categories of waterpipe-related products, and I appreciate that some of these definitions don't fall into how the FDA categorized tobacco and accessories. But those are what I call waterpipe products of consumption, divided into either a tobacco or a tobacco substitute product; waterpipe accessories, including the apparatuses that are used to smoke the products, charcoals, and any other accessories involved; and what I saw in front of me and can only be described as electronic waterpipe products or electronic nicotine delivery systems.

So let's go through what I was coming across. Certainly, on the left here, if we look at waterpipe products of consumption focusing on tobacco, on the left here we have what I would consider -- what's usually found behind the counter when you're looking at waterpipe tobacco, that is, a standard what I call processed tobacco. As you can see, a few health

warnings on there and certainly a picture of banana and some apples and peaches. That's, I think, the normal kind of waterpipe tobacco that I'm used to seeing in retail shops.

I also found -- it's kind of more of an unprocessed tobacco. That's probably not the correct definition of the word, but these tobacco flakes, if you like, that were just produced unflavored, and then you add these kind of molasses-type syrups to them to develop your own flavor. So kind of more of a manual development of your waterpipe tobacco experience. Certainly, it's tobacco, and as you can see on here, they also contain some health warnings on them as well.

So the tobacco substitutes I felt were really interesting. Here are just some examples. I know some of these have been mentioned already. If we start on the left, I found a quite heavily advertised product called Shisha Fruits, which as you can see are -- small pieces of banana in this one, at least, chemically processed and replace where the tobacco would go in the waterpipe apparatus. I'm not sure how clear it comes up here, but I can just read the ingredients to you, which says natural fruits, natural extracts, glycerol, tobacco 0%, nicotine 0%, tar 0%. Okay. That's on the back of this product.

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We also have the steam stones, which I know -- I think there's only been one paper published on the prevalence of steam stones, by Dr. Primack and colleagues. These certainly, I would say, perhaps the most popular tobacco substitute product, which are small kind of porous rocks that release flavor when heated. Not much is known about the chemical composition of these products. Certainly, more research is needed to figure out how exactly these are producing their flavors and chemicals.

I know this has also been mentioned today in a slightly different form, but these are called ice drops. And it's actually a gel, a tobacco gel -- sorry, a non-tobacco gel, and interestingly it does have a health warning on the back, saying that this product contains chemicals known to cause cancer and cause birth defect problems, but also has the same kind of descriptors, saying 0% tar and 0% nicotine and 0% tobacco and so on. So here's just an example of tobacco substitutes. And I know in the U.K. certainly, we have a new European Tobacco Product Directive saying that these products require health warnings similar to cigarette products. These are also included in bans on smoking indoors, and they're also included in prohibitions to under 18s, and I'm not sure that they're

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taxed at similar rates to cigarette tobacco.

We did some statistical analysis documenting which exhibitors were displaying which tobacco and non-tobacco types. Actually, we found that companies that were exhibiting these types of tobacco substitutes were far more likely to be also co-displaying tobacco products as well. Okay.

We've seen a whole host of waterpipe accessories, and I've just got a few pictures up here just to go through. There's one disposal hose here on the left: premium quality, single use, hygienic, leak-free. Interestingly, the company producing this also produced industrial plastic hoses for chemical waste and happened to just offshoot and produce hoses for the waterpipe industry.

In the middle here we have another harm reduction piece of apparatus. This is a mouthpiece filter. The company here, Palmer, actually produces cigarette paper as well and cigarette filters. So they were also offshooting and producing mouthpiece filters for waterpipe, certainly with claims of reduced harm. Maybe we can test to see if these also do what they say. However, I'm not entirely sure any research has been done on these kinds of filters.

Interestingly, we have many apparatus innovations. Here's

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an apparatus that's been innovatively made, where ice has been packed on the tube of the apparatus. This is a very intriguing looking apparatus here on the far right.

And I guess the point I want to make here is certainly under U.K. legislation, this is considered the tobacco pack. This is the cigarette pack equivalence, because it's being packed with tobacco and presenting to the consumer for sale. So that fulfills the definition of a pack. And I'm sure lots of effort is going into the branding and marketing and look and design of these apparatuses, which if you think about what cigarette companies do with their packaging and how much emphasis is made on the branding there, certainly calls for potential regulation of the design, style, and shape of the apparatus, in addition to the need for a health warning label on it, of course, because -- if I go back to this product, this product is what we try to enforce health warning labels on. But in a waterpipe café, this is rarely seen. What people normally see is just this. So that requires a health warning label too, in my definition and understanding of the law.

Okay. Then we have this very interesting category of electronic waterpipe products. We've actually talked about the first one on the first left. It's a electric coal, which was

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being described earlier, whereby the product is smoked as per normal and just the charcoal is replaced by an electric heating source. Okay.

However, the next four products here, you can see, are electronic cigarette-like devices. This product here, called Hooky, basically functions with a huge cartomizer and atomizer in the head, which is how electronic cigarettes work. They contain an equivalent of e-liquids, and they can be just placed onto any waterpipe apparatus and smoked as an electronic waterpipe apparatus.

Here we have what's a very large e-cigarette, called a waterpipe -- I'm sorry. It was called Shisha2Go, or an electronic waterpipe hose. So it's about 12 inches long and functions exactly the same way as electronic cigarettes. This is in a very interesting product, which is a waterpipe apparatus with a small e-cigarette on the end. Actually, that's the only thing that actually -- that's where all the heating of e-liquid occurs. Inside the actual apparatus is a battery or a wire of electronic heating source, which goes through the hose and just heats the end of the hose. This is just an electronic cigarette again, being advertised as e-narghile, which is the Arabic word locally for waterpipe.

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Again, you've seen this picture. This is just an e-cigarette disguised as a waterpipe synonym, which makes you wonder why are these products being produced in this way.

So after discussion with these companies, we came to the conclusion that electronic waterpipe products, and particularly the four towards the right, are likely to be offshoots of the electronic cigarette industry rather than the waterpipe tobacco industry. We showed this statistically through, again, display cataloging which products each exhibitor was showing, and we found that if you were displaying a waterpipe tobacco product or tobacco substitute product, very rarely was an electronic type apparatus seen. That was even the case on the marketing material. They were never seen on the same item of marketing material. Okay.

So towards the marketing material, which I don't think needs any further elaboration to what Dr. Griffiths kindly presented previously, but just as a formality, we collected 52 items of marketing material in 2014. There were 14 themes coded, and they were coded 169 times. The top four most popular themes were waterpipe as a healthier alternative, although I must emphasize, there was no indication of a comparator, so healthy alternative to what; and the other most

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common theme was about flavors, of course; but a big emphasis on safety, quality; smell, taste, and cleanliness.

Here's an example. Start from the left, of a tobacco company and their marketing material. "Our goal is to have our patrons with not only the best but the healthiest forms of smoking hookah." You'd expect that from a tobacco substitute company or an electronic company but not a tobacco company. And I found that quite astounding.

The tobacco substitutes had very common and similar themes. For example, with Shisha Fruit, they said they -- they said that it "contains no tobacco and no nicotine and is therefore less harmful to use." With our Shiasco steam stones, which we think is the most popular tobacco substitute, they've said that "Besides the convenient usage and the health benefits, there are many more advantages of using Shiasco as an alternative for tobacco."

Interestingly, these perceptions also extend to charcoal as well. So this is a coconuts-based charcoal company, which says that their charcoal product "does not contain any chemical substances like you would find them in quick lighting charcoal."

So actually even within each product category, tobacco,

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tobacco substitutes, and charcoal, there is comparison. People are just comparing against each other, saying, oh, no, our tobacco is better than the other tobacco, or our substitutes are better than tobacco, or our charcoal is better than quick-lighting charcoal. So that's a quite interesting finding.

So, therefore, our fourth finding for this visit to the fair was that claims of reduced harm are present across waterpipe products and accessories.

So packaging and labeling. We found not that many tobacco products were being distributed. As mentioned, the majority of the exhibitors were electronic waterpipe companies or e-cigarette companies. So of those that were left, not that many were actually giving out tobacco products. However, 10 of the 15, about two-thirds of the tobacco products, contained health warnings on their principal display areas. That is the area that is most shown to the customer. So for the tub that includes the top part of the tub, and for the rectangular packets, it's either front or back. The median coverage of the health warning label was about 22% of the principal display area, and no tobacco product exceeded more than 30% cover. And 30% is the minimum suggested from the World Health Organization Framework Convention on Tobacco Control. Actually, they prefer

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to suggest at least 50% cover.

Only three tobacco products contained pictorial health warnings. So we're still very much stuck in what I would call the medieval times of text only health warnings, nothing with regards to graphic pictorial health warnings, which is what we prefer to do to show our consumers these days because they're far more effective.

All the tobacco products contained misleading descriptives. And I would consider fruit imagery and pictures of fruits on a package as a misleading descriptor. But certainly emission yields are very common on waterpipe tobacco products. And we've seen so many times today 0% nicotine or 0.05% nicotine, 0% tar -- these are all emission yields that give a false impression of a healthy product.

Actually, something we haven't mentioned, but expiry dates are not supposed to be allowed, according to the WHO FCTC, because it gives an impression that a tobacco product is worse to use after the expiry date, whereas in reality there's no good time to consume a tobacco product.

Also interestingly, just to end, on our findings is about the charcoal products. Actually, 8 of 13 of them included misleading descriptors, usually in the form of marketing

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environmentally friendly products, i.e., like no trees were killed in the development of this charcoal product, or something about reduced harm, like our charcoal product produces no ash or produces better smoke or something along those lines.

Okay, so the fifth finding, that all tobacco products were not compliant with recommendations of the WHO FCTC. And the sixth finding, that charcoal marketing messages mimic waterpipe tobacco marketing.

Okay. I've got another 20 seconds to go, so this is the summary of all the six findings, a few to look at. I'll just give you 5 to 10 seconds to look at it, before I move on.

Okay.

Just to finish off, this is one of my last slides, to discuss what we've seen. So from my visits to this fair, it's clear that the waterpipe industry is actually quite complex. It's a lot going on. It's lots of manufacturers. Many of them are producing more than one product, and one of those products are for the waterpipe industry and others are not. For example, we had people who were glass manufacturers producing vases and chandeliers who were also producing the apparatus. We had barbecue charcoal manufacturers producing charcoal for

waterpipe charcoal. And we had, as mentioned with the hose -- industry hoses produced also for waterpipe. So we're not just dealing with tobacco companies and therefore not just dealing with tobacco policy. I think that's an important point to take forward.

I've asked the question should charcoal and apparatus companies also be regulated, given they play such an important role to what's presented to the customer smoking waterpipe? There's a wider discussion about deliberate marketing of e-cigarettes as waterpipe products, and this is actually showing that more industry accountability is required, especially given that there is no known lobby or advocacy group for the waterpipe tobacco industry that could provide resistance to any movement forward with health policy.

A few limitations, mainly that this is a cross-sectional study, and therefore we can't see what's going on before and after. It's not representative of all tobacco companies globally, and it is a small sample but produces very interesting insights into what's going on at certain tobacco fairs.

So thank you for listening. And here are my acknowledgments for my fellow colleagues who helped in this

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project.

(Applause.)

DR. DRESLER: Thank you. And just sit up here, okay.

DR. JAWAD: Okay.

DR. DRESLER: Thank you. Talk about a complex topic and product. So as the speakers are coming up, actually, I'm going to get my other microphone. Thank you. So again, if you have questions, we'll have cards, and you can write the questions up and then pass them in.

So I'm going to start out with one question. We know that waterpipe smoking is more prevalent in youth and young adults. However, given the increased social acceptability, is there evidence that older adults, older being greater than 40 -- I think this was a young person who asked this question, just saying -- okay, so evidence that older adults are initiating due to the influence of younger friends or family? So kind of like a reverse.

DR. GRIFFITHS: No, not specific. We're seeing this as something that it's definitely germane to the younger generation. We're not seeing a significant amount of consumers who are well beyond the 25- to 30-year category embracing or engaging in hookah smoking.

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DR. DRESLER: All right. What are the harm perceptions? This came up more through yours, Tracey. Harm perceptions between electronic cigarettes and waterpipes, so the comparison to cigarettes. So what do people think about waterpipes versus electronic cigarettes?

DR. BARNETT: I think the issue around that is going to come with flavors, which you heard quite a bit about today. I think the issue is with flavors being in both and being things like gummy bear and candy, that you're going to see quite an association. And I think that's also why it was brought up that they're being marketed together and under similar circumstances. I think the goal is to have them appeal in the same way.

DR. DRESLER: So do we ask those questions on any of the surveys, how people are perceiving the two of them and -- I'm just wondering if --

DR. SALLOUM: Well, in the PATH study, there wasn't a head-to-head comparison between waterpipe and e-cigarettes. But compared to cigarettes, there was a larger percent of young adults who said that e-cigarettes were less harmful -- or thought that e-cigarettes were less harmful than cigarettes, but waterpipe was number two, I think, close to 40% endorsed

the e-cigarette claim versus around -- or less than 20% for the waterpipe. But it was number two when compared to all the other tobacco products.

DR. BARNETT: I just wanted to add one quick thing. I did a cross-sectional of the tobacco survey, and we found when we were predicting that e-cigarette and hookah use was the most correlated; it's cross-sectional. We can't say it was longitudinal. But those two were the products that were most associated, and not cigarettes.

DR. DRESLER: All right. How are perceptions of addictiveness about waterpipe use associated with initiation? So you would ask the question of do people think that it's addictive? And so how is perceptions of addictiveness associated with initiation of the product?

DR. LIPKUS: First of all, we got to understand there's very few prospective studies in general about initiation. To my knowledge, there hasn't been anything from a prospective study that shows that perceptions of addictiveness leads to initiation. That doesn't mean it doesn't, but in terms of all the comprehensive measures you find, which aren't that many, there is none that I could think of that shows that association yet.

DR. DRESLER: So, Dr. Griffiths, this is probably for you too. Who are the major companies in the waterpipe industry? And perhaps, Mohammed, you too. Who are the major companies?

DR. GRIFFITHS: Interestingly enough, it's not very easy to identify. So, for example, the online retailers for hookahshisha.com, Mya Smoke Hookah -- there are a lot of them out there. It's hard to determine exactly where the source is. So we know that a lot of these products are made in China. We know a lot of the charcoal is made in China. However, the actual entities that are actually bringing them into the country, it's hard to -- we don't know. At least, I haven't come across any information that provides that.

DR. SALLOUM: So at the beginning of this epidemic in the 1990s, we have information that shows that it was coming and being imported into the United States, at least talking specifically about the tobacco, it was primarily coming from the Middle East. And now we're seeing more and more suppliers in the United States of tobacco, whereas the apparatus is being manufactured in China and other countries and being imported in the U.S. And we're also seeing -- I've had reports even in the Middle East of U.S.-based suppliers exporting tobacco into the Middle East, primarily into the higher end waterpipe cafés

where there is a huge demand for U.S.-based tobacco now. So we're seeing a reversal of roles.

DR. DRESLER: Mohammed?

DR. JAWAD: Sure. I mean, if you compare to what we know from the cigarette industry, where there is four main companies running the show pretty much in an oligopoly, that's not the case of waterpipe at all. Not only are there many retailers -- I'm sure we can name some of the main tobacco companies that we see in our stores -- but not only are there many, but certainly that's working at several levels. So at the level of waterpipe tobacco, at the level of the apparatus manufacturers, the charcoal manufacturers, there's also the retailers, not to forget the waterpipe cafés that play a huge role in kind of promoting waterpipe tobacco use, while they may not simultaneously produce or manufacture any of the products themselves. There's this added layer of dedicated waterpipe cafés that complicates the industry somewhat.

DR. DRESLER: So expand on that a bit. Are there chains of waterpipe cafés?

DR. GRIFFITHS: So yes. So Hookah Hookup, for example, is a chain. However, part of what makes it difficult to understand or see that it's a chain is that they operate as if

they're very local. They're part of the local environment, part of the local culture. And that's part of that authenticity that they're portraying. So there are chains of hookah outlets or lounges and cafés. You see the same names over and over again. Cloud 9 is another. So there is several that are actually chains.

DR. DRESLER: So you had presented some data saying that waterpipe smoking was the highest in some, with some college experience. That was the group with the most, right? So is it predictive that if people are using waterpipe smoking, that it's only some college and not graduate? I mean, it was looking at the risk behavior, right. And so you had looked at susceptibility and who is most likely to. So if people are more likely to be more susceptible, are they less likely to go on to finish college?

DR. BARNETT: That's a very interesting question. I'm not sure we -- you're speaking to the CDC work this morning, right, where it showed that many had dropped out? I mean, I -- even prior to hookah, we knew that many substance users at that age like use multiple substances. So in that respect, yes. Anyone who is during their early '20s spending a lot of time using multiple substances, they are going to be more likely to be

your college dropouts. I don't know that we can tease hookah apart for that necessarily. Again, it's going to be -- you know, we talk about people over 25 not really using, but who knows what that's going to look like in the coming generations, because it's become so popular. So it's liable to change anyway.

DR. DRESLER: Well, that and it also seemed weird to me that the mothers having the higher education didn't go with that either, plus higher income also. So there's a lot of conflicting information that's mixed up with some of the data, so it hasn't cleared out.

Have any of the panelists looked at how all this marketing differs or is similar to how cigarettes were marketed back in the day? Other than flavors, glamour, coolness, sexual appeal, et cetera.

DR. GRIFFITHS: Believe it or not, very similar. So if you remember, for example, the cowboy, the Marlboro man, the fictional Western cowboy -- you actually find the DJs with the highest clout scores, so they become the models and the images that you see in some of the ads. Or a unique-looking belly dancer that's unique to a particular area. So it's similar -- using similar images, the same kind of messaging, you know.

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It's great, it's a part of high life, it's the right thing to do, there's no consequence to it, similar to the '70s and '60s of what we saw with cigarette.

DR. DRESLER: Okay. Anyone else want to -- there was a -- one of the slides in the presentation said that waterpipe was less harmful than smokeless. Was that one of the questions? Was that in yours?

DR. SALLOUM: That was, again, not comparing waterpipe head to head with these products. It was comparing the perception of waterpipe to cigarettes. But in terms of the percentage of participants in PATH who endorsed that statement, waterpipe ranked higher. So effectively it was considered by them as less harmful than these other products, when compared to cigarettes, including smokeless tobacco.

DR. DRESLER: Okay.

DR. SALLOUM: So a smaller percentage of PATH participants in the young adult category thought that smokeless was less harmful than cigarettes, versus those who thought that waterpipe was less harmful than cigarettes.

DR. DRESLER: Okay. Okay. How were the concept flavors, such as blue mist and pirate's cave described in your study, were they described as fruit flavors? So blue mist I kind of

had a sense. But pirate cove, I couldn't figure out what flavor that was either. So was it described?

DR. SALLOUM: Well, we tried to capture some of the popular flavors that were being sold online. From these online retailers, you can find out what those flavors were. And, of course, in our experiment we couldn't include all the popular flavors, and we had to make some decisions. This was one of the top-selling flavors, and by the design of that specific flavor -- by design, it was not disclosed what the flavor was. That's part of the marketing strategy. So we wanted to emulate this realistic aspect of the choice scenario, and so we included that top-selling flavor, which is sort of unknown what the flavor is.

DR. DRESLER: So when you say that it's one of the top-selling ones, that means you've been able to track what is top selling. So if we look at either electronic cigarettes or cigarettes or smokeless tobacco, we've been able to track who are the market leaders in that. Are you able to track, and how frequently does it change, who are the market leaders for waterpipe tobacco?

DR. SALLOUM: No, I should clarify that this was according to the supplier themselves on their website. They claimed that

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these were the top selling. We don't have actual information on that.

DR. DRESLER: And I'm wondering, do we? Because as I said, for these other products, you've been able to track that, and there's many presentations in SRNT that would look at those sort of issues. But have we done any of that sort of work in waterpipe?

DR. SALLOUM: I think it's also very challenging because of how fragmented this market is. It's almost close to being a perfectly competitive market with a very large number of small suppliers, versus the cigarette industry that's essentially oligopoly with a small number so you can actually track that information. I don't know if there are government sources where you can track that specific information beyond the volume of imports and exports in the U.S.

DR. DRESLER: Your economist background is showing, you know. I'm just saying.

DR. JAWAD: I was just going to add the new European Tobacco Products Directive is going to enforce the need for retailers to register all of their brands and flavors with the government prior to being able to sell. So that should be a register being created in Europe over the next few years, which

is a --

DR. DRESLER: For e-cigarettes and waterpipes, or --

DR. JAWAD: This is for -- I'm not too hard on the e-cigarettes legislation, but definitely for waterpipes. Yes.

DR. DRESLER: Okay. Do you know, is there sensory testing for flavors going to be connected with that at all? Or just a listing?

DR. JAWAD: As far as my understanding goes, it's just the listing.

DR. DRESLER: Just the listing.

DR. JAWAD: Yes. Yes.

DR. DRESLER: Okay. Do perceptions of social norms of waterpipe use differ by demographic groups? So social norms and how does that change by demographic groups: age, race, gender?

DR. GRIFFITHS: I haven't found anything specific that indicates that there is a significant difference between generations or even between demographics. So, for example, the low-end of Gen Z and the top end of Gen Y pretty much are embracing it in the same way. There's very little difference that I've found so far.

DR. DRESLER: How about between race or gender or those

social norms? It's all the same?

DR. GRIFFITHS: It's about all the same. One of my studies, for example, I had -- I tried to stay away from the college crowd. And I was able to actually get two Jamaican consumers, and they talked about it in the same way as everybody else. They embraced it the same way. So, so far, I haven't found anything that indicates there is significant differences.

DR. MAZIAK: There is a couple of studies that looked at gender differences and the perception of hookah smoking in the Middle East, not the U.S. And they showed consistently that men looking at women hookah smoking as a sign of liberal kind of attitude, more open to relations and so forth. That was not reciprocal from women to men. So there is some kind of directionality here related to that. But that's specific to that environment probably, not generalizable.

DR. DRESLER: Okay. All right. Do we have any other questions from the audience? We've had a lot of waterpipe information today. Any questions from you all to ask each other? No.

All right. I don't have any more questions, and that means we are actually finishing about 25 minutes early. So

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thank you very much for today and for the other speakers for today. And tomorrow morning we start at 8:30, back in this room, and look forward to seeing you back again. So thank you very much.

(Whereupon, at 4:33 p.m., the meeting was continued, to resume the next day, Friday, March 18, 2016, at 8:30 a.m.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

WATERPIPES: A PUBLIC WORKSHOP

March 17, 2016

Silver Spring, Maryland

were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Tobacco Products.

ED SCHWEITZER

Official Reporter

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