

FOOD AND DRUG ADMINISTRATION  
CENTER FOR TOBACCO PRODUCTS

JOINT MEETING OF THE FDA RISK COMMUNICATION  
ADVISORY COMMITTEE AND  
TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE

Thursday, August 15, 2013

9:00 a.m. to 5:00 p.m.

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Rockville, Maryland

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P R O C E E D I N G S

(9:00 a.m.)

**Administrative**

DR. HALLMAN: Good morning, everyone, and welcome to the FDA Risk Communication Advisory Committee and Tobacco Products Scientific Advisory Committee meeting for this morning.

I'm Dr. Bill Hallman. I will serve as the chair of the joint committees today and chief traffic cop in trying to manage all of the comments in the short amount of time we have this morning and this afternoon to address the FDA's issues.

So if you would do me the courtesy of silencing your cell phones, please, or putting them on stun, that would be much appreciated.

At this time I'd like the committee to very briefly introduce themselves. So I will start. I'm Dr. Bill Hallman. I am a psychologist and chair of the Department of Human Ecology at Rutgers, the State University, and my expertise is in risk perception and risk communication issues.

To my left?

DR. SAMET: Good morning. Jon Samet, the chair of TPSAC. I'm a pulmonary physician and epidemiologist. I chair the Department of Preventive Medicine at the University of Southern California.

DR. PAUL: Good morning. I'm Kala Paul. I'm a neurologist. I've had 25 years experience with the pharmaceutical industry, and the last 13 have been involved in low literacy patient communications for patient education and risk communication.

DR. BICKEL: Warren Bickel, Virginia Tech. I do research on addiction, particularly the application on behavioral economics, to understand drug-taking behavior, including smoking, in humans.

DR. HENDERSON: Good morning. My name is Patricia Nez Henderson. I'm the vice president for the Black Hills Center for American Indian Health. I primarily work with tribes and tribal communities in tobacco control.

DR. STRICKLAND: Good morning. My name is June Strickland. I'm faculty in the University of

Washington School of Nursing. My research is in behavioral science with American Indian and Alaska Native populations.

DR. TURNER: Hi, everyone. I'm Monique Turner. I'm a professor at the George Washington University School of Public Health. My expertise is in risk and health communication and in risk perception.

DR. MCAFEE: Good morning. I'm Tim McAfee, and I'm the director of the Office on Smoking and Health at the Centers for Disease Control.

MR. TIPPERMAN: Good morning. My name is Doug Tipperman. I'm a lead public health advisor with the Substance Abuse and Mental Health Services Administration.

DR. DJORDJEVIC: I'm Mirjana Djordjevic at the National Cancer Institute, Tobacco Control Research Branch, and I'm representing NIH at TPSAC meetings. My background is in chemistry.

DR. RUTQVIST: Lars Rutqvist. I have a background in clinical oncology and epidemiology.

And since a couple of years, I head the scientific affairs team at Swedish Match.

MR. HENTON: My name is Hampton Henton. I'm a farmer and grower of tobacco and other crops in Central Kentucky.

DR. HECK: I'm Dan Heck, a research fellow at the Lorillard Tobacco Company. I'm a toxicologist by training, and I'm representing here the tobacco manufacturer stakeholders.

DR. D. JOHNSON: I'm David Johnson, and I'm representing the small tobacco manufacturers of America.

DR. DRESLER: I'm Carolyn Dresler, and I'm at the Office of Science at the Center for Tobacco Products.

DR. CHOINIERE: I'm Conrad Choiniere. I'm also in the Office of Science at the Center for Tobacco Products.

MR. ZELLER: Mitch Zeller, director, Center for Tobacco Products.

DR. ASHLEY: David Ashley. I'm director of the Office of Science in CTP.

MS. LEE: My name is Ji Sun Lee. I'm the director for the risk communication staff in the Office of Planning.

DR. COHEN: I'm Joanna Cohen. My training is in epidemiology and health policy, and I'm with the Institute for Global Tobacco Control at Johns Hopkins School of Public Health.

DR. SLEATH: I'm Betsy Sleath, and I'm professor and chair of the Division of Pharmaceutical Outcomes and Policy at the University of North Carolina Chapel Hill School of Pharmacy.

DR. WOLF: Michael Wolf, professor of medicine and learning sciences at the Feinberg School of Medicine, Northwestern University.

DR. KRISHNAN-SARIN: Suchitra Krishnan-Sarin. I'm at the Yale School of Medicine in the Department of Psychiatry.

MS. LAWSON: Madeline Lawson, the president and CEO of the Institute for Multicultural and Minority Medicine in Washington, D.C.

DR. CLANTON: Mark Clanton. I serve on the TPSAC, contributing to public health, pediatrics, and oncology. I'm currently an independent health care consultant, a former executive at the American Cancer Society, former deputy director of the National Cancer Institute.

DR. FREIMUTH: Good morning. I'm Vicki Freimuth. I'm a professor of communication at the University of Georgia. My areas of expertise are health and risk communication.

DR. EISSENBERG: Hi. My name is Tom Eissenberg. I'm a psychologist from Virginia Commonwealth University. My expertise is in clinical behavioral pharmacology, and I'm a TPSAC member.

MR. BRAVO: Good morning. Luis Bravo with the risk communication staff, and DFO for this meeting.

I'll jump into a couple of admin remarks. For any press currently in the room, our press officer is Jennifer Haliski. She's available here to my left. If anybody needs to speak to her, you

can find her there, or we have her email address to contact her. And that could be provided to you at our registration table right outside the room.

For any breaks, bathrooms are around the back right by the snack bar area to your left there. It's not hard to find. But if you need assistance, again, our folks at the registration table will be able to help you out with that.

I'll move into our conflict of interest statement.

The Food and Drug Administration is convening today's joint meeting of the Risk Communication and Tobacco Products Scientific Advisory Committees under the authority of the Federal Advisory Committee Act, FACA, of 1972.

With the exception of the industry representatives, all members and nonvoting members are special government employees or regular federal employees from other agencies and are subject to federal conflict of interest laws and regulations.

The following information on the status of the committee's compliance with federal ethics and

conflict of interest laws covered by, but not limited to, those found at 18 United States Code Section 208 is being provided to participants in today's meeting and to the public.

FDA has determined that members of this committee are in compliance with federal ethics and conflict of interest laws. Under 18 United States Code Section 208, Congress has authorized FDA to grant waivers to special government employees and regular federal employees who have potential financial conflicts when it is determined that the agency's need for a particular individual's services outweighs his or her potential financial conflict of interest.

Related to the discussions at today's meeting, the members of this committee have been screened for potential financial conflicts of interest of their own as well as those imputed to them, including those of their spouses or minor children and, for purposes of 18 United States Code Section 208, their employers. These interests may include investments, consulting, expert witness

testimony, contracts, grants, CRADAs, teaching, speaking, writing, patents and royalties, and primary employment.

Today's agenda involves the results of the FDA consumer research experimental study on the public display of list of harmful and potentially harmful constituents to assess the impact of HPHCs, information on consumer perceptions and comprehension, and how to effectively communicate information about the HPHCs of tobacco products to the general public. This is a particular matters meeting, during which general issues will be discussed.

Based on the agenda for today's meeting and all financial interests reported by the committee members, no conflict of interest waivers have been issued in connection with this meeting. Dr. Kurt Ribisl, a member of the Tobacco Products Scientific Advisory Committee, is recused from participating in the meeting.

To ensure transparency, we encourage all committee members to disclose any public statements

that they have made concerning the issues before the committee.

With respect to FDA's invited industry representatives, we would like to disclose that Drs. Daniel Heck, David Johnson, and Lars Rutqvist, and Mr. Hampton Henton, are participating in this meeting as nonvoting industry representatives, acting on behalf of the interests of the tobacco manufacturing industry, the small business tobacco manufacturing industry, and tobacco growers, respectively. Their role at this meeting is to represent these industries in general and not any particular company.

Dr. Heck is employed by Lorillard Tobacco Company. Dr. Johnson is employed by National Tobacco. Dr. Rutqvist is employed by Swedish Match. And Mr. Henton is owner/operator of Henton Farms, Incorporated.

We would like to remind committee members that if the discussions involve any other products or firms not already on the agenda for which an FDA participant has a personal or imputed financial

interest, the participants need to exclude themselves from such involvement, and their exclusion will be noted for the record.

FDA encourages all other participants to advise the committee of any financial relationships that they may have with any firms at issue. Thank you.

DR. HALLMAN: Very good. Thank you very much.

Just a couple of cautions. You will have noticed that the meeting this morning and this afternoon is being webcast. Transcriptions are also being made, so please be aware that your comments will be recorded for posterity. So please accord yourself accordingly.

At this time I'd like to invite Dr. Ji Sun Lee to give her message of welcome.

**FDA Welcome and Update - Ji Sun Lee**

MS. LEE: Good morning, everyone. I hope you all can hear me. I've been accused of being a soft talker, so if I drift at any point during this conversation, just wave your hands and I will

endeavor to speak up.

Good morning, everyone, and welcome to the FDA White Oak Campus for our August advisory committee meeting. My name, again, is Ji Sun Lee, and I'm the director for the risk communication staff in the Office of Planning, located in the Office of the Commissioner.

We're very excited to have our first joint meeting of this year with the Tobacco Products Scientific Advisory Committee, and we thank you all so much for joining us. We're very grateful that you've taken the time to join us, and we appreciate your participation and your insights.

I would also like to thank the staff of the Center for Tobacco Products and my staff, the risk communication staff, for their tireless dedication and effort in making this meeting possible. This one-day meeting is kind of like Christmas.

You guys have no idea all the work that is involved in making this one day happen, and so I want to thank all of them very much for all of

their work; especially this meeting, as it was conceived about a year ago, as Conrad can attest to. And after jumping many hurdles and going through many hoops on the government side, it's really great to be able to come full circle and finally be able to have this joint meeting on such an important issue.

I would also like to welcome the members of our audience for joining us today. I hope you find the meeting and its topics not only relevant but informative as well.

For the benefit of our guests, instead of jumping right into updates, as I normally do, from our last advisory committee meeting, I wanted to provide a bit of background regarding the risk communication staff and the Risk Communication Advisory Committee.

RCS works collaboratively to provide objective planning, analysis, and evaluation services to improve FDA's communication-related performance. The risk communication staff provides to the FDA social science research design and

analysis expertise, we conduct independent and objective analysis of communication tasks, and we assist in meeting the mission goals of communicating information needed to achieve the agency's public health mission.

Our staff has developed numerous tools to help the agency, its offices, and centers meet their mission goals. And in addition to providing social science advice, doing internal message testing, and providing social media trend reports, a key tool for us is our Risk Communication Advisory Committee.

Our committee provides specialized scientific expertise and advice. It provides an outside perspective and confirmation, transparency, and an avenue for facilitating public participation.

Since 2007, the Risk Communication Advisory Committee has provided independent expert advice to the FDA on the science of communication and the best practices to communicate effectively the risks and benefits associated with using FDA-

regulated products.

Since that time, the committee has assisted agency centers to better understand the public's perception of risks and benefits, has advised on the content and delivery of agency messages to multiple audiences for greatest impact, and has provided valuable insight to assist the agency in setting priorities, guiding research, and making policy to better communicate information about FDA-regulated products.

Our RCAC is composed of 15 voting members, and we have no representatives as standing members. And when appropriate, as today, we have nonvoting industry representatives that are drawn from a pool of industry-related individuals.

Our committee members come from various backgrounds. We have social and behavioral scientists. We have medical and public health professionals, marketing and public relations specialists, journalists, and community advocates.

In the past few years, the committee has discussed a wide range of issues such as

communicating and understanding uncertainty, communicating quantitative risk and benefit information for drug labels, the changing methodologies in the attribution of food-borne illnesses, and tracking FDA communications in social media, just to name a few of the topics that we've covered.

Finally, I wanted to provide a quick update from our April advisory committee meeting. We had a great two-day meeting in April discussing risk communication issues with the Office of External Affairs, CDER's Safe Use Initiative, and the MedWatch program.

The committee provided varied and very thoughtful recommendations to our offices and centers. They provided quick win recommendations regarding the appearance and organization of information on websites, possible new outlets for message distribution, and new organizations to consider for partnerships.

But they also provided very substantive long-term research and evaluation projects to

better understand the impact of their programs, the value of key initiatives that they have, and to better understand consumer attitudes and behaviors.

We have met with each of our partners from our last meeting, and we look forward to continually working with them to make the committee recommendations actionable in their daily operations.

Today we're very excited to be again working with the Center for Tobacco Products and discussing communication issues about harmful and potentially harmful constituents in tobacco products. I'm very much looking forward to this discussion, and I will no longer be an obstacle to that discussion. So thank you all very much, and I look forward to today.

DR. HALLMAN: Thanks very much.

I'd now like to turn the floor over to my colleague, Dr. Samet, for his comments.

**Presentation - Jonathan Samet**

DR. SAMET: Good morning. I've been asked to give an overview and introduction to the Tobacco

Products Scientific Advisory Committee, better known as TPSAC. And let's see, I should have some slides available for this. Okay. So go on to the next.

This is going to be a very brief tour of TPSAC. So here is our charge, which is in fact a broad advisory charge that you can read here, advising the commissioner-designee. And this charging responsibility is as they relate to the regulation of tobacco products.

Further, on the breadth of our charge, which you can read here as well, and a little bit more. Actually, as I looked at this, the slides are going to list out a set of meetings and topics we've taken on, so bear with me.

We started -- in fact, it will be four years ago, our first meeting, in March of 2010. Our first task was to write a report on the impact of the use of menthol in cigarettes, and this occupied most of our meeting time for the first year.

In fact, if I remember right, we met about

nine times during the first year of our operation to develop the report on menthol, which was mandated in the Act to be completed within the first year that TPSAC was in place.

Our second task was to do a report on dissolvable tobacco products. That report was completed March 1, 2012, a somewhat less demanding task because the extent of evidence available for review was far less than for the menthol report.

Again, other tasks that have been brought forward -- one listed out here related to nicotine yields, and then further discussions about modified-risk tobacco products and applications for such.

Our membership is 12, and you've heard from many of our members introducing themselves this morning that we are an interdisciplinary group. We have three nonvoting members representing the industry, who have introduced themselves this morning and the sectors that they represent.

Again, our membership is prescribed within

the Act and includes some members from the government -- the governments, state or local governments -- and also a representative of the general public. And we bring in additional temporary members as needed to fill out our technical expertise, depending on the topic.

Here is a list of our three nonvoting members: the tobacco manufacturing industry, the tobacco growers, and the small business sector.

Here is our current roster, and again you've heard from our members as they introduced themselves this morning.

Here, as you can see, are our meetings related to menthol. It goes on; this was a very busy time for the committee. I think there are four of us left who I'll deem as survivors of the menthol days, when we had a very busy agenda in developing this report, and then on to the dissolvable reports.

We've been a little quieter since, but our agenda is quickly filling up. And of course, you can find more information at the website if you

want to.

So that was a very quick tour of the Tobacco Products Scientific Advisory Committee, or TPSAC. Thank you.

DR. HALLMAN: Thank you very much, Dr. Samet.

At this time I'd like to invite Dr. Choiniere to present on the harmful and potentially harmful constituents topic.

**Presentation - Conrad Choiniere**

DR. CHOINIERE: Good morning. As I said earlier, I'm Conrad Choiniere. I am the director of the Division of Population Health Sciences in FDA's Center for Tobacco Products, Office of Science. I've been with FDA since about 2003, having worked about six years at the Center for Food Safety and Applied Nutrition before joining CTP in October of 2009.

Much of my work over the past ten years has been related to assessing the impacts of communications and marketing of FDA-regulated products on consumer perceptions, beliefs,

attitudes, and behaviors.

Before I move forward with my presentation, I'd like to read a disclaimer, and I want to let you know that this disclaimer applies to all of the presentations from FDA today.

The information in these materials is not a formal dissemination of information by FDA and does not represent agency position or policy. The information is being provided to the RCAC and TPSAC to aid the committees in their evaluation of the issues and questions referred to the committee.

As many of you are already aware, FDA was given the authority to regulate tobacco in 2009. This authority is a broad range of authorities related to the manufacture, distribution, and marketing of tobacco products. FDA's regulation of tobacco has given the federal government more tools to help reduce the public health burden of tobacco in the United States.

As a reminder, tobacco continues to have an immense public health impact. Smoking causes more than 440,000 deaths per year in the United

States. Each day more than 3800 youth under the age of 18 smoke their first cigarette. Nearly nine out of ten adult daily smokers use their first cigarette by the age of 18.

In addition, a total of 3 and a half percent of all adults and 6.1 percent of high school students use smokeless tobacco products. Despite this, approximately 69 percent of current U.S. adult smokers report that they want to quit completely.

Among those authorities related to tobacco, FDA has many requirements and responsibilities related to the provision of information about tobacco products. These are related to either the labeling for ingredients or constituents; the regulation of claims, such as modified risk claims on tobacco products; and the requirements related to health warnings on tobacco products.

Today we are here to discuss one of those requirements, and that is that FDA is required to publish information about harmful and potentially

harmful constituents in tobacco and/or its smoke.

The requirement specifically is that FDA establish and periodically revise, as appropriate, a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand.

It also requires that manufacturers, importers, or agents thereof submit a listing of the constituents that FDA has identified as harmful or potentially harmful by brand and by quantity in each brand and sub-brand.

In turn, FDA is required to put that information that is submitted by the manufacturers -- to publish this information in a format that is understandable and not misleading to a lay person, and place on public display this list, which is what we're here to discuss today.

FDA's current thinking on harmful and potentially harmful constituents was published in a draft guidance in January 2011 -- sorry, a guidance in January 2011.

Harmful and potentially harmful

constituents, which we will fondly refer to as HPHC for the remainder of the meeting, are any chemical or chemical compound in a tobacco product or in tobacco smoke that is or potentially is inhaled, ingested, or absorbed into the body and that causes or has the potential to cause direct or indirect harm to users or non-users of tobacco products.

Subsequent to that guidance, in March 2012, with input from the public and the TPSAC, we established a list of 93 HPHCs. We also published a draft guidance related to this list where FDA proposed to focus our initial enforcement of the reporting requirement for manufacturers on 20 of those HPHCs from the full list of 93. This was because these 20 HPHCs FDA understood as having well-established testing methods, and there was sufficient laboratory capacity for manufacturers to be able to test for these HPHCs.

We're currently reviewing feedback from stakeholders on this guidance, and we're also accepting submissions of HPHC information from manufacturers. Over time, we expect that

manufacturers will submit information on the full list of 93 HPHCs.

The Act does not explicitly state what the purpose of the HPHC list is. But we can say that the HPHC information may assist FDA in meeting other statutory obligations to protect public health, such as monitoring HPHC levels across products and over time; understanding relationships between product composition, design, and those HPHC levels; and assessing the potential of tobacco product standards.

We expect the HPHC quantities reported by manufacturers will be derived from machine-smoked cigarettes. Now, the results from this type of testing must be interpreted very carefully. Machine-smoked cigarettes delivery reflects merely a potential range of exposures that people get when they smoke.

We all know that smokers inhale a wide range of smoke levels. Individual smokers may smoke a cigarette differently than others. One particular individual may smoke cigarettes

differently at different occasions. They may inhale more deeply; they may take more frequent puffs.

We also know that there is variability in measurement of machine-smoked cigarettes from lab to lab, from technician to technician, and from method to method. Nevertheless, the results from the machine-smoked cigarettes have been widely used in the past to suggest substantial differences in exposure to smokers and to either explicitly or implicitly communicate reduced risk.

Many of us in the room are familiar with ads from the '70s and '80s where we saw the comparison of tar levels between cigarettes, which communicated relative risk to consumers. It was found that consumers mistakenly believed that low tar and light cigarettes cause fewer health problems than other cigarettes, and as a result, it reduced the motivation for consumers to quit smoking entirely. We also saw that there were ads that actually explicitly encouraged consumers to continue smoking, to just switch to low tar or

light cigarettes.

We also had issues with implied and express government endorsement of these numbers. The numbers in these ads were derived using FTC methods, and many ads actually suggested that the U.S. government condoned that certain cigarettes were less risky than others.

So with this historical context, you can see how FDA has concerns about the provision of HPHC information to the lay person. What does that information on the HPHCs list convey to the public? How will people respond to that information? Will the public understand the technical information, such as the chemical names and the units of measurement, which vary from chemical to chemical? And will the public understand the significance of those quantities?

In addition to the requirement to provide the information, FDA is also required to conduct periodic research to ensure that this list is not misleading to lay persons, and report those results to Congress by April 2015.

FDA has completed some initial research to assess the impact that the list of HPHCs may have on consumer perceptions, beliefs, and behaviors, and you will be hearing three presentations today related to that research.

We have Ms. Greta Tessman, who will present some of FDA's formative research; followed by Dr. Sarah Johnson, who will present the development and design of our first experimental study related to HPHCs; followed by Dr. David Portnoy, who will present the results from that study.

Now, the agenda says that there will be clarifying questions at the end of the three, but we do encourage that you ask clarifying questions in between each of the presentations to the individual presenters.

You will also be hearing from CTP's Office of Health Communication and Education, which has the primary responsibility for informing the public of FDA's regulation of tobacco products. And Dr. Tesfa Alexander will discuss the potential for

public outreach related to HPHCs.

In the afternoon, we'll come back to the committees with specific questions related to the topics that we've presented this morning. Our first question:

Section 904(d) of the FD&C Act directs FDA to publish and place on public display a list of HPHCs in each tobacco product by brand and by quantity in each brand and sub-brand in a format that is understandable and not misleading to a lay person. What potentially important communication objectives for the HPHC list should FDA consider when fulfilling its statutory obligation?

Our second question is related directly to how we assess "understandable and not misleading":

How could FDA assess whether the publication of the list of HPHCs in tobacco products by brand and by quantity in each brand and sub-brand is in a format that is understandable and not misleading to a lay person? What methods could be used to assess whether HPHC lists are understandable and not misleading to a lay person?

And what outcomes might indicate whether HPHC lists are understandable and not misleading to a lay person?

Our third question for the committee will be:

What additional research could FDA conduct to inform the development of the format and assess the impact of the public display of the list of HPHCs in tobacco products by brand and by quantity in each brand and sub-brand?

Our final question for the committees:

What strategies might FDA use in a public education effort aimed at a deeper public understanding of HPHCs? What should be the primary objectives of any FDA HPHC public education materials? How might linking educational materials to the HPHC list support public understanding? And how might public education efforts be used to correct existing misperceptions related to some HPHCs, such as nicotine?

So with that, I will ask if there are any clarifying questions before I pass the gavel on to

Ms. Tessman.

(No response.)

DR. CHOINIERE: Okay. Thank you.

**Presentation - Greta Tessman**

MS. TESSMAN: Hi. My name is Greta Tessman, and I'm a social scientist at CTP in the Office of Science. I've been with FDA for three years, and my background is in health communication.

Today I'm going to present findings from FDA's focus groups around consumer knowledge and perceptions of HPHCs. I'd like to begin this presentation by acknowledging my colleagues at FDA, as well as our contractors, ICF Macro and RTI, who helped with this formative research.

I'm going to begin the presentation by providing examples of how constituents have been made available to the public in other contexts. I'm then going to briefly discuss findings from the literature, and move on and spend the bulk of the presentation discussing the focus groups that were conducted by FDA in March of 2011. And I'm going

to conclude with the development of list prototypes that resulted from this formative research process.

As Dr. Choiniere mentioned, there have been references to constituent levels that have been used in pro-tobacco advertising to encourage continued smoking, so we've seen ads that have contained tar and nicotine levels in both qualitative and quantitative formats. So we've seen qualitative descriptors, such as lower levels of nicotine or tar, and we've seen quantitative examples, for instance with quantities in milligrams.

We've also seen constituents presented on tobacco packaging. A number of countries require a limited number of constituents, and the quantities of these constituents to be listed on the side of packages. So, for example, we've seen tar, nicotine, hydrogen cyanide, benzene, carbon monoxide, and formaldehyde with associated quantities, for example in measurements such as milligrams.

More recently, we've seen that some

countries are replacing numerical emission information with qualitative descriptors of constituents on the side of progress. So, for example, in Canada it says, "Tobacco smoke contains benzene, a chemical that causes cancer." We've also seen examples such as, "Smoking exposes you to more than 40 harmful chemicals. These chemicals damage blood vessels, blood cells, and the immune system."

When examining the scientific literature, this included qualitative and quantitative assessments of some of the examples I just discussed as well as other research that's been done in the area.

What we found is that studies have found that consumers have limited knowledge and awareness of chemicals in tobacco products. As Dr. Choiniere mentioned, they are often misled by numbers, such as the quantity of a particular constituent, and mistakenly believe that low tar and light cigarettes cause fewer health problems.

Consumers may have reduced motivation to

quit smoking if they hold mistaken beliefs about the health consequences of smoking low tar and light cigarettes, and historically have misinterpreted advertisements that stated or implied that one product is less harmful than a comparable product.

FDA conducted focus groups in March of 2011 for the purpose of exploring consumer knowledge and perceptions of HPHCs in tobacco products and how to disseminate information regarding HPHCs. We wanted to conduct these in the U.S. population.

Specifically, we wanted to assess consumer knowledge of HPHC constituents and identify any gaps in knowledge. We wanted to explore what information consumers would want to know about HPHCs and options for effectively presenting this information. We also wanted to understand consumer willingness to read and seek out information on HPHCs, and to gather information about what would motivate consumers to engage with this information.

After receiving IRB approval from the

FDA's IRB, we recruited 16 focus groups, which were segmented by gender, age, education, and smoking status. We had 149 participants who included regular smokers, occasional smokers, those who had plans to quit smoking, and teens at risk for smoking initiation who were ages 13 to 17.

The focus groups were conducted in Greenbelt, Maryland; Miami, Florida; Nashville, Tennessee; and Baton Rouge, Louisiana. These locations were selected based on the smoking prevalence of youth and adults, as well as allowing for geographic diversity.

We conducted 90-minute semi-structured discussions that were led by a professional moderator. We had participants begin the groups by discussing what they knew about chemicals in tobacco products and how important it was to them to know this information.

Next we asked participants to react to study stimuli. The study stimuli was based on the established list of 93 HPHCs published by FDA in 2012, and included chemical names, their associated

health outcomes, and quantity per product.

Participants were asked to discuss their reaction to the study stimuli, discussing their initial reactions, the content, the format, and the usefulness of the information. We had participants look at three stimuli. They included an example of cigarettes, smokeless, and roll-your-own tobacco.

What we found from these focus groups was that prior to exposure to the study stimuli, most participants thought it was important to know about the chemicals in their tobacco product and how the chemicals impacted their health. They understood that using tobacco could cause many health problems, but they believed that tobacco products contained fewer than 50 chemicals. They believed that tobacco companies add most of these chemicals. And they perceived products labeling "organic" as not containing chemicals. So what we heard is that few were aware that harmful chemicals come from the tobacco itself or are created during the process of curing or burning.

What we heard from participants after they

were exposed to the study stimuli was that most participants appeared to be surprised by the number of chemicals they saw. As you'll recall, most participants thought there were fewer than 50 chemicals in tobacco products, so seeing a list of up to 93 chemicals elicited some surprise by some of the participants.

Participants found the chemical names, amounts, and units of measure confusing, and said they would look at the list of chemicals for their product at least once if it was put in front of them. But few said they would actively seek out a list for their product or use the information to compare other products.

Several expressed that chemicals are everywhere -- in the air, in the water, in the food -- and therefore, it didn't really matter to them that chemicals are in tobacco products.

From this formative research process, which included review of the literature, internal FDA discussions about potential concerns, historical examples of the display of constituents,

as well as the focus group findings, we developed communication concepts to guide the development of a prototype and supplemental communication and education based on gaps in knowledge and potential misinterpretations.

We have nine communication concepts, the first being that chemicals come from the tobacco leaf itself and different parts of the tobacco product, such as tobacco smoke, glues, inks, water, paper, and additives.

Number 2, for smokeless products, many of the chemicals come from the tobacco leaf. For smoked products, many of the chemicals come from burning the tobacco leaf.

Tobacco companies are required to test tobacco products for these chemicals on the list and report the amounts to the FDA.

Science has linked the chemicals on this list to health problems or potential health problems.

Number 5, these lists do not necessarily include all of the health problems that may be

caused by a tobacco product.

Number 6, these lists do not necessarily include all of the chemicals that may be harmful.

Seven, the amount of a chemical listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem.

Number 8, the number of chemicals listed for a specific health problem does not necessarily indicate the likelihood of experiencing a health problem.

Number 9, when a chemical is listed without a quantity, it may mean the chemical was not detected or the information is not currently available.

We took these nine communication concepts and incorporated them into the design and text of sample prototypes for experimental testing. The supplemental text and icons were used to augment the list of chemicals and their associated outcomes.

We developed prototypes for brand X of

cigarettes, smokeless, and roll-your-own tobacco, and applied good practices of health communication, including plain language, white space, and color when developing the design and format of the list prototypes. This was followed by cognitive testing for information accessibility, basic understandability, and readability.

The information that was included in these list prototypes included the supplemental information used to augment the list, which you'll see at the top of the page as well as on the sidebar; the amount of the chemicals in the tobacco product and smoke, including sample placeholders to illustrate that some chemicals may not have been detected and some may not be available at the time of display; as well as the health outcomes associated with each chemical.

These list prototypes were then tested in an experimental study designed to assess consumer understanding of HPHC information. By consumer understanding, we mean that consumer understanding was based on comprehension of the information

included in the sample list prototypes.

Next you'll hear from Drs. Johnson and Portnoy, who will present the purpose, aims, design, and results of the experimental study that was used to test the prototypes developed during this process.

I'd like to take any clarifying questions at this time.

### **Clarifying Questions**

DR. HALLMAN: Dr. Cohen?

DR. COHEN: I just want to make a clarifying comment myself. I know on one of your early slides, you said that some countries are now listing qualitative data, not quantities.

I just wanted to point out that the Framework Convention on Tobacco Control, which is a global treaty with 176 countries that have signed on -- unfortunately, not the U.S. as yet -- the Framework Convention says that parties should require that relevant qualitative statements be made.

So this is a requirement by the Framework

Convention on Tobacco Control, which has gone beyond thinking of the past with quantities. So countries are required to put qualitative, not quantitative, data on their packs, just to point out for information.

It's very hard to see these graphics in the slides. Are there copies for people to actually see what the stimuli were and what the --

MS. TESSMAN: I believe that we do have some copies that we can pass around so you can take a closer look at those. And thank you for that clarification, Dr. Cohen.

DR. HALLMAN: Dr. Strickland?

DR. STRICKLAND: When you were talking about the focus groups that you conducted, you indicated your efforts to reach a broad scope of population. Could you elaborate a bit more in terms of the extent to which you had minority representation or low SES populations?

MS. TESSMAN: Sure. We developed a screener to ensure that we were recruiting those from various racial and ethnic backgrounds as well

as people with different education status. This was the first qualitative research that we did, so one of the things that we're thinking about for the future, and we'd like to hear you speak about, is additional formative research that we can do specifically with other types of populations to get a more in-depth look. This was sort of a broad-brush approach that we took. Thank you.

DR. HALLMAN: Dr. Samet?

DR. SAMET: This is probably not a question for you, but one that we may need to return to in the afternoon, which is the foundation that would be used by FDA for making linkages of specific chemicals to specific health outcomes.

In the sample list, you show a set of columns linked to specific health effects. And later on, I think, probably, I would like to hear what will be the basis for making the determinations as to what health effects may be linked to particular chemicals.

MS. TESSMAN: Thank you.

DR. DJORDJEVIC: The emissions of harmful

and potentially harmful constituents do not depend only on product characteristics and design, but also how the product is used. And that should be communicated to the users, so that behavioral questions should be part of these studies.

MS. TESSMAN: We appreciate that. Thank you.

DR. HALLMAN: Yes, ma'am?

DR. PAUL: This is a step-back question. One is -- and it may be for later discussion -- what constitutes public display? That's for me an issue I don't understand. I'm not sure I understand where and how and when. And the other question was, based on giving this information to patients, what I haven't heard is what is the desired or expected outcome of providing this information at all?

These are people who've already chosen to smoke and exposed themselves to the dangers of smoking or of tobacco product use. What is the purpose of giving them this information? Regardless of how it's displayed, I'd like to know

what was expected when the Act was written.

DR. HALLMAN: I think these are a number of questions that the group would like the Risk Communication Advisory Committee to answer for them as opposed to them answering them for us. So we will work on that.

There was another question. I'm sorry. Dr. Rutqvist?

DR. RUTQVIST: Yes. I realize that these are complex issues to discuss with lay persons. But did you attempt to explain the fundamental difference in analytical methods between smoked products and smokeless products? The smoked products, you attempt to measure what's in the smoke; whereas for the smokeless products, it's what's in the product. And that could be -- extraction is obviously an important issue.

Did you mention that at all?

MS. TESSMAN: The focus groups were not used specifically to educate or explain the information on the list. We were looking for reactions from participants. So that's something

to consider when you all are discussing, and how to address that appropriately. Thank you.

DR. HALLMAN: Dr. Cohen?

DR. COHEN: Just a question about the stimuli that was used for your study that I can now see in front of me. So were these based on actual data, or were they just examples for people to react to?

MS. TESSMAN: They were examples. The list of constituents themselves reflect the 93 that were published by FDA in March of 2012 as well as the health outcomes that were associated with them. And the quantities were examples derived from experts at FDA, from toxicologists and chemists at FDA, that were meant to serve as examples.

DR. COHEN: So the health effects -- because there are dots in different areas.

MS. TESSMAN: Yes.

DR. COHEN: So that was all --

MS. TESSMAN: Yes. That was included in the FR notice that was published by FDA.

DR. HALLMAN: Dr. Krishnan-Sarin?

DR. KRISHNAN-SARIN: So in response to also one of the comments which was raised earlier, in this area one of the things we are concerned about a lot is initiation of use by adolescents and by children because most tobacco use that goes on to become chronic use really starts really young, before the age of 18. So a lot of the display of information is important for the young population also.

So my question was about when you developed these stimuli and you developed this kind of materials, did you pick up on any differential response or input from the adolescent focus groups you did? And does the experimental study we're going to be hearing about actually test these stimuli with the younger population?

MS. TESSMAN: Yes. We didn't hear any specific differences by age or other demographic factors in the focus groups. But Drs. Johnson and Portnoy will address how we examined these list prototypes in youth, young adults, and adults.

DR. HALLMAN: A question from the chair. To pick up on an issue already brought up, in the focus groups did people have different views of the different varieties of tobacco products and the relative amounts of these HPHCs in those various products? Did they think that smokeless tobacco had less, for example?

MS. TESSMAN: We didn't hear a lot about that. The reactions that we heard tended to be reactions to being presented with this list of what appeared to be a lot of chemicals to them. So that's mostly what we heard the discussions around.

DR. HALLMAN: Other questions?

(No response.)

DR. HALLMAN: Hearing none, thank you very much.

MS. TESSMAN: Thank you very much.

**Presentation - Sarah Johnson**

DR. S. JOHNSON: Good morning. My name is Sarah Johnson, and I'm also a social scientist at the Center for Tobacco Products, where I've been for just over a year and a half. My training is in

social psychology. And prior to coming to FDA, I was the APA Executive Branch Science Fellow and spent a year at NIH in the Office of Behavioral and Social Sciences Research.

I want to start by acknowledging our collaborators on this project. So this research team is comprised of colleagues from within CTP, both the Office of Science and the Office of Health Communication and Education, as well as our contractor, RTI.

In my presentation, I will pick up where Greta Tessman left off and introduce the experimental study we conducted on the public display of lists of quantities of HPHCs. In particular, I will describe the purpose, aims, and design of the study.

As has been mentioned, the purpose of this research program, including this experimental study that we're presenting now, is to inform decisions about how best to implement Section 904 of the Tobacco Control Act by providing insights into how consumers understand information about quantities

of HPHCs in tobacco products.

Now, from that broad purpose, in the current study we had two specific aims. Our first aim is informed by the formative research that was just described in the previous presentation. That formative research identified gaps in knowledge about chemicals in tobacco products, and these gaps may affect how consumers are able to understand and interpret a list of HPHCs.

In turn, our first aim of this study is to examine the impact of augmenting the list of HPHCs with supplemental information that is designed to address these gaps in knowledge and potential misinterpretations of the information.

In turn, our first research question is: Does augmenting the list of HPHCs with this supplemental information improve comprehension of information on the list?

Next, as mentioned in the first presentation, several practical constraints influence the availability of the data that will actually populate these lists of HPHCs. In

particular, data for all the HPHCs may not be available at the time the list is displayed. In turn, the second aim of the study was to examine the impact of presenting a list of HPHCs when some constituent quantities are available and others are not.

So this aim prompts the following research questions: How does the format of the list, including the number of HPHCs listed and whether or not those HPHCs are listed with quantities, impact comprehension of information on the list and harm perceptions of tobacco products?

So now that I've presented our two specific aims and research questions, I want to start by giving you a brief overview of the study before explaining the design and method in more detail.

We conducted an experimental study online using an existing internet panel. Participants included tobacco users from various age groups as well as a sample of youth at risk of initiation. Participants were randomly assigned to see one of

several versions of the list of HPHCS. And I'll explain those different versions in detail in a minute. They saw only one list, and it was a list for either cigarettes, smokeless tobacco, or roll-your-own.

The remaining participants were assigned to the control condition, and those participants did not see a list. And then after exposure to a list or not, all participants completed a questionnaire, which included items related to comprehension and harm perceptions.

Now, a bit more information about the structure of the study. So lists of HPHCs will vary slightly across three different product types regulated by FDA: cigarettes, smokeless tobacco, and roll-your-own tobacco. Thus, the study actually comprises three parallel experiments to test lists for each of these three product types.

However, because the three experiments employ the same design and procedure, for the most part today we'll talk about them as one. However, they do differ; other than the product featured on

the list, they differ in terms of participant sample, and I'll describe that to you now.

The participant samples for each experiment varied slightly, and that was so that, where possible, participants were exposed to lists of HPHCs for a product that was most relevant to them. In short, participants who were smokers were assigned to see a list of HPHCs for cigarettes or for roll-your-own, and participants who were smokeless tobacco users were assigned to see a list for smokeless tobacco.

So now that I've explained some details of the larger study, I want to get more into the study design. We had three independent variables. The first one is the study population, which I just described, and the second two are the two variables that we experimentally manipulated, supplemental information and list format. And again, I'll describe those in more detail in a minute. Our dependent measures were comprehension and harm perceptions.

The first of our two manipulated variables

is supplemental information. Participants who were exposed to a list of HPHCs either saw a list that was or was not augmented by supplemental information. As I mentioned in the beginning and as was described earlier, this information was designed to address the knowledge gaps identified in that formative research, so it consisted of additional text and additional iconography to convey list information.

Here's an example. On the right, we have a list that is not augmented with supplemental information. And in contrast, the list on the left, you can see the additional text on the top and the icons representing the health outcomes. And here's a better view of that.

The second independent variable that was experimentally manipulated was list format. Participants who were assigned to see a list saw one of three possible list formats.

The first of these is what we'll call the full list, which was the list of all 93 HPHCs and quantities per product listed where available,

which means, as has been mentioned, there were values for some HPHCs but not all of them. Here's what that would look like. Obviously, it would continue down further on the page because there were 93 listed.

The second format type is what we'll call the segmented list. This format included all 93 HPHCs, just like the full list, but in this case, the list was segmented so that at the top were listed the HPHCs for which quantities per product are available, and then separately below that was a list of the remaining HPHCs for which quantities are not yet available. So to be clear, this is the same information as the full list, just organized differently. Here's what that looked like, and here's the segmented part.

Finally, the third format is what we'll call the abbreviated list. In this list, this was a shortened list of HPHCs, and it was only those for which quantities per product are available. In other words, this would be the top portion of the segmented list. And here's what that would look

like.

So now I've described the experimental factors. I'll describe some of the measures in more detail.

First we had a screening questionnaire, and the purpose of these questions was to verify the participant matched recruitment criteria in terms of demographics and tobacco use.

In this study, smokers were individuals who currently smoke and had smoked at least 100 cigarettes in their lifetime. Smokeless tobacco users were identified as individuals who indicated they used smokeless tobacco products some days or every day.

Youth at risk of initiation were identified using items from the susceptibility to smoking questionnaire, three items such as, "Do you think in the future you might try a cigarette?" Responding to all three items with an answer other than "Definitely not" on this four-point scale qualified them as at risk.

Next we collected a bit more information

about their tobacco use behavior, and this was intended to be used as covariates in the analysis. In particular, we included items from the Fagerstrom Test for Nicotine Dependence to measure the heaviness of tobacco use, and also an item assessing frequency of use of roll-your-own tobacco.

Now on to our outcome measures. The first of these is comprehension. We assessed comprehension with a total of 21 items, and these items were designed to assess comprehension of the information presented on the list. Again, this was based on the communication concepts derived from the formative research.

The questions took a number of different formats such as yes/no, true/false, and multiple choice questions. For example, the last one here: "According to the information above, who tests tobacco products for harmful chemicals and reports the amount to FDA?"

The second outcome of interest was harm perceptions. We had a number of items that

assessed a range of types of perceptions, and these varied as needed across different product list types.

So we had items that assessed perceptions of harm from tobacco products based on the product type, items assessing perceived likelihood of harm, concern about harm, and finally, an item asking about perceived harm of the specific product presented in the list for participants who were exposed to a list. Finally, we measured additional demographics as well as health literacy.

Now that I've described each element of the study, I'll just review the procedure. This study was approved by FDA's IRB. As mentioned earlier, it was conducted using a convenient sample from an online panel.

Members of the panel who matched our recruitment criteria received an email invitation to participate. If they were interested, they would click on that link, which took them to a consent form. If they consented, they first completed the screening questionnaire, and from

there were assigned to product type and then randomized to condition.

Those who were assigned to see a list then saw a list with the following instructions:

"Please take a moment to read the information above. Use the scroll bar on the right to see all the information. This information displays a list of chemicals that are in cigarettes. Please read and use this information to answer the following questions."

So participants could spend as much time as they wanted looking at the list. However, they were required to look at it for a minimum of 30 seconds. After 30 seconds, the "Next" button appeared at the bottom of the screen, which enabled participants to proceed to the next screen. Participants, the control condition who did not see a list, just went immediately to the questionnaire.

The questionnaire began with our comprehension questions that I described earlier. For participants in a list exposure condition, the list remained visible to them while they were

answering the questions, and so here's what that looked like.

The top portion of the screen was the list, which they could scroll through, and the bottom portion is where the questions were displayed. After the comprehension questions came the harm perception questions, followed by health literacy, and then finally, demographics.

So these data were collected in the spring, and the data files were delivered to FDA in June. Since then we have begun our data analysis, and in the next presentation you'll learn about the top line findings from these initial analyses. From here, we will continue our analysis, including following up on any recommendations received today from the committees.

So as I said, in the next presentation Dr. Portnoy will present the results of the study. But first I'll answer any questions about the study design before we proceed.

#### **Clarifying Questions**

DR. HALLMAN: Dr. Turner?

DR. TURNER: Thanks. I have a couple clarifying questions.

First, just to be clear, this is not a 3 by 3 experimental design. It sounds like you're saying you see this as three separate one-way experiments with three levels.

DR. S. JOHNSON: Right. Three separate in terms of product type, but then there are two levels for the information, supplemental information, and three levels for list format. So three 2 by 3's.

DR. TURNER: Exactly. Okay. Then on this last issue, you mentioned about comprehension. You only provided that visual for participants in the full list condition?

DR. S. JOHNSON: All participants who were exposed to a list saw the list while answering the questions.

DR. TURNER: So they all -- for everybody, it was aided comprehension?

DR. S. JOHNSON: Everyone in a list exposure condition.

DR. TURNER: Right.

DR. S. JOHNSON: Yes. Just whichever format of the list they were assigned to.

DR. TURNER: Okay. Thank you.

DR. HALLMAN: Mr. Henton?

MR. HENTON: I was wondering, the segregation between cigarettes and roll-your-own, since roll-your-own are cigarettes, why is that differentiation made?

DR. S. JOHNSON: In terms of the two different lists? So that there will be -- the HPHC lists themselves will vary between those two product types. So we wanted to test them separately.

DR. HALLMAN: Dr. Paul?

DR. PAUL: This is a question, and I'm sorry, I may have missed this. What constitutes comprehension for the study?

DR. S. JOHNSON: That will be described more when we present the results. But it's based on correct answers on those questions that we developed.

DR. BICKEL: Just on a go-forward, I think it would be useful to also measure educational attainment of the sample for all individuals because sometimes income gives some misleading interpretations of socioeconomic status.

DR. S. JOHNSON: In our final demographics, which I didn't describe in detail, we did have a measure of completed education level.

DR. HALLMAN: Dr. Strickland?

DR. STRICKLAND: Just to clarify, the question was asked about comprehension and how it was measured. And I'm assuming that you're referring to page 11, your outcome measures, and there are three of those listed that you've just covered. Is that correct?

DR. S. JOHNSON: I'm not sure about the page number. I describe the comprehension items. There are 21.

DR. STRICKLAND: I'm looking there on this, which was one of your slides. There are three outcome measures of the study. One, according to information above, "Can you tell

tobacco's use in the" --

DR. S. JOHNSON: Yes. Those are three --

DR. STRICKLAND: Those are -- these three listed here are the outcome measures?

DR. S. JOHNSON: Yes. Those are, just to be clear, three examples of the 21 items.

DR. STRICKLAND: Oh, these are just three examples?

DR. S. JOHNSON: Yes.

DR. STRICKLAND: Okay. Got you.

DR. S. JOHNSON: Thanks for making that clear.

DR. HALLMAN: Dr. McAfee?

DR. MCAFEE: This is kind of an early-stage question about why you designed it the way you did, following back with Dr. Turner's question, as to why you did keep these separate, that there's nothing in terms of comparison between how -- and again, it's a little bit back to, what's the point? What are we driving at?

If basically people do not perceive a difference between harm perception between, say, a

cigarette and smokeless, wouldn't that be important information to understand?

DR. S. JOHNSON: There are a number of important questions that need to be answered in terms of the different product types and how people may compare across them when the lists are available. In this study, in order to minimize the differences in the variables, we wanted to keep them separate because the lists themselves will vary by product type.

So in order to minimize any potential noise of differences between the actual information on the list, since we're interested in the effect of manipulating the format, we kept them separate for now. But in future research, I expect that we'll want to address questions that you've raised.

DR. HALLMAN: Dr. Wolf, and then Dr. Clanton, and then we'll come back to Dr. Turner.

DR. WOLF: I'm thinking that there's probably other people on the committee that have the same kind of feeling. It's hard to really

assess the quality without really seeing the survey, or at least how you assess comprehension in particular is one thing that I know we are mentioning, and how you reverse-engineer the task that you would expect people to be able to -- how would they want to use the information?

So is it not just are they able to add up the numbers of ingredients in a product, but are they retrieving it? Or is there any information about the efficiency of the document, how long they spent on it? I'm assuming some of that data's not probably available, or is it? Time for the task.

It's an open-book assessment, which I think is commendable, and it's reflective of what you would expect with somebody. But it's so immense, the amount of information that someone's going to have to navigate. Just a thought.

DR. S. JOHNSON: Yes. I think we can make available the materials so that you can have a view of that. And in terms of questions of how best to assess comprehension and all the questions you've raised, these are all things that we look forward

to getting recommendations on.

DR. HALLMAN: Dr. Clanton, and then Dr. Turner, and then Dr. Sleath.

DR. CLANTON: It would appear that a lot is riding on how people interpret what I'll call your health icons because whether or not a chemical has an effect on a system or causes a disease, I think you're trying to understand whether people are able to impute exposure and a following outcome.

So here's my question about your outcomes and how they're interpreted. It looks like two of your five outcomes are actual diseases. So cancer and addiction would be classified as a health outcome or a disease. But you have three other health icons or categories which are not disease categories. They're actually systems, cardiovascular system, fetal system, et cetera.

It would seem that those three categories are open to a very wide interpretation by someone who's looking at this as to whether there's a disease, an effect, a potential effect, potential

disease, in contradistinction to cancer. That's a disease; we know that's bad.

So what does a tick mark mean to the people you're studying? If there's a tick mark under cardiovascular in blood flow, what does that mean to them or what do you expect that means to them?

I think I can impute that if there's a tick mark under cancer, that's probably a bad thing. But from your perspective in the study design, what does it mean that there's a tick mark under fetal development or one of these other more general categories?

DR. S. JOHNSON: As Greta Tessman mentioned, those categories, that health information, was based on the information in the FR notice. We did, to answer your question, get some information from the cognitive testing we did of the prototype, and that's when we were designing the icons to help convey that information and wanted to be sure that those icons were readable and people were interpreting the way they were

intended.

Based on that, we had some indication that people could take meaning from those about -- that problems in those areas were indicated from that. But I appreciate the larger question that you're raising, how meaningful are these and how meaningful should they be?

DR. HALLMAN: Dr. Turner?

DR. TURNER: For the participants in the segmented list condition, were they told why some information -- for why quantities per product are not available for some? Or were they just told that it's not?

DR. S. JOHNSON: Yes. Actually, for all the lists except, I guess, the abbreviated list, there was a placeholder indicating that the information was not yet available. So that was noted, that this information is not yet available.

DR. TURNER: But that's it? Not why? Not that the science is being done or something? Just, it's not -- we don't have it. Correct?

DR. S. JOHNSON: I think we kept pretty

simple, yes. I'll check that for you, though.

DR. HALLMAN: Dr. Sleath, and then  
Dr. Paul.

DR. SLEATH: I had a question about on  
slide 15 and slide 17, you're putting in the black  
boxes under the diseases, even though you're saying  
the information is not currently available.

So I just want to make sure I'm right on  
that, that you're putting things under cancer,  
heart, et cetera, so it looks like the above where  
you actually have amount per gram of the chemicals,  
but then below you don't have it. I see the little  
plus signs. But that's almost a contradiction in  
itself, that you're saying you don't have the  
information yet you're putting the black boxes,  
like you did, above.

Is that right?

DR. S. JOHNSON: Right. I can see how it  
conveys that. So the information that's not  
available is the quantity per constituent on the  
left, in those left columns. But the information  
linking those chemicals to those health outcomes is

established, as conveyed in the FR notice. But I appreciate that comment because I think, from the text as is, it's --

DR. SLEATH: But can you see how a person would read it as, since you put the stuff on the right-hand side, that there's that link. It also reads as if you're saying there's enough in the cigarette that there's -- I'm just saying, that's a potential confusing --

DR. S. JOHNSON: Right.

DR. SLEATH: Maybe it's just me.

Then the other thing is you recruited all the participants via an internet panel, and there's a lot of potential biases there. And hopefully you're going to present more on the sample. But could you describe that internet panel?

DR. S. JOHNSON: Yes. We appreciate the limitations of the internet panel, and did do some quota sampling to try to adjust for some inherent biases in the samples that usually comprise those panels.

So in particular, we quota sampled for

lower education attainment and African American and Hispanic individuals because I think predominately it skews higher SES and white.

DR. SLEATH: Okay. Thank you.

DR. HALLMAN: Dr. Paul?

DR. PAUL: Pass.

DR. HALLMAN: Are there any other clarifying questions on the study design? I'm anxious to get to the actual results.

(No response.)

DR. HALLMAN: Hearing none, let's hear about the results.

**Presentation - David Portnoy**

DR. PORTNOY: So on to the results. Good morning, everybody. My name is David Portnoy. I am a social scientist in the Office of Science at the Center for Tobacco Products. I've been at FDA for just over a year. And by way of introduction, my background is in social psychology and public health. And prior to coming to FDA, I was a Cancer Prevention Fellow at the National Cancer Institute.

So as you've all been waiting for, I will

be presenting on the analysis and results of our experimental study. More specifically, I will provide an overview of the samples that we recruited for the study, the analysis strategy that we employed, and results from that study.

Just as a note, these are our initial top line analyses. We will be conducting future analyses based both off of our original analysis plan as well as the recommendations from the committees today.

So to answer this last question, or one of the earlier questions, I want to show the allocation of participants to condition. In total, we had just over 3500 participants, and you'll see along the left-hand side the three different product types, cigarettes, smokeless tobacco, and roll-your-own. Within each product type, we had a number of different populations that Dr. Johnson outlined.

Each population was roughly evenly split to either view the list that was augmented with supplemental information or a list that was not

augmented with that supplemental information.

The next three columns are those three list formats that you've heard about, the full list, the segmented list, and the abbreviated list, as well as those participants who are scientific control condition.

Next I will present an overview of the samples, and as we have already talked about some, these really were three parallel experiments. So it's not fully appropriate to compare the demographic characteristics between the three lists because we recruited different populations for each list.

For example, you see that participants exposed to the smokeless list, the population had a much higher proportion of males due to the profile of users of those products. But in general, participants were in their 20s. There was a fairly good distribution of race and ethnicity.

Getting back to the question about SES, we see somewhere between 20 and 30 percent of the sample that reported a household income of less

than \$25,000 per year. For health literacy, we see that a sizeable proportion of the populations reported some lower levels of health literacy. And we see a fair amount of use of these products.

Moving on to educational attainment, here it's split by the adult sample and youth sample. And looking at the adult sample, we had around 35 percent of participants who reported having a high school education or less.

Next I'll move to discuss the analysis strategy. First, to examine the first research question, we examined the effect of appending the lists with supplemental information and its effect on comprehension. And in that case, we compared the list that was augmented with supplemental information to the lists that were not augmented with supplemental information.

Next we examined the effect of list format, that is, comparing the full list, segmented list, and abbreviated list, both to the control condition as well as to each other on our two key outcomes, comprehension of list information and

harm perceptions.

So first I will present results from our first analysis that resulted from the first research question: Does augmenting the lists of HPHCs with supplemental information improve comprehension of the list?

First, I do want to take a minute to talk about how we define comprehension. For each product type we created comprehension scale, and this was based on those up to 21 items. And those items were in turn based on the communication concepts that resulted from the formative work presented earlier.

So for the cigarette list, the comprehension scale included 21 items. For smokeless tobacco, it included 19, and the reason for the discrepancy there is that when asking about comprehension of information about HPHCs for smokeless tobacco, obviously it's not appropriate to ask about if HPHCs come from tobacco smoke. And for roll-your-own tobacco, it had 21 items.

So what I'll be presenting to you is the

percent correct of items on the scale, again as compared to the information that was presented on these different lists. And again, here is just a reminder of what those communication concepts were that informed the development of the list as well as the comprehension items.

So on to actual results now. We found that for each product type, participants that viewed a list that was augmented with supplemental information had higher comprehension scores compared to those that viewed a list that was not augmented with supplemental information.

So if you look in the left, grey column there, we see that for the cigarette list participants that were exposed to a list that was augmented with supplemental information had statistically significantly higher levels of comprehension -- in this case 78.3 percent correct -- as compared to those participants who were exposed to a cigarette list that was not augmented with supplemental information, in this case 71.5 percent correct. And we see a similar

pattern for both the smokeless list and the roll-your-own list as well in terms of the statistical significance there.

Next we move on to our second set of analyses, looking at how the format of the list impacts both comprehension and harm perceptions. So due to the results that I just presented showing that augmenting the list with supplemental information was beneficial for comprehension, in the following analyses, we only examine the list that was augmented with that supplemental information.

Our general analysis strategy was an analysis of covariance, where independent variables were the list format as well as the populations, and our dependent variable was the comprehension of the list information that I previously described. And all these analyses control for a number of demographic and use factors.

So presenting results for comprehension of information on the cigarette list, we found that there was no difference in comprehension between

the different list formats. We found that there was no difference in comprehension between the different populations. And also, we did not find any statistical interaction between list format and population.

I'll be presenting a number of results, so I just want to take a minute on this slide to orient you. You see along the bottom we see the different populations, and again here we're talking about those participants exposed to the cigarette list.

On the Y axis, you see the percent correct of cigarette comprehension. In this case, the scale has been truncated to only show a range between 50 percent and 100 percent correct. Then within each population, you see the different formats.

So the dark blue bars to the left of each grouping are those participants who are exposed to the full list, the lighter blue bars were those who were exposed to the segmented list, and those greyish bars are those participants who were

exposed to the abbreviated list.

So here, as you can see, we don't see any difference either between the different populations here or between the different list formats.

Moving on to the results for comprehension for the list of HPHCs in roll-your-own tobacco, again we found no difference in comprehension by the different list formats. We did, however, find a statistically significant difference in comprehension between the different populations, such that current adult smokers had lower comprehension as compared to both current young adult smokers and current youth smokers. However, there was no statistically significant interaction between list format and population.

This is what that looks like. So you see that adult smokers, this grouping of bars on the left, is significantly lower than the other two populations. However, we do not see any statistically significant effect of this format or interaction.

Moving on to comprehension of the list of

HPHCs in smokeless tobacco, we again find no difference in comprehension between the different list formats, and no difference in comprehension between the different populations.

There was, however, a marginally statistically significant interaction between list format and population such that youth smokers had higher comprehension compared to adult smokeless and youth smokeless users, but only when viewing the full list.

So what that looks like is the youth smokers, here, who viewed the full list were marginally statistically significantly higher than both the adult smokeless users and youth smokeless users, but only when exposed to the full list.

Next I'll describe the analysis for the effect of list format on harm perceptions. On the next slide I will talk about the harm perception scales we created, and again, our analysis approach was an analysis of covariance, with the independent variables of list format and population. The dependent variable was either a harm perception

item or a scale. And we conducted planned contrast between each list format and control, as well as among the three list formats.

So now I'd like to describe the scales that we created for the harm perception items, although for some items we did do analyses on the individual items. So, for example, for one of the harm perception items, "There is no safe tobacco product," that item was analyzed individually. And I should say that on all the harm perception items and scales, higher numbers represent greater perceptions of harm.

For items that assess the likelihood and concern about health outcomes, those were averaged into a scale, and we had separate scales for cigarettes, smokeless tobacco, and roll-your-own tobacco.

We assessed harm perceptions of each product type, cigarettes, smokeless tobacco, and roll-your-own, and we examined that both as a composite variable that assessed harm perceptions of all those tobacco products. And in addition, we

also assessed harm perceptions of each product type individually. Finally, we analyzed the single item that assessed harm perceptions of using the product that was presented in list, that brand X.

So moving on to the results -- and I should say I will be presenting the results for all of these for all three lists, so get ready for a lot of results; you have all been waiting for it.

For the first item, there is no safe tobacco product. We found that there were statistically significant differences by both format and population, but no interaction. And for the difference by format, we found that the abbreviated list was statistically significantly higher than the control condition.

On the likelihood and concern scale from cigarette harm perceptions, we found differences only by population. And for harm perceptions of all tobacco products, we found differences by both format and population, but no interaction.

In a pattern that I'll be presenting a lot of, we found that the control condition was

statistically significantly lower than each of the three list formats; however, those three list formats were not significantly different from each other.

For the harm perception of smoking, we found again that there were differences by both format and population, but no interaction. And again, in that same pattern, the control condition was significantly lower than each of the list formats, which were not significantly different from each other. And finally, for harm perceptions of using the product that was presented in the list, we find significant differences only by population.

So here I'm presenting the harm perception of smoking. This is the single item, and this is the general pattern that comes up a lot. You see that the control condition is significantly lower than either of the three list formats, which are not statistically different from each other, although I should note that harm perceptions in all conditions were towards the top of the scale.

Moving on to the results for harm perceptions of smokeless tobacco, for the item, "There is no safe tobacco product," again we find differences by format and population but no interaction. And again, we see that same pattern, where the control was significantly lower than each list format, which were not different from each other.

For the likelihood and concern scale, we found no differences by either format or population, and no significant interaction.

For harm perceptions of all tobacco products, we found differences by format and population but no interaction. And again, the control was significantly lower than any of the three list formats, which were not different from each other.

For the harm perception specific to using smokeless tobacco, we found differences by format only such that, again, control was significantly lower than each list format, which were not different from each other. And finally, for

smokeless tobacco, for harm perceptions of using the product presented in the list, we find differences by population only.

On this slide I'm presenting the harm perceptions of using smokeless tobacco, the single item. And again, we see a similar pattern such that the control condition is statistically significantly lower than either of the three list formats, but the three list formats were not different from each other.

Finally, I'll present the results on the effect of list format on the harm perceptions of roll-your-own tobacco. For the item, "There is no safe tobacco product," we see that same pattern, where the control was significantly lower than each of the three list formats.

For the likelihood and concern scale, we find differences by population only. And for harm perceptions of all tobacco products, we find a difference by format as well as a significant interaction between format and population such that both youth and young adult smokers, as compared to

adult smokers, had lower harm perceptions about roll-your-own tobacco only in the control condition when not exposed to a list.

However, when exposed to any of the three list formats, those differences were attenuated such that harm perceptions were equal across the populations. And here's a figure that explains that interaction.

So if you look all the way to the right, you see that young adult smokers and youth smokers, as compared to adult smokers, had significantly lower harm perceptions, but only in the control condition. The differences between those three populations in the full list, segmented list, and abbreviated list were not statistically significant.

To close out the harm perceptions of roll-your-own tobacco, for the harm perception item specific to roll-your-own tobacco, again we find differences by format and population but no interaction such that the control was significantly lower than each of the list formats, which were not

different from each other.

Finally, for the harm perception of using the product presented in the list, we found no significant differences by either format or population, and no interaction. And here we see the difference by list format in the harm perception of smoking roll-your-own tobacco in that same pattern, where the control was significantly lower than either of the list formats.

Before I conclude, I do want to note a few limitations of our study. First, we were unable to measure the duration of exposure or attention to the list by participants. Similarly, we did not include a manipulation check, so we're not able to determine if the lack of differences between the three list formats is due to a true lack of difference in the impact of those formats or if the differences between those list formats were not attended to by participants in the study.

The HPHC list formats, which were differentiated by factors relevant to FDA -- namely, the full list, the segmented list,

and the abbreviated list, and if quantities for HPHCS were presented or not -- may not have been the most relevant factors to consumers and the participants in our study. And finally, the novelty of exposure to any information about HPHCs may have overwhelmed any effect of list format.

Just a few conclusions. In general, we found that supplemental information was associated with higher comprehension, and we found that exposure to any HPHC list, compared to the no-exposure control group, was associated with both higher comprehension scores as well as higher harm perceptions. But we did not find any effect for list format.

So with this in mind, I'm looking forward to hearing the discussion of the questions posed to the committees about how we can define if a list is understandable and not misleading, as well as what additional research FDA could conduct in support of the development and testing of these lists.

With that, I'm happy to take any clarifying questions on the analysis or results of

the study.

### **Clarifying Questions**

DR. HALLMAN: Okay. So I'm going to take the chair's prerogative. You presented a great deal of information to us. What I would like to do is take a 15-minute break, let us consider the data, help us formulate the questions, and come back and maybe give you a minute to get a drink of water as well.

We'll come back. We'll pose questions, and then we will address the specific questions you have raised as well. So we will come back at 10:50. Thank you very much.

(Whereupon, a brief recess was taken.)

DR. HALLMAN: Good morning again. We're going to return to our questions. I'd like to recognize the addition of Dr. Huang to the group. And Dr. Huang, if you would just give us a brief introduction of yourself, please.

DR. HUANG: Hi. I'm Phil Huang. I'm the medical director and health authority with the Austin/Travis County Health and Human Services

Department in Austin, Texas, and prior to that was with the State Health Department over tobacco control, and have been involved for several years.

DR. HALLMAN: Thanks so much, and welcome.

So I've been struggling to try to figure out how to marshal all of these questions. I suspect that everyone around the table has at least one question. But rather than go around the table, what I think I'd like to do is to try and categorize the kinds of questions that we might have and try to work through that in some sort of a systemic way.

Let me begin by saying, so I've been doing experimental psychology for 30 years, and I realize that this is probably more nerve-racking than your dissertation defense.

(Laughter.)

DR. HALLMAN: I think we all around the table realize that no study is perfect, that there are things that you wish you could have done that you can't do or didn't have the money for. Part of our job is to look at the current research and to

perhaps suggest lines of future research that might help to clarify what you have found.

So I think the place to begin, actually, is with some of the bigger picture questions that are implicit in the research design that you have presented. So very clearly, one of the hypotheses, I suspect, is that the augmented version of the list would be better than the un-augmented version.

So if you could talk through some of the bigger picture, why you did what you did what you did, why you tested what you did, augmented by what, what information was included and why you thought -- and perhaps this is a larger question for the research team -- augmented by what and why. If you could start there.

Then I think we'd like to talk about some of the measurement issues. So what does it mean? What do the scales mean? What does a one-point or two-point difference -- even though it's statistically significant or marginally, what does it mean in terms of its practical significance?

DR. PORTNOY: Sure.

DR. HALLMAN: So let's start with the big picture questions. So why did you do what you did?

DR. PORTNOY: Sure. First, let me say that this is the first study in a program of research. And I think, as has been mentioned earlier, we are required by the Tobacco Control Act to conduct research on this topic and report back to Congress.

So this was our first step at trying to pare down some of what we thought were the important factors in the design and presentation of this type of HPHC information. And I think this has already come up in some of the questions, why would it include other factors?

Well, in this first study, our goals were really to look at the format of the list itself as well as the effect of that supplemental information. And the supplemental information, as you may recall from Dr. Johnson's presentation, was the information at the top of the list, the additional icons. And that information was there to provide some context for the more numerical and

quantitative information. All that supplemental information was derived from the formative work, so including the review of the literature as well as the focus groups that FDA conducted.

So in this first study, we really wanted to focus on those two main issues first. But obviously, we're looking to the committees for recommendations and suggestions for what kind of future research FDA should conduct to support the development and testing of these HPHC lists.

I hope that provides a little bit of the big picture overview.

DR. HALLMAN: Mr. Heck and then Dr. Wolf.

DR. HECK: Yes. Just a quick question. I do think Dr. Portnoy and others have done about as good a job as could be done on presenting such a complex survey in the high line fashion they did. And I did appreciate the provision here at the table, briefly at least, of the full questionnaire.

Will that questionnaire be part of the meeting record so we can look at it in more detail?

DR. PORTNOY: Yes. We -- yes, Conrad, if

you want to --

DR. CHOINIERE: I believe we can make it part of the record. It is available publicly through the OMB regs. I'll get the website. But because it went through OMB clearance, the materials should be available on the OMB website.

DR. HALLMAN: Dr. Wolf?

DR. WOLF: Yes. Can I just clarify, is one of the roles of our -- the task of the committee at hand to -- I mean, obviously we don't -- I think there's a lot of value, first off, from what you've done, and I think it's very commendable and incredibly extensive. So I wanted to at least lay that out.

I was trying to figure out how to think about moving forward, as to what can you take away from these findings and what level of confidence you have in what we might be able to state, and is that one possible task of our committee. And also, then, as to your point, what could you do next in your program of research.

From that end, I do think that you have

extensive data, and I know that this is probably -- if you presented it in June, you're still just reeling from thousands of cases and all the general data points you have. So I get that.

Some of the things I was going to ask, and I'm just going to list them out here so they're on record, but looking at your comprehension scores, what would you target as an acceptable comprehension level?

I think that varies, and people have lots of assumptions -- and actually, I just had to do this for another FDA-related complement activity or informed activity -- that it's not that clear. What would you accept would be a target goal for you? You've got all the things left in 80 percent, 80, 90, 95, what have you.

The other thing is, I would also on the 30,000-foot level, as our chair put us to, I'd still want to consider how you could build a better mousetrap. So I think that I am not really fully understanding how you came to the intervention, the format, that you did. And I think that there could

be a lot of work to really explore more of what you could do to convey the information, not just modality but in thinking through beyond some of the icons, which again might be okay for this age group. But I really don't know how this is supposed to reach people. If it's the size of it, the location, how it gets in their hands does make a difference to me. So again, that's just a big issue.

Just so I won't take up much time, the other things that are more on the nitpicky things is, again, I did think that the overall comprehension did seem quite high for me, given what I thought the level of difficulty the documents presented.

So I was curious if the item difficulty, the comprehension assessment, might have not been that difficult. And again, I don't think I fully understood how you assessed that.

The absolute differences between the formats that were significant were small. I didn't see interactions by education or health literacy,

other patient factors that I would like to be able to see, and maybe that could be your next run of analysis. Again, I thought you're just reeling from all this data.

I'd also think about -- internal consistency on the perception outcomes also seemed a little bit lower than I would expect. So I'm wondering if you could re-look at those items and how they performed.

Sorry for the length.

DR. HALLMAN: Dr. Samet is next.

DR. SAMET: My comment actually relates to the impact of viewing the information and looking, for example, at the harm perception. I don't know if we could put up slide 27 as an example.

DR. PORTNOY: Certainly.

DR. SAMET: So this one, where you highlight statistical significance of differences, but in fact the actual quantitative difference is rather minimal. This is the product which is, of course, most widespread, associated with the greatest harm. And my looking at this would

actually say, I'm not sure I see any meaningful impact on harm perception of viewing the list, regardless of format. They're all hovering around 4.5 out of a possible 5.

So I would ask you the big picture: What would you like to do? The pictures are a little bit different for the smokeless tobacco and the roll-your-own, where there seems to be greater impact of seeing the list. But for the product that is most important for public health, it looks to me, looking at this, that I don't see much evidence of the impact of viewing the list itself.

DR. PORTNOY: Right.

DR. SAMET: So what would you like to see? I think this goes back to your hypotheses. In fact, what did you design around in terms of differences as you developed the experiment?

DR. PORTNOY: I appreciate the point about the restricted range here, and that's something that's obvious here, and for a number of the other harm perception items, where even where there are statistically significant differences, the range is

somewhat restricted to the top end of the scale.

I think, addressing your big picture question, this actually goes back to one of the things that we were asking the committees about. What should be the communication objectives of this list? And we have the statutory requirement to publicly display this information in a manner that is understandable and not misleading to a lay person.

So whether or not a difference in harm perception would inform whether or not the list is understandable or not misleading is one of the things that we're looking for some guidance on from the committees.

DR. CHOINIERE: If you look at the four questions, which we'll get back to in the afternoon, they build upon each other. So you really need to figure out, or we need to figure out, what the answer to question 1 is before we can move on -- which is what should the objective be of this list -- before we can move on to question 2, which is, well, what outcome do we want to see to

indicate whether a list is understood or misleading?

In many ways, I want to reiterate the point that David made, that this experiment was never intended to be the ultimate experiment to inform the final list or the final format that was to go out to the public.

You could almost look at this experiment as part of the formative stage. We have hypotheses that the list would affect harm perceptions and it would affect comprehension, but we had no a priori desire for the size of the effect. And in many ways we were hoping that the results from this study would help inform, well, what's the next iteration? What formats should we look for next? And what types of measures should we include in the subsequent studies?

But we would like to get some input from the public and from the committees about, well, what should the list be doing? And once we get that input, then it makes it easier to figure out which way to move with the formats and the studies.

DR. HALLMAN: All right. So I have Dr. Strickland, then Dr. Paul, then Dr. Lawson, then Dr. Rutqvist, then Dr. Freimuth.

DR. STRICKLAND: First of all I'd like to congratulate you on this work. I can see that you've put a great deal of effort into it.

I really want to raise some questions about race and ethnicity. I guess I'd like to hear a little bit more about your thinking. And I was wondering why there wasn't perhaps over-sampling attempted or what your future plans might be.

Because when we think about the very high-risk populations, our young people in these populations where we have these small percentages here, what your plans might be in the future or when you're reviewing the literature relative to risk, what your thinking was in terms of reaching these populations.

DR. PORTNOY: Sure. So in terms of the sampling plan, we did employ a quota sampling plan to over-sample both African Americans and Hispanics, in addition to over-sampling of

characteristics related to lower SES.

So that was one way to try to correct some of the potential differences between an online sample and perhaps other sources of data. So in that way, we did try to get a more diverse population into the study itself.

In terms of if there are specific subgroups that it would be important for us to look at differential impacts by, we certainly could do some of those analyses with the current data. But if we were looking to test specific hypotheses about factors of race and ethnicity as it relates to the provision of this information, that might require some additional work.

I should say, though, that in the sample we did include those youth who were susceptible to initiation. So although that doesn't address the question about race, it does somewhat address the issues about those who perhaps have a higher likelihood of initiating tobacco use.

DR. STRICKLAND: Thank you.

DR. HALLMAN: Dr. Paul?

DR. PAUL: Thank you for presenting this data and starting this study. Clearly, we wouldn't have anything to respond to if you hadn't taken the trouble to put together such a complex program.

I did want to ask a couple questions, both from a 30,000-foot level and then drop a little bit. One of them was, it seems to me that by the nature of your questionnaire, you have actually already defined the reason for this list, the message of the list, because you're asking people for harm perception. What did they learn from the list?

But I would ask you, in terms of what you gave them, it seems to me you stated those precepts in the augmentation, in the augmented questionnaire. So the people who read the augmented questionnaire already had a sense of the answers that you were looking for, as opposed to those who didn't and just got the list. So I'm wondering if that was looked at at all in terms of the verbal statement that smoking products cause harm.

I'm also wondering about whether or not -- one of the questions on the list is not whether it provides a perception of harm, but given our environment in which there is such a perception of harm from cigarettes, does it increase the perception of harm? What do people take away from the list that they didn't take away before?

Then one other thing -- you indicated the health literacy or the adequacy of the literacy. I don't know on what basis you're assigning low literacy, adequate health literacy, so forth. But just looking at the red folder that passed along, I found that it was exceedingly difficult for me to pay attention to it. I don't know people would understand milligrams, micrograms, nanograms, and so forth.

So I'm wondering about the health literacy aspects and if in any future work there's any reason to consider addressing the quantitative nature of the data when it gives actual amounts versus any of the iconography, or giving the data at all.

DR. PORTNOY: Sure. So let me address your last question first, and then I might ask for my collaborators here to also chime in.

In terms of the health literacy measure, we used the Newest Vital Sign. If any of you are familiar with it, it basically asks participants a number of questions of a mock nutrition facts label about ice cream, and it asks questions mainly focused on their ability to derive the relevant information from that label.

So those categories I put up in terms of adequate health literacy and those other categories are derived from that measure itself. And I should say although I didn't present it, the measure of health literacy was not different between any of the different experimental manipulations.

So we did look at the adequacy of randomization across the different conditions of that. However, we certainly could see if there are different impacts on those with more limited health literacy as compared to those with adequate in involved analyses.

Moving back, your previous question -- I'm sorry. Could you remind me of the other two questions?

DR. CHOINIERE: I think I'll start with the first one, which I'll restate in case I asked the wrong question. I believe that your question was related to the design of the questionnaire, and that the design of the questionnaire implies that there is a defined level, or that we've defined comprehension and we've defined a purpose for the list because we measured harm perception. Is that correct?

I would say that we grant you the first point. Yes. We had to start somewhere in terms of comprehension. How do you define comprehension? And so from the focus groups, we used the knowledge gaps that we identified to create some concepts or to develop the concepts.

Those were the ones that we focused on for -- and we can bring those nine up again; they appear in two of the presentations. Those concepts we decided to use -- to address, with the list.

Then with harm perception, we were concerned, for the reasons that I outlined in my presentation, about the effects that the list may have on harm perception because we view harm perception as a precursor to behavioral intention, which is a precursor to behavior.

So we wanted to see, well, by providing this information in order to increase comprehension on these nine concepts and all the technical information in the list, what effect does it have, if any, on harm perception of the products?

Now, this again was an initial experiment to just tackle some of the bigger picture items of comprehension and harm perception. Then we would move forward with a maybe more finely tuned experiment to get at some of these details that you've addressed, such as quantitative information, what impact is of the units of measurement, for instance, the level of comprehension there, or what Dr. McAfee referred to earlier about comparing products. We decided not to tackle that in this study, that we could tackle that in future studies.

We also had to address Dr. Strickland's concerns about other populations, and also someone raised a concern about internet panels, that we would have future studies that would not be on the internet, that would be with certain subpopulations. But before we invest too many resources in all those, we wanted to get some input from the committees about what's the most fruitful avenue to pursue, or avenues.

I don't know, did I address all of the comments that you had?

DR. PAUL: The only other comment was on whether or not there was an effect of just the augmentation alone since it contained most of the risk messages that were tested in the questionnaire.

DR. PORTNOY: Yes. So I can try to go back to that slide. So this is the effect of the augmentation of the list on comprehension. But I think more to your point, we did not compare the augmented list versus the not augmented list on the risk perceptions, and I did not present those data

here.

DR. HALLMAN: So while you're on this slide, and then we'll come to Dr. Lawson, I'm very interested to understand a bit more about the meaning of these particular results.

There are some statistically significant differences between the augmented and the non-augmented list, but it looks like perhaps one or two more correct questions. We're getting one or two questions correct.

What's the item analysis look like? Where is the difference? And it also looks like, with the augmented list, even though the percentage correct increases, so does the standard deviation. So it suggests that it isn't all positive news.

DR. PORTNOY: Right. One of the other things on the slide is the range of percent correct, and there is a fairly wide range for each group, ranging from anywhere from about 20 to 100 percent. So there was a good amount of variation.

But I think more to your point, when I looked at these results item by item, there were

certainly were items for each product type where there were not any statistically significant differences between these two lists, and then others where the differences between these two lists was quite large, in fact.

DR. HALLMAN: So I guess the question is, where are the differences? Are there particular concepts that people are getting better with the augmented list that they're not getting with the straight list?

DR. PORTNOY: Yes. And I can just present -- I don't have slides for this, but I can just highlight perhaps one from each product list as an example.

So for the item, "Who tests tobacco products for harmful chemicals and reports the amounts to FDA?" -- and this is for cigarettes -- participants who viewed the list that was augmented with supplemental information had a score of 75 percent correct on this, whereas those participants who viewed the list without supplemental information had a score of 40 percent.

DR. HALLMAN: Right. So there are differences in their scores. Are there particular concepts, particular items, where the score is better, as opposed to an overall score?

DR. PORTNOY: Right. So I did look at patterns to see if it's possible to categorize certain items where everyone had high scores as opposed to those where there were larger differences. And there wasn't a real clear pattern across the three product types. However, I will say that in general, the items where people got more correct seeing the augmented list, not surprisingly, were those items that focused more on, if I can call it, the process of how the list works, so asking, for example, of that item, who is actually testing these HPHCs? What does it mean if there isn't a quantity there? Those types of items. There were more general items where we saw fewer differences between these two lists.

DR. HALLMAN: Okay. So given that, do you feel like the augmented list actually is achieving the hypothesized aims that you had for it?

DR. PORTNOY: I think that the augmented list is achieving the aims of improving comprehension of these key concepts. And whether or not these key concepts are the things that we should be focusing on in these lists is part of one of the questions we're asking these committees for your expertise about.

So as Dr. Choiniere said, we did have hypotheses about these general effects. But it's not as if we came in and expected effects on certain classes of items and not others.

DR. HALLMAN: All right. Dr. Lawson, you're up.

MS. LAWSON: Yes. My question is about the procedure. And I understand that this was done through an internet panel, but you know there's a great segment of the population that, one, is not computer-savvy or has access to a computer. And I wondered if any consideration had gone into looking at other ways to reach out to a broader segment of the population.

Also, in designing the study, if there

were any advice and counsel from those who are culturally sensitive to ensure that you have a good representation in your study.

DR. S. JOHNSON: Yes. Thank you for those comments. We do appreciate the limitations inherent to using an online panel. However, as you know, it's a convenient and accessible way to recruit a large number of participants, particularly tobacco users. So for our initial study, it felt as though it was the most appropriate choice.

But we certainly have plans for future research to employ other methods, including in-person one-on-one, where we can access people in a different context, as well as hopefully expanding the sample and targeting populations of special interest.

DR. HALLMAN: Dr. Rutqvist, and then --

DR. RUTQVIST: Yes. First I'd like to compliment the presenters on a very interesting and rigorously conducted study.

My question concerns the definition of

endpoints for the study and its relation to the statutory requirements of presenting the lists in an understandable fashion and not misleading fashion.

Now, the endpoints, as I understood, was first a global estimate of comprehension based on a number of items, and that could be said to relate to being understandable. I can understand that. But the other endpoint was harm perception, and that doesn't really address this issue of not being misleading. I can't see the connection between not being misleading and harm perception.

So I was wondering, have you thought about defining what being misled is, perhaps define the proportion of individuals before and after the intervention who are misled, and whether that proportion increases with the different lists presented here?

DR. PORTNOY: Yes. I think that's an excellent point, and we certainly are interested in what measures or outcomes would categorize a list as being misleading. And in fact, one of the

questions to the committees today asks just that question.

So our initial study looked at harm perceptions. And whether or not that is an appropriate outcome to define it as misleading or not is one of the things that we are asking the committees about today.

DR. HALLMAN: Okay. So we have Dr. Freimuth, Dr. Clanton, Dr. Bickel, Dr. Cohen, Dr. Huang, Dr. Strickland, Dr. Johnson. It sounds like a law firm.

(Laughter.)

DR. FREIMUTH: Yes. A slightly different point here. I wanted to point out that as I understand the study, it's all forced exposure to the materials. Right?

DR. PORTNOY: Correct.

DR. FREIMUTH: So what we don't know anything about is what people would do with the opportunity to see material like this, whether they would even bother to look at it.

My own sense of looking at it from someone

with pretty high literacy is, it's too complicated for me to make sense of it. I don't see it being very useful. I wouldn't even bother to spend any time with it.

DR. PORTNOY: Right. But -- sorry.

DR. FREIMUTH: So let me suggest that one of the future -- I understand there's a mandate to present it, and I'm not suggesting it shouldn't be available. But I'm wondering if you're thinking at all of the possibility of presenting this in a chunked kind of format so that you present some of the information in a more qualitative way, as you've done with the augmentation, perhaps. I couldn't read all of that.

But present some of that that addresses these larger communication objectives in a much simpler fashion, with the availability of the other information for people who really want to dig and get to that level.

That may be a much more usable or important, even, research question because then people may actually be using this. In its state

right now, I just don't know how many people would use it.

DR. CHOINIERE: We really appreciate that comment. I just was wondering, we were hoping that this period right now would be for clarifying questions on the actual analyses and the study design. And that comment that you made is certainly welcome, and we would want to hear that in the afternoon when we talk about how we want to move forward with the lists.

DR. PORTNOY: We still have one additional presentation.

DR. CHOINIERE: But I did want to -- and Ms. Tessman can speak about this -- is that in the focus groups, the general consensus was that they might look at it once and not necessarily seek out that information.

DR. HALLMAN: Dr. Clanton?

DR. CLANTON: Based on that statement, I'm actually going to hold my question. My point has more to do with number 1, and I want to think about the list.

DR. HALLMAN: Thank you very much.

Dr. Bickel?

DR. BICKEL: First, great work. Right?

Data is really important, and this sets the stage for a lot of interesting questions. Your study examined risk comprehension, but I think an important concept that we need to explore in the future is risk perception, which is part of what that document is trying to accomplish.

The concept of risk has traditionally been defined as, "A quantitative measure of the hazard consequences expressed as a conditional probability of experiencing them." But smokers have a decisional bias. They discount the future, so they discount the immediacy of risk.

They also may discount the certainty of risk. They may also discount the severity of risk. So I think an important future question to ask is whether we can design materials that can help diminish or limit this decisional bias.

DR. HALLMAN: I agree with that, and we will take up those questions in the afternoon

session. If there are other clarifying questions about the results, I'd like to hear them now. So I have Dr. Cohen up next.

DR. COHEN: Great. Just a comment about the sample. You did a number of analyses by population, which normally we might think of as by sociodemographic group, but in this case it was adult smoker, youth, et cetera.

For your adult smoker group, the heaviness of smoking index was quite low at 1.3. That's an index that goes from zero to 6, I think, the heaviness of smoking index. I'm not sure how you calculated it, but that's generally --

DR. PORTNOY: I can double-check.

DR. COHEN: So I guess one thing is, who are the smokers in the sample, I guess is a question, and are they typical cigarette smokers in terms of amount smoked? Which you didn't show us, you just showed us the heaviness of smoking index. So I don't know if you're able to answer that.

Then my question follows on Dr. Hallman's question about where were the differences in terms

of what people got? I'm particularly interested in the five questions that no one got, generally, so the comprehension questions. So 75 people, on average, got 15 of the 20 questions. What didn't they understand?

DR. PORTNOY: Okay. In terms of some of the items that had the lowest comprehension -- and I can just run through one example for each format. So for example -- let's see -- for cigarettes, "When a chemical is listed without an amount, it may mean the chemical was not detected." And that was actually the lowest item of the comprehension scale for cigarettes.

For the list with the supplemental information --

DR. HALLMAN: I'm sorry. Could you repeat and slow down just a little bit?

DR. PORTNOY: Sorry about that.

DR. HALLMAN: I couldn't hear that.

DR. PORTNOY: I apologize. So the item that had the lowest comprehension for cigarettes was, "When a chemical is listed without an amount,

it may mean that the chemical was not detected."

For the sample that saw the list with the supplemental information, it was 49 percent correct, and for the list without the information it was 47 percent correct. And that's not a statistically significant difference.

For comprehension of smokeless tobacco, there are a few different ways of looking at it. But you can see that for the item, "How many of the chemicals in smokeless tobacco come from the tobacco leaf?", for participants who saw the list with the supplemental information, 60 percent got it correct, whereas only 22 percent got it correct in the list that was not augmented with supplemental information.

For comprehension of roll-your-own, the lowest item again was, "When a chemical is listed without an amount, it may mean that the chemical is not detected." And there it was 43 percent for the list with the information and 48 percent for the list without it, although that difference was not statistically significant.

DR. HALLMAN: Dr. Huang, you're up.

DR. HUANG: I apologize that I missed the presentations earlier, so I don't know how much this was discussed. Also, it sounds like my comments might be relevant to the later discussion.

But it seems fundamental to the whole study, and it goes back to Dr. Wolf's, I think, initial discussion about how the initial prototypes were developed. I almost feel like, just walking in, it's like a PC versus Mac commercial, and these are all representing the PC constituency in terms of the format.

I look at this, I guess the first presentation, and you compare to the tobacco industry's -- how they present and abuse constituent information, and just that contrast in presentations.

Again, it goes back to Dr. Wolf's, I think, question how these initial formats were even selected. Did you look at some other more creative ways of presenting this that were more sexy or whatever?

MS. TESSMAN: So we used the formative research process that I outlined earlier with the focus groups and a review of the literature to develop the first prototype. And the first prototype was really just to be the first attempt at outlining the information.

This may vary when we think about the channel, the way we're distributing it, the type of information that we want on it. I think that we recognize that there could be a variety of different formats that may be more appropriate based on what we hear from the discussion today. But we're very interested in hearing your comments. Thank you.

DR. HALLMAN: Dr. Strickland, you're up.

DR. STRICKLAND: A number of people have made comments, and so some of my comments are following up on some things that Dr. Cohen has asked about, and Dr. Hallman, too.

As I'm listening to all of this, I'm thinking you've shared with us the key concepts that you're aiming to address, and you've said that

there were between 19 and 21 items that you had in this comprehension measurement.

What we didn't see is the concept and the items so that we could see for this concept what items were asked. So that was one of my comments in terms of it would have been helpful to have had that.

But the other is really more of a process piece. How did you arrive at these items, given the concepts? Can you talk a little bit about the development of your measurement tool?

DR. PORTNOY: Sorry. We're trying to figure out who the most appropriate person to best answer your question is.

MS. TESSMAN: So we chose some of the comprehension questions based on the communication concepts. Some of the risk perception questions came from standardized measures that we may have adapted for particular products where measures weren't available. And then these were cognitively tested with a different group of participants prior to their inclusion in the experimental study.

DR. STRICKLAND: Let me see if I'm understanding. So you're saying the operational items that you were measuring came from the assessment, and then you categorized them into the conceptual areas?

MS. TESSMAN: We used the communication concepts to then develop the questions that were tested.

DR. STRICKLAND: No. I guess what I'm asking is, you have concepts and you have an instrument that is now measuring these concepts. Normally I'm thinking that we use a panel of experts as well to look at these and say, given this concept, what do we think about these items?

So I guess that's a process I'm trying to ferret out, is how did -- it sounds like of it was grounded in the focus group work.

MS. TESSMAN: Sure. Sure.

DR. STRICKLAND: But was there any other involvement in terms of --

MS. TESSMAN: We developed these items internally for the purposes of this study. But

again, we'd like to hear from the committee, as we consider moving forward, the process that you would suggest taking for future measure development.

DR. CHOINIERE: We should add that there was non-FDA expertise as well tapped. We had a number of researchers from Research Triangle Institute in their tobacco control, with extensive tobacco control, recent experience as well as we had Ellen Peters review the study prior to completing the design.

DR. HALLMAN: I have Dr. Johnson and then Dr. Turner.

DR. D. JOHNSON: I have two questions. The first one is, was the original objective of this piece of work to determine how comprehensible this particular set of data was going to be to the general public? That's question number one.

Second question is, it appears from one of your comments, Dr. Portnoy, that the participants in the study had a significant opportunity to question you about the content of that list, to ask questions about it and enhance their ability to

comprehend the information contained in that.

If you would, please comment on how that impacts the comprehension of the general public not given that opportunity, please. Thank you.

DR. PORTNOY: Sure. I'll address your second question. So the way the study was run is, it was an internet panel. That is, the participants were exposed to this list on a website, so they were not given any additional opportunities to question us about that information. They were presented with one of the different list formats, and following that, they responded to the items that assessed their comprehension of that information as well as the harm perceptions.

I should note that participants who were exposed to the list for certain questions had that list information still visible on that screen. So they would have been able to scroll up and down on the list prototype to look for that information.

In terms of the first question?

DR. CHOINIERE: Yes. Yes, the question

is, yes, it was designed to get an initial impression of what providing this type of information to consumers -- what does it convey to consumers?

I think to address your second point, this really is a limited study. It's a single exposure. We don't know -- it doesn't give us any insight as to what people will get over time if this list is made available, if there's repeated exposure, and if there is any accompanying education, which Dr. Alexander can discuss after we're done with the clarifying questions.

DR. HALLMAN: Dr. Turner?

DR. TURNER: My question is really following up on Dr. Strickland's comment about the comprehension measure. Given that a number of us have asked about that measure, I was wanting to ask you if you could talk to us about the psychometric processes you undergo before you took the overall percentage.

To be fully transparent, I was a little surprised that it was unidimensional. You'd think

that it would be -- 21 items might break down into a couple different dimensions.

DR. PORTNOY: Sure. In terms of -- and it actually works out while I have the slide up here -- so we did actually do a factor analysis on some of these.

DR. TURNER: Exploratory or confirmatory?

DR. PORTNOY: Exploratory factor analysis. And that's in part how we came up with the likelihood and concern scale. My initial thoughts, I thought that those would be separated in a different way. The data did not bear that out.

So for that, as well as for the harm perception for the three tobacco products, the Cronbach's alpha on that is high. It's not .90, but it's well above the generally accepted limits.

For the likelihood and concern scale, despite the exploratory factor analysis, some of the sub-scales by product type are a little bit, admittedly, on the lower end of the spectrum. However, I did do some additional analyses looking at the items individually, and the pattern of

results on all these is virtually identical.

So for parsimony, to not present you any more data than I already did, here I'm presenting them in terms of these scales.

DR. TURNER: Thank you.

DR. HALLMAN: Dr. Paul?

DR. PAUL: I wanted to build a little bit on Dr. Johnson's comment, and also go back to the distinction between the exposures. I would be curious to see, in terms of the message, the distinction between what people got, how they did on a control where they didn't see the list -- that would be your baseline, what they knew already; what they got with the un-augmented list -- what did the list do; and then what they got with the augmented, which of course made it very clear what the purpose of the list was in text.

Because Dr. Johnson talked about, if I may misquote you, the comprehension of the numbers, the table, the data, which is not the same as getting a message from it.

So I think it's a little bit of mixing

apples and oranges, and I'm curious to know, that table, was it -- we are asking them for an interpretation of it as opposed to, do you know what these numbers mean?

So we're getting a different view of the list itself because we've given it a purpose. And so the comprehension research isn't really comprehension of the list. It's messaging. It's a different thing.

So that's what I was wondering. I didn't see a comparison of those three, and I'm looking for that thing.

DR. PORTNOY: Sure.

DR. PAUL: Did the list augmentation -- by itself, no other data, just, these are the words, "Smoking is bad for you" -- was that a sufficient piece of information so that the message got across regardless of the quantitative information that followed?

DR. PORTNOY: Sure. So I did not present those data here. In other analyses, I did examine the difference between the control, the list that

was not augmented, and the list that was augmented. And the general pattern -- I don't have slides or even notes about this -- but the general pattern is that any list, either augmented or not, was significantly higher than the control condition. And for many items, although not all -- and I've already talked about some -- the list that was augmented was statistically significantly higher than the list that was not augmented.

So I think that addresses part of your question. And I've already talked some about which items were more or less influenced by exposure to that additional information.

Does that answer your question?

DR. HALLMAN: So on the slide that we have up about the effect of list format on harm perceptions, I'm interested in drilling down a little bit more on the measures in this particular scale because I think this is a particularly important piece.

In terms of the likelihood and concern scale, what do the items look like?

DR. PORTNOY: Sure. I have that right here. Give me just a second. I can read them off to you.

Here we go. "How likely do you think you are to get a disease from smoking cigarettes?" This is the cigarette question. And then the related concern question: "How concerned are you that smoking could affect your health?"

The response scales, it's a 5-point Likert type scale. For the likelihood, from very -- excuse me. It's a 4-point scale for that. It goes from "Very unlikely" to "Very likely." And the concern is a 4-point scale that goes from "Not at all concerned" to "Very concerned." We also have an item about, "How concerned are you that smoking could affect the health of someone else?"

DR. HALLMAN: So if you could briefly summarize again for us, what is the impact of the various formats on these particular outcomes?

DR. PORTNOY: Are you asking about the different list formats on the likelihood and concern scale?

DR. HALLMAN: Yes. In particular, on the effect of harm perceptions.

DR. PORTNOY: Sure. Excuse me. Let me just go to the right slide here.

So for cigarettes, we did not find any different by list format on the likelihood and concern scale. For smokeless tobacco, we found no statistically significant differences by either format or population. And for roll-your-own tobacco, we see only a difference by population but not by list format.

DR. HALLMAN: So essentially, presenting the list in any format doesn't necessarily increase perceptions of harm based on control? Is that correct? Am I reading that right?

DR. PORTNOY: Let me see. Before I respond, I just want to make sure that I'm responding accurately. If you'll give me just a minute, let me check my notes.

Yes. That's correct.

DR. HALLMAN: So there's basically no impact of providing the information on perception

of harm?

DR. PORTNOY: As it's operationalized,  
as --

DR. HALLMAN: As it's operationalized by  
these questions?

DR. PORTNOY: Likelihood and concern only,  
yes.

DR. HALLMAN: Okay. Thank you. It's one  
of the issues I think maybe we'll talk about this  
afternoon.

DR. PORTNOY: Okay.

DR. HALLMAN: Great.

I have Dr. Krishnan-Sarin up.

DR. KRISHNAN-SARIN: I was going to ask a  
question, and then I decided maybe I wouldn't. But  
I'll ask it anyway.

Just to remind me, just to take a step  
back from all this, what is the plan for this list?  
Can you remind me? Is it going to go on the  
cigarette packets? Is it going to go in some other  
format?

Because depending on how it's going to be

displayed, that's going to make a big difference in terms of what goes on it. And I could hardly read it with my reading glasses on, and it might be very difficult to comprehend some of these things. So can someone remind me?

DR. CHOINIERE: Yes. The plan is not entirely fleshed out, but it certainly will not be on the packs of cigarettes, although we have the option to go through rulemaking to do such a thing.

To fulfill this requirement, it is to put on public display in a -- and I don't know the rest of the statutory language off the top of my head. But if there is some thought from the committees about the appropriate public display, obviously what comes to everyone's mind is on the FDA website or on the internet somewhere. But if there is some other appropriate means of putting this on public -- a manner of putting this on public display, then we would welcome input from the committees on that.

DR. KRISHNAN-SARIN: Just to follow up on that, so if someone was interested in getting this

information, they would have to actually go look for it and find it in order to understand.

Correct?

Is that -- it wouldn't be -- so if somebody walked into a store and is trying to make a decision about whether or not to use a product, it's not as if the list is going to be available right in front of them for them to make that decision, at this point?

DR. CHOINIERE: At this point.

DR. HALLMAN: But I think part of our charge as a committee is to talk about how we might display this, and that's why they're coming to us.

Are there other clarifying questions?

(No response.)

DR. HALLMAN: So you're all clear?

(Laughter.)

DR. HALLMAN: Okay. There are related questions that you have raised, and I think I'd like to spend a little bit of time addressing the first question here, which is, how can FDA assess whether the publication of the list by brand and by

quantity in each sub-brand is in a format that's understandable and not misleading to a lay person? So based on what we have been presented, do we have some suggestions?

DR. CHOINIERE: Dr. Hallman, if I can interrupt, should we hear from our Office of Health Communication and Education, or would you prefer to address that question now?

DR. HALLMAN: We can do that. What I'm struggling with is time. It is now 10 minutes to 12:00. We must have public comment exactly at 1:00, and the question is whether there is enough time for that presentation before lunch or after.

DR. CHOINIERE: Okay. Understood.

DR. HALLMAN: If you would prefer us to hear from them before addressing those questions, that certainly makes sense to me. We could also break early for lunch.

Go for it? Okay. All right. Let's go ahead and do that.

**Presentation - Tesfa Alexander**

DR. ALEXANDER: Good almost afternoon. My

name is Tesfa Alexander. I'm a health communications specialist within the Center for Tobacco Products, specifically in the Office of Health Communication and Education at CTP. My background is in cross-cultural health communication, and I've been with the CTP for approximately three years.

I'd like to acknowledge my colleagues, both in the Office of Health Communication and Education, as well as my colleagues in the Office of Science, for their contributions to this presentation, and also acknowledge RTI for their contributions to this presentation as well.

The purpose of my presentation is twofold: one, to provide a framework to aid in the evaluation of the issues related to public education of HPHCs, and second, to provide background information for the committees in their response to the question, "What strategies might FDA use in a public education effort aimed at a deeper public understanding of HPHCs?"

The content of my presentation is divided

into three areas. First I'll start with an overview of current consumer constituent knowledge and misperceptions. You've heard a lot of this investigation in Dr. Choiniere's presentation as well as in Greta Tessman's presentation.

Then I'll move into findings from an environmental scan of past and current tobacco constituent public education initiatives. And third, I'll close with a discussion around potential HPHC public education opportunities and challenges.

Starting with what we know around consumer knowledge of tobacco constituents, there are limited data on consumer knowledge and perceptions of tobacco constituents. But from the available data, we know that a large portion of smokers in the United States are unaware of constituents in tobacco products as well as in tobacco smoke.

It's worth noting that level of awareness of constituents among consumers is significantly lower when consumers are asked to recall, freely recall, the information, as opposed to being aided

with a list of constituent information.

There are studies that have looked at awareness of particular constituents, and from those studies we see, in comparing awareness of constituents, that smokers in the U.S. are more aware that tobacco smoke contains carbon monoxide in comparison to other constituents such as mercury, arsenic, lead, and ammonia.

Moving on to consumer misperceptions of tobacco constituents, studies show that consumers have varied misperceptions of constituents information as it relates specifically to the health effects constituents of constituents as well as the origins of the constituents.

We've heard this information again -- this is serving as a refresher -- in previous presentations, that a majority of smokers mistakenly believe that nicotine causes cancer. Many smokers mistakenly believe that low tar and light cigarettes cause fewer health problems. And as found in the research results presented by Ms. Tessman, few consumers are aware that constituents

naturally occur in tobacco and are created during the process of curing and burning, and assume that tobacco constituents are included or added during the manufacturing process.

Now that we've covered an overview of consumer knowledge and misperceptions of tobacco constituents, moving on to sources and types of constituent information that consumers may be exposed to.

An environmental scan that we conducted of internet content as well as community programs focused on constituents of cigarette smoke showed a few things, a few top line things, one, that there are numerous health organizations that provide constituent information. However, the information they provide is often not prominently displayed or provided. And what I mean by "prominently," that information is often buried within the organizational websites.

Second, we found that most health organizations, when providing constituent information, do so primarily in a text-only format

or just simply provide a list of chemicals, as opposed to providing the information in graphic nature or using graphics, symbols, pictures, et cetera.

That was an interesting finding for us because we know from the health communication literature providing such information in graphical format or aided with videos or pictures would help with memory as well as persuasion of the information that's being communicated.

Lastly, we found as a top line finding that many states, communities, and school districts support or sponsor programs with a component that aims to educate about constituents in tobacco products, and more often, if not all the time, in an effort to encourage prevention or cessation of tobacco products.

Some of the sources of that constituent information, the major sources of constituent information, not surprisingly, include health-focused organizations such as the Department of Health and Human Services.

There are non-health-focused organizations that provide constituent information such as the Department of Defense and the Building Construction Trades Council, just as examples. And their primary purpose for providing constituent information is to basically prevent their members from using tobacco, encouraging them to abstain from using tobacco, because they may have unusually high rates of tobacco use among their members.

There are other organizations that provide constituent information, including organizations focused on the health and well-being of children, as well as state communities and school districts.

Using information that I just provided as cursory background information, the information that you've heard earlier from my colleagues as it relates to what we know about consumer knowledge and perceptions of tobacco constituents, as well as research we've conducted thus far, there appears to be potentially an opportunity for FDA to increase accurate consumer understanding of HPHCs through public education efforts.

A point of clarity of what I mean by HPHC public education efforts, these are efforts that would be led, or potentially led, by FDA that has a particular focus on the science of HPHCs or may be linked specifically to the HPHC lists, as opposed to other public education efforts that may have a constituent component that's wrapped into a larger strategy, or maybe one of many messages for a different purpose, such as preventing youth and young adult tobacco use.

That being said, through the information we've gathered thus far, there are five key areas for potential HPHC education opportunities. The first is potential opportunities to increase public awareness and understanding of the presence of HPHCs in all regulated tobacco products; as we know and as we've heard, there seems to be a lack of consumer knowledge and awareness of the wide array of constituents that are included in tobacco products and tobacco smoke.

Secondly, there's a potential opportunity to increase public awareness and understanding of

the origins of HPHCs. Again, as we've heard in Ms. Tessman's presentation, many consumers believe that constituents are added to tobacco products rather than occurring naturally in tobacco, as well as in the curing and the burning stages of tobacco.

Third, there may potentially be an opportunity to increase public awareness and understanding of the health effects associated with HPHCs. Existing knowledge of the health effects associated with HPHCs often is inaccurate when it relates to consumer understanding, again going back to the perception that nicotine causes cancer.

Fourth, there appears to be potentially an opportunity for FDA to increase public understanding of how HPHCs are measured in tobacco products and tobacco smoke, as well as an opportunity for FDA to increase public understanding of HPHC brand and sub-brand quantities, going back to earlier discussions during the clarifying questions related to the previous presentation around HPHC amounts and the interpretation of that quantity information within

a HPHC list.

All of these opportunities are not without their unique challenges. One challenge, as again discussed during the discussion beforehand, is that an HPHC public education initiative may potentially have to target a very large and diverse audience.

When you consider whether you're segmenting our audience by tobacco users, non-users, and then the various subpopulations within those segments, we have to ensure FDA would be required to make sure that messages targeted towards those audiences are easily and accurately understood by all segments.

Second, a second challenge that needs to be taken into consideration, is that consumers may assume that risk information may be obtained from HPHC brand and sub-brand information, and mistakenly believe that lower amounts of individual HPHCs or fewer HPHCs mean a product is less harmful.

A third challenge, which could potentially have been the first bullet, but taking a couple of

steps back, we've heard in our discussions and we all know for those of us who are familiar with the science of HPHCs, for us it's a complex topic, and we'd have to consider that it would be even more of a complex topic for the lay audience. Therefore, it may be difficult to explain the science of HPHCs without being misleading.

Lastly, related to challenges associated with the HPHC public education effort, there are common misperceptions that we have to take into account associated with HPHCs that consumers may have prior to receiving public education messages around HPHCs that may affect their receptivity to HPHC messaging.

In closing, I hope that information that I presented, as well as the information presented by my colleagues, is useful to you all and will help aid in the discussion this afternoon. And we look forward to discussions and your responses to the questions posed.

At this time I'd like to open it up for any clarifying questions related to my

presentation.

### **Clarifying Questions**

DR. HALLMAN: I have one question. So throughout the morning, one of the key concepts that has been brought up is the idea that many consumers don't understand that the harmful constituents are actually part of the tobacco product and are produced through burning the tobacco product.

Why is that a key concept for people to understand, as opposed to simply understanding that the chemicals are in the product itself?

DR. ALEXANDER: To answer your question, I work that's a great point. What was presented is, I should say, not etched in stone as a key concept. These concepts or opportunities were presented just to provide you all with a framework for further discussion of identifying what essentially would you recommend as being key concepts for FDA to take into consideration.

DR. HALLMAN: Dr. Choiniere?

DR. CHOINIERE: I wanted to add that one

of the reasons why that is a key concept is that there is -- and Ms. Tessman can chime in if you need more details -- in the focus groups, there seems to be a believe that roll-your-own and more natural and/or organic tobacco didn't have these constituents because constituents are added to the product by manufacturers.

DR. HALLMAN: Are there other comments or questions? Dr. Lawson?

MS. LAWSON: I noticed you mentioned that FDA is focused on public education initiatives. I wondered where that might be. Is that basically a concept, or have you given any thought to the direction that might take?

DR. ALEXANDER: For us, this is a starting point in terms of receiving your recommendations around public education efforts around HPHCS, and again, going back to previous discussions, whether public education efforts tied to the list or not tied to the list are needed to help for understanding and comprehension of HPHC brand and sub-brand information and quantity information.

DR. HALLMAN: Dr. Huang?

DR. HUANG: Yes. I would just say, I really appreciate -- I think these are really important education opportunities and can really drive a lot of the recommendations and discussion later this afternoon, and go into again what we're talking about in terms of the format that we're presented. But I think it's really important information.

DR. HALLMAN: Yes, Mr. Henton?

MR. HENTON: In your last slide in your second bullet, you say consumers may "mistakenly believe that lower amounts of individual HPHCs mean a product is less harmful."

If you had stated that the other way, if it had a higher amount, would it have been more harmful? Would it have been correct to say that a consumer could assume that if the numbers were higher, that it would be more harmful? The way you said it, it's kind of a negative statement. I'm just trying to figure out what you're trying to say there.

DR. ALEXANDER: What we're trying to say is or what I'm trying to say is that in looking at the information -- let's say we're using the list as an example of HPHCs -- consumers may try to compare and contrast the list information by quantities.

Let's say there are cigarette brands that have lower quantities of arsenic, for example, compared to other cigarette brands. Right now we are unable to deduce risk information, where consumers may assume that they can deduce risk information, if that answers your question.

MR. HENTON: No, it doesn't answer my question. My question is, if the amounts were higher -- you stated this, that they mistakenly believe that lower is not better. The statement is sort of a -- it's a definitive statement. And if it was reversed, if the numbers came out higher for a product, wouldn't it be correct to say that it would be more harmful?

DR. HALLMAN: Dr. Choiniere, do you want to comment on this?

DR. CHOINIERE: Yes. I believe that is correct, that if the perception is that if by reducing one constituent then another product would be safer, then the converse is also true, that they could use the -- they may infer that one product is more harmful if a particular constituent is higher.

The concern is that a consumer may just glom onto one particular constituent without looking at the full picture of all the constituents. So a mere reduction of a single constituent without considering changes in other constituents could convey some relative risk information that may not necessarily be accurate.

DR. HALLMAN: It would also seem as though, given the large number of unmeasured constituents, that making an overall statement about the safety of a particular brand or another would be inherently misleading.

Dr. Clanton?

DR. CLANTON: I've been resisting putting this out, but the last three or four questions I think will justify putting this question out and

then setting it up.

But it appears that there's a desire to take a list and turn it into a dissemination tool. Lists are designed to simply present data, and the purpose for presenting data is usually for analysis by some other interested party. Those lists, those data, can be transformed into something else for the purpose of education or dissemination, to improve health outcomes, or change behavior. But the lists in themselves typically are inadequate for that purpose.

So I wanted to make the point that we seem to be asking quite a lot of a list as it relates to interpretation, education, and maybe to even serve the purpose of dissemination. So I think that's an important idea to get out.

So here's my question, and there actually is one. Based on the statute, is it a requirement to take a list and make it do all these things you're attempting to do -- impute knowledge, understanding, behavioral change, et cetera?

Or, as your question pointed out

beautifully, is there room to simply produce the list whose purpose is to simply present data, whether it's higher or lower or worse or not -- you can present it any way you want -- and then in a secondary way and in a secondary fashion, use those data to transform them into tools that would necessarily be used for education and dissemination and behavior change and outcome?

Is there an opportunity to do that and meet the statutory requirements?

MR. ZELLER: That's a great comment and question. And I think the answer is, Congress chose to be silent on what else should be done beyond tasking the agency to put out a list, as you said, as long as we can put it out in a way that's understandable and not misleading. And that's as far as Congress went.

But you're asking a very fundamental question, and it captures a lot of the questions and comments that have already come up this morning, more in the spirit of the precautionary principle than anything else.

I think that's where public education comes in because while that's not specified in the law in the context of putting out this list, as you say, we want you to come into our world and figure out what role public education could play in any number of ways, as we've tried to tee up for you, without telling you necessarily what we think the outcome should be.

DR. HALLMAN: Dr. Huang and then Dr. McAfee.

DR. HUANG: Again, understandable and not misleading -- and I see there is tremendous opportunity just with that. And to make sure that it isn't misleading, there are some practices that need to be implemented in terms of how it is implemented.

I think simply if there were opportunity to make recommendations that it is -- maybe you go through particular ingredients, and there's some during some time period that are on the packs of cigarettes.

To say that there's 100 nanograms of

arsenic on this particular pack of cigarettes would be very informative, would be understandable, and presenting the information in a very matter-of-fact manner, but I think would be very informative and potentially have some of the effects that we were talking about.

DR. MCAFEE: I would just echo this perhaps consensus that is emerging a little bit that it might be a diminution of the amount of intelligence that you have in this room to really focus on trying to perfect a list if the list is only going to live on an FDA website. And perhaps that actually is the best place for it to live because of all this.

But my issue in terms of the concerns about the list essentially are, are there other possibilities in areas where you need to be really careful about this, not because the 55 people who will go and find it on the FDA website will be misled or misinformed by what's on the list, but that the list itself will be misused?

I'm assuming because of the modified risk

requirements that it would not be feasible for the tobacco industry to easily do what it did historically with some of the numbers that came up, were produced in prior government efforts.

But I'm curious, if there are things like that you really need to worry about, that this will be misconstrued and misrepresented by other people besides the tiny, tiny, tiny handful of people that would find it on the FDA website because otherwise it's like we really should move on quickly to talk about whether there's a "there" there for public education, whether there's a "there" there that this should influence or you should steer clear of it for future graphic warning labels, et cetera.

MR. ZELLER: I think what we're interested in hearing is what you all see as the potential unintended consequences and misinterpretations and misuse. Our focus for now is the list. That's the statutory commandment that we're grappling with, and the reason why we brought the committees together.

DR. MCAFEE: Can I just have a quick

response, then? Again, what I would say is you found some stuff already about that, and it's worth paying attention to. But the numbers themselves, if they can be repackaged by others and redisplayed in other ways, would have the capacity to be misrepresented, that would be quite worse.

Frankly, I don't think it really -- the extent to which you should worry about nuances and complexities for something that is only going to be displayed on an FDA website are -- you should worry about it some, but it's this larger life that it would have. And again, I assume the modified risk tobacco product requirements will provide some significant protection.

DR. HALLMAN: Dr. Huang?

DR. HUANG: I guess in terms of definition of a list, is there some flexibility that -- does it have to be -- can the list be this rolling release of information? Or does it have to be all on one setting as one big list?

Because I do wonder. When you have a side-by-side comparison, that's where you start

seeing this opportunity for this one is better than that one. But if the list is -- again, to make it more understandable, I think the information can actually be digested more as released in pieces, and also less opportunity for making those incorrect interpretations about relative -- but again, I'm sort of asking, is there opportunity in terms of definition of list that it doesn't have to be all out there, but it can be revealed?

DR. CHOINIERE: I think there possibly are opportunities for defining the list in different ways. What I think would be useful is to hear from the committee about what other ways you might define them as; then we can always explore those options and explore the legal requirements and whether or not those ideas would be legally permissible.

DR. HALLMAN: So one of the things that I don't think we have a good sense of when we talk about "the list," given the stimuli that we've seen, there are a very limited number of columns. Each -- well, we've only seen essentially one brand

at a time.

How many brands and sub-brands are we talking about? The list is immense.

DR. ASHLEY: If you're talking about the extent of tobacco products by brand and sub-brand, you're talking about thousands.

DR. HALLMAN: So the list is incomprehensibly huge. And in terms of trying to compare one to another, it's not like they're lined up in columns where you can go across and see, oh, yes.

Okay. With that pithy observation, I think we're going to take a break for lunch. Mr. Bravo, you have a couple of comments.

MR. BRAVO: Thank you, sir. For the panel members, lunch is set up right behind me. If you are paying by credit card, we're asking you to step out into the kiosk and make a payment there. If you're going to be making a cash payment, we have our interns -- if you could raise your hand -- back there that will gladly take your payment for lunch.

DR. HALLMAN: So we will return at 1:17,

at which point we will have public comment. Thank  
you.

(Whereupon, at 12:16 p.m., a luncheon  
recess was taken.)

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

(1:00 p.m.)

**Open Public Hearing**

DR. HALLMAN: All right, ladies and gentlemen, let's resume. If you would please take your seats. Put your cell phones on silent or vibrate.

At this point I'd like to open the public hearing. And so the bit of legalese that goes with this is, welcome to the open public hearing. Please state your name and your affiliation if relevant to this meeting.

If you have any financial interests relevant to this meeting, such as a company's or group's payment of your travel or other expenses, FDA encourages you to state the interest as you begin. If you do not have any such interests, you may wish to state that for the record. If you prefer not to address financial interests, you can still give your comments.

We have six speakers signed up for this afternoon. Given that, each person will have a

limit of eight minutes. When there are two minutes left, a yellow light will come on. With zero minutes, a red light will come on, and we respectfully ask for you to yield to the next person.

So with that in place, I'd like to invite Dr. Michael Ogden to the floor.

DR. OGDEN: Thank you, Mr. Chairman.

Mike Ogden of RAI Services Company. It's a pleasure to present to the joint committees this afternoon, and my comments that I make today are on behalf of the Reynolds American family of tobacco manufacturing and operating companies that include R.J. Reynolds Tobacco Company, American Snuff Company, and Santa Fe Natural Tobacco Company.

The appropriate and effective communication of HPHC information to the general public presents different issues, and in my mind those issues differ on whether or not the data are determined to be sufficiently accurate and precise for the intended purposes, or whether they are determined to not be sufficiently accurate and

precise.

I think, from listening to the discussion this morning, the majority of the discussion, I think, assumes two facts that are not in evidence, and it assumes that the data, as available to FDA presently, are sufficiently precise and accurate for the intended purpose.

But the comments that I will make today are really on the second point, that I believe the data demonstrate or the available information demonstrates that these data are not sufficiently accurate and precise to communicate in a quantitative fashion to lay persons.

So briefly, to support that point, you can look at intent, fit for purpose, in terms of accuracy and precision. I'll make a couple of brief comments.

In terms of accuracy of the numbers that are available to FDA, there are no certified reference materials available for tobacco products today, nor will there be any time in the near future. The current measurements, HPHC data, that

are on file with FDA are then of unknown accuracy.

But the more important point, and of greater concern, is the degree of precision with which these data have been gathered and reported to the agency. This is important because of the way in which the data were gathered, multiple laboratories measuring certain products under multiple different methods of measurement.

For accuracy -- or, sorry -- for precision to be relevant and, importantly, controlled in this case, the measurement process must be in a state of statistical control. The measurement process, as outlined in the guidance from FDA and employed by the manufacturers in the testing labs, is demonstrably not under statistical control. And I'll make a couple of points about that.

What do I mean by statistical control? And that's summarized on this slide. And there are really two points. The entire measurement process is stable, meaning that repeatability and reproducibility within and among testing laboratories are known and they're comparable.

And more importantly again, I think, in this context is that the individual measurements that are generated throughout the process are independent of one another.

What that means simply is that if you imagine two laboratories using different methods testing different products were to switch those products and reanalyze them, they would get equivalent results. And that's demonstrably not the case.

A couple of points on this slide. I won't read through them all. But elements of statistical control -- this is not just my opinion. These are a number of quotations and summaries from a number of well-relied-upon statistical and quality assurance experts in the field, some of which work for National Bureau of Standards, et cetera.

But I would point you to the middle bullet, which I think is particularly relevant to the case in hand. Reliability considerations are important in practically every data situation, but they are especially important when data

compilations are made and when data produced by several sources must be used together. And that's exactly with the situation we have with the HPHC data that are on file with the agency.

So to briefly review some considerations for how these data were generated and how they've come to be, there is no FDA regulatory requirement for harmonized or standardized methods or processes to evaluate the proficiency of the HPHC data. As such, as I indicated a moment ago, laboratories have independently developed, validated, and implemented their own methods according to their own internal needs and their own internal processes.

So while these data are unlikely to be reliable in all cases for comparisons amongst laboratories, they do have some usefulness, perhaps in the regulatory scheme. If you look at a particular laboratory employing a particular method, it's appropriate to compare products. But when you compare those products across laboratories and methods is where the issue becomes.

Tobacco reference products exist. They're not certified reference materials, but they are consistent products that are used in the quality assurance of laboratory measurements. Those data exist.

They were not requested to be submitted to the agency, but laboratories in their general practice analyze those types of products as a matter of course, and data are available that allow to compare a single product across multiple laboratories and multiple methods.

So in response to FDA's HPHC guidance in April of last year, most manufacturers collected HPHC data using tobacco reference products. What I'm going to show you here is an excerpt of some analyses that were done to compare those reference product results among laboratories, among methods, looking both within lab and across lab variation. These results -- in fact, more results like these -- were shared with FDA at a meeting that was held on behalf of industry back in February of this year.

So briefly, some key findings. The majority of smoke analytes demonstrated statistically significant temporal variation and lab-to-lab differences. For example, under the more commonly used ISO smoking conditions, more than 60 percent of the smoke HPHC data showed lab differences, lab-to-lab differences, of 20 percent or greater.

Generally it's true that the standardized methods -- and there are some, particularly for tar, nicotine, and CO, particularly under ISO smoke conditions -- those types of methods show lower variability, and generally the analytes that are present at higher concentrations -- for example, in milligram levels -- tend to show lower variability than lower concentration analytes, which typically can be in micrograms or nanograms. The findings are similar for the Health Canada intense smoke conditions, and also for smokeless products and for tobacco cut filler.

I'll show you some charts just to illustrate my point. All of these charts are for

smoke, analyzed according to the -- or generated under the ISO conditions. They're all for the Kentucky Reference 3R4F cigarette.

So this is a cigarette that was made at one point in time and that all the laboratories use this -- not all laboratories use it, but many of them use this as sort of a quality assurance from day to day, run to run, year to year.

So this chart shows ISO nicotine yield in the smoke according to a number of different laboratories. And the colors and the different symbols represent different laboratories as they reported their QC data over a number of days in grouped analysis sets.

So the red, for example, is a different laboratory than the blue, than the green, than the black. And you can see a variation among the yields reported, which is typically, for example, on the order of .6 to .8 milligrams per cigarette.

As an example of temporal variability, for example, you could show one particular set of analyses in one day in one laboratory would might

average around .65, and another laboratory on separate days, you're looking at something about .85. This is about as good as it can get, high levels, with a method that has been standardized and used for decades.

Looking at carbon monoxide, you see a very similar picture of the type of precision that's available. Again, now you can look at -- within a laboratory, you can see some differences, on the order of 1 or 2 milligrams, even within a given laboratory.

More importantly is the case where you look at method bias, and I'll show you two quick examples. Here's for benzo(a)pyrene. So you can see quite a bit of scatter in the blue dots and a bias between those levels and the ones, for example, in some of the other labs.

The most alarming is for a case of isoprene, where in this case you have different labs, different methods, and you could have easily a threefold difference in the amount of HPHC that's reported to FDA under the current measurement

process. Thank you.

DR. HALLMAN: Thank you very much.

So next we'll hear from Andrea Villanti.

MS. VILLANTI: Thank you. Thank you to the joint committees and to the FDA for the opportunity to present today. My name is Andrea Villanti. I'm the associate director for regulatory science and policy at the Schroeder Institute for Tobacco Research and Policy Studies at Legacy. I have no financial interest to disclose, and I'll be presenting today on some of the key points from our written comments that we submitted prior to this meeting.

First, I just want to highlight that Section 904 provides novel requirements and transparency essential to understanding both the composition of current and future tobacco products and their potential health, toxicological, behavioral, and physiological effects.

Availability of these data to researchers, advocates, and policy-makers in tobacco control will promote sound science and policy, but we want

to raise concern about the potential of this information to mislead the public, precisely one area that Congress sought to prevent in passing the Tobacco Control Act.

Specific language in the Act related to providing quantity of harmful and potentially harmful constituents by brand and sub-brand is a particular concern, given recent scientific evidence showing that the presentation of quantitative information on tobacco constituents on cigarette labels and packaging is misleading.

Many consumers are unable to accurately recall numeric information from their cigarette labels or packaging, and many use the information to draw false conclusions, specifically interpreting lower numbers with a reduction in risk and using this information to guide their choice of brands.

We're particularly concerned about potential unintended consequences among people of low literacy and low numeracy. Individuals who have a high level of understanding of numbers are

more likely to pay attention to numbers associated with risk, better comprehend them, translate them into meaningful information, and ultimately use them in making decisions. Less numerate individuals, on the other hand, are more likely to rely on emotions, mood, or trust or distrust of an information source.

Given that the FDA will likely be seen as a trustworthy source of information, presentation of levels of HPHCs by the FDA itself may inadvertently serve to reinforce perceptions of reduced risk or increased safety of certain products.

We also want to note that low numerate individuals are also likely to be disadvantaged by poverty, lack of education, or linguistic barriers, and highlight the potential for presentation of quantitative information to lead to disparities in understanding in the same groups in which we see tobacco-related health disparities, specifically, individuals of low socioeconomic status and racial/ethnic minorities, concerns that have been

addressed earlier today.

Recommendations for the presentation of information on tobacco constituents focuses on the need for descriptive text on toxicants rather than numerical presentations of the levels in the product to reduce false beliefs about relative harms or safety of a given product. And while we understand the requirements of Section 904, the data, together with expert recommendations, strongly advise against FDA's presentation of numeric levels of HPHCs to the general public.

In the era of FDA regulation of tobacco products, publication by FDA or by tobacco companies of levels of HPHCs present in various tobacco products could mislead consumers in several important ways. We note a few of them here:

First, that consumers, unaware of what constituents are, will be unable to interpret this information;

Second, that many people will believe that there are meaningful differences in levels of risk across products where there are none;

Third, that published a list of HPHCs in products could result in perceived government endorsement or evaluation of these products, as seen in some of the advertisements for light and low tar cigarettes we saw earlier today, which could have deleterious impacts on consumer perceptions; and finally,

That to the extent that publishing this information leads to reduced risk perceptions of these products or reduced readiness to quit, provision of the information to the public would actually undermine the FDA's mandate to act for the protection of public health.

These inform important indicators to be assessed in future research, which we highlight in red here:

First, we need to have a better gauge of awareness and understandings of the different constituents themselves in future research;

Second, that we can look at differences in risk perceptions by type or level of constituent;

Third, that we can look at levels of

perceived government endorsement of these products in future studies, and their potential impacts on behavior; and finally,

The impact of risk perceptions on behavior and behavioral intentions among non-users, current users, and former users of tobacco products.

We also want to highlight that extensive research needs to be done on tobacco constituent messaging using validated and standardized procedures prior to communication with the public. And we also want to highlight some at-risk subgroups in which evaluation is particularly important, including youth and young adults; racial and ethnic groups; those of low SES, literacy, and numeracy; smokers interested in quitting; and those with a mental illness.

In summary, the Tobacco Control Act requires FDA to publish the list of HPHCs in a format that's understandable and not misleading to a lay person. However, it also provides some leeway by stating that the Secretary may determine how that list is publicly displayed.

The law is correct in wanting to shine a light on the HPHCs in tobacco products, which have been concealed from scientists and the public, but we want to encourage that the data be made available to experts in tobacco and tobacco control, and that the FDA exercise caution when communicating this easily misinterpretable information to the public.

Extensive research and in important population subgroups will be essential to demonstrating that publication of a list of HPHCs does not mislead the public. And we look forward to working with you and the FDA on this important issue to protect the public, in line with the goals of the Tobacco Control Act. Thank you.

DR. HALLMAN: Thank you very much.

Next we have Danny McGoldrick.

MR. MCGOLDRICK: Good afternoon. I don't have any slides; I'll just make a few quick points. We have submitted written comments on two occasions for the committee's consideration, so I'll just make a few brief points this afternoon.

First, thanks for the excellent presentations this morning. They were insightful. Of course, this is our first exposure to the results of the experimental study, so we look forward to spending more time with it.

To that end, it would be nice if all the materials from the study -- the instruments, the results, any of these presentations -- were in one place, a one-stop shop so that we could really dive into them, spend more time with them, and provide more feedback to the agency.

A few quick points, though. As the formative research showed, and as we heard clearly this morning, there's a clear lack of understanding among consumers about the chemicals in tobacco products, and that they don't just come from additives but come from the tobacco leaf itself and the burning of tobacco.

This provides a real opportunity, which is what the Act was designed to do, to use the information required by the Act to better inform consumers as they make decisions about the us each

of tobacco products.

But as others have said, the big question, of course, is how you can do this, how we can better inform consumers about all these toxic chemicals that are in tobacco products, without leading them to make some of the invalid comparisons that we've talked so much about that can lead to bad decisions, as we've seen over the years, like switching instead of quitting.

Even if we could measure everything precisely, people could still use that information in a wrong way. So it's important that we understand this tradeoff in informing consumers versus them using the information to make invalid comparisons.

So how consumers use the information is vitally important. This is obvious, but a point that can't be made too strongly. The current research doesn't appear to have really gone into detail about, do they understand the information, what are their risk perceptions, but what do they do with the information?

How do they compare products if they see two products that have different numbers of these chemicals or different volumes of these various chemicals? How do they react to that? Do they, in fact, try to make comparisons and switch to a less harmful product when they might otherwise try to quit?

This is obviously critical to ensuring that the information is not misused and has lots of implications about, do we provide quantitative data or just more of a qualitative nature to better inform them about the things that are in these products?

So clearly this is just the first study in what will have to be a series to really understand how consumers use this information that, again, is very important for them to understand but has a lot of potential for misuse and unintended consequences.

Future research should also address, as others have raised, the usability issues. In what format is it provided? Studies to understand how

consumers interact with the information or the data in whatever format it's ultimately provided so we can better understand how in fact they use it to try to make decisions.

As was just mentioned, too, there are other uses of the data for other audiences. It's really important, I think, that researchers, policy-makers, advocates, public health practitioners, have these data so that it can be taken into consideration to try to improve public health.

So there are uses beyond just informing consumers, and so I think the FDA should consider how it can make these data available to different audiences, perhaps in different levels of detail, who can make the best use of it. I think that's a very important consideration moving forward because this is valuable information to a number of different audiences at different levels of expertise and sophistication in consuming it.

Also, as was mentioned earlier this morning, the FDA should consider how making these

data available, aside from just these lists, can be complemented by broader public education campaigns. We know that FDA is undertaking efforts in public education, and this, I think, is a prime area where a broader public education campaign is going to accomplish some things that perhaps providing just a list of numbers that are difficult for even many of us in this room to understand -- to make that useful.

Finally, it's vital that the FDA consider how others might use the information to mislead consumers. Even if consumers themselves aren't misled by it in the format that may ultimately be decided, the FDA has to be vigilant in using its authority over any type of modified risk claim to make sure that this doesn't happen, that other parties don't use the data, I think, as others mentioned earlier this morning, to mislead consumers, as we've seen happen in the past.

So I will yield the rest of my time to other speakers. But thank you for the opportunity to make these key points, and we look forward to

participating in the process as it moves forward.

Thank you.

DR. HALLMAN: Thank you very much.

Next we have Dr. Kelvin Choi.

DR. CHOI: Good afternoon, everyone.

Thanks for the opportunity for me to provide my comments on the study. I'm an assistant professor at the University of Minnesota. I do have a problem being serious; it does mean that the content I present is not serious. Particularly this afternoon and after lunch, I want to be a little more light in that regard.

I'm here also as a member of the Society for Research on Nicotine and Tobacco. As the leading international professional organization specialized on nicotine and tobacco research, we would like to let the FDA know that we are here to assist the FDA's implementation of the Family Smoking Prevention and Tobacco Control Act.

That being said, my comments, the following comments, are not necessarily reflective of the opinions of the society nor the University

of Minnesota, other than myself, and I have no financial interest to disclose.

A little more about my professional background. I received my PhD in social and behavioral epidemiology, and my research has been focusing on adolescent and young adult tobacco use, tobacco marketing, and health communication.

So Dr. Paul asked the question this morning about what we're going to with the information, and this is the purpose of the study, of the experiment, is to actually, maybe as a first step, to figure out how to effectively communicate information about harmful and potentially harmful constituents of tobacco products to the general public.

What we hope, and this would be my hope and the ideal scenario, that when the lists are being published, the smokers, or tobacco users in general, would use the lists and understand the information presented on the lists and decide either to maybe quit using tobacco products or, if not, choose a "less harmful" tobacco product.

Now, for the nonsmokers or non-tobacco users, we're hoping that if they are exposed to the list, they will use the information to decide that, well, tobacco products are really not for them and they will abstain from using tobacco.

There are a few challenges that actually prevent this ideal situation to be happening. One is that we know, among the tobacco users, it is hard to quit, and it is even harder to switch to different products.

As you can see here, representing data from the Minnesota Adult Tobacco Survey Cohort Study, so we followed smokers over time or tobacco users over time, and we found that the majority of the people stay with the product that they prefer over time.

Even if there is movement, like in a dual use group, which means they use smokeless tobacco and cigarettes concurrently at baseline, when we follow them over time, more people move to using cigarettes, which is a more harmful product, than smokeless tobacco exclusively.

The other thing I want to point out is that the idea of lower risk or lower perceived risk is associated with or triggers young people to try these products.

This is data from the Minnesota Adolescent Community Cohort Study, which we followed a cohort of adolescents through the young adult, and the data was collected when the participants were between the age of 20 to 28.

This is what we found, that the amount on the left -- you can see the amount of smokers, those who perceive that the electronic cigarette is less harmful than cigarettes, are more likely then to subsequently try electronic cigarettes, which, if electronic cigarettes are actually less harmful, that would be a good thing.

Unfortunately, the same pattern is observed among the nonsmokers who don't use tobacco products, and yet when they perceive electronic cigarettes as less harmful than cigarettes, they will subsequently go try electronic cigarettes.

Now, the tobacco companies know all about

this, as we have discussed this morning. They use the descriptor of "low tar," "light" kind of descriptor to trigger young people to using these tobacco products.

But this is actually not assessed in that experimental study, and I think this may be something that subsequently you would actually address in terms of the relative risk to regular cigarettes.

This is the third challenge. It's just, simply put, when we talk to young adults, smokers or nonsmokers alike, they don't evaluate risks of tobacco products in a single dimension continuum. And it seems like the lists, the prototype discussed this morning, kind of addressed this issue, so I'm not going to go into details.

So my examples of the challenges just highlight how difficult it is to actually achieve this ideal scenario just by putting out the list available to the public that would have these tobacco users quitting using tobacco or using a less harmful product, or for the non-tobacco user

to actually stay away from it because of the list.

If we have to do this -- and it seems like we have to; it's mandated -- this may be what we want to do. Instead of just comparing tobacco products against each other and try to rectify the risk of these products against each other, maybe we should associate the risk of using tobacco products with daylight activity, like driving.

Every year, driving kills 40,000 Americans in a year's time. Every year, tobacco use kills 400,000 people. That may be a better comparison that people can actually fully comprehend the extent of the harm and the risk associated with tobacco use, regardless of presence or absence of particular harmful or potentially harmful constituents. By the way, driving and texting kill 4,000 people a year, and we all talk about the risk of it.

A couple more comments specifically to the study is that I'm glad that the study mentioned the associating of the exposure to the prototype and the perceived risk of the tobacco products. But I

think some of the panelists also mentioned this morning is that it would be better if we can actually assess what they do with the information. For example, whether it doesn't actually affect their intention to continue to use the product among tobacco users, or among the non-tobacco users, would then the people exposed to the list be less likely to think about using these products subsequently?

Also, the study did not actually take into account the brand loyalty of the consumers to the product they choose to use. The prototype being used is kind of a hypothetical brand X, so it doesn't really tap into a specific brand when somebody have an emotional attachment to the brand, which research show that they are highly likely to discount any factual information that disagree with them.

I think the other thing that I just picked up from another speaker is that I think we must think proactively about what and how the information can be misused by other parties. And

maybe one way to do it is actually hire the marketing firm that work for the tobacco company to actually look at this data and see how they can use it to actually promote their product, sell more tobacco products for the tobacco company.

One last comment I want to make is that in terms of public displays, I don't know whether that would be a good idea. But if we can blow it up in a font size 50 and put it in every point of sales, it may be a good message to have there. Thank you.

DR. HALLMAN: Thank you very much.

Next we have Jim Dillard.

MR. DILLARD: Good afternoon. I'm Jim Dillard. I'm senior vice president for regulatory affairs at Altria Client Services. We provide regulatory and health science services to the Altria family of companies, and I'm here today on behalf of Philip Morris USA and US Smokeless Tobacco Company.

I'd like to thank the FDA and both committees for the opportunity to share our perspective today on the Section 904 requirements

to publish the harmful and potentially harmful constituent list.

Our remarks today will address some concerns that we have with the validity of the HPHC data, some questions that we've raised and other stakeholders have raised about publishing the list, and some potential solutions that you might consider as you're thinking about these preliminary data and other data that might be generated to support publication.

We've provided our perspective on the collection and public reporting of the HPHC data in a number of ways, including through written submissions, meetings with the FDA, and participating in agency-led constituent workshops. Our communications on this topic have really focused in three primary areas.

First, we encourage the FDA to define the intended purposes for developing the HPHC list and the goal of making the information available to the public. We are pleased that one of the topics being considered today is in fact spot on with this

objective.

Second, we encouraged FDA to lead development of validated, standardized methods for testing HPHCs, of which Mike Ogden spoke in great detail earlier. For example, for smoke constituent testing under the ISO smoking conditions, only 14 of the 18 constituents on the abbreviated list have standardized methods developed through a voluntary consensus standard process. There are no standardized methods for the Canadian intense smoking condition. For tobacco, both smokeless and tobacco used in cigarettes, it's only 3 out of the 9 constituents.

This is important because in the absence of validated standards, manufacturers and contract labs have likely adopted different methods to measure the abbreviated list, which gets me to my third point, and this is that the lack of validated and standardized methods means that the HPHC data are inconsistent for product comparisons and other regulatory purposes.

We were pleased to participate at the July

FDA-led workshops on constituents that began to address many of these issues and encourage FDA to continue this important work.

As I said, Dr. Ogden reviewed much of the results that we put together as an industry group just on the reference product, and this analysis confirmed that laboratories have independently developed, validated, and implemented methods according to their own internal processes. It also showed significant temporal variation and statistically significant lab-to-lab differences for some of the constituents under the ISO and the Health Canada testing conditions. And it really raises concerns about the validity of this entire data set.

Publishing the HPHC list is a topic of great interest to many, including public health agencies, tobacco control organizations, and tobacco product manufacturers, as you've heard from all of us today. We and many others have submitted comments to the FDA when it first proposed conducting its experimental study.

I've summarized here some of the broad themes and questions raised by many stakeholders, and we believe these are all important questions for you to consider as you review the experimental study results.

The first question: Given that much of the data is not from standardized methods, how will the agency communicate the HPHC list? And I won't read them all, but these are questions that we have posed to the agency in future meetings.

I want to raise an additional point. We and others have shared perspectives with the FDA that it's important for tobacco consumers to understand that the HPHC data are from machine testing and do not necessarily reflect human exposure.

In May 2012, FDA responded to these comments to OMB and said, "FDA agrees that the list format may have the potential to mislead consumers, which is why FDA plans to conduct an experiment with consumers to assess the impact of various formats of the HPHC lists on consumer comprehension

and precursors to behavior such as beliefs, attitudes, and intentions.

"The study will assess various formats for conveying the communication goals enumerated in this document, such as the uncertainty about the information contained in the list; that other relationships between the constituents and tobacco products and health problems may be discovered in the future; that the values are the results of machine testing; and that exposure to the chemicals also depends on other factors such as the variability of human use."

Much of the other proposed language on the stimuli is directly assessed, but we cannot find items in the survey that pertain directly to machine testing of human consumption, which are important factors. And this may be very important as we think about additional follow-up research.

I've raised a number of questions here. I also want to offer you some points to the committee as well as the FDA that might be helpful as you consider what some next steps might be with respect

to publishing of the list.

First, some of the HPHC data do come from validated and standardized methods. This would be true for nicotine and carbon monoxide. FDA might consider a near-term step of publishing only those data that are known to be of good quality through validated and standardized test methods.

Health Canada's efforts may also be informative, and we heard a little bit about that this morning. They changed their conclusion about how to talk about constituents following research, which concluded, "That the numerical values are not clearly understood by some smokers, and that most have little idea what the range of numbers displayed for each chemical means." And as we heard, Health Canada requires now more descriptive language.

We would strongly encourage FDA to make the experimental study results available for comment by a wide variety of stakeholders. We share that with some of the other stakeholders today. And given the importance of this topic and

the fact that many of us have just seen recently these preliminary survey results, this would allow for a more in-depth review and commentary back to the agency.

Finally, FDA indicated that later this year it would issue Section 915 regulations that would detail future testing and reporting of constituent requirements on ingredients and additives. Given the issues discussed here today and the fact that many of the constituents on even the abbreviated list still lack validated standards, we believe that FDA should consider delaying those future requirements.

Thank you for your consideration today. I'm happy to answer any questions if you have any.

DR. HALLMAN: Thank you very much.

Finally, we have Christopher Proctor.

MR. PROCTOR: Thanks. Good afternoon. I'm Chris Proctor. I'm the chief scientific officer for British American Tobacco. I want to give you some data from a study which we are just writing up that wasn't designed to interrogate the

impact of information on harmful and potentially harmful constituents on behavior, but because the study didn't go as we might have planned, it actually provides some data on that. So hopefully it will give you a little insight into that. If I could have the slides up, please.

(Pause.)

MR. PROCTOR: I can also talk and I can tell you a few jokes. The slides are actually quite important because they illustrate -- let me at least start into this. So what we were doing --

DR. HALLMAN: Give us a minute, and we'll pull your slides up. I'll allow the time.

MR. PROCTOR: Fantastic. Thanks.

DR. HALLMAN: What we'll do is we'll take a five-minute break, we'll pull up your slides, and then we'll allow you to do it with the visual aids.

MR. PROCTOR: Thank you very much.

(Whereupon, a brief recess was taken.)

DR. HALLMAN: All right, ladies and gentlemen. If you would take your seats again,

please. Apparently we have visuals.

MR. PROCTOR: Fantastic. Thank you.

Really sorry about that, and I really hope this is worth it now.

(Laughter.)

MR. PROCTOR: At least you got a break.

I'd like to acknowledge my co-researchers on this, Jim, Nick, and Hermione. I'm going to present you some data which wasn't designed to test what you're discussing today, but because the study didn't go quite the way we had hoped it did, we ended up getting some data which might be relevant to the risk communication of harmful and potentially harmful constituents.

The study's a clinical study, six-month clinical study, looking at switching smokers in a forced switch design from conventional cigarettes to cigarettes with reduced toxicant levels, prototype cigarettes, and measuring biomarkers at exposure and biomarkers of biological effect. It's a study which, as we always do with clinical studies, we registered the trial and we published

the protocol in BMC Public Health.

The test product is a cigarette that looks like a kind of shortened cigarette. At least, it's got a large filter on it. It's because we put technologies into it to reduce substantially some of the harmful and potentially harmful constituents. And this technology is both in the tobacco and in the filter. So it looks and smokes a little like a cigarette, but it is also a little different.

The control product is a conventional cigarette, actually from the German market. This was a study done in Germany. And we at the switch point changed that product only by changing the tipping paper, from a cork tipping to a white tipping, just so there was a change.

Because we always go through proper clinical procedures in doing these studies, we had to get informed consent, and we gave a subject information to all the volunteers. That subject information included that the products, under laboratory analysis, had levels of toxicants that

were lower than conventional cigarettes, and that the purpose of the study was to try and find out what is the potential effect on the body by lowering those concentrations.

In a study we'd done previously, which was only a six-week study, we found really relatively little difference in consumption as the study progressed. But this was a six-month study designed so that we could actually get some biomarkers of biological effect data.

The study is broadly ambulatory, with occasional clinical confinement. We started with 140 smokers that, for the first month, were all smoking the control product, and then were switched, 70, to the reduced toxicant product and 70 to the control. We also analyzed the ex- and never-smoked data just to get a comparison, particularly on the biomarkers of biological effect.

This is the important slide in terms of why it didn't do what we would hoped it would do. So they started off at typically 20 cigarettes per

day consumption, and you can see the left, the blue, is control; red is the reduced toxicant prototype.

Where we circle, we got clinical confinement. So we bring the volunteers to clinic for a couple of days so we could do 24-hour urines and blood analysis. They also checked in in a more ambulatory way. And you see we go from 20 cigarettes a day to, in some cases, considerably higher than that, almost up to 30.

This concerned us dramatically. We set up an independent data safety monitoring board. We got in contact with our ethics committee. And what the board decided and what the ethics committee agreed is that rather than cease the study, we should set off a questionnaire which asked, why were these consumption differences happening in the study, particularly when it was happening for both control and the test product.

This is data from that, and we got a 4-point score of a preset questionnaire. We did two things. We asked kind of free questions, and

then we did a preset questionnaire. The 4-point score, the 1 doesn't apply at all, the preset question "For it complies completely." And then we converted those into percentages, so a 1 would become a zero percent and a 4 would become 100 percent. So this is how we got the scores.

You can see the thing, both for control and for the reduced toxin prototype, that was driving it mainly was, "The cigarettes don't last as long as my normal brand." Quite bizarre because actually, in the control case, these were exactly the same cigarettes; they just had a different tipping on them. And in the product, which was the reduced toxicant, there were some differences, but there shouldn't have been that many in terms of those consumption features.

The one that is particularly interesting, the third one down, so the people who were smoking the reduced toxicant prototype cigarette were more likely to say the reason they're consuming more was because they thought the cigarettes to be less harmful than their usual brand.

If you look, then, further down one more, the driving force for the people who were smoking the control cigarette was because the cigarettes were free of charge during this period. That was the study design.

If you did the free text, we just simply asked the questions, "If you were to change your behavior, why did this happen?" For control, it was availability and the thought they were smoking faster. For the reduced toxicant prototype, it was format. It was effectively half a cigarette with half a filter, a reduced sensory. And some of those thoughts of reduced risk potential of these really weren't being volunteered.

You have to remember, we weren't giving any messages to the volunteers at all apart from that first setup questionnaire -- or not questionnaire, the subject information, which gave them the informed consent right at the beginning. So during the whole of the period, we weren't informing them anything about the study other than they were coming to the clinic, obviously.

We made sure that we went back to the ethics committee and said, we need to just study these post-study to see whether this effect is a permanent effect or it returns back to normal. And what we found is that post-study -- so people came off the study, they went back to normal consumption of cigarettes -- they returned to their normal consumption, if anything a little bit below. We also were obviously putting in a whole bunch of cessation advice and clinics at that stage.

So just to conclude, the study wasn't designed to look at the kind of issues you're dealing with today, but as a consequence of what happened, it may provide some useful information.

I don't think we can, from our study design, tell you the driving force of those additional consumptions was simply information about toxicant levels or harmful or potentially harmful constituents, but I think it's quite likely. The factors are related both to study design, the subject information, and the project features that were changing some of the behaviors

that were happening in this study. Thank you very much.

### **Questions to the Committee**

DR. HALLMAN: Thank you very much, and thank you to all of the speakers for taking the time to provide public comment to the committee.

At this point, we're going to shift to perhaps the most difficult part of the agenda, which is to try to address the questions that have been posed to the committee by the FDA.

So Dr. Choiniere, maybe, if you'd like to start with the first one, and then I can adjudicate.

DR. CHOINIÈRE: So to reiterate the first question, given the statutory requirements on FDA to put this list on public display, what potentially important communication objectives for the HPHC list should FDA consider when fulfilling its statutory obligation?

### **Committee Discussion**

DR. HALLMAN: We'll begin with Dr. Sleath, Dr. Paul. Wrong hands. Dr. Cohen, please.

DR. COHEN: Great. Well, I think this has been addressed already. We know that it's very hard even for literate people with content knowledge to understand the quantitative data despite the mandate that the FDA has to publish that information.

So I think in terms of the communication objectives, I think the key thing is to be able to distinguish between major relative classes of products and make sure people can understand risk information, or the risk quantitative information, across classes of products that have actual differences of risk; and in terms of not misleading, being misled, is that they're not going to interpret differences within classes of products that really aren't different.

So to me it's having measures that can distinguish across major classes of products and be able to tell relative differences when there are differences and not infer differences when there are not, none of them.

DR. HALLMAN: Dr. Paul?

DR. PAUL: I'd like a quick clarification in return. Reading the charge from Congress, it does not appear that there is a requirement to publish quantitative data. It is only that you must publish lists -- because this is what it said. So the issue is, is the requirement --

DR. CHOINIERE: I don't have the --

MR. ZELLER: It's the opening slides.

DR. CHOINIERE: So we have a requirement first to establish a list of just the constituents. But then if you look on my slide 6, it does say that, "Publish in a format that is understandable and not misleading to a lay person, and place on public display the list in each tobacco product by brand and by quantity in each brand and sub-brand."

DR. PAUL: The question becomes, for me, when you talk about communication objective, the concept of usability, which is, what do you want the person to do with the list? How would you expect them to use it?

We've been talking about this. Do you want them to just read it? Do you want them to

take away a message, to form their own message? So it seems to me that usability implies a use you have in mind for it.

If they're going to -- we've been driving at this from different aspects all morning, which is, do they just simply get the information? Do you want them to walk away with the idea that cigarettes are harmful, that tobacco is harmful? And is the fact that they see this list going to get them there?

If that's the case, then you need to decide -- and in my case I would think you would want to make this as clear as possible -- cigarettes are harmful. Tobacco ingestion, tobacco smoking, whatever, is harmful. And that's the information you want them to get. That may be the primary communication goal of this list. But it's not a new piece of information. They obviously have heard this again and again and again.

So there's got to be more to what is usably pulled out of the list, whether that is

something like relative amounts, which we've heard over and over again we don't want, or the idea -- I lost my thread there -- the idea that you don't want people to even get started. But that wasn't where I was going. So I'm going to stop here before I get more confused. Sorry about that.

DR. HALLMAN: Is there a response?

DR. CHOINIERE: I think we would be interested in hearing what other committee members have to say in response to that comment.

MR. ZELLER: Yes. The only thing I would add is Congress must have assumed that if this could be done in a way that was understandable and not misleading, that there would be some good that would come out of that. What we're asking for help on is assuming we can meet the statutory standard of doing it in a way that is understandable and not misleading, what are the potentially important communications objectives that could come from it?

So I hate to answer a question with a question, but it's why we brought the committees together, assuming we get to a point, based upon

the research, that it can be done in a way that meets the standard of being understandable and not misleading.

DR. HALLMAN: Dr. Rutqvist, then Sleath, then Huang, then Turner, then Bickel.

DR. RUTQVIST: I think when communicating quantitative data on HPHCs, there are several layers of complexity in translating that kind of information to exposure, and ultimately, risk, which I think many lay persons will do when they see that kind of data.

One of the perhaps most important considerations was brought up during the public hearing, and that is the lack of validated methods for actually the majority of HPHCs that have been identified by the FDA.

Just to expand on what Mike Ogden presented, in our experience, if we sent out the sample of smokeless tobacco to ten different well-renowned international laboratories, the same sample, for instance with aldehydes, we get a variation in the results with a factor of ten. And

I think it's very important when you communicate those data that you make the public understand that this is an inherent problem in the data.

Also, I'm a bit concerned about the type of risk communication that was included in the trial that was presented this morning. I think the only risk communication message was, there is no safe tobacco product. And this may be technically correct, but then again, you could say that about any consumer product. And I think that statement doesn't adequately reflect the present state of science when it comes to comparisons of using cigarettes versus smokeless tobacco of the type that is prevalent in the U.S. and in Europe.

I think that that risk differential should be conveyed to the public when these data are presented. In Europe, for instance, this is reflected in the warning labels that are included, where the cigarette packages have these standard warning labels warning for cancer and other diseases, whereas smokeless tobacco have a more generic warning of addictiveness and that it may

harm your health.

So I think this distinction should be made because there is this risk differential, even if the reported levels of HPHCs may seem to be the same between a lot of cigarette brands and smokeless tobacco.

DR. HALLMAN: Dr. Sleath?

DR. SLEATH: I have a different train of thought for an objective, is I doubt this list will be used in a vacuum. So I think it's important to think about health care providers or other people that a consumer might take this list to, and making sure that you develop training programs for whether it's pharmacists, physicians, nurses, so that when you do your testing, I think don't just test it with lay persons but also with health care providers to see if they can even comprehend what it means to maybe a patient they have that wants to consider quitting smoking or reducing risk of certain things.

So that's just something when you were talking this morning that came to my mind.

DR. HALLMAN: Dr. Huang?

DR. HUANG: Yes. I think some of the communication objectives relate back to the potential opportunities and challenges that you identified in the earlier presentation, recognizing that a large proportion of smokers in the U.S. are unaware of the constituents in tobacco products and tobacco smoke.

So there's opportunity to increase public awareness and understanding of the presence of some of these in regulated tobacco products. And so I think that that's what some of the future studies really need to look at in terms of the messaging. Because I agree. It shouldn't be a relative comparison, but just the fact that this product contains -- where there's 100 nanograms of radioactive polonium or arsenic or cyanide or something, what is the response to that? What sort of effect does that have on behavior?

But to really get away from making that comparison that one's safer or not, but that all of these have this level. And I'd be curious to test,

is it more relevant and seems less just generic when you actually say, this 100 nanograms of this in this, and it makes it more real, possibly, versus -- but again, not misusing that information in a comparative way, but just the fact that it actually has this measured amount. What is the response?

DR. HALLMAN: Dr. Turner?

DR. TURNER: I have two potentially important communication objectives that you might consider, and the first loops back to Dr. Cohen for a second regarding understanding whether or not the presentation of the material is misleading.

Our current experiment certainly tells us a little bit about comprehension, but low comprehension isn't the same as having been misled. So we need to understand whether people are misled by this presentation of information. And certainly it could be the case that presenting the quantitative information is what misleads, and that's what Congress would then have to understand, that both of those objectives they wanted you to

meet are impossible together. But we would need the experimental data to know that for sure.

If I may be so bold as to give you a methodological suggestion, you might even consider in the next study using hits, misses, and false alarms for the comprehension measure because I don't know if you're familiar with that paradigm, but certainly it would be something to say that a false alarm is where people think they got something out of a message that was never there. Right? That is showing that they were actually misled by the message, if we could actually objectively enumerate how many false alarms people had after being exposed to a certain kind of message.

My second recommendation for these communication objectives is about the format of the risk message. Certainly in this experiment we used the word "format" a couple times, but the accurate issue is that all three messages were one format. They were a table. And that's okay.

You did vary the amount of information

people saw, and so that's really what we have is, does the amount of information affect comprehension or harm reduction, those kinds of things? But these lists can be presented in numerous ways. There's risk ladders.

If you even just -- I know you know this, yes. But even looking at Edward Tufte's work on how to present numerical information to people or just information to people in graphic ways that increases their understanding. And I would suggest that that would be the communication objective, is to figure out how to best present this information to people so that it had meaning versus just the amount of information.

DR. HALLMAN: Dr. Bickel?

DR. BICKEL: Yes. My suggestion is how you deal with these lists really depends on how you curate them. Imagine if you go to a website and it says, "Below is a list of all these products," and you can drill down further to look at all the constituents.

But all the ones in this list have

comparable risk. That is, there's a lack of sufficient evidence to be able to distinguish them in terms of their health outcomes. Then you're conveying, I think, who cares about the variation in some of the constituents. I think you've laid out an important message to the people who are going to look at it; all these things are comparable. And when there's meaningful differences, then you can start developing other categories that would be part of the curation of these lists.

The idea of just having an endless series of lists of thousands of tobacco products doesn't make a lot of sense. But if you curate them in the right way, I think people could understand and not be misled. Any variation they see in this list of products are not meaningfully different, at least on the evidence to date.

DR. HALLMAN: Dr. Samet?

DR. SAMET: So if you look at how many compounds are said to be present in tobacco smoke, the figure these days that's given by CDC, I think,

is 7,000. We're dealing with 93 that have been identified for various reasons and based on various prior reviews that they have specific toxicities.

Nicotine is an agent of addiction. Some of the others have specific toxicities. But undoubtedly, the different organ outcomes are determined by multiple compounds and their actions and not typically, unless the science leads us there, by a single agent.

I think, in thinking about what should be communicated, I see two things that should be separated. One is what is present, and that is a list of components that have been identified individually as having one or another toxicity. And then the second is the quantitative information.

It seems to me that in terms of communication, we are able to communicate that a specific set of compounds have been identified that affect reproduction, affect the heart, affect the lungs, and so on, and that needs to be communicated.

I don't know that the public wants to know the toxicity of each individual component. That is too much to ask. I think none of us can list all the toxicities of all 93, unless it's perhaps David. But I don't -- he can't do it, either. So I don't think that's something we want to achieve.

As to the quantitative information, that becomes much more problematic. Of course there's measurement error, and so on. I think that's beside the point. I think, in fact, we aren't ready to communicate about the risks or to say that lowering or raising the level of any single component is necessarily indicative of overall mixture toxicity.

There's a lot of work underway, a lot of work that will be undertaken. And I think the state of the science will advance. So my suggestion at this point is that the communication objectives should focus on the qualitative side, the presence of compounds of known toxicity, that in part we acknowledge that there's quantitative information.

But Congress has said, make measurements. Measurements will be made. And I think our ability to interpret those measurements will advance. So perhaps there should be some staging of the approach to this very challenging problem. And I think the potential to mislead perhaps comes more on the side of over-interpreting differences in levels across products or in a product over time of single components. I'm just not sure we know how to do that yet.

DR. HALLMAN: Dr. Eissenberg?

DR. EISSENBERG: Yes. I like what I'm hearing from a lot of the folks around the room. And so what I'm going to say is probably going to just reinforce some of what you already heard.

It was, I think, Dr. Clanton who said it first, but others have followed on, that this actually presents a great opportunity for FDA, this list issue, not so much for the presentation of the list itself but, rather, for the opportunity to first reinforce the full range of health risks that are associated with tobacco use in all its forms;

and then second, where applicable -- and that's an important first clause -- where applicable, to reinforce the idea that the risks might be greater with some classes of tobacco products, not some individual products but classes, relative to others.

So for me that's the opportunity presented by the lists. The lists themselves, I liked Dr. Bickel's method of grouping them. I think that's a great idea. It sort of reminds me of Sesame Street; one of these things is not like the other.

What surprised me, what I guess I'm looking forward to in the future, is FDA studying through formative work, as we already heard about, and then advancing forward, how consumers would see the data presented in the lists contributing to this idea of reinforcing the notion of the full range of health risks associated with tobacco use, and how some of the data, where applicable, might help them distinguish between those classes of products that have greater health risks versus

those that -- well, let me stop there, greater health risks.

So clearly, for instance, with regard to carbon monoxide, when smokeless tobacco products are used as intended, there isn't a lot of carbon monoxide exposure relative to cigarettes. And how would that information be useful for a consumer, and what would it mean? That seems to me the types of questions that we should be asking in our formative work.

DR. HALLMAN: Dr. Lawson?

MS. LAWSON: I think maybe some of the comments have already addressed what my concern was because I had the same question as Dr. Paul about what we would do with the lists. And the question is, it would be on public display.

So I was thinking that perhaps the communication objective could be that we would develop a public awareness campaign that had the benefit or input from health professional and consumer leaders so that the campaign is fully understood by all of the segments of the

population, that it's really geared not for one audience but for the multiple discipline audiences that we're trying to reach.

DR. HALLMAN: Dr. McAfee?

DR. MCAFEE: Great. Thank you very much. I think part of what you're hearing is that you may be making it more complicated than it has to be in the sense of just because you have a requirement from Congress to make a list of constituents publicly available, that's not the same thing as a requirement that you aggressively communicate this to 40 million, 45 million, tobacco users.

So they're very different questions. To me, I think it's pretty clear that just risk communication 101, that the idea of taking a very large, complicated, or even a distilled down harmful constituent list, there's a lot of risk.

Actually, if you look at your list of nine concepts that you want to guide it, eight of them are really risk mitigation; how do we make sure we don't screw things up by doing this list? And one of them, "Science has linked the chemicals on this

list to health problems or potential health problems," is a message you want to get across.

So to me, that's symptomatic. If eight out of nine of the things that you want to make sure are happening are things about why you shouldn't take this list too seriously -- it doesn't include all the chemicals, the chemicals listed don't necessarily indicate the likelihood -- if eight out of nine of those could do harm and there's one you want to do, then maybe the list is not the main thing you want to push.

You've got to put it up and you want to make sure it's not itself -- but again, there's probably going to be -- it'll probably be 500 people that'll be looking at it, but it's not going to be 40 million.

But you've got at your fingertips mechanisms to communicate with consumers in the U.S., smokers, nonsmokers, that are in the tens of millions of people, and that's what you really -- and to require things to happen around it, and that's what you really want to look at.

And it just doesn't seem like that's probably going to be a list.

I just also wanted to highlight -- I thought the point that the speaker, Dr. Choi from the University of Minnesota, made about comparators was also important, that people don't know anything to do with nanograms per milliliter or something like that. It's totally meaningless. So there's no point in giving an ordinary human being those numbers without some kind of comparator.

You could give non-tobacco comparators -- how does this compare to orange juice? How does this compare to something that you might think you were scared about, like exhaust fumes in Los Angeles or something?

Then the last point I want to make, though, is that it of comparators, there was another thing that actually worries me and makes me even more nervous about this, which is actually from the data, which was slide 30 in the data slide, which is the one that shows the smokeless tobacco people.

When I first thought about -- well, finally, we've actually made something here, the smokers, even though it's significant, there's really no meaningful difference between the controls and the people that got this thing, like a tenth of a percent or something. But in smokeless, you successfully increased their perception of harm closer to the perceptions of harm associated with cigarettes.

But then as I thought about this, I said, well, wait a minute. Is that what you want to do? In terms of this issue of categories, just giving people the data without a way to compare it, one might argue, actually made their harm perceptions less accurate because now people who are using smokeless tobacco are more likely to think that the risk is the same as the risk with cigarettes. And on that happy note --

DR. HALLMAN: Dr. Wolf?

DR. WOLF: I'm just going to be brief. This is not my area of research; I mostly spend time on medication adherence and issues on the

safety side with the risk communication group. But it does feel like this is a distraction, I think, a lot of what's been said. You have a lot of information, and I think the Legacy presentation as well. It may confuse people, and you're concerned not to make sure that they confuse them in the wrong direction. And I think that point's really important.

But I understand if this is like a congressional mandate and you want to make sure that the information is understandable to the point that it can be if people choose to use it or go get that information. And I think this was mentioned by Dr. Clanton earlier, that what is the onus that you're really putting on this?

The reality is, this is going to be like -- I'm doing a lot of work right now that made the analogy I was thinking. This is like the benefit summaries of your health plans, where you're going to get that 200-page booklet and you're going to put it away, and nobody really cares if you read it so much. You're going to go

to a summary of benefits, or there's other directions, but it's a check box that you have to make.

But if you do want to say that, I want to give you this list that is just going to make you completely think to some people that, wow, maybe I should quit because there's lots of harmful stuff here, and whether you chunk the information and just kind of say, here's everything and here are all the -- that magnitude of harm, and maybe there is a signal that we saw in the data this morning that suggests that, in fact, this improved comprehension with this supplemental information is helping people think their perceptions of harm are changed for the better in the public health direction we want, maybe that's of value.

But it's kind of a health literacy angle where we do a lot of our work in that space. You can limit it in layer, and it may be only of value to 10 percent of the population who want it and maybe are at that moment of decision-making, and that's great.

But to spend a lot of time to really be concerned that whether or not this is going to change the behavior of the majority of people, or if they're going to read it or be attentive to it, I think we have to have realistic goals as to what you're going to expect out of anything that is conveying this intense and incredibly complicated info.

DR. HALLMAN: Which brings us back to the question, what potentially important communication objectives should FDA consider? That's sort of the root of the question here.

So I have Dr. Heck, Dr. Clanton, Dr. Huang, and Dr. Paul, and then Dr. Strickland.

DR. HECK: I just had kind of a thinking-out-loud moment during some of the prior comments, and I don't know the answer to this. But I think most of our shared concern here deals around the quantitative information. Is it solid, or will it be misused, or could it be misinterpreted?

Is it possible to meet the statutory requirement for both qualitative disclosure and

quantitative statement with a kind of a qualitative statement of quantity? Something similar to, product X contains benzo(a)pyrene in quantities likely to or highly likely to or possibly sufficient to raise your cancer risk, something along that line, where you're getting a weight around the quantity without getting down in the complexities that accompany trying to specify a number or a range.

Something like this, if that were an adequate way to express quantity, there might well be products or product classes down the road where entire categories of compounds are missing. And those products might have other categories that are appropriately quantitatively appropriate for a message.

So I'm trying to back away a little bit from the precision, or artificial precision, of these specific numbers to get the underlying message. There are lots of carcinogens, let's say, in cigarette smoke. We don't know for sure which ones are the key players. It's probably many. But

a lot of them are there in sufficient quantity in probably all cigarettes that that message, that quantitative information, could be, in a qualitative way, communicated.

DR. HALLMAN: Thank you.

Dr. Clanton?

DR. CLANTON: Mr. Chairman, I've actually been staring at the communication objectives and fulfilling statutory obligation for the past 20 minutes or so, and it looks like one of the best ways to offer up suggestions and to understand this is through communicating three words that have D's in them.

For communication, there are really two fundamental ways. One is disclosure and the other is dissemination for the purpose of changing health behavior or health outcome. And the reason why I want to separate those is that disclosure is not the same thing necessarily as dissemination, and dissemination is more complex than simply disclosing. So the two possible ways of going about this is to simply disclose.

I would agree with what we've heard thus far is that assuming analytical chemistry is at a state, it's fairly easy to figure out whether something or a substance exists in a product or not. There may be great variability, as we've seen in terms of its quantitation. But the techniques are pretty good at figuring out whether arsenic is there or not or radioactive polonium is there or not.

So disclosure and using a qualitative presentation, I think, would meet the third D, which is, do not deceive. Actually, deception is an adequate synonym for the word, do not allow people to misunderstand things.

So the idea here is not to deceive. And again, qualitative presenting a list, disclosing a list, I think is fairly easy to do. But with that said, it appears to me, based on the question I asked before the break, that there are infinite and unbound opportunities to use these data and other data for the purpose of dissemination around risk related to these substances and opportunities to

reduce risk as it relates to being exposed to these substances, and that the legislation is not in any way constricting, I think, the FDA in sending out health messages through dissemination.

By the way, campaigns are a normal or normative way of doing dissemination, media, through various channels; are normative ways. A list might be one of many ways of disseminating, but it is not an adequate way to disseminate anything.

So I would say three D's. Either decide to disclose, and if you decide to disclose qualitatively, I think you'll meet your statutory obligation very simply. Number two, plan to disseminate using a more complicated -- or not complicated but complex -- suite of methodologies that are used in a standard way to communicate risk and risk reduction. I think you can do that without confining yourself to a list.

DR. HALLMAN: Dr. Huang, you're up.

DR. HUANG: Yes. I really would support the disclosure concept, and also what Dr. McAfee

was talking about earlier, keeping it simple and not making this too complex.

I think the complexity also is if you -- it also gets back to that question, are people going to really look at this information? And if you have this huge table of everything, people are just going to gloss over them. But to really hone in on the messagings and the disclosure of what specific ingredients are in these products, they get to some of these education and messaging opportunities that have been identified.

The one issue that has been brought up that I think does complicate things, and I would encourage, again, keeping it simple, is even when you're talking about the different classes of products and differences -- because there are still the different population effects and the aspects of whether dual use and effects on those that -- I think when you start getting into that area, that's where there's potential for misuse or misinterpretation and misleading or muddying the message.

Whereas if it is a simple message of disclosure that these constituents are in the products, that's very simple. It's very straightforward. It is not misleading. It's understandable. And I would encourage not getting into that area of even trying to go with different classes.

DR. HALLMAN: Dr. Paul?

DR. PAUL: Just looking at where it appears you're standing right now, you have a mandate to do something, and the lists exist. You have to make them quantitative.

There's just a certain amount of material that -- I mean, you can't back out and say, regardless of the fact that we think the lists are going to be not looked at because they're quantitative and they're mega-miles long, it doesn't matter. That's where you're stuck, as far as I can see. You have to implement what you're being told is the law of the land. Okay.

So the question then is going back to what are potentially important communication objectives.

Once you've got the numbers out on the website, you can't control how people use them. That's going to be a given.

So the issue is, what do you tell people, which is what we're asking. And you've already made a fairly good stab, I think. You and the research have decided what is one of the key objectives of exposing people to the list, is the perception of harm. What do you want them to know? That cigarettes and tobacco contain harmful substances. That's one of the statements in the augmented piece at the front end.

So that's one of the statements that's going to be part of your campaign. And the other thing that I keep hearing -- at least, that's from my perspective right now -- is the uncertainty around that because we -- uncertainty not around that they cause harm, but the uncertainty around the quantities so that you don't want people to make relative statements -- because this has less or that has more, they cause more or less harm.

You want them to know that these

constituents are what they say they are, harmful and potentially harmful constituents of tobacco, either naturally occurring or additive, and that these are not -- and that the numbers that you presented in looking at them don't necessarily imply that one is worse than the other. I think this has been mentioned by several people.

But if I'm looking at what you want to get from those lists, you want people to look at them and say, yuck. I don't want to put this in my body. There is harm potentially from this. It's also new information from what they may have seen on the Surgeon General's sign on the tobacco packages.

It seems to me that at this point there should be some easily identifiable, maybe even certain constituents that are the most commonly occurring, that could be constructed -- you can construct a message that could -- again, I don't know what the legalities are -- that goes back and replaces the Surgeon General's or is in addition to the Surgeon General's warning that says, these are

harmful constituents and potentially harmful constituents in tobacco, but this is only a partial list. There are a zillion of them, or whatever, 93. You're not going to put 93 on the package.

But I think you already made certain assessments when you did your research as to what people need to know, what you want them to get from the list. So I will say that you've already to some extent answered your own question.

DR. HALLMAN: Dr. Strickland, you in fact are up.

DR. STRICKLAND: Okay. I'm just going to really spin off of what you said, Dr. Paul, with a more pragmatic suggestion for an objective.

It seems to me that we're really dealing with how do we deal with these misperceptions when you've got this list and the data. And so one of the things I was thinking about was the importance of partnerships. You could have an objective that you aim to partner with the National Cancer Institute, the Cancer Information Service, the American Cancer Society, the Heart Association, the

Lung Association, and you have your concepts that you want to move forward. And you have some research that suggests the direction you want to go.

So you could partner with these agencies to explore ways to do this offset in terms of the potential miscommunication/misunderstanding, particularly the Cancer Information Service and the American Cancer Society, where you can have people call in and speak to individuals who could help people understand and interpret the information, but not suggesting how you work with these organizations; explore with them ways that they can work with you to help achieve these objectives.

DR. HALLMAN: Dr. Krishnan-Sarin?

DR. KRISHNAN-SARIN: I would just like to add, I agree with everything that was suggested about having a clear list on the FDA website about all these ingredients, about what their contents are.

I'm going to argue, people have brought up this issue earlier about how testing, machine

testing, may differ from one place to the other and the content, actual content of the amount in there is going to differ from one place to the other.

But isn't that what smoking these products is all about? Every smoker is going to get a different dose of these products, depending on how they smoke it. So any machine test is never going to give you the exact amount that a smoker is going to ingest of any of these compounds.

So I think when the lists are presented, they need to be presented with a lot of caveats on your website, including the fact that your intake of these products is going to be altered by how you smoke them. It's going to be altered by genetics. It's going to be altered by race. It's going to be altered by age, your weight.

All these things need to be listed in big, bold letters on the site to let people know that this is not an all-in-one thing. This is not like a drug or a pill that you pop that you're going to get exactly the same amount of the medication every time you put it in your mouth. You can actually

vary how much of all these products you're going to get. So that's one issue.

I would also suggest that this list be accompanied -- not necessarily that everybody's going to look at it, but the list needs to be accompanied by literature about each of these 93 compounds and at what dose levels they actually produce the effects that they are supposed to produce if there is literature supporting that.

So if there is a dose level of a particular compound which increases cancer risk, that needs to be part of that background material so people, if they want to access it, they have the option of accessing that piece.

My last suggestion is that all tobacco products that are marketed out there, and I believe somebody mentioned this already, need to have a link or this website or whatever it is where you're going to display this information. The information needs to be clearly listed there so people know that if they want, they can go and access this information for themselves.

DR. HALLMAN: Maybe. I said maybe.

DR. KRISHNAN-SARIN: Maybe.

DR. HALLMAN: I haven't had a chance to ask questions or make comments, so I'm going to jump in here.

It seems to me that inherent in the question about what potentially important objectives should FDA consider in terms of what messages, what communications, should occur, has to do with the particular audiences you have in mind as well. And we actually haven't talked about that much.

It seems to me the statute, in saying that it's not misleading to a lay person, has one particular audience in mind. But are there other particular audiences that you have in mind that you want us to talk about?

DR. CHOINIERE: I hate to answer your question with a question, but original drafts of the questions that we have presented today did include a sub-question on whether or not the committee recommended that we focus on certain

subpopulations.

Clearly we included certain subpopulations in our study, and it would be interesting to know if we should expand to other -- and we have heard some input on that earlier this morning. And we're inferring from those recommendations that that would apply not only for the studies but also for potentially any communication objectives that we have.

So if there are any other thoughts for other populations, that would be of interest for us.

DR. HALLMAN: So getting to Dr. Clanton's point about disclose, disseminate, and don't deceive while you're at it, it seems to me -- and picking up on Dr. Paul's comment, it seems that, by statute, you have to produce this list, and you have to do it by brand and sub-brand, and you have to put out quantitative information.

One of the things that I think we need some additional research on, given how large this "list" is going to be, is understanding how

potential lay people might actually access that list and what their entry point is likely to be. And my guess is that for current tobacco users, they're going to go in and look up their own brand, and then that's going to be the specific entry point.

One of the questions I have is, well, what do they do then after that? Do they seek to understand just their brand? Do they look at some comparators? Do they look at other brands? Is there some plan to have mean data, for example, over all cigarettes against which they could get some sort of sense?

If that's going to be calculated, is there an overall message that FDA wants to deliver about all cigarettes, using that particular information? So I think that's part of the question. Are you planning on -- and if you're not, somebody else is going to. I guess that's the issue.

DR. CHOINIERE: These are all questions that we've had as well in thinking through what other research we might want to explore. And so,

yes, we've thought about them. We're considering which direction to go next, where the most important direction is to go. And we were hoping that today we would get some insight on that. We have so far heard some very interesting ideas for future research, that being one of them.

DR. HALLMAN: So that brings me to the next issue, which is, again, by statute you have to provide this information. My feeling personally is once you put out the information, you have very limited control over how third parties are actually going to use that information, interpret it, disseminate it.

I think part of what we need to consider as a committee is what information needs to go along with that list that perhaps can preempt third parties, or at least provide enough information for an enterprising journalist to at least have some of the caveats along with perhaps the third party interpretation so these issues of the variability in machine smoking and differences in how people -- the dose that someone would get based on

how they smoke, and all of these other issues, I think, certainly need to be part of whatever this list actually looks like. And I think we should consider perhaps some of those other helpful interpretive statements as a committee.

I see other people raising their hands. I have Dr. Strickland, actually, who raised her hand first, Dr. Clanton, Dr. Huang, and who else would like to -- Mr. Henton.

DR. STRICKLAND: Yes. You just gave me a lead-in in the discussion on target audiences because I'd already made notes here about the importance of having the objective to address very high-risk populations and to also aim to partner with the organizations that would allow you and support the outreach to those populations.

Of course, our Office of Minority Affairs has those linkages for a number of the organizations, and for those of us -- our Indian constituency sitting over here -- the importance of understanding the structures of those organizations and how best to alert and prepare them to be able

to support the objectives and continued research, as we've had earlier in the discussion this morning, particularly with populations like our American Indian populations, where cultural values and the traditional and sacred use of tobacco is a part of our tradition.

So further understanding and research with our diverse populations and linkages to the organizations and the organizational structures that would allow you to partner with these populations to be able to achieve some of these objectives that you're addressing.

DR. HALLMAN: Dr. Clanton?

DR. CLANTON: I feel like I'm on a roll with these D's here. I actually have a fourth D that might be helpful, and it'll create some symmetry here around the two questions of communication objectives or options and meeting your statutory obligation.

So for communication, you can either disclose and/or disseminate. I'd prefer you do both. And in meeting your statutory requirement

not to deceive, I think disclaimers as the fourth D is a way of enhancing your ability to be truthful and to present information in a way where it's not misunderstood or misinterpreted.

So if the statute does require that quantitative data -- and I needed to go back and look -- if it requires you to present quantitative data as distinct from qualitative data -- this substance was found by some tests in tobacco -- if you've got to do that, it appears disclaimers are absolutely required in order to have people not misunderstand.

I think it's a natural process for people to look at quantitative data and say, this is more, this is middle, and this is less, and then interpret that. I think appropriate disclaimers easily -- and attorneys certainly know this -- disclaimers could easily maintain the level of truthfulness and reduce the level of misunderstanding and still allow you to present quantitative data.

One last comment. A list here means, in

the world of Microsoft Word and word processors and computers, something different than it did 50 years ago. And what I mean by that is you can present a list in multiple pieces electronically -- part 1, part 2, subpart whatever.

So it would be fairly easy to present a quantitative piece, and then as a part 2 piece to the list -- I mean qualitative piece. And then as a part 2 to the list present whatever quantitative data, with disclaimers, that you think you need to do. That would allow someone looking at a website and looking at part 1 to take what they can from the qualitative piece without being confused or misinterpreting whatever vagaries come with the quantitative piece.

I think this is fairly easy to do. I realize I'm over-simplifying it. But you can disclose. You can subsequently, with the larger plan, disseminate. And you can also maintain the integrity as you're required, under statute, by applying the appropriate disclaimers to the quantitative data.

MR. ZELLER: Can I respond? Are you saying -- well, let me respond with a question. Do you think that however we meet this statutory requirement, that the first port of call should be to figure out a way to do it without having to require disclaimers?

Do you think that -- and it's a question for everybody else as well -- do you think that in order for something to be understood and not misleading, it should be understood and not misleading without disclaimers? Or are you saying disclaimers are kind of important and should be considered as some kind of mandatory component?

If that's what you're saying, then what does that mean -- and I'm not asking this as a legal question; I'm asking it in terms of achieving something that will ultimately be beneficial to public health. What does that mean in terms of being able to provide a list that's supposed to be understandable and not misleading? Because Congress didn't say anything about disclaimers.

DR. CLANTON: I think, in response to the

multiple options, I'm supportive of using disclaimers in order to prevent people from misunderstanding or interpreting in the wrong way data.

I think if you create a simple text table several thousand lines long that has brands, substance found, and at some level a quantitative number, if you create that text table and it's presented together, you're going to be openly criticized by any number of venues as being misleading or misinterpreting, at least as it relates to the quantitative data.

So I think disclaimers will be required in order for you to meet your statutory -- this is my opinion -- your statutory requirement. I think it can be clear, and again, this is the issue of presenting a list as part 1 and part 2. I think if you create that text table with the substance and the quantities it's found, you're going to create lots of misunderstanding and it's going to be very complex to deal with.

If you create a part 1 and 2, part 1

saying, here qualitatively is all the stuff we find in various cigarettes, and you can do it by brand, et cetera, looking just at that information is pretty straightforward. If disclaimers are appropriate there, then we would recommend you put them as well. But it's less likely you'll need a disclaimer on that page 1 showing only qualitative data. Click, page 2, quantitative data.

I think we've heard that there are going to be arguments over one lab versus another, and reliability, and variability in terms of quantitating various substances. You're going to need disclaimers there.

So if you can't just present it qualitatively, which is what I'm hearing, and you have to do both, I think you can split them in terms of how the public looks at it, give them an opportunity to see part 1 and 2, but part 2 is probably going to require some form of disclaimer in order to try to meet as closely as you can your statutory obligation not to deceive.

DR. HALLMAN: Dr. Huang?

DR. HUANG: Yes. I guess in disclaimer, it might be methodologic description or something like that. But I guess, getting back also to that interface, and you had talked about how people will look for this data, I do think that there's been a very common message that the comparisons are not desired.

So in that interface, to make it so that there is not a list where they're all listed together and you look next to each other, but instead you would search for a particular brand and product, and you get on that and you get the detailed -- or you get the information on that particular product, it's not side by side with the other ones. But then you have to go to the other product and get theirs, and then people would have to -- and there may be third parties that construct something like that, but it is not facilitated by this process to have it readily compared.

Again, you got hundreds of numbers. It's going to be hard for people to just pick up and say, oh, that one's better than this one. And so

again, from that process and the interface that you all have, I would encourage not facilitating that comparison.

But I do think also from that qualitative standpoint, I liked what Dr. McAfee also talked about, having that context. So as you're putting out -- maybe there is a methodologic description in saying there are differences in some of the methodologies.

But to put that in context, that at these levels this is like what someone working at a toll booth in Los Angeles experiences, or something that gives that perspective in that qualitative manner to show the harm and that perceived harm with that.

DR. HALLMAN: Mr. Henton?

MR. HENTON: In terms of the potential importance of communication, some of this works back upstream a little bit. You talk about the naturally occurring components of the leaf. Well, it's not the leaf. There are lots of leaves. And there are lots of types of tobacco, lots of styles of tobacco, maturity. And some of this information

has a lot of validity back to what we do with the farm gate, how we adjust going forward. So the value comes back to us as how do we adjust?

There's a lot of tobacco products sold in this country that are raised and sold completely from offshore sources, and how does that affect that issue onshore? Who can adjust, and how will you adjust? This has potential value to lots of people, including the growers of tobacco, if we're going to try to adjust our product in this new environment.

So I want to make sure that that issue is pointed. We are very willing to try to adjust our agronomy, our economic practices, maybe even the genetics of our crop, to try to move in some direction. We want to be part of the solution if we can. So the value is here. We'd like to be included. Thank you.

DR. HALLMAN: Thank you for that valuable comment.

Dr. Cohen?

DR. COHEN: I'll first comment on the

disclaimer question. So as was pointed out already, five of your communication concepts are disclaimers, and you address that already in what was tested in the experiment. It was all disclaimers, basically, at the top, so you've already incorporated that.

So it's going to be hard not to have disclaimers, but I don't think that just because you have disclaimers, people are not going to compare. And I'm really afraid of the third parties that were mentioned. Whether you have two lists or separate pages where hundreds of numbers are located, that's not a problem these days for people to do the comparison, do the averages themselves, compare.

So I think that's going to be an -- it's not going to be five people looking at it. There are going to be third parties who are going to put the numbers together. It's not going to be difficult. So how do you separate the -- and they can take it out of context without the disclaimers.

So I'm going to -- I sort of can't help

myself -- suggest one communication method you might consider. Further, it's not answering your objectives, but one where you might consider presenting information so that it's not necessarily misleading.

So I think we all agree that the qualitative information that a chemical -- a compound is present, we feel comfortable with that. And the quantity, there are issues with it.

So could you potentially think about having what some food labels do, where they have the green, yellow, and red light? So every compound would have a red light if harmful. And in that red light, you'd put the quantity, and with the disclaimers, of course. But the quantity is within this red light, that it's there and that means it's harmful. And whatever number -- it could be 10, it could be 1,000, but it's harmful.

So a way to not take away the interpretation of the quantity, in the end, whatever quantity it is, is harmful. And I wouldn't separate it out by five different outcomes

because that's too complex. Bring them all together. If it's harmful for one of the categories -- cancer, fetal development, et cetera -- it's harmful. And then you combine them together, and that might help in the presentation of the data.

DR. HALLMAN: Dr. Paul?

DR. PAUL: A question on the concept of misled, someone doesn't get misled by the data. You put the data out, and the average person reads it. That's one possibility. But the fact that it's there doesn't mean that someone's going to be misled by it in the same way that if somebody mines the data and misleads intentionally from using the data.

They're not quite the same thing. And I may be splitting hairs, but the question is, if you say these are all toxic substances, these are all potentially harmful substances, the average person -- and this is a guess on my part -- is not likely to go through and say, well, this one has less or more of this compound that I've never heard

of, so therefore it's a safer bet.

But you will have potential third parties mining it. I don't know how you control that. But in terms of what you're charged with, does that imply that the misleading comes from the way you present your data to the individuals reading it, the lay reader? Or does that mean you have your data set so that nobody can use it to mislead a third party -- a person who smokes? Because I don't think they're the same thing.

DR. CHOINIERE: The first. Our presentation of the list is what should be understandable and not misleading.

DR. PAUL: That's not misleading to a lay consumer. That's not that somebody else couldn't use it to mislead. So once you put the data out, again you have no control over it. But the issue is not whether the lay consumer goes in and looks at it and says, okay, this brand is safer than this brand. But if you can show that that's not the case with the way you display it, then you've met the confines of the charge you have.

MR. ZELLER: I think the answer on third party usage is, it depends. It depends who the third party is and what they're saying. And there are going to be -- I'll just put it this way. There will be some third parties that we would not have regulatory authority over, and others that we would. And so it depends upon who the third party is, and how they're trying to use it, and what they're saying.

DR. PAUL: Who is responsible for reviewing the advertising for cigarettes and tobacco products? Is the FDA responsible for reviewing it again, so that somebody making a claim like that would come under the review for labeling?

DR. CHOINIERE: A claim such as that would be considered a modified risk claim, and so, yes, that would be under the authority of FDA.

Dr. Hallman, I didn't know if this was a good opening for us to move into the second question.

DR. HALLMAN: I believe that it is, now that you mention it.

(Laughter.)

DR. HALLMAN: All right. Go ahead.

DR. CHOINIERE: So our second question -- I'm sorry -- is, how could FDA assess whether the publication of the list of HPHCs in tobacco products by brand and by quantity in each brand and sub-brand is in a format that is understandable and not misleading to a lay person?

The first part being, what methods could be used to assess whether HPHC lists are understandable and not misleading to a lay person? And the second, what outcomes might indicate whether HPHC lists are understandable and not misleading to a lay person?

DR. HALLMAN: Dr. Clanton?

DR. CLANTON: In reading this, a thorny question comes up. And, by the way, I don't know if your statute requires you to do these studies at all or if in fact your doing this is just part of, I guess, agency due diligence. That adds a question about whether you're required to do these follow-up studies.

If the effort do to these studies and create this evidence is designed to defend or rebut criticisms that they are misleading, then I think that's a really tough row to hoe because no amount of evidence, no amount of study in this area is going to prevent anyone from saying, I'm sorry. I was misled by X, and therefore you need to change your standard.

So first question, is this required by the statute? And the second point is, I'm questioning the utility, the value, of doing this if it was intended to create a defense of having met the standard.

DR. CHOINIERE: The answer to the first question is no, we are not required to conduct research to inform the development of the list and how to put this out. But we are required to conduct periodic research once the list is out about the impacts that this list may have, and to assess whether this list is misleading the public.

The answer to your second question is, we don't do these studies in order to be able to

defend from future -- it is a matter of due diligence, is that when we are -- we strive to be an agency that is based on science, and that our decisions are made based on science. And so that if we're going to go out with a communication, that we want to make sure that we've done the scientific research to inform how best to do that communication.

DR. CLANTON: I certainly accept that. Again, this is a small point. This is not about a decision, as I understand it. So certainly you're obligated to support your decisions as a regulatory agency with evidence and science. So I don't dispute that, and it makes perfect sense.

But it appears that's not the reason you're doing a study to find out if the list is misleading or not. And again, I'm being very anal here because the whole purpose of this discussion is about whether you're meeting, whether you have met and continue to meet the statutory requirement not to mislead. Am I correct that that's what we're talking about?

DR. CHOINIÈRE: I'll be anal back.

(Laughter.)

DR. CLANTON: Oh, that's okay, perfectly okay.

DR. CHOINIÈRE: I don't think the purpose is to determine whether or not we have established a format that does not mislead. It's rather we have done some research to see what impact these lists have on people. And the discussion is whether these impacts are misleading, and if so, how might we develop a list to counteract those effects?

DR. HALLMAN: Dr. Wolf?

DR. WOLF: I'm going to try to be focused to the questions here. The one thing I think that's missing is you can be understandable but not impactful. Right? If people aren't finding it, the likelihood of it misleading is -- so I guess part of it is if you're looking to find ways to -- can I ask a question, at least?

Are you trying to find out not just about the misleading aspect of it, which is kind of the

byproduct of misunderstanding, but also whether or not people are accessing it? Is that part of the evaluation you want to incorporate? Does that seem fair?

DR. CHOINIÈRE: I missed that one word. What was the verb that you said?

DR. WOLF: I was saying, are they finding it, the access? Is that something of interest to you, not just about -- because to me, understanding can be done in an offline assessment. To me, that's the only way you can really do it and, well, do it well.

Misleading might be captured by a lot of secondary opportunities. And also, this reminds me of things that we've been -- I'm just curious like whether it be even piggybacking on other national surveys.

I feel like I brought this up at one of our other meetings for medications, where are you finding, through hints or other surveys, BRFSS, that people are getting the information out, or even looking at how they shift if one product might

have lower numbers in the quantitative data, if you start to see a shift in purchases or something like that.

But are you interested in finding out whether or not they are going to where you're putting the information? Again, I'm being naïve here. Is this something that's going to be on the FDA website we were talking about versus on a point of packaging where there they really can't ignore it? Which I don't know how that would happen.

DR. CHOINIERE: Well, at this point we have not determined exactly where the list would be. It's not likely to be on the package.

DR. WOLF: Yes.

DR. CHOINIERE: And certainly if we want to report to Congress about the impact that this list may have on consumers, we will need to understand if the beliefs that exist or the behaviors that are resulting or that we're seeing over time are actually related to the information that's on the list.

I'm not sure, given the third party issue,

whether or not we could identify with certainty that it was FDA's display of the list. But we could probably infer that the provision of this information, whether it was on the website or wherever it was, or through a third party, is causing -- or we'd have some sort of -- we could establish an association, at least, between the presence of that information and whatever behavior we may have concern with.

DR. WOLF: Yes. I guess, just to wrap up, I was just thinking like on the most obvious, I just don't know how you'd do it or where you'd get access to the resources to reach people. But the way Joint Commission and CQF evaluate quality information, if you know what the right answer is, that they're both dangerous, and yet you're seeing people looking at different sets of information around two different brands, that seems like -- I don't know. I'm probably being too grounded here as far as how an evaluation would go to get at understandability and potential from being misled.

DR. HALLMAN: Go ahead.

DR. ASHLEY: One of the things we have not talked about much today is the fact or is the question of whether this list actually can have a public health benefit or not. We've really talked from the negative standpoint, how to make this understandable and not misleading, how to prevent there to be damage, and that is something that's very much on our minds.

But one of the things we are considering is, along with everything else we try to do within the agency, is can we actually have a public health benefit by filling our requirements in the statute? So that is clearly on our mind, and I don't want people to walk away thinking we're just doing this as a defensive exercise.

We're looking at the possibility. Can we have a positive public health impact of putting this list out or not? And so we really want to know whether that can do, and then if we do that, can we do it in a way that's understandable and not misleading, and minimize any kind of negative impact of putting the list out?

DR. HALLMAN: I think that's a very, very valid and valuable comment. I'd like to pick up on that. But several people are looking at me like we need to take a break.

So why don't we take a break, and we'll come back to exactly that point. And there are a number of other people who want to speak, and if I let you all speak before we break, there'll be problems.

So we'll be back at 3:45. Thank you very much.

(Whereupon, a brief recess was taken.)

DR. HALLMAN: All right. Let's go ahead and get started again. As you will recall, in our last episode, Dr. Ashley was making the comment that there may in fact be an opportunity to put out a specific health message, or set of specific health messages, in relation to the list itself.

I want to pick up on this point. We've been talking about avoiding misunderstanding. Well, one way to figure out whether we're avoiding misunderstanding is to be fairly clear about what

we would like people to understand and what specific messages we want to put out there.

I think the committee -- it's part of the committee's charge to make some recommendations about what some of those messages could be. And if Valerie Reyna were here, who is a very valued member of the Risk Communication Advisory Committee, channeling her for a moment, she would say, so, yes, there's of this data. But people don't really think in terms of the micro-data that you're presenting. They want to walk away with some sort of a gist, some sort of a bottom line message. And I think we want to get to what those bottom line messages are and how to measure against those.

So it seems to me, based on what I have heard and what I have seen and the comments, that yes, there are some issues related to measurement error. There are certainly differences in the amount of dosing that people get, depending on how they smoke the cigarettes.

But it is pretty clear that these

components or these constituents are present in most of the brands, or many of the brands, and it seems like there is an opportunity to say, well, in addition to what we thought we knew about the problems with smoking cigarettes, here are 93 potential others.

Is that about right? Committee?

(Heads nodding affirmatively.)

DR. HALLMAN: So it seems like one of the clear messages we want to get across is that as a result of the presence of these harmful constituents, that people should be perhaps even more concerns about the dangers of tobacco consumption.

So I think that one of the things we will want to measure is whether people get that message or not, whether they don't get that message, whether they do get that message; and as we look at specific subpopulations, whether subpopulations are getting those messages in particular or whether they're being missed, and looking at ways to try to communicate that particular message in a more

effective way.

So having said that, I have a list of people. I have Dr. Wolf, Dr. Strickland, Dr. Bickel, Dr. Paul, and Dr. Henderson up. So Dr. Wolf, if you want to --

DR. WOLF: I think I'm going to defer. I think I forgot where I was.

DR. HALLMAN: That's one of the reasons I called a break.

Dr. Strickland?

DR. STRICKLAND: Well, I make a list so that I don't forget. So along these lines, I guess one of the things I was thinking is that we have had these discussions around what's not misleading or understandable, but we really don't have a good conceptual definition, operational definition.

You provided a very good example this morning of your focus group work and your concepts that you're moving forward with. And so it seems to me, as you move forward now, what methods could be used.

Some of the very important work is to

define what we mean by understandable and to define what we mean by misleading, and operationalize that, and to use some of these techniques that you've used before with focus group work to be able to get at that and to carry it forward, both in the definition and also, once you have that understanding of how you're going to define it and operationalize it, then be able to move forward with the related search.

DR. HALLMAN: Dr. Bickel? Oh, absent.

Yes, Dr. Paul?

DR. PAUL: Yield.

DR. HALLMAN: She yields. Awesome.

Dr. Henderson? No?

DR. BICKEL: I want to just do two things. One is I looked up on the web what the legal definition of misleading was. I thought that was very informative, and I don't think we have anything to worry about:

"Knowingly making a false statement, intentionally omitting information from a statement, and thereby causing a portion of such

statement to be misleading, or intentionally concealing a material fact, and thereby creating a false impression by such statement with intend to mislead." I can't imagine how that would fault this.

But the important consideration is, right, so numbers are good. But if I see my doctor and he says, I have a cholesterol reading of X, I can't interpret that unless I have some other information. And I think one thing that could be very helpful is to provide some other information so people can interpret the numbers. And I was just chatting with some people there, and we were talking about, what's the natural level of these substances in a nonsmoker? Out of the normal range or not? And that provides a point of --

DR. HALLMAN: But I don't think we're talking about body burden. I think we're talking about the amount of --

DR. BICKEL: All right. But ingestion for a nonsmoker of these substances.

DR. HALLMAN: But presumably, that would

be the same for a smoker at baseline. So what we're talking about is in addition to what you would normally get. So I'm not sure that's the comparison --

DR. BICKEL: Yes. Well, maybe it's not the best comparison, but I think --

DR. HALLMAN: But I take your point, that there needs to be context.

DR. BICKEL: That's right.

DR. HALLMAN: I think one of the questions is, how do you provide context for potentially 93 substances without just -- is there some way to create a priority list of these things? So how do we do that?

DR. BICKEL: When I get my blood results from the doctor, there's a long list of items. Right? But each one has a reference point, and I know if I'm outside of the normal range. So I don't know if we can accomplish the same thing.

DR. HALLMAN: But I think part of the problem is that there really is no normal here. What should the standard be? What should the

background be, especially given if there are variations in measurement issues?

But I agree. We need to provide the ability for people to acquire the context, even if it's a link out from the specific -- from arsenic, are we measuring organic or inorganic arsenic? Are we doing both of those things?

Then there needs to be, for the person who is persistent, the ability to get the information that they need. I think I absolutely agree.

Okay. I have Dr. Henderson, Dr. Rutqvist, Dr. Turner, Dr. Huang.

DR. HENDERSON: I was just back on the Navajo Nation a couple of weeks ago, and we were before an IRB. And at the end of our discussion for our project, a traditional healer asked me in Navajo, he says, "Dr. Henderson, are you saying to me that in a ceremony, for example, a Native American church, which is inside a teepee, at a certain time of the night people begin to smoke cigarettes, and it happens like three or four times throughout the night, and then usually ends at dawn

with another smoking session."

He says, "During this time," he goes, "are you telling me that when people are smoking and I'm sitting next to it because I'm a nonsmoker, that breathing in that smoke from the cigarette is harmful for me? And what is in the cigarette? What is in the cigarette smoke that I'm breathing?"

I said to him, "That's a wonderful research question." So I think that even down to our community levels, people are wanting to know what is in side cigarette smoke, for example. And there's definitely lots of ways to get that information out to our communities.

I just think about my 11-year-old daughter and how she would interpret that list of 93 or 94 products -- or chemicals that are found in tobacco smoke and tobacco. And we'll just leave it to them. They're very creative. I can see like a rap song being made out of these words. Some of them I can't even pronounce. But I think there's a lot of potential for use in our communities, particularly with the youth, which is where we're really wanting

to address.

DR. HALLMAN: Dr. Rutqvist?

DR. RUTQVIST: Today we've talked about HPHCs and how quantitative data may relate to individual risk. We've also talked about modified risk products. And that concept, the definition of a modified risk product, integrates individual risk and the population perspective that Dr. Ashley mentioned before the break.

So I think it might be most appropriate that the FDA communicates the significance of specific levels of HPHCs to public health in relation to the modified risk process because I think that would allow for the more nuanced messaging that's required to relate specific levels of HPHCs to population effects.

So my suggestion would be that this type of communication activities are connected with a modified risk process rather than with the publication of lists of HPHCs.

DR. HALLMAN: Dr. Turner, you're up.

DR. TURNER: I wanted to loop together

some of the comments that have been made in an attempt to make a point. Earlier, Dr. Ashley, you did ask if there could be any positive effects of posting these lists, right before we went to break.

Then Dr. Hallman brought up the gist theory. Right? So people take away a gist. They're not going to take away a bunch of micro-risk assessments. They want to know, what's the bottom line here?

I strongly hypothesize that that depends on whether you're a current smoker or not. And this is inextricably tied to how you interpret these quantitative assessments, so that brings back this idea that what does this mean?

For a nonsmoker -- and I'm a nonsmoker but I'm a former smoker. And I come from a poor, rural, working class, farming, smoking family, so I feel that I understand a little bit about the smoking culture. For me, if I were to look at this list, I'd say, "I don't want any of those toxins in my body." No level would be acceptable to me.

But I can guarantee you if my brother were

here today, he'd say, "Microgram? That sounds pretty small. Nanogram? Okay. Well, all right. I'll just keep going about my business," because he wants to keep smoking and he's seriously addicted to smoking.

So especially if we -- and I don't disagree with the claim earlier -- I don't know how I feel about it, I should say, about the disclaimers. I understand where your comment was coming from, and my head isn't fully sure of how I feel about it.

But if that were a bunch of disclaimers and I were a smoker, I'd say, "Even the experts aren't sure about all this. It depends on a million factors. So I'm just going to keep going about my business." Whereas a nonsmoker might say, "This uncertainty leads me to -- I'm just going to stay a nonsmoker." Right?

So I don't have data on that. I suggest a study be done on the interpretation, the gist that people take away of these quantitative assessments, depending on whether you're addicted to nicotine or

not. But there's a lot of concerns I have. People walk away, depending on where they are with their smoking habit.

DR. HALLMAN: Dr. Huang?

DR. HUANG: I was just responding to your question earlier about how would we get this message about the 96 chemicals or whatever. I guess -- and it goes back also to the other -- really, now, if we know the message and we've simplified the message to, really, that these products contain these harmful chemicals, it's just a marketing issue, and to really draw in the experts in terms of, how do you get it in bite-sized pieces, or what are the recommendations on how many they can absorb at one time, and if it's a rap song or whatever.

So I think to really be creative, I think there is some consensus regarding some of the simplicity of the message, keeping it simple, giving these other contextual examples of what this means. But again, I would not say we have to get all 96 or however -- the 7,000 at once, but really

use the experts as if we were the tobacco industry marketing some of these, messaging or whatever for our purposes.

DR. HALLMAN: Dr. McAfee?

DR. MCAFEE: I defer to Dr. Freimuth.

DR. FREIMUTH: I wanted to turn more specifically to the question that you ask here, and it's kind of a follow-up from what Dr. Turner is talking about with the gist.

I think, at this point, one of the methods that you need to use to complement what's already been done is a more naturalistic exposure method, and whether that's following up with people who seek this information out, for whatever reason, or whether it's like displaying at a point of purchase and then interviewing people after they've seen it in a very natural context, and trying to find out the gist that they're taking away from that, find out if they're interested in pursuing it to get the more details, all those kinds of things.

But the other point I would make is that in your measurement, I think you do have to use a

technique that allows you to be fairly broad about looking at their interpretations. In your experimental study, I understand why you stuck very closely to the actual content that was there.

But I think when you're doing this kind of study, you want to broaden and find out their interpretation. You may not have even thought of it. But I think that's the only way that you'll be able to find out what people are walking away from with this information, and be able to avoid this kind of -- what was the D you used? I can't believe I've forgotten it.

DR. CLANTON: There were so many.

(Laughter.)

DR. FREIMUTH: But the deception idea or the misleading idea because sometimes you're just shocked by what the gist is that they take away. So I think that kind of study would complement the things you've already done.

DR. MCAFEE: So I guess just again coming back to what David had asked before the break, which I think it's really important to think about

what you can do that's not just defensive around this, but where is the opportunity and where is there an opportunity that really -- in terms of Congress's intent, which I suspect was not just that you spend several thousand hours figuring out how to get the perfect web page buried 16 clicks inside the FDA website, but that some of this is how do you get the information that's important for the lay public to understand. And I think we've all come around after multiple hours to saying, just getting the perfect list is not going to do the job.

So what I heard -- and I guess in terms of what Dr. Rutqvist had said, I agree there's an element relating to modified risk that dovetails with this. But I don't think that's enough because that's really a passive activity other than what -- that relies upon the tobacco companies. And so I would encourage you to feel like this is something where, in addition to putting a list up, you do have a public health education obligation and opportunity.

I actually have another -- whether this is the fourth or the fifth or the sixth D at this point, I'm not sure. But it's really distillation, that because this is so complicated and there's so much stuff, to distill out of this the two or three important messages that really need to be delivered effectively. And then we're actually looking to see what actually happens.

Again, I think this is something that is known. We know a lot about how to do that. But the first thing that I think you have to do, which again wasn't part of the first assignment, is to figure out what are the two or three things that are buried in these thousands of pieces of data that are the key take-homes?

I'll just toss out one of them, which is sort of a secondary one for our perspective but is really that it's not -- these are not just about additives that are being put in by the tobacco companies. These are core characteristics of a product that are almost impossible to get rid of or to compare between them.

Then the second one is sort of like there's a lot of really bad things that you're really not going to want to put into your body. And that's the generalist one. If you understood this, once you understand this, you will not want this to be coming into your body. And some of this requires -- would require -- may require, again, analogies to understand what would actually help people to understand that.

I think one of the things we probably saw with this is, well, if you put up a list and it's got 90 things on it and a bunch of checks that are associated with bad, yes, people are going to have a sort of vague feeling. And maybe it's going to move them a quarter of an inch up on there, like, I know cigarettes are bad for me.

But again, there are other things that maybe much more really hit home with people, and that's going to require a different kind of research to distill those out. And some of those may be around a handful of very specific elements within that.

Then my last thought around this, which was I thought -- Dr. Cohen had given the example of the red/yellow/green around food. And that scenario, where I don't know a lot about it, but I think decades were spent essentially asking your first question: How do we make a really big list that will help people understand what's going on in their food?

There's been a lot of confusion around that, and the individual constituent focus hasn't really worked because the companies then chase salt, or they'll chase fat. And then it turns out that it isn't really just all about fat, it's about a sub-component of fat. But they do fat, and they do reduced fat, but then the sodium is five times.

So it just doesn't work, particularly for probably any of us, but certainly people in a target audience of low socioeconomic status, to expect that we're going to train people to do this. So I think trying to get to something that's more like green, yellow, and red is likely to bear fruit. Thanks.

DR. HALLMAN: That is my area of expertise, and you're exactly right. That's very, very problematic, and for all the reasons you just suggested.

I have Dr. Krishnan-Sarin, Dr. Sleath, Dr. Samet, Dr. Huang.

DR. KRISHNAN-SARIN: Actually, Dr. Turner covered what I was going to say. But I do want to make another point, which is regarding something which is near and dear to me, which is the effect of all these changes, these lists, on initiation of smoking. So I think it's something we really need to pay attention to when we are generating these lists.

When I first started working with adolescents and children, I thought, give them too much information, they are not going to understand it. But they have proven me wrong over and over again. We've done focus group and survey work with them.

Adolescents, young adults, children, are remarkably perceptive at understanding stuff if you

present it appropriately to them in a way that they can understand it. And they can actually even make comparisons for you between different products, and can actually tell you what would be the best way of presenting this to them.

So I would really encourage you all to do -- I know you did some of your focus group work with adolescents and some with kids who you labeled as being susceptible.

But I would really encourage that you do more of that because not just with those who are susceptible, but also those are not susceptible, most substance use behaviors, including tobacco use, is a very peer-related phenomenon and most kids -- we always marvel at the rates that -- till eighth grade, you see all these kids who don't smoke anything, don't use any substances. All of a sudden in ninth grade you get this huge peak in use of tobacco products, use of marijuana. And the question is, what's moderating or what's leading to that? And I think it's a very peer-influenced behavior.

So, anyway, all I'm suggesting is that I think you need to do a lot more focus group-related work and develop an understanding of how to get at this issue, which is make it understandable and not misleading to a lay adolescent.

DR. HALLMAN: Thanks very much.

So being mindful of the time and realizing that we have half again as many questions to get to, I have Drs. Sleath, Samet, Huang, and Clanton. And we want to try to get to these other questions.

DR. SLEATH: My question is actually related to part (b). What outcomes might indicate whether they're understandable?

The first thing I wanted to ask is, your study was experimental. Right? So there was no pre/post assessment. So I would suggest, because you talked about public health impact, is one of the things you need to know if you gave people these questions with no exposure to anything, what's the ceiling of the number of people that would do really well?

So that's the first point because in

assessing things, if everybody already knows 80 percent of the answers, can you really have that much of an impact?

The other thing in terms of outcomes is, I agree with what was said about what are the key messages that you want. I think you have to determine that first. What are the three to five messages that the FDA wants to get across in this whole thing, and kind of back up from there? And then what are they key outcomes?

You had 21 items for comprehension, and I can see why you did that. But what are the key comprehension messages? You probably don't want 21 of them. And what are the potential harms, that kind of thing?

So do you want to look at things more like, what is the person's intent to start smoking if it's an adolescent, their intent to quit if they're already smoking? Is it looking at the quantity of smoking? Will this impact how much somebody smokes?

Then in terms of where you put these

lists, I think you need to look at things like where do people purchase their cigarettes? That might determine how you get information for people. And then, really, where do people look for information? Because that's very much going to vary by sociodemographics and whether it's adolescents or adults.

DR. HALLMAN: Dr. Samet?

DR. SAMET: I'm a little bit back to David's point about public health impact. And I'm reminded, in 2004 with the Surgeon General's reports, we started putting together these public communication pieces. The 2010 report was on how smoking causes disease. And the communications materials for that, which are written at the fourth to fifth grade level, included materials on various components of tobacco smoke, using pictures and analogies.

I think the general approach might be one that could be useful. It seems to me the other way to address this is to do some grouping around toxicity, and you could potentially develop some

focused materials that relate to reproductive outcomes, that relate to cancer, that relate to pulmonary disease and compress down what is far too much data in terms of communicating overall and qualitatively. But I encourage you to look at some of the communications materials that have been developed.

DR. HALLMAN: Dr. Huang?

DR. HUANG: Yes. Again, I think that the messages are being distilled and just that the presence of these harmful chemicals -- and I do like adding in also that they're not additives only -- are some of the key messages that have already been identified, really, in these education opportunities.

But it really does boil down -- again, it's really now become a marketing issue, and this is not a new -- there have been posters and things with -- it's got rat poison and embalming fluid and all these things that have been out there. But it's really looking at and testing some of these. And that even goes back to the study that was

presented earlier, just looking at the initial materials that are being used, and are we really taking a Madison Avenue approach or looking at this as marketing, getting these messages out there effectively?

So in terms of the methodology, this is what the marketers do. It's doing some market research and assessing some of this. But we want to be effective, and earlier had said we don't want to be the PC versus the Mac in terms of methodology. We don't want to have such an academic approach to this. We really want to be most effective in getting these messages.

DR. HALLMAN: Dr. Clanton?

DR. CLANTON: I'm responding to the comment about how the list might be used for positive purposes. I know that others threw out a really crazy idea.

Typically, when we think about toxicologic exposures, particularly through background experiences -- food, air, water -- the paradigm is usually to look at a single toxin and create a

standard of tolerability or acceptance -- and organic arsenic is an example; there are EPA standards for how much of the stuff you can find in food or water or air -- and make judgments based on where it fits in that range of tolerability.

The crazy suggestion I'd offer for you to think about is to don't do that, which is to in fact use the entire list. As opposed to talk about the individual toxins within this list of 95, is to actually talk about the entire list of 95 and speak of it in terms of, there aren't any foods, water, or air that present this many toxins as a profile.

So again, it's a little strange, and it's certainly not the way we normal do it. But there is an opportunity to say, there may be no other naturally occurring thing that you imbibe, whether it's wine, water, air, or food, that's going to give you this large profile of toxins.

So just something to think about. Maybe a different way of using the list.

DR. HALLMAN: I think we would want to test that. I could readily see people saying, "If

I'm going to be exposed to these things anyway, I might as well be exposed to them using the thing that I really like." So I think we would want to certainly test that.

I want to move on to question number 3, and as a segue to that, talk about some additional research that may make some sense. So one of the things, if we're going -- it sounds like you need to, by statute, present this list.

I think some eye tracking studies would make a lot of sense as you present the information and figure out where people are actually looking on the list. Do they key in on particular parts? Do they key in on the numbers, for example? Or do they look at the numbers and quickly look away because they don't understand them?

Do they focus on particular chemicals that they may or may not understand? And so trying to figure out how people use that information would be important.

Understanding how people would come to the list, I think, is also important. I've mentioned

that. Again, I suspect that they would come in looking for information perhaps by their brand.

I don't know whether you could actually link the list by UPC, because that would be on every package of product, rather than requiring a QR code. The technology to do that is actually relatively easy. And I'm not suggesting you necessarily do this, but you could actually have an iPhone app or an Android app that could allow you to scan and go to the list. Whether once you got there or not, you understood it, is a different issue.

I would also suggest that some talk aloud studies be done. So these are intensive. They cost a lot of money. You're going to need the resources to do this. But sitting with people and having them talk about what it is that they're seeing and their understanding of -- so basically generating their gist of what they're seeing all along, and that would help you understand whether people are actually getting what is there in the list and where their potential misunderstanding

might be.

Dr. Turner?

DR. TURNER: I'd like to echo that. And in fact, there are technologies now where you could collect all of those measures simultaneously. I actually have such a lab, so I know that. You could collect eye tracking and think aloud at the same time, and in fact even measure EEG and GSR, all simultaneously, to see if it also increased arousal.

That would be an important thing, to see if people have some of affective reaction while viewing the list, in different formats, even. So I just wanted to put an exclamation behind that suggestion.

DR. HALLMAN: Yes, sir. Dr. McAfee?

DR. MCAFEE: This is just a real quick follow-up around this. I think this question has within it -- again, I think, what we've identified as one of the biggest dangers. So I think trying to figure out how you can do research to make sure that the danger isn't happening would be critical,

which is this idea of brand and sub-brand.

If people are going to a list, my bias would be what you want to avoid like the plague at our current state of knowledge is somebody with what we would view as the same class of products, like they're trying to decide, well, let's see. Should I smoke a Camel or a Marlboro? I'm currently smoking this brand of Marlboro.

So now instead of actually taking in information about how all this awful stuff that's in Marlboro is, the first thing again that a smoker's going to go to is, can I mitigate the risk enough I can quiet that voice that's telling me that I really should quit?

So I'm desperately looking for an alternative way to cognitively process this disturbing information. And what I want, and I want on the fast, is I want an exit strategy.

The first one I'd look for as well as -- maybe there's a sub-brand, like I'm using this Marlboro product, and if I just switch over here, "Oh, look. That thing is 10 points lower.

Whew. I'm going to stop reading. I'm willing to do that to improve my health." And we've lost that person for another decade.

So again, I don't know if that will happen. But it would actually surprise me if it didn't happen. And what can you do in terms of the way you're formatting this, you're setting this up, either in a list or, more importantly, in a public health campaign so that people don't engage in -- they understand that that's just really not the point of the whole thing.

DR. HALLMAN: I think that that's clear, that that outcome is the definition of misunderstanding. And so, I think the question is, what methodologies can we use to figure out whether that's actually happening or not? So that's where we need to head.

I also wanted to ask the question about -- is it 93 substances that we're talking about? We keep batting around the number. So how many of the 93 actually bioaccumulate, and whether that information is part of this as well.

Because people discount future risk, and many smokers believe that they will quit before it becomes a problem. Is there a way to communicate that every cigarette is problematic? I guess that's a rhetorical question.

DR. ASHLEY: I'm afraid, sitting right here, I can't tell you how many of the 93 bioaccumulate. But it's actually an interesting thing to talk about the impact of each successive cigarette and the fact that they don't clear themselves out. You don't remove all the effect by stopping, that it's a slow process. Yes.

DR. HALLMAN: Dr. Paul?

DR. PAUL: I know Bill has brought up something that relates to this question in terms of what research are you looking at because as Dr. Strickland said, defining understandable, to me the question is, are you talking about can I understand the list? Can I understand that it's got column A, column B, column C? Or do I come up with a message from the list?

If you wanted to know if people understood

a message you want them to have as opposed to a message that they come up with -- which you can ask, "What did you get from the list?" -- then you have to write that message. And in that message, it's text. So the message could contain a number of these issues.

You can easily test with comprehension research. Do you understand the way the words are here? These compounds or these chemicals do not leave your body. They do not leave your bloodstream, or many of them don't.

There are ways to say it very simply if you want to know, if you want to add in that information, which could be part of the research. But then the question in part of your research is, do you want to put in a statement of what you essentially want them to get from the overall experience of looking at that list, which is, this is a list of chemicals that have these kinds of consequences for you.

That to me would be very important. And I think Dr. Freimuth mentioned, in terms of some of

your research, making it less structured and finding out what people actually do take away rather than what you ask them did they take away in terms of fixed answers. But you ask them, what did they take away, and what would they do with their information?

DR. HALLMAN: So on that note, and then we'll come to Dr. Strickland -- I think based on the known research, if you want people to walk away with a particular message, you need to state what that message is. And I can foresee, since you're required to put this information out, really the interpretive statement at the head of whatever this is and explaining why the data was collected -- and it's essentially collected for scientists. It's not necessarily collected for lay people.

But if you draw the interpretive statement, saying, "There are 93 chemicals that you are potentially putting into your body that may not go away, and here is a list of the 93," my sense is that people would actually look at that list and not go much farther than that. I don't think that

they'll necessarily dig very deep.

There's a difference between not drawing meaning and misunderstanding. So if you actually draw the meaning for them, if you essentially summarize what the chart actually means in a gist way, my sense is that people will probably not spend very much time on the individual components or the numbers. And that's a testable hypothesis.

DR. STRICKLAND: As I'm listening to this discussion, I'm thinking we're mostly being directed to think about those who have accessed this information and what they did with it.

It seems to me that it's also very important to try to gain some understanding of who never accessed this information at all, and which populations are they, and are they part of our very high-risk populations that we'd really want to be sure that we're reaching with some kind of message? So just to keep that in mind.

DR. HALLMAN: On the issue of actually how to drive people to the information itself, we've talked about having things in cigarette packs. I

don't really see that as very practical. There's just too much information, and I don't know how you would do that in the first place.

Point of sale, you couldn't have all of the lists of the information. It would be like going to the auto supply store and trying to figure out which rear light bulb you need, going through page after page. It would literally be a book.

So the issue is, how do you drive people to the website or to where the information is from the point of sale? Maybe there is campaign information with a QR code or some way that would quickly drive you to the website and allow you to look at your particular brand. And I would recommend that.

Dr. Huang?

DR. HUANG: I guess I'm not totally ready to throw out the cigarette pack idea, just from the standpoint could there be some sort of rotating messaging, like Surgeon General warnings. But it's the ingredient or the constituent of the week or something, but something that goes -- you got a

long supply of messages that would make it fresh, perhaps. But to explore that as a possibility, not all 93 at the same time.

DR. HALLMAN: No, no. Clearly not.

Dr. Cohen?

DR. COHEN: Yes. I'll just pick up on that We talked about the importance of qualitative data in promoting good health and informing people -- well, pharmaceutical products have inserts in them that you open up and it lists all the possible side effects. And there's no reason that a cigarette pack could not include that qualitative information as an insert that you would open up and be able to ask --

DR. HALLMAN: So Dr. Cohen, I would invite you to the next meeting of the group that asks us how to help consumers interpret those. That's maybe not --

DR. COHEN: Well, you need a step towards informed consent, ideally, with a product like this.

DR. HALLMAN: Other comments on this

particular question? Dr. Strickland?

DR. STRICKLAND: Well, on that note I just can't not comment. It's really important to recognize that using advanced technology and written word is not necessarily a means of gathering and seeking information and communication among many populations. And so understanding communication patterns and the way information is sought and used is really important.

So it seems to me we should begin to think about some of this again with some of our diverse populations. It's important to understand the communication patterns.

I was struck because Patricia, as she was beginning to talk, she was storytelling. And storytelling is such an important part of many cultural ways of communicating. So I think that's an example of how important it is to understand the ways of gathering information, the ways of sharing a lot of her research about how diverse populations get their information from people that they trust, and so understanding those issues and trans-

cultural patterns of communication.

DR. HALLMAN: So we're really beginning to touch on the issues in question 4, so I'm going to go ahead and click to that. If you want to go ahead and introduce us.

DR. CHOINIERE: Question 4: What strategies might FDA use in a public education effort aimed at a deeper public understanding of HPHCS? What should be the primary objectives of any FDA HPHC public education materials? How might linking educational materials to the HPHC list support public understanding? And how might public education efforts be used to correct existing misperceptions related to some HPHCs, such as nicotine?

DR. HALLMAN: So great ideas from the committee? Dr. Lawson?

MS. LAWSON: We have touched on this before, and Dr. Strickland has certainly touched on it quite a bit. I think it's important, once we have clarified what the objectives are, that the staff, the health communications staff, would look

at how you could have some input, whether it's formalized or informal, but have some input from some of the key constituent health and consumer groups and associations to give some input on this outreach strategy, how to get this information.

There are a lot of ways that you would do that -- the website; most of us are now into social media. But there are many people who are not touched by the social media. But we can work through many of the organizations to get that information out to the people. But the organizations have to have some level of buy-in with the agency.

So I think it would be good to have a core group, like the American Heart Association, the Cancer Society, or the National Urban League, or National Council of La Raza, many organizations where their interest, primary interest, is with the consumer. Their messages go directly to the consumer.

So they have a level of trust. There's buy-in. And if they have a partnership with FDA,

whether it's formal or informal, they can help to deliver the message with FDA.

So I think there are a number of ways. But you certainly need to have this kind of dialogue with an association, with a core group, and how you're going to develop it and how you're going to deliver it. And I think you can reach people with the message. But I really do think you need to have some input from some of the constituent associations and organizations.

DR. HALLMAN: I think I would second that, and I think understanding how they are likely to use the data and putting it in formats that would be useful to them would be a very important thing to do as well.

Dr. Huang?

DR. HUANG: Again, with this question again to reemphasize the opportunity to not be using just the traditional methods and the bureaucratic methods that we've done in the past, but to look at what opportunity there are to be creative and cutting edge with this.

DR. HALLMAN: Dr. Turner, and then Dr. Heck.

start DR. TURNER: I want to go to part (c), if I may. Directly before lunch, when we heard from your colleague in the communication office -- I believe that -- yes -- we learned about some of the common misperceptions of the public.

I think that in terms of supporting public education efforts, that myth-busting materials should be used, quite literally. It could be just a flier that was graphically appealing and really well-designed that said, "True or myth?"

With these common myths pulled out of the formative research that you've collected, perhaps there are different myths among different subpopulations. So this could be tailored -- it should be tailored to population. And then let people know what's true and what's myth and why it's a myth, and I think that that would go a long way. So it might be a myth that some cigarettes are safer than others. Well, put that in there in just three or four words, very clearly.

DR. HALLMAN: Dr. Heck?

DR. HECK: I've almost gotten the sense today as the conversation has proceeded that it's -- with our underlying directive, first do no harm, in this well-intended messaging concept, almost like the less said the better. We shouldn't try to use this particular vehicle necessarily to get too much of these broader messages across. I think some simple corrections of misunderstandings would be worthy.

It's hard for me to envision why any smoker or pre-smoker would ever refer to this list except for the purposes of comparing products and maybe rationalizing a brand choice or rationalizing a switching decision as an alternative to doing what they know they need to do, is quit.

So perhaps a simple, straightforward message. There are a lot of unfamiliar and scary-sounding chemicals on this list, and while they should be scary-sounding, trying to dissuade people from making those comparisons, I think, are naturally going to flow out of having a lot of

information available.

DR. HALLMAN: Dr. McAfee?

DR. MCAFEE: Well, I would just follow up on that by saying that I think one of the logical consequences of that would be an answer to question (b), and that is in terms of how might linking educational materials support public understanding?

I would say the default should be that it probably wouldn't, and you'd really need -- because first of all, it would take a whole lot of work to get people to go to something compared to what they might get through mass media or whatever. And then secondly, it would just open up this sort of potential Pandora's box.

So I would actually encourage that the default should be that you deliver the message that you think is important. The lists exist, but you're not aggressively trying to drive people to a list unless you've really done some homework to show that that would benefit.

I would just put in one other plug, which is, I think, many things have been pointed out that

would be great that FDA could do to do this. But I would just say that ideally, those would be enhancements on the one thing that FDA has that basically nobody else has had or has ever had that has done these kinds of campaigns that Dr. Samet and others have alluded to, which is, they have the resources to do a comprehensive, ongoing, well orchestrated mass media campaign that could truly change people's understandings and potentially outcomes. Other stuff would be frosting on that cake.

DR. HALLMAN: Dr. Strickland?

DR. STRICKLAND: I'm just reminded that much of our mainstream approach to health promotion is based on the cultural norms and values of the mainstream population. And in many of our communities that are more community-oriented, group oriented, we find that the message needs to be, take care of yourself for your community and for future generations.

In the mainstream culture you may see a message that says, take care of yourself for

yourself. And so just to recognize that the message needs to be tailored to the value orientation of the population, and sometimes the mainstream forget that there are other worlds and other ways of seeing things.

DR. BICKEL: So when we think about education campaigns, we often think about broad-based systems. But there's a lot of value in a lot of companies that do marketing, right, do micro-targeting to particular subgroups.

I think that might be a viable way to think about this, particularly as we have the continuing hardening of the smoking populations. Right? The comorbid, they're more likely to be low SES. They're not going to be necessarily the ones that are going to go and be as susceptible to a broad-based -- but if we could figure out a way to micro-target them, that might be a more viable method.

DR. HALLMAN: Dr. Strickland?

DR. STRICKLAND: Yes. That actually was going to be my comment, that it's really, I think,

important in these primary objectives to really focus on the very high risk and the populations that have been listed here is segment to do just as you're saying, Dr. Bickel.

DR. HALLMAN: Dr. McAfee?

DR. MCAFEE: This isn't exactly a counterpoint to this, to your two perspectives. And I come from this having overseen a large mass media campaign that CDC has operated now for several years.

You're absolutely right. A lot of attention has to be paid to make sure you're reaching the people that you're the most interested in. But that can be done within the context of the kind of large mass media campaigns that companies that are marketing products do. And it takes attention to detail.

This is something I think FDA has the capacity to do. They're doing very sophisticated work around targeting among youth. So I think there's no reason to think they couldn't also do that around this issue with youth, but also with

adults who are also suffering from misinformation about harmful constituents.

I just don't think -- in terms of hardening, there are still 40 million people that are smoking in the U.S., one out of five. And we've seen that we've been able to reach the same kind of high percentages within low SES within critical racial and ethnic groups using a mass media, digital campaign as long as you're consciously working to do that.

So I think otherwise we run the risk of being very effective at reaching a few thousand people in terms of populations, but not reaching hundreds of thousands or millions, which is what has to be the name of the game.

DR. HALLMAN: Dr. Turner?

DR. TURNER: Piggybacking on that and answering part (a), I think that what we're saying is that one of the primary objectives of the public education materials is dissemination. And an additional way to get that out besides running your own campaign is to partner with the existing

campaigns, like Text for Baby or Text to Quit, and see if it they -- in the Text to Quit you obviously are getting these anti-smoking messages on your telephone. And you could see if they would send out the link to your list with a savvy message. And there are lots of these existing campaigns that would be -- I'm guessing -- would be willing to partner with you.

DR. HALLMAN: So one of the things I think is important, I think I agree with Dr. McAfee. I still think it's unlikely that individuals are probably going to get driven to this information.

We could spend a lot of time -- we do need to spend the time figuring out whether, if you find that information, you are not misled; you can understand it. I actually think the bigger bang is going to be by the third party interpretation. And I actually think that the biggest impact this is likely to have is that it's a new conversation to have about smoking. It's a new reason for media to pick up data from FDA. It's a new opportunity for FDA to say something about smoking. And I think

carefully crafting what those few messages actually are is really where the bang comes from.

MR. ZELLER: Let me take the prerogative off kind of reframing this question just to see if you have any thoughts in response. And that is, would you answer this question differently if it were being framed in the context of using the list as an agent of prevention aimed at kids versus as a tool of information aimed at current tobacco users? And if your answers would differ depending upon the target, say why and say something about the strategies or tactics that we should be thinking about differentially for those different targets.

DR. HALLMAN: So that's an interesting question. And one of the comments I wanted to make is this is very complicated information. Again, we need to get to gists. And as I think about my own kids, in the 5th grade they had health class, and every one had an assignment where they had to write about cigarettes and about other issues.

Here's another possibility, particular information aimed at that particular audience,

knowing that they're all going to get assignments at some point 5th to 8th grade to look at cigarettes. So where does this information fit into that kind of assignment?

Even at the college level, I teach a course on health risk and safety communication. I ask the students to pick one health risk. They all want to pick cigarette smoking. I don't let them do that because they did it in the eighth grade.

But nonsmokers do seek this information because they're forced to do that. So they're pre-smoking. There is an opportunity to frame this message that may in fact be different than trying to dissuade current smokers.

I saw another hand somewhere.

Dr. Krishnan-Sarin?

DR. KRISHNAN-SARIN: Thanks. I'm going to play devil's advocate here to the point that you just raised. How is anything that you're going to be doing through some of these avenues different than what's already being done?

There are already a lot of education

efforts around tobacco that are being presented to the kids. I'm talking specifically about adolescents and children. How is this reframing going to make a difference? Is telling them about 93 HPHCs going to differ from showing them a diseased lung or showing them some of the things that we're already doing?

So I'm not really sure that -- this is going to be too much information. They tune you out as is, and then if you present additional stuff with them, I don't know that it's really going to make a difference.

DR. HALLMAN: I'm not suggesting that we show them a list of 93 components. That would be foolish. But I think that there is a way to take this information and to create a kind of gist for them.

If I had the contract to do this, I could readily see doing an animation, for example, showing 93 drops into whatever. Because I think that people think differently in terms of health outcomes. Cancer is something that people get when

they're old, and the kids can't think of themselves as being old, ever.

But they can think of chemicals. I think they can think of chemicals differently. I think they would think of adding things to their bodies in a different way than a disease outcome. And I think one of the messages that could be crafted is about the kinds of things that are going into your body. So I could see that.

Dr. Paul?

DR. PAUL: This is apropos of using what you're talking about. Jamie Oliver did this experiment where he showed kids what into Chicken McNuggets, and the oohs and ewws for the sugar and the salt and the chicken parts that they didn't even recognize was -- the kids were just discussed.

Then he took the little things that he put all the stuff through a blender; it came out a pink mess, kind of like pink goo, breaded it, and fried it, and he said, "Would you eat it?" And they said, "Oh, yes. We're hungry."

(Laughter.)

DR. PAUL: So they had seen just how disgusting -- and in fact, McDonald's wouldn't even comment on it -- how disgusting it was what he had made. But he literally put the chicken and the guts and everything through, and they still felt that it was desirable because they were hungry.

So the question is, really, what do you do to make young people think that what you're showing them has potential harm if they like the idea of -- if for whatever reason they -- now, maybe they're not already smoking, so they don't know that it's pleasurable or don't know how pleasurable it would be for them. But I'm not sure that you really can show somebody all the constituents and then come up with the idea that that's going to make them less likely to engage in the activity.

DR. HALLMAN: No. I think that's clear. What do you suggest? Don't eat Chicken McNuggets. Great.

DR. PAUL: I'm not sure. I mean, I think it's unfortunate that what I have is a negative. I don't have the positive to go with it. I have to

think about that one, but I'm not sure I'll come up with anything.

DR. HALLMAN: Still, I think that there is an opportunity here with the release of new information to revitalize or focus people's attention on the issue again.

Dr. McAfee?

DR. MCAFEE: I'm struggling, Mitch, trying to think in terms of your asking about youth and adults. And just two thoughts about that.

The first is I think in some ways youth should be easier because in terms of initiation, they're not already addicted. And we have made some strides in the last 10 to 20 years at diminishing the aggressive exposure to positive imagery around tobacco, and there's been a sort of frame shift, even within youth culture.

So I think that that's something that could be done, and it could be incorporated into some of the existing -- I think adults, though, are the place where this really provides a more important both opportunity and obligation.

The thing that's different is I think people are thinking of all these different things that they've done within risk, et cetera, that have worked or haven't worked, and how do we do it. I think the short story around this is going to -- it boils down to dose.

The thing that's different is that adults are -- for sure adults, and then with some secondary exposure to kids, are exposed to 8- to \$10 billion worth of promotion that is giving a message that is subconscious and subliminal. But it is generally associated with positive imagery, positive health associated with smoking.

People, even though they may have some little piece of cognitive information that smoking is bad for them, they don't have the kind of ammunition that they've got to keep smoking that that 8- to \$10 billion in promotion plus addiction gives to mess with their brain.

So this is an opportunity to counteract and give them some ammunition that we know they want because we know 70 to 80 percent of smokers

want to quit. But because the scale is so large, really it requires, I think, FDA to commit to doing something in terms of a public education campaign to make people get these three or four key issues.

We can talk about different mediums, community versus media, et cetera. But some of it is just going to boil down to a significant commitment of resources and not a one-shot deal, something which most of these campaigns that have been created and done, including, I must conference, the one with the Surgeon General report that Dr. Samet proposed.

The dose is tiny, and it's administered once or twice. And this is happening in a world where the other imagery is -- kids and adults are continuously exposed to.

DR. HALLMAN: Dr. Strickland?

DR. STRICKLAND: It occurs to me as I'm listening to the discussion that our emphasis has been on the influence over individual behavior change. It may be important to think about ways to frame messages that would be aimed at the influence

of policies and structures and normative behaviors within populations.

DR. HALLMAN: One of the issues that was raised earlier was the issue of secondhand smoke. And how does that figure into any of this, or does it not figure into any of this? I assume that the exposures are supposed to be to the smoker, not to the people around them.

DR. CHOINIERE: Well, yes. The constituents are derived from machine-smoked cigarettes, so it is to the smoker.

DR. HALLMAN: So we're almost out of time, and so I'd like to give my colleagues from the FDA the opportunity to pose follow-up questions or, if there are particular things that you'd like us to clarify or summarize.

MR. ZELLER: Our only message at this point is a tremendous amount of thanks to members of both committees, to the staff that helped put this together. I'd like to personally thank David and Conrad and team for a remarkable job in assembling the science that could be assembled on a

really, really tough set of questions and behaviors. So on behalf of the Center for Tobacco Products, I just want to say a big thank you to everybody who contributed to today.

### **Adjournment**

DR. HALLMAN: Thank you, and thank you to the committee. Thank you to the audience for sticking with us. And for those of you seeing this by webcast, thank you for tuning in.

We will reconvene tomorrow. The Risk Communication Advisory Committee will reconvene at 9:00 a.m. tomorrow. Thank you very much.

DR. SAMET: I think TPSAC reconvenes at 8:30, if I'm correct. TPSAC is at 8:30.

(Whereupon, at 4:53 p.m., the committees were adjourned.)