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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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CENTER FOR TOBACCO PRODUCTS

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BATTERY SAFETY CONCERNS IN ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS): A PUBLIC WORKSHOP

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April 20, 2017
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FDA:

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PUBLIC COMMENT SESSION

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American Academy of Pediatrics

JAMES XU
AVAIL Vapor

STACEY YOUNGER GAGOSIAN
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SESSION 4: SAFETY FEATURES FOR RISK MITIGATION

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SESSION 6: BEST PRACTICES FOR RISK COMMUNICATION

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M E E T I N G

(8:36 a.m.)

DR. YEAGER: Welcome to the Center for Tobacco Products public workshop on Battery Safety Concerns in Electronic Nicotine Device Systems.

Yesterday we went over in Session 1 -- oh, sorry. Administrative detail first is if you want lunch today, you want to try and get over to the kiosk before about 9:30, 10:00 at the latest; otherwise, you may be waiting in a long line and it could take a while. That administrative portion is covered.

Yesterday in Session 1, we covered the Scope and Impact of ENDS Battery-Related Fires and Explosions. In Session 2, we covered Cell, Battery Pack, Charging Safety, and Risk Control. And in Session 3, we covered Failure Modes and Design Strategies, and we had some great speakers and some great panel discussions.

Today we will be going over the Public Comment, then Session 4 will be Safety Features for Risk Mitigation. Session 5 will be Current Practices of ENDS Battery-Related Risk Communication. And Session 6 will be Best Practices for Risk Communication.

And we will now move to our Public Comment Session, and in

our public comment we will be starting with Milton Tenenbein, American Academy of Pediatrics.

DR. TENENBEIN: Thank you very much and good morning. And good morning from the American Academy of Pediatrics.

My name is Dr. Milton Tenenbein. I'm an injury prevention pediatrician with over 30 years experience studying the child health implications of product safety issues, including burns and explosions. I contribute to the development of child-resistant lighter regulations that have resulted in reductions in deaths, injuries, and property loss due to fires from children playing with lighters.

I am here today on behalf of the American Academy of Pediatrics, the AAP, a nonprofit professional organization of 66,000 members dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults. We are grateful for the opportunity to provide input at today's Open Public Hearing on battery safety concerns and electronic nicotine delivery systems.

Electronic cigarettes are a child health issue. In 2015, more teens used e-cigarettes than regular cigarettes. Ten percent of eighth graders, 14% of tenth graders, and 16% of twelfth graders used e-cigarettes compared to 4, 6, and 11% for

cigarettes respectively. The AAP has been concerned about the child health effects of electronic cigarettes for years.

For many reasons, the APP supports the FDA's work to regulate electronic cigarettes. That authority is critical concerning the latest emerging threat these cigarettes pose due to burns and explosions. These products pose a risk when the battery explodes. The primary concern for this is with rechargeable vaporizer devices. This is possible when the device is charging, particularly when used with an aftermarket charging adapter.

In addition, the devices can explode or catch fire in a user's pocket or during use. While lithium-ion batteries can pose these risks on their own, they are heightened because of the construction of the vaporizer devices, which vary widely in production quality and which the user often modifies.

The injury risks these devices pose are substantial when charging the devices can cause fires resulting in burns and smoke inhalation. They can also explode, which additionally can cause physical trauma. Many case reports exist of devices exploding or igniting in users' pockets, leading to serious third-degree burns on the thighs and genital areas. Third-degree burns require frequent and painful dressing

changes and skin grafting and often result in lifelong physical and psychological scars.

There are also case reports of devices malfunctioning during use, leading to burns and injuries of the hands, mouth, and face. These injuries can cause serious and permanent harm and disfigurement.

Concerns about the hazards associated with e-cigarettes have resulted in the U.S. Department of Transport last year banning portable electronic smoking devices in checked luggage. The AAP is concerned about the child's health implications of these burns and explosion risks. Infant and young children can be at risk of injuries from fires and explosions in their homes when parents and relatives use e-cigarettes.

Toddlers and young children expressing developmentally appropriate curiosity and modeling behavior could sustain injuries from insufficiently secured electronic cigarettes that overheat or explode.

In addition, adolescents using these devices could experience serious burns and physical trauma. Children are uniquely vulnerable to these injuries because of their growing and developing bodies, and it's critical that FDA take all available measures to protect children from the hazards from

these products.

There are important design changes that the FDA could require for these products to enhance the risks for burn and explosion injuries -- rather, to reduce the risk, I should have said. We, as pediatricians, do not profess to have the expertise regarding design and manufacture of these devices, and we rely -- and would rely upon design engineers of that industry for these developments. We hope the FDA will recommend that the industry do so.

I'm concluding. And in conclusion, as noted, electronic cigarettes are prohibited by the U.S. Department of Transport in airline checked luggage. This is a testament to the hazard of these devices. We need to make them safe both on land and at 35,000 feet.

Thank you again for this opportunity to provide testimony today about the risks of injury from electronic cigarette burns and explosions. The AAP looks forward to continuing this work with the FDA to protect children from the many harmful health effects these products pose, including burns and explosions. Thank you ever so much. Have a good day.

(Applause.)

DR. YEAGER: Our next speaker is James Xu with AVAIL

Vapor.

MR. XU: Hi, everyone. My name is James Xu with AVAIL Vapor. AVAIL Vapor has over 100 stores. We definitely have our firsthand experience with battery-related issues.

Before I started AVAIL, I already had over 2 decades sourcing experience from China, and for the last 4 or 5 years, I have visited at least 70 ENDS manufacturers in China. Doesn't matter what industry you're in and what product category you're sourcing from China, the distribution, they can make the best product in the world, they also make the worst product in the world also. Every single industry, they all follow this pattern.

When you go to China, you can find many suppliers who make the exact same thing. On the top, you have the state-of-art, best of the practice. For the e-cig industry, there's no exception. So in our industry, you go to China, you will find some of the -- you have about a dozen of them that's actually over 1,000 employee in size, and many of them, they are ISO-certified, some of them even GMP-certified.

If you talk to -- learn about battery safety, that's music to the ear because they have a large staff of engineers. But for every one of them, there's at least 10 that fly by night,

that kind of sweatshop, and that's the one that you have to avoid. That's the trend of the number of manufacturers because China market is growing.

So you can see that some factories are very well run, but just like the last -- some speakers point out yesterday, for some of the shop, if you set one foot in, you already saw more than enough.

So, unfortunately, for many of the smaller shops, they just don't care because today they make ENDS product, tomorrow they can make battery power bank, and who knows what's the next day.

So for the key components after the -- our device, which is the lithium battery, they follow the exact same pattern. There's over 1,000 battery manufacturers in China. To the left, you can see some fully automated state of art. To the right, I have been to some of the factory, they literally making lithium battery by hand or even worse. Some of them actually use -- collect used 18650, recycle them, rewrap them, and sell U.S. new.

So that's the relationship between the battery supplier and ENDS manufacturer. On the bottom, that's your trouble spot; that's what you try to avoid because when you have -- you

know, a company don't have any standard and buy the wrong lithium battery, you have double whammy. So how do you avoid that? You have to do your homework.

Unfortunately, the vaping industry is so new, many have to buy in the space, they don't have the sourcing experience, how to deal with China, and they just don't know how to -- they just get fooled by the fancy website, and we all know over the website you can be easily fooled by the fancy whatever they're saying on a website. You have to go there; you have to do your inspection before you place the order and after you place order. There's no shortcut.

Then also, we need a standard. Industry is desperately waiting for a standard, and all the manufacturer, especially the top tier manufacturer, they actually welcome any standard to regulate this industry.

Thank you.

(Applause.)

DR. YEAGER: Thank you very much.

Our next speaker is Stacey Gagosian with the Truth Initiative.

MS. GAGOSIAN: Good morning. As it says, I am Stacey Younger Gagosian. I'm a public -- Managing Director of Public

Policy at Truth Initiative. We're an organization dedicated to youth rejecting tobacco and making tobacco a thing of the past. I appreciate the opportunity today to speak about the need for expeditious action on battery safety standards in e-cigarettes or ENDS.

There have been many reports in the news media regarding exploding or malfunctioning batteries as well as other basic safety concerns. Just last week the Navy banned e-cigarettes from naval ships, aircraft, submarines, boats, craft, and other heavy equipment. This is due to 15 such incidents reported between October 2015 and October 2016.

While the focus of this workshop is on the more technical issues associated with e-cigarette batteries, we cannot forget the reason we're discussing these technical issues in the first place, that is, FDA's public health imperative and ensuring that consumers will not be harmed by these products, especially due to a lack of quality and manufacturing standards.

Dr. Williams's photos from yesterday were a stark reminder of the kinds of injuries that occur from low-quality batteries and the unregulated Wild West in terms of battery standards that several speakers highlighted yesterday. Standards must be developed in order to protect consumers from the dangers not

only associated with what's in the product but the device that delivers the product as well.

We are glad that FDA is moving forward with this public workshop, but more importantly, we urge FDA to take what is learned from this workshop and quickly develop product standards for the batteries and other manufacturing standards for these products.

As has been pointed out, the subject of this workshop is not just any consumer product with a battery; this is a product that delivers an addictive substance that people put in their mouths and breathe the vapor into their lungs.

Truth Initiative has supported a harmonization approach to tobacco use. Under that policy, the best way for smokers to reduce their harm is to quit as early as possible using FDA-approved cessation methods. However, for those smokers who can't or won't quit, Truth Initiative supports the idea of moving people off combustible products to the exclusive use of the least dangerous products, which once having undergone FDA review, is a category that e-cigarettes may very well fall into. However, this potential cannot be reviewed -- excuse me, cannot be realized in an unregulated environment, including regulation of the battery.

This should not only be a priority for public health but also for the industry. It will level the playing field, and only the safest highest-quality products will be on the market.

Standards to ensure that e-liquids are as clean and free of impurities are also necessary, and we urge FDA to move forward on those as well. However, in the near term, we hope that standards regarding battery and other aspects of device safety are forthcoming. I cannot emphasize enough the urgency for this. Public health cannot be left to voluntary standards, and FDA must take action sooner rather than later to ensure that e-cigarettes are as safe as possible, and we look forward to working with FDA to do this.

Thank you.

(Applause.)

DR. YEAGER: Our next speaker is Patricia Kovacevic with Nicopure Labs LLC.

MS. KOVACEVIC: Thank you. Thank you for this opportunity. I'm afraid the mouse doesn't work. Can we -- okay, I'm sorry. So I represent Nicopure Labs, a family-owned leading manufacturer of e-liquids based in Florida. We have sales in over 65 countries.

Basically, battery safety concerns are not specific to

vaping products. Very recently, the U.S. Consumer Product Safety Commission pointed out issues with safety standards for lithium-ion batteries, basically following a massive recall of Samsung Electronics phones. The slides will be available, so I'll just breeze through them.

This is an example of some battery recalls on the U.S. Consumer Product Safety Commission's website. The U.S. Consumer Product Safety Commission also has voluntary standards activities, and they provide a report, an annual report on those, and of course, all types of batteries are actually abundantly featured. And the latest reports are also available on their website.

Our company understands how important safety is to all of our consumers, and therefore, our products have a variety of safety features, including overheat protection as well as short-circuit protection that make sure that the batteries are not damaged by faulty tanks or coils.

We also have overheat protection where batteries are equipped with automatic cutoff safety feature if the button or the activating button is unintentionally pressed for more than 10 seconds, such as when it's in a bag. And also low voltage protection. As you've abundantly seen yesterday, there is all

kind of issues, and low voltage can be an issue.

But it is misleading to think that there are no battery safety standards; in fact, there are -- I looked up, and there are probably hundreds of battery standards worldwide, some under ISO and some other international organizations. So we really have a very good starting point.

I have taken a few screenshots here of existing battery standards worldwide, but there are many more than these, and you're welcome to look them up. So when people say we don't have battery standards, actually, we do. They're not being applied in the U.S., and they're not mandatory at this time. FDA has authority to issue product standards. The development and use of standards have been integral to the execution of the mission of FDA since its establishment. These are the very words of the FDA on their own website.

Standard-setting activities include matters such as testing methodology, manufacturing practices, product standards, labeling, or other technical or policy criteria.

Section 907 of the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, authorizes FDA to issue tobacco product standards that the Agency finds are appropriate for the protection of the public

health. Thus, in that circumstance, battery safety standards would be issued pursuant to notice and comment rulemaking.

Now, how does that square off with the industry's attempt to change the deeming rule? Those are two very different things. Of course, we all are aware of judicial or court proceedings in the Nicopure Labs and others lawsuit, but should the deeming rule in its present form withstand judicial review -- that's an option, of course, it's always an outcome that is possible -- we believe FDA has sufficient information to initiate notice and comment rulemaking under Section 907 with respect to battery product standards. Comments collected in response to the advance notice of proposed rulemaking will provide additional actionable information to inform FDA's final rule on this subject matter.

However, should the litigation result require FDA to engage in notice and comment rulemaking with respect to the entire deeming rule, we believe FDA should revisit its assertion of jurisdiction over vaping devices sold independently of tobacco products, as these products are neither made nor derived from tobacco, nor are they an accessory, part or component.

Thank you.

(Applause.)

DR. YEAGER: Our next speaker is Amy McCann with Smoke Free Alternatives Trade Association.

MS. McCANN: The Smoke Free Alternatives Trade Association, or SFATA, consists of 1,300 retailers and manufacturers of electronic cigarettes. We support any efforts to protect our consumers to the proper education and quality control in a diverse vapor market. SFATA supports and encourages public education on the proper care and handling of all batteries. While the incidence of injury from overheating batteries is low in vapor products relative to many other consumer electronics that use the same type of batteries, we take any accident very seriously.

Proper storage, charging, and use patterns are important practices for all batteries that consumers should understand. SFATA opposes battery law proposals if they single out vapor products from other devices, like cell phones and laptop computers, for enforcement. SFATA also opposes defining batteries as a tobacco product and regulating them as such simply because they can be used to power a vapor device.

Since its inception, the vapor industry has made consistent upgrades to its hardware. The tube-shaped mods that

were referenced several times yesterday lost their popularity in the marketplace due to consistent innovation. I personally own 14 retail establishments. We have not ordered or sold two mods in about 16 months. These devices have been replaced with products that offer more control and safety to the customers.

With all the improvements made, the devices are not perfect. This is largely due to the fact that the market has been frozen since August 8th of 2016, the day that FDA's deeming regulation became effective, bringing all of these products that contain tobacco-derived nicotine under FDA's tobacco authority. There can be no safety improvements made to any of the products currently on the market, both devices and liquids, without going through the extremely onerous and expensive premarket tobacco application process.

Battery companies have made slight improvements, such as including plastic safety cases with their products to help ensure that loose batteries are properly stored when not in use, and are also using rubberized wrappings. Unfortunately, this is as far as the electronic cigarette industry is allowed to go.

Yesterday we heard several suggestions as to how we can potentially go about making these products safer to the public.

Since these products have been placed under the Tobacco Control Act, no further innovation or improvements can be made without going through a premarket tobacco application. If it is decided by a work group or any type of standards company, such as UL or an agency such as CPSC, that certain improvements or requirements will be best for consumer safety, under the current law they will not be able to incorporate -- be incorporated into the products. This application process is not slightly burdensome like doing proper cell testing or having a certification problem. Yesterday it was quoted it was like 2 cents per item. Buying them from specific reputable companies was recommended yesterday.

This application process, which has no guarantee of approval, can cost upwards of $1 million. This, in itself, incentivizes manufacturers to continue producing a product that could be made safer if the ability to make changes was granted to them by the FDA or by Congress. We encourage the FDA and CTP to work with CPSC in order to create standards that are attainable and allow for a diverse marketplace.

Since we are legally not allowed to make changes to any of our products, including the batteries and devices discussed at this workshop, our only option, as retailers and manufacturers

in the current market, is proper and effective consumer education. Later today we will have a section on this topic in which one of our member companies will present several consumer education options.

Our association has also reached out to CTP to assist them in a new consumer education campaign, and we look forward to further promoting battery safety to all electronic cigarette users while we wait for improvements to be legally made to our products.

(Applause.)

DR. YEAGER: Our next speaker is Matthew Tyler, ON Semiconductor.

MR. TYLER: Good morning. I wanted to thank the FDA for pulling this gathering together. I think anytime you bring a lot of intelligent people together in the same space to work on a common problem, we usually find excellent ideas, and we start to very quickly advance the state of the art on what's capable.

Things that I have drawn from our discussions over the last 36 hours, I feel like the industry is maturing in a positive direction, and when I say the industry, I mean battery management in general. As has been highlighted by many of the previous speakers, we see lots of products, many products from

different market segments that have had battery-related issues. Now, as a technology developer and supplier into multiple markets, ON Semiconductor feels that there are many new technologies available, and we strongly urge the FDA and all people related in this space to work collaboratively to establish standards and to establish a system of best practices that not only brings the best technologies to bear on the market for the safety of the end user, but also accelerates safety enhancements to these devices.

I'll cite one example. I was going to prepare some slides, I apologize, but they're not available for you this morning.

When we look at batteries themselves on a molecular level, as we have in many presentations through the course of the last day and a half, we do recognize or we can see very clearly where there's physical degradation of the battery, and there's sequential degradation as these devices are abused. There are technologies available today that can identify the damage being made to small sections of the batteries, and we can preemptively warn the end user that a battery is either inappropriate, insufficient for the task at hand, or is unsafe to be used.

Now, without the ability to accelerate the introduction of those technologies into the market, we guarantee that this particular piece of the battery management market will consistently stay two to three generations behind the most advanced products available for sale today.

So a great example of that is an emerging technology in hearables. Now, these are not hearing aid devices that are regulated by the FDA, but these are consumer audio products that do lots of advanced processing and have lithium-ion batteries; people are placing them inside of their ear. We have been working very closely with the industry to bring technologies to bear, to make those devices absolutely as safe as possible.

So when you look at that technology, the ability to understand the health of the battery and to be able to implement adaptive charging, then we strongly feel that there is a methodology available today that can substantially reduce the risk to batteries in the field for any product.

Now, as mentioned, that's only one part of the equation, and you have to look very closely at manufacturing and sourcing and quality management. This is the case with any industry. I think where we find specific challenges here, this is a new

market, a very fractured manufacturing base, very fractured endpoint of sale base, and when you compare large technology companies that manufacture smartphones or tablets or hearable devices, they have substantial revenues and substantial potential losses if they bring products into the market that are unsafe.

As we've seen with many presentations throughout the course of the last 36 hours, there are companies that simply -- they'll make one product today, they'll make another product tomorrow, they're in and out of business. Regulation will help smooth a lot of that process out. I fully support that; my company fully supports regulation.

But I do believe very strongly that we need the ability to peer review standards of practices, best products and best technologies being brought to bear on the market so that we can make the end users, customers, and the general population much safer.

Thank you for your time.

(Applause.)

DR. YEAGER: Our next speaker is Patrice Carroll from Global Vaping Standards Association.

MS. CARROLL: Thank you very much. Good morning. I am

with the Global Vaping Standards Association, and as we heard yesterday from a lot of the esteemed speakers, there is clearly an opportunity in the industry to improve a lot of the products and quality that the consumer is having with their vaping products. This association was formed to fill that vital role in ensuring that we have the top products that are coming to market.

And our membership is based on reputable manufacturers. This is not a membership group open to anyone. They have agreed to adhere to the highest of standards, again, to ensure that we are mitigating some of the issues that were discussed yesterday.

(Off microphone comments.)

MS. CARROLL: Okay. Would you mind advancing it for me? Thank you. The purpose of GVSA, as I said, we can move forward, but we use ISO and GMP standards to set the foundation, and then we've taken it a step further and have required all of our members to adhere to a higher level of standards.

This membership group comprises manufacturers and retailers that equate to over 50% of the products that are being sold in the United States. Again, these manufacturers

are not just anyone that wants to join; these are top reputable manufacturers that see the need and the opportunity to reduce and mitigate the issues that are coming to place that we were all here discussing yesterday.

We have some of the top manufacturing groups here on the list that you can see are some of the largest and, again, most reputable manufacturers and retailers within the vaping industry.

All of our manufacturers agree to use UL-certified only batteries. As we saw yesterday, the importance of those components, the majority of instances that were noted yesterday had to do with the batteries, obviously, themselves and the charging factors and having integrated batteries, and all of those components are a very primary focus to what the association is currently working on.

We have other multiple lists, this is just a few of our standards, but I do have those available if anyone is interested in seeing those. But we also have that all of our manufacturers will have the integrated batteries by the end of 2017, which is pretty aggressive for this industry, but we feel that's an important component.

If, however, the manufacturer does have in place for a

removable battery, then they will be required to have additional protective housing. Again, that was brought up several times by our speakers yesterday about the importance of protecting that fuse so that it won't discharge or create an incident.

We have four core components to protect the chips and the fuses and protect from overheating and, again, to reduce any charging issues that were also identified yesterday.

And we also talked yesterday about the importance of being able to trace back. Now that they are starting to look at the issues that are noted and they just kind of simply put it under e-cigarette or e-vaping or the vaping, we feel it's important to be able to get down to the root cause of some of these issues and really identify which manufacturers or which products are causing the issues.

We are endorsed by the Shenzhen Vaping Technology Association, which they are behind this effort as well.

We will have a quality seal to indicate that those members are adhering to these standards within their products and will become recognized.

And historically, many industries only react to issues once there have been issues. We feel this was a very proactive

approach to setting standards in place to reduce the mitigated -- and mitigate the issues that were noted.

Thank you.

(Applause.)

DR. YEAGER: All right, thank you very much. This brings our Public Comment Session to a close, but I'd like to remind everyone it's not the last chance to respond to the FDA. There's still an open public docket for anyone to respond to about ENDS battery safety concerns or hazards.

So I also want to make a brief reminder about lunch, to go out to the kiosk before 9:30 or 10:00 to order; otherwise, the line gets a bit long and there may be a delay.

So we will now move on to Session 4, Safety Features for Risk Mitigation. And we will be starting with Larry Albert, and Larry Albert is with Stanley Black & Decker.

MR. ALBERT: Hello, everyone. It's a pleasure to have this opportunity and this interesting experience of addressing a product other than power tools and appliances. I work for Stanley Black & Decker. I'm also involved with a lot of standards development activity, safety standards in appliances and power tools and other related products. Even though we recognize that ENDS are not categorized as appliances, we

believe there may be things in our experience that we went through in sort of developing the lithium-ion battery requirements for appliances and how we apply them that might be instructive for ENDS standards.

Okay, there we go. All right. So battery-operated power tools, in particular lawn and garden appliances and to a certain extent other home appliances, had a well-established application with the use of batteries prior to the application of lithium-ion systems. Most of these systems were NiCad-based, and we also had some sealed lead-acid and nickel–metal hydride.

Most of these cells are fairly robust with respect to high-current discharges which are found in the products, required minimal charging control, and in general were fairly resistant to faults in the discharge and the charging system of the appliances.

Around 2005 the power tool industry was interested in starting to use lithium-ion batteries in their products, and there were no specific requirements at the time that applied to them. The advantages of lithium ion, of course, are in part their gravimetric efficiency and also the fact that they have very low self-discharge.

In December 2006 Dell announced a recall of laptops with lithium-ion batteries where there was fire and explosion, and we took note, as an industry and as well as certifying bodies such as Underwriters Laboratory.

Battery-operated appliances, including power tools: Generally, you'll find three different design styles. Integral designs, where the battery is not removed; it's internal to the product; it's not removed for charging. Detachable, which uses a battery pack, which has a separate enclosure from the cells that are -- these are multi-cell devices, and that is detached from the product for charging. And separable, which uses a battery pack, but that battery pack is tied to the end product through a cable or a tether.

So the approach that we had in the industry prior to lithium ion is a systems approach where the batteries and the chargers were all integrated, not necessarily together physically, but by correlation between each of those to each other. So you were supposed to use the battery pack; it was detachable from the product with a specific charger, and that battery pack was only supposed to be used in certain specific products. And so there was not this idea of having random batteries that you'd pick up from various locations. So

there's no general purpose batteries that were recommended for the use of -- for use in power tools and other battery-operated appliances.

Okay, this is not supposed to be a shameless self-promotion here, but here's an example of what we do in the power tool industry anyway. You can see there is a battery charger and batteries that are intended to go to each other. They have a defined interface system, and that interface is designed to work with the charger and also with the end product. And there's a marking that's on the battery and the chargers to indicate the suitability for each other. You may also notice, too, that there is -- that these are the terminals for the battery, and you can see that they're completely shrouded.

So the appliances that we're mostly concerned with are -- fall into some categories of being motorized or using electromagnetics for movement, including air moving, heating appliances, and lighting appliances. They're characterized by some fairly high discharge rates both in running conditions, normal running conditions, but also high transients for motor inrush currents and also for locked rotor, which occurs with things like drill drivers and so on. This excludes the use of

most of what are called energy cells, which are cells that are optimized for their energy capacity, and we look for what we call power cells; these are optimized for higher output currents.

So energy cells have higher output impedance, and they also often use internal PTCs, that is current -- positive temperature coefficient devices that are essentially overcurrent limiting devices.

Detachable batteries have to be, by design, protected by the hazard that's due to accidental discharge by the inaccessibility of the terminals and/or some sort of internal short-circuit protection.

So in 2006, the situation was that we had standards that were written around AC-powered products and -- but they also occasionally would have requirements, in addition, for battery-operated versions. And so for power tools and many lawn and garden appliances, these requirements were written directly into the standards. In many other cases when the agency had to deal with a product for which there was no explicit requirements, they would borrow appropriate requirements from other standards. In any case, all of the hazards that were dealt with were related to discharge, either

normal discharge that would cause, let's say, heating of the product or abnormal discharge such as short circuits, locked rotor conditions, shorted batteries, back-feed, failure of electronics, and so on.

So with the advent of lithium-ion batteries in power tools and appliances, the power tool industry worked with Underwriters Laboratory to generate a working group to create lithium-ion battery requirements for power tools and other appliances.

We had a broad range of stakeholders in this working group, including the Canadian Standards Association and trade associations, in addition to power tools and home appliance manufacturers, at the time represented by AHAM. We also had lithium-ion battery suppliers and their principal trade association at the time, the Battery Association of Japan.

The first standard we developed was UL 2575, which had an earlier name of UL 2054A. This is intended to layer lithium-ion requirements on top of already existing end product battery requirements with the focus mostly on lithium-ion charging. This, as well as subsequent standards, was a horizontal standard that was referenced, or was supposed to be referenced, by other end products.

So later on, that saw a second generation as UL 2595, which is binationally harmonized as CSA 0.23. It forms a superset of UL 2575 to cover not only lithium-ion requirements, but also discharge conditions, abnormal and normal.

The content of this standard is incorporated directly into the UL power -- UL/CSA power tool standards, and it's incorporated by reference in other end product standards such as vacuum cleaners, lawn and garden appliances, and others that are in process of adopting it.

So in UL 2595, which is CSA 0.23, the general philosophy is similar to what we have in our design of our products, that is, there's a systems approach to dealing with the risks and risk mitigation; that is, the presumption is that the product, the pack, and the charger are coordinated and correlated, and that the manufacturer has control and is responsible for all elements, and there's no general purpose cells.

Generally, we look at cells, lithium-ion cells in particular, as being not something that you'd want consumers to be interchanging themselves; you'd want to make sure it was protected in a battery enclosure.

Battery enclosures, then, are also designed to accept the abuse that's likely to be encountered in life, both normal and

under abnormal conditions. And also with respect to lithium ion, there's allowances for the release of gases that might be produced under a fault condition of the cell. So we can't have gases building up. I think this was addressed yesterday about creating a greater risk in a battery enclosure if it wasn't properly vented.

We still retain the legacy discharge testing, both normal and abnormal, so all of that stuff that we had before that might be appropriate for nickel-cadmiums and sealed lead acid still applies now for lithium-ion batteries because there is a significant risk associated with the energy delivered to an external circuit.

Self-heating, which occurs in these cells, is relatively a lower-risk issue. While there is self-heating during discharge, the temperatures that occur, occur at a much lower level than you would have in a higher cell impedance cell, and also they all occur at lower SSCs. The standard also requires that cells comply with 62133, which is an IEC standard but has been adopted both by Canada and the United States and is currently in the process of being binationally harmonized.

And the charging system, that is, it's a system and not just the charger itself, has to perform with defined safe

limits of the cell, and these safe limits come from 62133. So the voltage can't be higher than the upper limit charging voltage, the current cannot be greater than the maximum charging current, and both of these limits are a function of temperature.

We also in the standard address the real likelihood of cell imbalance, particularly in multi-cell systems, which is, I guess, not usually the case for ENDS.

So this slide or some variant of it showed up several times yesterday. This, again, points out the content of 62133 Annex A, which talks about the safe operating region of the lithium-ion cell. It shows both a maximum charging current here and a maximum limit for the voltage. Typically, it's 4.25 V, but it is temperature dependent, so at lower and higher temperatures the limit voltage can change. Also, that's true for the current. This is provided by the cell manufacturer, and it is presumably verified in 62133.

So one of the other elements of this is that -- the clear distinction between the safety of the charger, which is typically considered as a power unit where the risk of fire and shock is evaluated by standards other than this standard; it's evaluated by, for example, UL 1310 or UL 1012 or similar

standards and the functional safety of the charging system, which is addressed in this standard.

So in the standard, a single fault, the system has to be able to tolerate a single fault, where a single fault would be either a single electronic component failing or a complete failure of the software is treated as a single fault.

And this also has to be safe under conditions of cell imbalance in multi-cell systems. And you can't have an excursion above the -- under single fault condition more than 150 mV per cell, than the upper limit charging voltage, which typically ends up being 4.4 V per cell. If it goes above that, then there has it to be one and done; in other words, it completely disables the system.

So for most systems what this means is you generally cannot have what is called stack monitoring. It typically ends up -- although it's not prescribed in the standard, it means that you typically have to do cell-by-cell monitoring, and it has to be fault tolerant.

So possible applications to ENDS: So just our experience with batteries for power tools and other appliances is that batteries have to have their own enclosure if they're going to be removable. And this controls the potential for accidental

discharge, which is apparently one of the areas of injury, and it also allows the possibility of distributing some of the charge functionality into the battery pack so that it is not all reserved for a battery charger.

It makes the ENDS manufacturer, who are the manufacturers of the end product, responsible for the design and reliability of the battery, and it's not -- doesn't become a general purpose type of cell that's dropped in after the fact.

We don't believe that loose cells are suitable, are appropriate for consumer replacement, and it should not be permitted in the design. Certainly, not in appliances it wouldn't be. We'd recommend using 2595-style discharge tests, both normal and abnormal, including terminal shorting for unprotected terminals of batteries, and also following the general requirements for 2595 with respect to charging, both in terms of cell-by-cell monitoring and also fault-tolerant systems.

The other issue, I think, is the necessity of making sure that physical abuse to both the end product and the battery system is appropriate for the likely abuse that these ENDS systems will see in application.

And lastly, one of the things that we don't probably

adequately address right now in 2595 is the question that came up the other day with respect to USB chargers. Part of the philosophy we have in 2595 is that these charging systems have very well-defined chargers; these chargers are controlled by design by the end product manufacturer.

We recognize that the current trend is to have these USB-type chargers of questionable quality, and so there needs to be some way of making the system sort of fault-proof with respect to variations that could occur in USB-type chargers.

All right, thank you very much.

(Applause.)

DR. YEAGER: And I would like to remind everyone that we're saving questions for the panel discussion. There are cards, index cards on the sides for you to write on, but there will also be a microphone for people to come up and ask questions at the panel discussion.

Thank you very much, Mr. Albert. We will now move on to Douglas Lee with the U.S. Consumer Product Safety Commission.

MR. LEE: Thank you. As Dr. Barnes said yesterday, it's great to be here at White Oak. I actually got my start here, also, as an electrical engineer in the main building. I worked here 13 years, and now I'm working on consumer products for the

last 20 years.

So this is what I'm going to talk about this morning: the CPSC risk management process. I'll talk about a project we have on lithium-ion batteries in all consumer products; I'll talk a little bit about our data, e-cigarette data, from our databases; I'll talk about the battery safety features, which is mostly redundant, you've heard the last couple days, in the safety features in consumer products. And we'll talk about some case studies: hoverboards and cell phones.

So the first one, risk management, the CPSC is basically a reactive agency, so we take a look at our incident data, we determine the frequency of the hazard, the level of hazard, and then we try to reduce the hazard either by education, compliance, or corrective actions with recalls, and then I get involved with standards and either voluntary standards or mandatory regulations.

So we have people at the ports making sure our products that are coming in are safe, certified to the appropriate standards or regulations. And then we do this all again, look at data, so it's a repetitive process.

Looking at our databases, we have basically four of them: The injury and potential injury database. Death certificates;

we buy death certificates from the states. In-depth investigations; we'll send out our investigators to consumers' homes and sample the product, get exemplars if we need to, and test. And then we have our NEISS system, which is a collection of sampled hospitals to give national estimates on injury risk.

So, again, reducing the risk: Our job is to change or create voluntary consensus standards; change or create regulations; reach out to manufacturers, distributors, and importers; and educate the public on the hazards.

So the CPSC statute requires us to go through the voluntary standards. You probably heard a little bit about that today as opposed to where FDA is on their regulation. The CPSC cannot issue regulations without making sure the voluntary standard is not adequate or there is not substantial compliance with the voluntary standard.

So, again, this is a reiterative process. We look at the data, review standards, and propose requirements to the standards.

I'll talk a little bit about a project as a result of hoverboards the last couple years, and the cell phones and recent laptop recalls.

The Commission has directed staff to look into all

consumer products that have lithium-ion batteries. So we're basically to look everywhere, voluntary and mandatory standards, import surveillance and compliance, and we're really focusing in on looking at industry cooperation, interagency cooperation. Right now we have a federal interagency working group looking across at the different product categories; each is a different jurisdiction. We're working with FAA, PHMSA; FDA is now involved from the e-cigarette point of view. Shipping/transportation are the main issues, but any safety-related issues across the government. We're also reaching out to other countries.

We'll be going to China to do some training to give the basics, the same message you heard here yesterday and today, about system safety. We want to make sure the cells, the battery packs, the chargers, everything's talking together and system safety is achieved. So we're going to go into small factories, the large factories, and kind of see for ourselves what the challenges are across manufacturers. A lot of it's been pointed out here today, but until you step your foot into some of these factories, you probably don't appreciate really what's going on. This work or assessment this year will kind of direct future budgets with the Commission.

I'll talk a little bit about data. I guess it was 2008 the Consumer Product Safety Improvement Act put a system into place where Congress wanted us to look at data a little bit better, and so we have the system to look at anecdotal incident reports from our public sources. So it's basically all the data that we had before; it's taken out of the NEISS, the hospital reports, and manufacturer-reported information to the Commission. So what we're doing is taking a look at the last 5 years. Our epidemiology folks came up with these key words to search, and they're actually pretty good because they came up with 21,000 hits in 483 product categories.

Each week the electrical staff is taking a look at between 300 and 500 incidents reported, and we got to process those weekly. A lot of those are battery incidents.

So what we're trying to do is manually filter this; it's a lot of data for our epidemiology staff to look at. We're categorizing in like product areas based on the battery capacity and size. We want to really separate what are the real hazards, the fire and explosion issues, as opposed to the little bit of smoke. Sometimes electronics go, and you get a puff of smoke or a little bit of melting.

Again, sort out non-lithium ion batteries, incidents that

are charger only that may be electrical shock or something with the plug lights pulled out or a cord; we got a lot of cord flexing issues. So it's really not related to the battery, although it could be, so we need to sort that out.

We really recognize the data here is raw, so it's not for statistical analysis; it's anecdotal, and there's a lot of duplicate information there. We really have to look at our NEISS data for injuries, death certificates. Fortunately, there's not too many deaths with these products, but there's a few.

But we really get most of our information from the in-depth investigations where we send out our investigators to consumers and get the incident product. It's most helpful if the product is really not completely consumed, and we can learn more information in our laboratory about that.

We now have a CT scanner at the agency, we have SEMs and high-powered microscopes, so we have the materials and engineers to evaluate at a forensic level on these products.

We're also looking at the recalls. In the last 5 years, we've had 49 related to lithium-ion battery products. Over four million products were recalled. Of course, the Note 7s, the scooters are high on the list. These are, I guess, the top

four that I found that were the most incident products, and the laptops, I think, combine with several. So there are many others that make up the 49 and the balance of the four million products.

What we're trying to do is take a look at the recalls, the root causes of the recalls. We talked about battery management system and cell manufacturing quality issues, the main two categories; lack of any system integration where people put -- just buy chargers, put it together with a system, and you get some combined tolerances that may not be correct. Non-listed cells is an issue, or systems. Want to take a look at the standards, both voluntary and mandatory standards, to see if we can address these or not with what's going on.

So breaking these down a little bit farther: battery pack design problems, they lack safety circuits, adequate overcharge or overdischarge protection, or lacks adequate physical protection. So, again, the quality control problems seem to be the heart of issues where there's already standards in place, but if you're not diligent in that manufacturing process, you know, 10 to 20 microns separating the positive and negative electrode could be very hazardous, as we've seen.

So most of the things we get are improper placement of

leads, contaminants in cells, uneven forming of the cell. Everybody's talked about the automated processes. As these cutting tools get dull or the automated equipment gets a little out of line, there's room for these types of failures. And I'll talk a little bit later on about the welding and missing insulation tape issues that they found with cell phones.

Taking a look at e-cigarette data, it's estimated that children under 5 in the last, I guess, 5 years, the emergency department -- ingestion of liquid nicotine or e-cigarette fluids. There's been 1,200 reports in the last 5 years, 1,500 in 2015, and our epi folks are talking about in 3 or 4 weeks we'll have the 2016 data available.

So this is some incidents that's captured in our database. Again, e-cigarettes is not part of the CPSC's jurisdiction, but we're sharing this information with FDA and any technical information that we can share with them.

There are 34 emergency room visits up to 2016; 29 were reported as explosions, 5 as fires. The same thing, in the pocket. We've had 19 -- or 23 in the pocket; 19 were reported as batteries but it could've -- it's likely the battery, that's the issue. A couple in the face, near the eye; we have burns. And then take a look at the ages of the incident victims, so

kind of interesting. There's three that were older than 45 years, and the rest were kind of evenly distributed.

So next we're going to take a look at the battery safety features we see in consumer products, the same everybody's been talking about, drills. I guess worth mentioning here, again, is the safety circuits that control voltage, current, and temperature during charge and discharge are critical, but again, they don't do any good for these internal shorts.

This is shown from JEITA and BAJ. I won't go into that. Save some time here.

And these we talked about, also, but I'll go through an example here of what we're seeing. Again, these are dependent on the particular chemistry of the cell, the actual cell, what's in -- and the capacity. You have a maximum charge voltage, you really don't want to go, you know, more than 4.25 on something that's rated at 4.2. And it's a very tight tolerance.

Same thing with a minimum discharge. It's not an immediate hazard, but it can show up from internal plating later on; 2.75, you know, you've seen ranges anywhere from 2.5 to 3.3 depending on the cell, what the minimum voltage is.

So if you take a look at C, the capacity of the cell as an

example, we've seen in hoverboards 2200 mAh. If you don't choose that cell properly, you can have some serious events. So a typical laptop cell may be rated at a 2C discharge, and a cell at the same capacity has a high or a 5C discharge, so they're two different cells. In one case you get 8.8 Ah, in the other case you get 20 Ah, so -- and that all depends on the winding, how the manufacturer makes the cell and stuff, so overheating can occur internally.

So we're not looking at any vaping products, but I've seen from yesterday, I think these numbers are probably pretty accurate, and on the internet, 10 to 30 A, and it's really critical to maintain charging at these temperatures and the use of temperatures within 0 to 60 degrees.

So these are other things that we've seen that have caused recalls. Probably 8 years ago or so we started seeing toys come in, or flying helicopters, and they used multi-cell packs, and they didn't balance the cells. So they actually came out with a corrective action, it's called a balance module, so they provided that as a fix to the consumers to make sure that the cells are balanced during charging.

So it's critical to disable charging if the cells are greater than 45 degrees C; we've seen incidents with this.

Disable charging below 3 V or whatever the manufacturer says with the cell, or perform a pre-charging, roughly 150 mA charge before hitting it with a high current charge.

And the last thing is you need to make sure that you're not trickle-charging these cells. You want to discharge or disable charging when -- I think Judy mentioned this, when the current drops to roughly 0.05 C, roughly 50, 100 mA depending on the cell.

So this is a look at, you know, the -- my last three laptop batteries. You notice thermal sensors in circles here are all on there, and you notice this top one has these thermal insulators. So I think they talked a little bit about it, but I'll talk about it here.

What we're seeing in hoverboards is the cell was a plastic that melts when you go into thermal runaway. So if you have one cell that goes off, you essentially have voltage, you know, depending on how the battery pack is configured; you're actually shorting out the other cells. So it all propagates and all the cells go off, and I'll show you pictures of the hoverboards a little bit later. So that's something that's very important; I think the standard should address that with multi-cell packs.

This was discussed before, so I won't go into that.

This is probably worth repeating. I think this is a common theme here. Consumer replaceable electronics should have this battery management system, a safety circuit within the cell if it's replaceable. You know, this may be what's happening with people putting them in their pockets. The bare 18650 cell is -- 18650, that's the dimensions of the cell, but one with a BMS circuit in it is a little bit longer, so you really want that one, you know -- consumers are replacing these units.

And I think in most of the standards -- Joel will talk a little bit about that afterwards. I think most of the standards essentially have requirements on consumer replaceable units.

I guess as these incident products are looked at, you know, it could be that the coins in our pockets and other things aren't triggering the electronics to open up the cell. It could be a higher impedance and 100 milliohms or 80 milliohms that's causing the overheating in your pocket.

So I guess lastly I'm going to talk about hoverboards and cell phones. Let's see, how are we doing with the time here?

(Off microphone response.)

MR. LEE: Okay. So I'll start here in the upper left; this is a typical hoverboard. Of course, you probably figured out by now, it doesn't hover. We've seen, in our lab, I think I have over 40 different units, probably two to three of each unit. They come in different varieties, different colors. I have one that looks like a fire. It, you know, looks like flames. But there are different colors; the wheels are 6-, 8-, 10-, 12-inch wheels.

The battery pack is usually shrunk-wrapped in two different layers. It's a nominal 36 V pack, 20 cells, a 10 F2P configuration, 10 groups of 2 cells in parallel. And they're typically 2200 mAh cells. We have a couple other different configurations, but for the most part they're all like that.

This is the battery management circuit right here. Typically, what they're doing here is taking -- there are comparators on there to look at all the cell pairs. When one sees 4.2 V, it shuts down charging. And then the other way on discharge, whatever it's set at, 2.5, 2.75, or 3, it's shutting off to prevent further discharge. So, in theory, it's really not too bad, but I'll talk a little bit later on about the thermal sensors that are missing in this. It's really because the whole system's got to talk together. You don't want to be

riding one of these things and all of a sudden your thermal goes, so you do a face plant or fall; it's really a very serious injury that can occur.

So this is the basic inside you have. There's the battery pack. You basically have a left and right motor control circuit board, and then you have your main microprocessor electronics, which is the brains of it. And then we have roughly four configurations. There's one that has another board on top of this; there are some units that just have all the electronics in the left and right motor control boards. And so it's kind of been a nightmare for us the last year or so.

Normally, with a consumer product that has a fault, you have one change; somebody changed a resistor or something like that. And here I have, you know, probably 10 different versions of this battery management system, probably 20 to 30 different cell manufacturers. I got probably four or five different versions of these circuit boards, and you know, then I got different colors for those circuit boards, so they're different productions. So there are a lot of combinations, but we found some commonalities with these.

And this is the charger here. This one's a non-certified

charger, typically 42 V, 1½ to 2 amps. It's basically providing the raw power and the electronics over here to activate it or deactivate the charging, and then we talked about the crude battery management system in these.

So this is, of course, what can occur. Unfortunately, just last month in Harrisburg, Pennsylvania, there was a fire during charging that killed two little girls.

So what typically happens is all the cells, one goes off, we don't know which one, typically, but they all went off from that propagation, that thermal overheating.

This one on the right is a Tennessee fire; I think it was a house that was over a million dollars burned to the ground.

And I think this one here is a mattress up in Gaithersburg, so you're discharging. This one caught the bedspread on fire, and I think it propagated a little bit outside the room, outside the house window.

And the one on the left, you know, this is typically what happens; the whole doesn't burn. It's taking out the area where the battery is, and then it's shooting these cells or the jellyrolls, you know, maybe 20 yards across the room in some cases.

And, again, this one here in Pennsylvania, the folks were

actually sitting in the living room, and they saw it go off. So we're telling people to attend these things, but unfortunately, the kids went one way and the parents, you know, were trying to get others out of the house as well as the other kids, and the two died.

As we take a look at our incident data, this number is actually up to 150 fires and probably closer to 4 or 5 million in damages. The incidents are occurring during charging or during and after riding the hoverboard and during and after charging, so we're seeing all sorts of things which says that these are not meeting any standards.

So we talked about the two deaths that we had with that one fire. We also had an elderly person try and ride this and fell over and hit their head and unfortunately did not make it. And then we had a person from the fire services died on the way to this fire in Pennsylvania.

If we take a look at our incident NEISS data, there's over 10,000 estimated emergency room visits, and most of them are sudden stops and falls with head injuries, arm injuries, fractures, sprains, and abrasions.

So looking at the battery management system on this, what you see as opposed to the laptop DMS that I showed you before,

they're actually missing this thermal sensor, and that's because, again, that you don't want to be riding this unit and have the thing suddenly stop. So it's very critical that the system safety works together.

Down here on the right -- it was on the right. This is a run profile of the current with a 180-pound rider on a typical hoverboard, and just like any motor device, there's a large in-rush current. The average current is probably below 10 amps, but what happens here is internal to the cell, the components are actually much hotter, so there's actually a stair-step function of the temperature because there's no time to cool. So that's one area that Srini was supposed to present on before me. But he's done some research at Johns Hopkins with internal sensing and some algorithms to detect that.

So, in conclusion with our hoverboard assessment, you know, the standard allows you to push up to the highest -- you know, in any means run the device, and we did that on hydraulically loaded rollers, and we can exceed 80 degrees in this particular test, but we've actually run some up to 130 degrees. So we didn't really get any go to fire, but you really shouldn't be -- you know, they should be cutting off at 60 degrees C.

So these are the basic things we found: improper battery management, cell -- unknown cells that we don't have data sheets on them and we can't tell what the risks are involved. We want the cells to be certified, we want chargers certified, and then wiring in those things. In the pivoting base, it's kind of like an oscillating fan; there are sharp edges that can cut the wires there.

So a little bit I talked about voluntary standards. We worked with UL to get a consensus standard in place. We want the cell pack charger in the entire product as a system tested together; that's the same theme you've heard over the last couple days, and we're working with ASTM to address the fall hazards.

So a real quick look, in my time left, looking at the Samsung cell phones. This is from Dr. White's presentation earlier at Samsung.

The first fault they found is the radius of the pouch in that process had impinged on the corner and basically caused shorting. This is publicly available at that reference there. But we want to go back into -- we're in at IEEE 1725, making recommendations. We're trying to encourage the industry to come up with good requirements.

I think others talked about it, that there's a dissection process that later on they can come back and look to verify that these corners aren't shorting. There's inspection process, x-ray process in the manufacturing and cell aging, open circuit voltage process.

So the second problem they found was the ultrasonic welding of the electrode to the tab could have high burrs, and then they also found tape that was not there. So the same thing there in the standards, you can verify that the tab welds are correctly in place, the weld height is correct, and that the tape is installed properly.

So a couple of things we'd like to do. Make sure that consumer information -- the cell phones are getting thinner, and the one incident, somebody sat down and caused a fire. We've had other incidents like that with other manufacturers, and we make sure that people are recommending cases as they get thinner. And then also adding external forces tests. You've probably seen the Samsung commercial where they're flexing on the cell phone; that needs to be implemented into the standards area.

So, in conclusion, again, we want system testing, and then we need to update the standards as we find issues like this.

So this is my contact information. If any of you find a good solution to the problem here that we can promote, let me know.

Thank you.

(Applause.)

DR. YEAGER: Thank you, Mr. Lee.

Our next speaker is Joel Hawk from UL, LLC.

MR. HAWK: Hello, I'm Joel Hawk. I'm a principal engineer at UL. Our company, if you're not familiar with it, we've been in business for over 120 years, so we've been in the safety game for quite some time. And for all that time, we've always shied away from tobacco-related products and nicotine-related products, and basically any product that has questionable merit on your health, let's say, we tend to shy away from those types of products. So we consciously stayed away from the e-cigarette business for -- since its beginning for -- until recently. And what drove our change of mind was really the incidents that were occurring in the field.

We came to realize that as part of our mission statement, even though we don't want our image associated with it, we aren't really the physiological science research development organization that would get into the toxicology of the

materials. We realize that our expertise in battery and battery systems may lend itself to providing a basis of requirements and work towards standards development for the ENDS systems, personal vaporizers, inhalers, those type of devices.

So with some resistance and some argumentation within the organization, we did change our position, and in order to address what we're seeing occurring in the field, it was decided that we would move forward and develop requirements and move the ball forward in creating a consensus standard towards these very products and address the very issues that you've heard over and over again. So true to all the science that's been described here, that is our aim, too, to look at the batteries, the chargers, the devices themselves and how that interacts as a system and address what we're seeing as far as the hazards and reduce the injuries.

The UL standards are voluntary; they're not mandated. They can be referenced in the Code of Federal Regulations and other areas as needed, but they are voluntary.

So standards development can take quite some time to do. So our initial objective was we realized this is an issue, it's really taking off very quickly, and if we form committees and

try to start from scratch from, let's say, a consensus and committee-based development standpoint, it's a slow start, and that can take quite some time to develop.

So we volunteered to develop an outline of investigation, so that is a little different than a standard in that it's not covered under the ANSI process, the American National Standards Institute. It's developed by UL, it's used by UL for the purpose of evaluation and certification, but what we do with those outlines is use that as our platform to gather industry, motivate the experts out there than can contribute to it, and work towards a standard. And later on, I'll talk about the status of where we are now and where we're going from here.

But with that, we have published an outline of investigation or a body of requirements. They look into the various aspects that you've seen on the displays throughout the last 2 days, systems approaches, battery requirements, charging systems, protection levels, and a lot of that is done through performance testing. So while you will see some standards, like IEEE, a lot of times we'll look at best practice and how to evaluate products.

Our outline, our requirements moving towards a standard really would be more performance-based. We don't want to

dictate how you design a product, but as long as you design it and it complies with all the performance requirements, then that allows for -- doesn't restrain design characteristics, allows you to build it using new technologies, but using a common platform for what is considered safe by the document.

As a certification organization, UL is actually a test organization and a certification organization. That means we can test to a standard, evaluate it to a standard, and then provide a certification, and what that certification does is it demonstrates that a product will comply with the minimum requirements that have been developed for that product. What certification organizations commonly do, UL definitely has a robust system for after -- or after test surveillance. We call it follow-up service; you hear it called by different names by different organizations, but that's the after-the-fact coverage of the product.

So if you test this little black box today and it passes, well, we need to make sure that you're still building in core specification. So we send inspectors out to the factories, directly to the factories, not the design houses, but to the factories, each and every one of them under our programs, and assure that they comply with our reports and the description of

how the product is to be made, what the manufacturers are supposed to be doing as far as production testing and traceability of their materials, sometimes all the way back to the source. You know, it could be all the way back to the plastic pellet manufacturer that is used to form the enclosure.

We also are tied into customs. We have a great relationship with port authorities and customs to monitor incoming products. We have found there are many manufacturers out there that would love to counterfeit our mark and get into the marketplace by applying that to the product, but we have a very good system with customs to identify those incoming shipments and make sure they're on the system. If they don't check out through a very diligent process, then those are addressed, and the product doesn't get into the market, and we actually will send people out to investigate where that shipment came from and under what circumstance. In some cases that can even result in litigation and ultimately even imprisonment, even.

So we are not a government agency, however. We are in the private sector; we're a not-for-profit and a for-profit organization at the same time, but we do work very closely with CPSC and other government agencies. We actually have a full

division of our government affairs that works very closely with the government, but we are -- you know, what is often confused is we are not actually a branch of the government. So that's a little bit about UL.

But the last piece is we are a standards development organization. We do not just sit on committees and participate. We actually have an administrative branch that facilitates the publication of standards in the organization of the events and the proposal process and the adoption process. That's very unique for an organization to test, be a certifier, and a standards development organization, and we do all three. One of my main roles is part of the standards development process.

So with that, everybody is looking towards a standard, and what UL has done is provided a starting point, and through the starting point UL can -- you know, theoretically we can certify to this, this document. It's not binding to other organizations, but this is what we wanted to start with. Again, if you get pen to paper and you get started, then you can get your interest levels and move forward. Again, if you start with a committee, sometimes that goes a little slow, and there seemed to be a call to action required here.

And for that reason, the question always comes up, okay, you're writing requirements for North America, why -- are you partnering up with the international community, IEC and other organizations? We didn't want to start there. And, again, a slow process; those other committees are inherently fairly slow to get their materials out. We wanted at least to have something out and published and move the ball forward, but absolutely, if there is a demand to look towards a common ground with the international community, harmonize, create a single standard with possibly a different country, deviations, absolutely that's something that we can pursue; there's a process for that. So that could be another phase down the road.

But for now, we've created an outline of investigation, and for this presentation I'm not going to go into, you know, line-by-line requirements and specifics; I'm going to keep it very high level, but -- there we go.

So I just wanted to cover very briefly what the scope is. The title is UL 8139 - Outline of Investigation for Electrical Systems of Electronic Cigarettes. Again, it's an outline. It's not yet an ANSI-covered standard. We'll be working towards that, and I'll discuss what those next steps are

shortly.

And this title will probably change. You know, we hear the acronym ENDS, which is, you know, one identifier. You could call it personal vaporizing systems, there could be a number of names you could call this product, so likely the standard name will change, but there's a couple of fundamental elements in here; it's the electrical systems of the electronic cigarettes. It's not the materials, it's not the consumables, the wicks, whatever you breathe in. We don't want this document to cover that. Other areas of expertise, which is outside UL's wheelhouse, if you will, they're free to pursue the safety of the materials themselves, but this is just for the battery safety, and that is pretty much the focus of this forum.

We actually put the term "electronic cigarettes" in the title on purpose. Now, we know it would change, but to gather some interest, if we gave it too fancy a name or too technical, somebody searching around or if somebody's interested, they may not find it.

So we wanted to specifically get cigarettes in the title for that reason, to give it some promotion and some connectivity to the internet and other interest groups. And,

you know, if you hear personal inhalant device, you may be thinking of an asthma puffer or something like that; you may not associate it with what we're talking about here. So, again, that will probably change, but that's the present title.

And in the standard, this is directly from the scope of the outline, it's specifically for electronic cigarettes and their charging systems, but there's -- this is common science even with other inhaled vaporizers. You know, even if it's cannabis related or aromatherapy or whatever it may be, these are all very similar devices, and those could all be covered under this outline.

The standard under this 1.2, it does not cover what we call a consumable, and that's basically the e-liquids; it can be the wicks, other particulate matter, it's whatever you breathe in, you know, touching the product, what you put on your lips. We're not getting the toxicology and the physiological science of what those chemicals do to you. That's not our expertise, and we do want to focus on the battery, and there does seem like there's a lot of international work already looking into that, so again, that would've been further delay if we were to -- if we tried to cover that, as well, and bring in that expertise.

Again, I'm not going to go through all the very particular items, but to give you kind of a laundry list of what the standard is basically going to look into is the general construction of the product, the components they use. Now, those components, on their individual basis, are going to have to comply with various component standards or requirements or some limited design features, but how are we going to be looking at these components throughout the body of the requirements through the performance, again, as a system like we've seen. All you need is one weak link in that system, and that may translate back to the battery and hazards associated with that explosion point or fire propagation from the battery cells.

On this third bullet item, we place deterrents to replace critical parts, and the critical parts, as we see here, are the battery packs themselves and the atomizer. And commonly, in the market right now, you would have the ability, you could just go down to whatever store and buy a replacement lithium-ion battery and stick it in one of these products.

And because there can be many manufacturers, if somebody is to use a battery that's not compatible with the system itself -- maybe it discharges or charges or overheats because

it wasn't designed by the battery cell manufacturer for that characteristic -- and what we basically found, and what I think a lot of you know is with electronic cigarettes, what we're looking at is almost a direct short from the atomizer. This is just a small piece of wire that heats up as a result from energy of the battery, and if that energy system is not managed, then you are essentially using the battery for normal use under its overload condition. Like it has been said before, you may not see an immediate reaction, and there can even be some battery protection schemes where that may help for a while, but over time you are stressing that battery beyond the chemical science of how it was designed and how the chemistry is protected from the cell level.

So these deterrents are really looking similar to like what Larry was saying where they have to be more of a battery pack, they have to be customized and for use only with this product and that -- and the same thing with the atomizer, you can't just go down to a store and put a replacement part with kind of an industry standard geometry connection means or battery configuration.

Now, we call them deterrents because there's simply no way you could ever fully prevent somebody from coming up with a

bootleg replacement part that hasn't gone through the regulatory system, that isn't covered, but somehow makes its way onto the market. There's always ways of these type of replicated devices to get out there, but the deterrents themselves should hopefully make it impractical for any manufacturer to decide they're going to go offline and develop a replacement part because they can make some quick money on it. I think what they'll find is, hopefully, the hassle factor's not worth it to their business, and it makes it very difficult to do or reduces the numbers, at the very least.

We talk about two-step activation, and this can be a little bit more than just meaning there's two switches you need to push, but there needs to be two levels of known activity taking place that the device itself will know that I am in my atomizing mode, I'm in my operational mode, I should heat. It's not just it's in my pocket, and it incidentally pushes the button, and all of a sudden my device is on, or it has no switch on it whatsoever and an air current is traveling through it even though nobody's using it, and now all of a sudden it's also energizing when it's unintended.

So there are some measures that try to offset that as well as protect any switching mechanism that will have certain

levels of guarding that you can certainly depress the button, but a blunt object pushing against it will not have that -- do that nuisance activation or an unintended activation. Again, the pants pocket issue is always a classic example of a coin or keys or something like that that may push into an activation device.

We also are looking at battery parameters, charging, overcharging, discharging, short circuit, heating, component faults, mechanical abuse, water ingress, environmental conditions, and impact testing. Based on my time, I'm going to have to hurry up here.

But we will also have safety marking and labeling that will be applied. That will be a big challenge in some areas because of the size of the device, and therefore we will return to grain. Interesting. Okay.

But I think it's okay to race over a lot of these comments here because they are very much the same material that you've heard over and over again, and I think the next part is probably what the audience is a little more interested in seeing.

But with these requirements, it -- you know, we acknowledge that we -- UL has applied research department and

doing testing. Our principal engineers like myself have reviewed the battery science and the overall system science. We've had other individuals within the organization weigh in, but you know, we have not seen as large a sampling of the diverse products out there that we'd like to.

So there are some unknowns out there for us, exactly what we might come across, but that is part of the process of getting requirements out there that are not design prohibitive as much as they are performance prohibitive, and from those we will certainly learn a lot, as well as through developing a committee with various stakeholders to become part of the standards development process and help us develop, further develop this living, breathing document. You know, once a standard is established, it is not necessarily set in stone forever. If it is, that's a great thing, but standards always have to develop and evolve along with the technology and the issues that we come across, you know, behavioral changes, new sciences.

Is lithium-ion battery going to be the ultimate battery for the next 50 years? I doubt it. There will be some replacement battery that may be more stable and address the issues, or perhaps a newer battery has better output with

better characteristics, but it's even more volatile. Those are all things that we'll have to always keep in mind and monitor. And, again, with the assistance of CPSC, general incidents that are reported through us, examination of the NEISS reports, this helps us understand what's going on out there without -- and try to get ahead of it before it becomes too much of a problem.

So for this outline, again, right now this outline, it's published. It's the outline of investigation. You can purchase this. I apologize, I did not put it on the slide, but we do have a vendor, its comm-2000.com. It's c-o-m-m dash 2-0-0-0 dot com. They're our vendor, and you can actually purchase the standard.

If you're a UL subscriber, you have listed products with us and certifications, you can actually get this standard for free. I believe panel members are also extended a version, but it is a for-sale item; we don't hand it out for free.

We have formed a standards technical panel, but it's still growing. There is ability to still get on the technical panel, I believe, but we are forming a group of members who will serve as the experts, and I'll give you an idea of how that's done and who's part of that process and how we view those standards. But we will be assembling the STP, the Standards Technical

Panel, on May 4th, so that's just in a couple weeks, and the effort is going to be "let's talk about this document and let's advance it towards a nationally recognized standard under the ANSI process."

And the date of publish of that ANSI standard, that's going to be determined, that's -- you know, it can take years, sometimes. We're hoping it doesn't take that long, obviously. We're hoping that we can get this squared away very quickly and get everybody on board. Again, we think we've captured a lot of the concepts that have been talked about here, so we think we -- and we've used other battery standards like the hoverboard standard and 950 and other standards that have already addressed this issue, so we felt we were pretty well along the way there. So we are interested in seeing what the industry thinks, the supply chains and other stakeholders.

Okay, so the Standards Technical Panel is made up of producers, those are manufacturers of the end product; test and standards organizations, that's like UL; supply chains, those can be your component manufacturers like the circuit boards, the batteries, you know, other parts of the charging systems, other parts of those. Authorities having jurisdiction, those can be code officials, regulatory bodies, government, which can

be CPSC or the FDA. Consumers and general interest, so the general public or academia.

And the voting for the requirements is to the STP members. When we finally come to a conclusion that's timed that we want to go to publish, we'll actually put the document out, we'll discuss it, and then we'll vote on it through a formal process that's done online; it's not done in closed session. Anybody can view that part of the process.

And anybody can submit proposals. You don't have to be an STP member to submit proposals and go through that due process to be heard, be formally recognized and responded to. And although you may not be able to vote, you can also comment on the proposals that are out there.

So this is public information; you just have to be connected to the system. We have somebody here today who can help get you connected to that. And what happens is you'll put a proposal out, there will be a preliminary comment period; then after all of those comments are resolved or decided that they're moving forward, then we do ballot, and that's a yes, no, or abstain. Abstain ends up being much like a no vote, but that is -- you need half of the STP members to vote, and at least two-thirds of those who vote must agree with the

proposal.

So with that, right now that's the status of where we're at. We are interested in others who are interested in that process, and we're looking forward to joining with the experts and move the standard forward.

Thank you.

(Applause.)

DR. YEAGER: Thank you, Mr. Hawk.

Our next speaker is Srini Srinivasan from Johns Hopkins Applied Physics Laboratory.

DR. SRINIVASAN: Good morning, everybody. First of all, I apologize to the organizers and to the audience. My talk was supposed to be the first one. I'm late. No other explanation for that. And thank you for being kind and forgive me. Thank you.

So this morning's session is obviously on safety-related issues and ways to mitigate safety concerns in lithium batteries, especially in the context of electronic cigarettes. I am an electrochemist working in the area of batteries and corrosion, electrochemical sensors, and Bliss Carkhuff is my colleague. He is the electrical engineer who --

(Off microphone comment.)

DR. SRINIVASAN: Yeah, I see the cursor's on here. I see. Bliss is the electrical engineer who helps me in the instrumentation part.

I originally designed this talk assuming I am going to be the first speaker; it turns out I am the last speaker in the session. So I designed it to give you an introduction to what are the safety concerns and why the existing sensors that are used in various standards may not work. If they did work, we shouldn't be seeing any fire anywhere, but we do. Obviously, there is some problem with that.

And then you go into the chemistry of lithium batteries, and you begin to understand what is going on inside the cell and how would you tackle this problem from looking at the inside part rather than from the outside surface, monitoring the skin temperature, etc. Unfortunately, my speakers who went ahead of me, they already told you all the story. So now I have to change my way of presentation and challenge you to think; in a sense, that's what people from universities and educational institutes do. We don't accept conventional wisdom, so that's what my talk is going to be. I'll provide you a way out of it toward the end of my talk, but you can also make your own conclusions. Thank you.

Okay, this is the place I come from. This is the Johns Hopkins Applied Physics Laboratory established in 1942 with intent of helping the U.S. Department of Defense in the Second World War. The proximity fuse that you see here, World War II proximity fuse, is one of our first inventions, which helped the Allied forces to shoot down enemy war planes.

Before that, before the existence of the proximity fuse, people had to aim at airplanes and shoot accurately, whereas the proximity fuse helped explode the bomb when it was very close or the missile when it was very close to the airplane, and then the success rate of shooting down the enemy planes went up.

Subsequently, the next star invention from APL is gun positioning systems, GPS. We used it for a long period of time, unbeknown to the rest of the world, to navigate submarines, of U.S. submarines and Allied force submarines. It was retired in 1992. When it retired, it had much more sensitivity than what you think you have sensitivity in terms of spatial resolution that you have with today's GPS. It was an extremely advanced system that existed since it was invented soon after the Sputnik. Sputnik actually helped Applied Physics Lab to invent GPS.

We contributed to the Big Bang theory; the master inventor of the Big Bang theory was a part of Applied Physics Lab. And since 1960, we constructed about 60 different satellites, including the New Horizon that went to Pluto and sent those wonderful pictures, and it sent a lot more than pictures. The amount of data that is coming in, they're still analyzing to understand what's going on with respect to Pluto and beyond.

In today's talk -- so many of those satellites and many of the other things that we use carry batteries. And today, they carry lithium-ion and lithium primary batteries, so we are always concerned about the safety of the batteries and how to manage these batteries, both in terms of electrical and in terms of thermal events. Lithium-ion battery is also an electrochemical system. That means you have the actual chemicals inside, it is responsive to electrical discharge and charge, and it is also responsive to thermal events. Unfortunately, all these things are interconnected; that means if one thing goes in one way, then the other things will try to respond to it.

When a fully charged lithium battery begins to burn, it burns like an electric torch. Just your 18650 small cell that most people are familiar with, when it is fully charged, can

produce a 22 kW equivalent of electric heat. It's a welder's torch. When it is fully discharged and if it went into thermal runaway, it can still produce 3 to 4 kW of electric heat.

The amount of heat, the total energy, heat energy that a burning lithium-ion cell produces is approximately the same, whether it is fully charged or fully discharged.

When it is burning, it's not only sending out heat, but it's also sending out those potent chemicals. Some of them are very powerful oxidizers. When they are in the proximity of a human being, it is reacting in multiple ways. One is heat and fire, but there is also chemicals that are spewing out of that, and those chemicals are reactive even at room temperature, but any rate of temperatures they could be much more reactive, and they are going to react to the body.

If we understand why all these are happening, perhaps we'll have a chance to prevent fire in most devices, including electronic cigarettes.

Here is an example. This is a little bit personal. This is not a figure that -- a picture that we downloaded from internet. It happened to a family member of one of my colleagues. You can see the cigarette on the -- broken cigarette on the left side. It was in the pant pocket when it

caught on fire and burned this person, and 19% of his body experienced severe burn.

The graph at the bottom tells you that, okay, when it is fully charged or fully discharged, an 18650 lithium-ion cell will produce the same amount of heat energy, approximately 350 kJ. But when it is fully charged, it's going to release all that heat very quickly within -- in less than 1 minute, and it can reach a peak of 22 kW equal in heat. And when it is fully discharged, the heat energy is still 3 to 4 kW. So that is one reason why you have burn, okay, but there is also a chemical reaction that is associated with -- that this person, when the body experienced this kind of injury.

These are things that people are quite familiar with, that is, you know, why would a battery go into, you know, more venting, it explodes, goes into thermal runaway, catches on fire, etc.?

There are three major reasons why it can happen. There can be electrical abuse. This is not quite uncommon in e-cigarettes. People try to charge it fast, and they could be pushing a lot more current through the cell, and bad things can begin to happen.

They could overcharge it because there is not a proper

control on how much charge you could put inside the cell in the e-cigarette, or overdischarge. We want to puff more and more and more, and if there is no limit on when to stop the battery from operating, then you could overdischarge.

And all these things can eventually begin to degrade the chemical construct of your e-cigarette battery cell and eventually drive it into venting and explosion and sometimes thermal runaway.

Thermal abuse is another reason. You could be -- if the cell or the battery gets exposed to temperatures that are in excess of 60 degrees constantly, then you are also beginning to change the internal chemistry and the construction of the battery and of the cell, and eventually, that will degrade the cell and build a path for thermal runaway.

Mechanical abuse, compression, putting it in your pocket and compressing the entire device, in the process compressing the cell, lithium-ion cell, can also cause the battery to degrade and then during use go into thermal runaway.

Now, the paper that I am citing here, at the bottom, actually published -- some of them are published by FDA. The 2014 papers, they're pretty instructive. The authors of this paper have gone through the various problems that were

associated with many e-cigarettes, at that time of publication, 2014, and one thing that I got out of this paper is the e-cigarette parts can be easily exchanged by the user. You can get those parts in the black market or white market.

E-cigarette is not only used to vaporize nicotine; it is used to vaporize a number of other chemicals that human beings, some human beings, want to inhale. But chemicals, all chemicals do not evaporate at the same temperature. That means the resistive heater that you are using should be changed according to which one of these chemicals you are inhaling at a given time. Unfortunately, a resistive heater heats by drawing current from the battery or from the cell that is associated with that, and that battery may or may not be able to sustain that current that that heater is demanding.

Batteries are designed and defined to be used under certain conditions. If those conditions exceed, then the battery is not going to perform safely. And then the user can also buy another battery or cell that will extend the usage; at least that's what the cell manufacturer might advertise, but that long-performing enduring cell may not be able to supply the current that is demanded by the pumps and the heaters that are associated with the e-cigarette.

So there are a number of ways to abuse a cell, and there is plenty of opportunity for the consumer to do that. So all these things will have to be taken into account, whoever is designing standards for e-cigarette cells and batteries.

So this is just a rehash of what I told you just now. Your battery can be charged by a dedicated charger, which is the safest thing to do, but people also use USB ports to charge cells. The only problem is there are at least three types of USB ports that are available to the consumer today, each one of them supplying different amounts of currents. If there is no way to regulate the current that is passing through the cell, you could be charging the cell at a much higher rate than it is intended to charge.

You can also buy fast chargers. People who sell the fast chargers are not completely regulated, and therefore they could be selling things that say, okay, you can charge your cell in 30 minutes, no problem. But if you were to do that, certain cells may not like it, and they will go into thermal runaway.

The battery activation technique can also generate a huge amount of current from the cell, more than the cell can sustain, so you have to be aware of that.

So, clearly, the battery's powering the pumps and the

heating elements, and if these heating elements and pumps are regularly changed by a customer, then the battery may or may not match in terms of the power demands by the pumps and the heating elements.

A battery is supposed to get hot when it is in use, but there are limits. If those limits exceed for whatever reason that I just pointed out earlier, then the battery could go into thermal runaway.

Here comes the technologies that we use in order to create our standards, safety standards. The most common two sensors that people use in a battery management system are voltage monitors and temperature monitors. Almost every battery that you have today that is a thermal sensor, that is kept on the outside surface of the cell, and that's all it is doing.

The voltage could be -- cell voltage could be monitored, or the entire battery voltage could be monitored, but there is some kind of voltage monitor.

The question is, is that really providing you a safeguard against battery fire? Remember battery fire, if you can stop battery fire, then you have solved a majority of the problem.

An e-cigarette battery is not going to give you an electrical shock and kill you. An e-cigarette battery is not

going to spontaneously leak chemicals on you and cause burns. You have to somehow activate the cell so the temperature goes up, and then it explodes, and then the chemicals come out and burn the person, and the heat also burns the person. So if you can contain the heat generation to a safe limit and never allow it to go above that, then you probably have solved a majority of the problem. But the sensors that we use today may not necessarily serve that purpose, and that is the highlight of my talk.

If you believe that those things are safe, meaning a battery management system with voltage sensor and thermal sensor are safe, then this should not have happened. This is an incident that took -- that happened in -- lab in June 2016, and again, see, this is a well-tested battery; this is a well-tested robot, multi-million dollar. But it only took 3 seconds when they put a new battery inside the robot and started charging it. In 3 seconds the overload starts because the fire from the start to end only took 3 seconds.

Battery management systems, the one that people currently use, consist of voltmeter, ammeter, and thermocouple, archaic sensors that seem to be doing nothing to help you from saving the battery from fire. And I'll show you some examples why it

might not be helping you. And we create standards such as the ones that are listed in the bottom of that slide based on these sensors. So we keep pushing this -- we have to take a step back and say are we doing the right thing, is there any relationship between the sensors that we're using and what is actually happening inside this, and then begin to create safety standards. If you don't do that, I'm sure that 10 years from now we'll be sitting here -- like my friend Joel's prediction, I think batteries will last for at least another 10 years, maybe more. But we shouldn't be sitting here 10 years from now and talking about the same thing.

Here is a battery that we deliberately constructed with a bad cell and five good cells, did the voltage monitoring. Well, from full charge to almost near complete discharge, the cells, all the cells had similar voltage. So voltage monitor does not tell you whether the battery is good, the cells in the battery, which one of the cells is good, which one of the cells is bad; it doesn't tell you. There is no clue. We have repeated this a number of times; you can do the same thing.

The cell was intentionally abused; two times it was overdischarged. It's really a bad cell, but voltage monitor does not help you to identify that.

Surface temperatures, skin temperature sensor: Out of those six cells, I provided one good cell example here, which is in green, and the bad cell example in red. And looking at the surface temperature here, and this is the cell battery voltage, fully discharged, fully charged, and you can see there is virtually no difference in the skin temperature between a good cell and a bad cell.

So these are the sensors we routinely use and tell the customer we have very good battery management systems, so your battery should be safe, your device should be safe, and you can keep it in close proximity of your body and no harm will occur, and then 100 fire incidents and 3 people die.

What I think people should be concerned about is what is happening inside the cell, and when you look at inside cell with a battery management system -- this is a battery management system that we developed, it's widely published, it's open to -- you can access this, you can look at it, you can try to redo these experiments.

And when you do that, on the left is normal cell behavior versus on the right is bad cell behavior. You can see it instantly, almost instantly, identifies the difference between a good cell and a bad cell. So you have a prayer of saving

your battery and cell and the people who are using it, if you were to begin to monitor what is happening inside rather than monitoring something happening from outside.

Here is another example. In this case, we discharged the battery in less than 1 hour from full charge to full discharge. That's a very high rate of discharge. Some people attempt to discharge it in half an hour, some even faster. If you do that, there are two temperature curves here. The one in green is the skin temperature and tells you the surface; the skin temperature is less than 40 degrees and everything is safe.

But is it really safe? The answer is no. When we monitor the internal temperature, you find that the internal temperature can go way up and well above 60 degrees. And 60 degrees is really bad; 80 degrees is where the cell begins -- the internal components begin to degrade, and then by the time you go to 120, you have gas generation, pressure increase, and then when you go to 190 there is thermal runaway. We don't want to go even above 60, but you are routinely going about 60 if you are discharging it in less than 1 hour. This is a very good cell.

So suppose if you were to monitor the internal temperature, then you can identify a warning stage when it

exceeds 40 degrees, and you can really cut off the cell from operation when it goes to 60 degrees or close to 60 degrees. You still have 15 minutes to do it at this rate, but if you monitor only the surface temperature, you might believe in your mind or you could make the customer believe that he or she is safe, but they're not really safe.

Our internal temperature sensors are based on impedance techniques. It can identify all the cells, good cells, bad cells. The bottom line is we can identify bad cells from good cells within -- you know, in less than a minute.

This is electronics BMS that we designed and tested and used. This is now old. This was last used 3 months ago. It has two limitations. It can only monitor a battery with 16 cells in series, and it has a large capacitor. We have since then changed this design. We can now monitor any number of cells, one cell, a hundred cells in a series, it doesn't matter. And it doesn't have any capacitor and the size is actually smaller than what you see here.

It monitors the internal temperature, internal impedance, cell voltage, state of health, state of charge, etc. Fast. Each cell takes about 1.3 seconds, and you can monitor the whole pack.

Now, in conclusion, I want to tell you, yes, a sensor like the one that I showed is very large, would never fit into any e-cigarette format. Pretty expensive.

There are two ways to solve that problem. We can start making chips, which is pretty expensive, but it can be reduced in size, and when it is produced and mass produced in millions, then the price might actually be acceptable for electronic cigarettes.

Short-term solution: It's wise to avoid surface-mounted sensors, and we have other alternate technologies which are at this point proprietary, and I'm not allowed to talk about it, but there are some short-term solutions that we can derive based on our experience in this field.

Thank you very much.

(Applause.)

DR. YEAGER: Thank you, Dr. Srinivasan.

Just before we go to break, I would like to announce that any requests for workshop slides can be sent to workshop.CTPOS@fda.hhs.gov, and it should be on a slide up here during the break. But we will break now, and we will return for the panel discussion for Session 4 at 11:05.

(Off the record at 10:48 a.m.)

(On the record at 11:07 a.m.)

DR. YEAGER: Welcome back. We will be starting the Session 4 panel discussion, Safety Features for Risk Mitigation.

If we can get Dr. Srinivasan, Mr. Albert, Lee, and Hawk up here. So we do have a number of questions. We may not actually be able to get to all the questions. We have tried to combine questions where we can, but I also want to encourage people that you can also come up to the microphone to ask a question.

(Pause.)

DR. YEAGER: I believe we're rounding up Mr. Albert, Mr. Lee, and Mr. Hawk.

(Pause.)

DR. YEAGER: And Mr. Lee. All right, I believe we're about ready. So we'll start with Mr. Lee. Could you discuss more about the protected 18650 cells with built-in battery management systems? What are appropriate applications for these cells, and would an ENDS device require reengineering in order to accommodate the larger length of the cell?

MR. LEE: Yeah. Typically, in consumer products that we've been seeing, like flashlights and stuff, those

replaceable cells or when consumers are -- you know, there are other products out there where it's a consumer replaceable battery. We want to see those battery management systems in place within the battery so it becomes a battery pack, if you will. I guess we were having a little discussion about that.

With the ENDS products, some of the safety circuits, it's a higher current device and stuff, so it may need to be a little bit bigger. You could probably take the 18650 cell and make another enclosure and to contain the added battery management functions that are necessary for -- to handle the ENDS currents.

DR. YEAGER: Okay, thank you.

This is for Joel Hawk. What feedback did you get from small ENDS manufacturers about their ability to complete testing and include the design features listed in the outline of the investigation?

MR. HAWK: Very simply, we do not have feedback yet; that is what the Standards Technical Panel meeting that's going to be held is going to be part of that discussion. What we relied on more was our experience with other types of products that had the same issues at hand, like the hoverboards, cell phones, and other standards where we've had these similar issues. So

we're relying mostly right now on experience and analogies to other products. But the true test of the ENDS products, we are looking for that input and again, we're starting with the Standards Technical Panel meeting, but there's ability to provide feedback in other forms as well.

And what I would recommend is if there are individuals that are just interested in providing feedback or data, they can contact UL, and we will take that information and discuss that with you. I will not be serving as the ultimate principal engineer, I'm actually handing that over, but for the purpose of this forum, you can start with me.

DR. YEAGER: Okay, thank you.

So given that lithium battery failures are not an exclusive product type and CPSC already has a working group on battery safety, will the FDA be working with CPSC, and where is the line of jurisdiction over ENDS batteries? I gather this is for you, Mr. Lee.

MR. LEE: Yeah, we've already been working with the FDA engineering staff to share information that we have related with similar batteries and stuff, and also to share the data that we're seeing from our databases. So I'm actually quite glad it's their problem, really, just because you have the

heating element there and, you know, the potential flammable nicotine liquid, but we're willing to share and help with what we know.

DR. YEAGER: Okay, thank you.

So this is a general question for the panel. Successful implementation of standards requires collaboration, and the devil is always in the details. Standard interpretation carries all the way to the laboratory floor where technicians must wrestle with diverse architectures to produce correct test results. How and when will UL reach out to industry to ensure successful implementation of UL 8139? And I gather this is for you, Mr. Hawk.

MR. HAWK: Yeah. Well, it's an interesting question because it sounds like it's not the development or the requirements themselves; it's the implementation of requirements. And let's not limit that to just UL. There are other certifying bodies. There can be others that can take a UL document and certify it to -- or certify to that standard. Just because UL's name is in the title does not mean UL owns it once it's a UL standard. It's a consensus-based standard. It just happens to have UL in the title for legacy reasons. For consistency in implementation, I cannot account for being the

police for other organizations that are competitors of UL. UL itself has a very robust process for competency, training, and it includes the laboratory technicians, those who are performing the evaluations and setting up that testing, all the way to reviewers who review and sign off that work for certification.

And there are qualifications even for the follow-up service that is performed after the product is certified to ensure that it complies with -- it continues to comply with those requirements.

So that's a bit of a general answer, but there is an infrastructure to promote consistency. And we do have processes. When we discover there is an inconsistency, we have processes to deal with that, and those usually get brought up to my level in the principal engineers division.

DR. YEAGER: Okay, thank you.

Please identify yourself and then ask your question.

MR. TYLER: Hello, I'm Matthew Tyler with ON Semiconductor.

DR. YEAGER: A little closer.

MR. TYLER: I'm Matthew Tyler with ON Semiconductor. I have a question for Dr. Srini. So, first of all, I'm delighted

to see that there's corroborative research around internal battery impedance characterization being critical to understanding the safety and health of these batteries.

My question is when you're characterizing the impedance of a battery, are you simply superimposing the stimulus to extract that information from the battery on top of the -- you know, the input charge currents, are those steady state chargers or pulse charge currents? How do you differentiate between your characterization stimulus and the actual loading of the battery?

DR. SRINIVASAN: We do perturb the cell with a current that is approximately C over 200 but never more than C over 100 of the battery capacity. There is a 1 A cell. We typically use about 10 mA AC signal to put them in.

We use multiple frequencies in the 2 Hz to 1 kHz reading, and when we impose that current, let's say 20 mA current on, yeah, a 1 A cell, it will polarize the cell by less than 1 mV, typically about 500 mV. So there will be a noise that is equal to 500 mV between the terminals, and we do that independent of whether the cell is at rest or whether it is under charge or whether it's under discharge. During discharge, you can have currents going up and down, there could be pulse. Because ours

is an easy technique and it is based upon a locked loop, any outside frequency, frequencies outside the ones that we use, do not disturb our measurement, so that's why we do it.

MR. TYLER: Okay, very interesting. I have one short follow-on question, and that is, do you see any reduction in the efficacy of the algorithm by recycling your measurement? Maybe, you know, you make a measurement and an internal impedance assessment at different points of the operational state of the battery where you don't have to stimulate it constantly? Or is this, you know, based on the AC stimulus, is that something you have to do perpetually while the battery is connected to the system?

DR. SRINIVASAN: You can do it perpetually, or you can do it at discrete times and -- because the currents that are flowing during our interrogation, the currents that are imposing during the interrogation, it doesn't change anything with respect to the state of charge. So any change that is occurring with respect to the state of charge or internal impedance is purely of the battery and how it is being used, or the cell, how it is being used, whether it is charged or discharged.

MR. TYLER: Okay. Thank you very much.

DR. SRINIVASAN: You're welcome.

DR. YEAGER: Thank you.

So this question is for Larry Albert. Can you discuss the formation of the working group to develop standards for power tools? How did this group form, and what events led to the formation of the group and subsequent standards?

MR. ALBERT: So that's a little complicated. Well, it's an easy question but a complicated answer. So standards panels, as Joel mentioned before, within UL are handled through the Standards Technical Panel. There are equivalent constructs within other -- within Canada, for example.

So early on, probably back in the early '90s, we had started to put together a binational working group, which are now called technical harmonization committees. But more importantly, we started early on getting involved with harmonizing to existing IEC standards, and so most of the work that occurs today occurs in working groups at the IEC level. We have a technical committee, and we have several working groups within that technical committee, and we propose changes to the standard as technology changes, as problems occur and so on.

So we're not just -- we're just not involving members of

industry and just not U.S. manufacturers, but a wide range of people from a number of different countries with a variety of different experiences and also different, sort of, environments with respect to product safety considerations and so on.

The specific issue with respect to lithium-ion requirements that occurred with our development of originally 2575 occurred in a working group that was comprised of members of UL, CSA, trade association members, members from the Battery Association of Japan, and other parties that all had an interest in this. So it was a very broad consensus group.

And the idea, basically, was to try to come up with, you know, requirements that made sense, right, both in terms of addressing the true hazards that were associated with these cells and also sort of being cognizant of the fact that the kinds of applications that we have with power tools and appliances are fairly rough; they have really high discharge currents and, you know, they see a lot of rough use, and so we wanted to make sure we had something that made sense, that wasn't, you know, a laptop standard that was grafted into appliances. I don't know if that answered the question or not, but --

DR. YEAGER: Thank you very much. The next question is

also for Larry Albert. With the availability of different high-rate lithium-ion battery chemistries of different operating voltage ranges available and with the proliferation of charges in the consumer market, what has Black & Decker done to have an independent fault power of battery? Currently, the batteries do not have any overvoltage, overcharge protection and depend on the charger controls only, which is a major concern.

MR. ALBERT: Well, again, I think the idea that we have both in our design and also in the standard is that the battery pack, if it's detachable, is intended to only be operated with the associated charger. And so it is not necessarily true that all of the functionality with respect to overcharge is located in the charger. There are a variety of different designs where the functionality may be distributed to different degrees in the various components, right, either in the charger or in the battery pack.

So the idea, however, though is that there is the possibility that someone would come along and open up the battery pack and try to charge the cells independent of the circuitry. I think that's something that exists, but it is a possibility, but it's less of a reality in our experience.

What we find is that, you know, people who buy the system, they buy the tool, the battery pack, and the charger, and that integrated -- that combination of components together are used to charge the battery pack. We don't see very much -- you know, very much, sort of, disintegration of those parts in the use of individuals.

DR. YEAGER: Okay, thank you very much.

This is a general question. We have heard that an 18650 cell is designed for specific applications, i.e., high drain or low drain. However, 18650s can be purchased at retailers, and the form factor lets them fit in a variety of devices that consumers use. What is the best way to ensure that consumers using the appropriate 18650 -- sorry. What is the best way to ensure that consumers are using the appropriate 18650 off the shelf for their device?

MR. HAWK: I'll attempt to answer that. That's a very complicated -- or simple question, complicated answer again. With specialty batteries -- this sounds like it's general and not necessarily for these devices. But as a general rule of thumb, really, when you have a high energy output battery, if there are -- if a standard does not have measures to control specific battery packs, and it will usually result in relying

on instructions, markings, other forms of information to best advise a user.

In the ENDS type of program, we're looking at a different solution where those off-the-shelf or readily available battery supplies would not be accommodated by the product so that you would not be able to insert one of those and have it operate. It wouldn't be smart enough or not have the geometry to fit into the device. So that's our solution, or our proposed solution, in moving forward at least with the outline of investigation, is to make it prohibitive of using general-use batteries with these characteristics. Other products, yeah, this can be a complex matter and really needs to be looked at individually, in a sense, because these batteries tend to have special applications that have demand drivers to use them. Not every product may have the need for these type of batteries that are going to be of greater expense, but those are battles for the individual product types.

DR. YEAGER: Thank you. Okay.

(Off microphone comment.)

DR. YEAGER: No, please. Go ahead.

DR. SRINIVASAN: I go and buy a bottle of aspirin. How do I know there's a correct amount of sodium salicylate in that

tablet? Absolutely no clue to that. I just trust some kind of certifications, FDA or whoever certified it. What if somebody is -- a generic drug manufacturer is not following the standards and put it in? And people do experience that kind of stuff every now and then, and there could be problems like that.

So, individually, institutions will have to take some measures, and we do that. And I'm sure that my colleagues here can talk more about how they take measures against illicit batteries that might say something on the nameplate, but it could be performing completely differently inside.

DR. YEAGER: Okay, thank you very much.

Okay, please identify yourself and ask your question.

MS. CLARK-ESPOSITO: Sure. Hi, everyone. My name is Deanna Clark-Esposito with the Clark-Esposito Law Firm.

My question is for you, Mr. Hawk. I'd like to know is UL 8139 more geared to evaluate e-cigarettes with a rechargeable battery or equally to an e-cigarette that contains a disposable battery?

MR. HAWK: Yeah, it's a good question. The outline is intending to do both, everything from an incorporated battery that is, say, a throwaway device to a replaceable device or

replaceable battery. However, again, those measures are intended to make it so that it's not so easy to just go to the store and get a replacement or order one online. You would have to get the specific battery pack for that device, and that would have to be managed through the manufacturer or one of their processes. So it intends to both or allow that full spectrum.

MS. CLARK-ESPOSITO: Thank you.

DR. YEAGER: Thank you.

So this is to the whole panel. Hoverboards and other products noted in your presentations have caused deaths. They have also been allowed to make changes to their products to make them safer. Do you think that electronic cigarette manufacturers should be allowed and encouraged to make safety improvements to their products?

MR. HAWK: Yes.

(Laughter.)

MR. ALBERT: Yes.

DR. YEAGER: Dr. Srini?

DR. SRINIVASAN: Of course, it's a yes. I was thinking that that's the only reason we all convened here.

MR. HAWK: Yeah. Well, it is a serious question, so --

and a serious response. What we are trying to elevate here is due diligence, responsibility, responsible sourcing, and this is an effort in the overall improvement of safety, which never stops. Safety is always an ongoing mission; it's always evolving.

How it manifests itself, how quickly, rapidly, and effectively it does in the marketplace, that is the part that's going to be interesting to see, whether we do our job adequately and improve that safety level to an acceptable degree. I think ultimately the answer is yes, but the measure will be in the extent and the speed.

DR. YEAGER: Go ahead, Mr. Lee.

MR. LEE: Yeah, safety standards are a continuous process of improvement, so the answer, of course, is yes. Just like hoverboards, UL started out with an outline of investigation, and then it did the STP forum, and we got input from CPSC and other manufacturers, so it's a consensus process. I don't think we can completely eliminate these hazards, but we can mitigate them with improved standards.

DR. YEAGER: Okay, thank you.

Go ahead, please. Identify yourself and ask your question.

MS. McCANN: Hi, I'm Amy McCann with the Smoke Free Alternatives Trade Association. I just have a follow-up to that question.

With the regulatory framework as it is now, for us to make any improvements, we'll have to submit a new premarket tobacco application for every improvement we make, which is so burdensome that it will pretty much not be able to happen. So do you have an opinion on whether or not perhaps CPSC or a similar company should take charge of the battery and the electronic device certification process to avoid having to go through the big process, the big expensive process before they can make any change?

MR. LEE: I guess --

MS. McCANN: I know you don't want to.

DR. YEAGER: Well, I think part of the question that's difficult is you're asking -- that kind of relates to FDA regulatory authority and that might be better to ask CTP because you're trying to ask a question that relates to what the FDA does, and that may be a better forum. I think that the position these gentlemen represent may not be able to completely answer a question of what framework the FDA falls in.

But again, we have a couple places where people can go. We have AskCTP for questions like that; we encourage people to go there to ask. But we also have an open docket that -- where comments can still be submitted on information that's going on, on battery safety. So I think that might be better to send to AskCTP.

MS. McCANN: Okay, thank you.

DR. YEAGER: Thank you.

MR. LEE: Correct. And you can send comments to UL, too. If you want to make changes, start looking at the standard; it's a good place right now.

MR. HAWK: Yes, that's absolutely correct. And to follow up on just the general question of burden to manufacturers as a result of changes to requirements, that is part of the process, too. There are administrative steps that certifiers and other agencies have in place, too, to try to make that manageable and through an effective time period.

So in other words, if a requirement changes today, does that shut down your production tomorrow, or are you allowed a certain amount of period to be brought into compliance? There are measures to make that manageable and the concept is, is even though that may be a burden, if all manufacturers who are

complying with these programs are all subjected to the same issues, then everybody's sharing that burden equally, and it's not an individual burden, if you will.

MR. ALBERT: I'd like to make one additional comment on it.

DR. YEAGER: Go ahead.

MR. ALBERT: So our experience in power tools and other industries is that trade associations can have a very dramatic effect in driving well-crafted consensus standards for product safety. I think the perception in the public sometimes is that trade associations are there to protect only commercial interests. I think it has been our experience, anyway, in power tools and some of the other fields that we're in that the trade association has been a very strong advocate for product safety, has initiated or has worked in cooperation with other entities to move product safety forward right through the standards-making process.

So I think there's a great opportunity there to harness some of the membership in some of these trade associations that I was not even aware existed up until today.

DR. YEAGER: Thank you.

The next question is for Srini Srinivasan. Impedance

sensors would need to be miniaturized in order to work with ENDS, but are there other internal sensors that could be used in ENDS at this point?

DR. SRINIVASAN: The answer is possibly yes. We are developing a design. At this point, I cannot describe all of it, but it's basically not a very high-tech solution, and if our concept works, that may be something that you could just -- a cheap solution but potentially wide. Most of the incidents, certainly not all of them.

DR. YEAGER: Okay, thank you very much.

So this is a general question. If replaceable battery packs rather than loose cells were used in ENDS, is there still a chance of the user buying wrong and potentially dangerous replacements for their devices, or would these be specific to the device?

MR. HAWK: The attempt will make deterrents for inserting a battery that is not suitable for that application. Is it 100% foolproof? And I think the answer to that in any context is no. The best we can do is reduce the hazard. I think anything in the world presents a safety hazard. Just give me enough time with this piece of paper; I could kill you with it somehow --

(Laughter.)

MR. HAWK: -- choke you with it, write a note to the mafia. You know, there are many -- many things can be hazardous. So what we try to do is get the level of risk to an acceptable level, and there are concerns that if we have a product type that is so popular that it will have its custom battery pack for use just with that product, can that be copied by somebody through some illegitimate means and put out on the market? That is possible. There isn't a 100% guarantee that you can prevent that, but there's certainly deterrents that can reduce that ability.

There may also be manufacturers that design products and make -- you know, on the battery level or component level that may make claims; those are difficult to manage as well.

So I think the short answer is there is never a 100% guarantee. Our goal is to get it to an acceptable level, at least, that the consensus would agree to.

DR. YEAGER: Okay, thank you.

Go ahead.

DR. SRINIVASAN: One additional comment. The same line as Joel was describing. What we have seen is counterfeit cells. It says something on the -- a brand name on the label could be

sold that is manufactured by some illegal outfit. And then some of them claim that, okay, it's an 18650 cell with 4.5 A capacity. We know that is difficult to manufacture, and if you test it, it gives you 2 A or 2.5 A. But a customer who doesn't have the facility to test it and make sure that everything's correct may face challenges.

DR. YEAGER: Thank you.

The next is a general question. It seems like many different industries have begun to use 18650s without thorough understanding of its use: hoverboard, e-cig. Is there anything that can be done to prevent future industries from encountering similar issues? For example, limitations or monitoring of wholesale battery purchases. Anyone?

MR. ALBERT: I guess all I can say is that, you know, certainly in the industries that I'm familiar with, there's an intense concern on the part of the manufacturers of the end products as to what cells their purchasing and the suitability of those cells for the end products.

While there are battery cells, safety standards like 62133, they characterize the battery, but there's nothing that forces you to use that battery in the manner that it's characterized. People could always misuse a battery if they

don't really have good understanding of the interaction of the battery or the cells to the end product. So it still depends upon the good design engineering that's part of the end product manufacturer.

And product standards, however, that in fact make a point of talking about the interaction of the cell requirements or the cell parameters and the end product requirements do a good job, I think, of at least putting this under the control of a safety standard, and then it's just a question of whether that safety standard is implemented by members of the industry and it's recognized by the public that's buying the products.

MR. LEE: I'd just like to add, I guess that's kind of part of the work that we're doing with other government agencies as product comes into the U.S. I know that the reputable manufacturers, you know, the larger ones certainly limit where they sell their cells to. It's critical, as we talked about over the last couple of days, that the cell manufacturer talks to the end product manufacturer and makes sure that, you know, the cell was used with its intended use or designed use.

So that's something that we're going to look at, you know, because the reputable ones really are trying to control that.

But they're getting out on the internet, people are taking apart, you know, battery packs, we've heard, repurposing these cells, so it's a concern for all in the industry.

DR. YEAGER: Okay.

Go ahead, Dr. Srinivasan.

DR. SRINIVASAN: There is a cost associated with every step that you take when you try to buy a battery and make sure that it is the correct battery to go into a device. Now, if it already comes with the device, such as your laptop or a cell phone, then the manufacturer of the original equipment has already absorbed the cost in the price for which he's selling to the customer. But there is also a proliferation of other devices that -- no batteries included, though I suspect people are beginning to use.

So the way we are trying to handle, we are an organization with 6,000 people, and many more than 1,000 people are involved in making custom designed equipment, and they have to take a battery and put it in and operate it.

So what they're trying to do is if it is a certified battery that comes with a device and it is intended to be used in that device, then we don't do much about it, let them use.

But if somebody has to buy separate cells, make a battery

out of it or buy a battery, then they are trying to create a center where the user can go in, conduct certain tests and make sure it is in compliance with whatever application that they're trying to use. And then if it doesn't pass, then the battery does not pass. We have not yet created -- we're in the process -- we're discussing it and trying to put a facility where an engineer or a scientist who is using it could go in and test it and come out.

DR. YEAGER: Okay, thank you.

Another general question. The focus has been on the mod circuitry, but are there atomizer protections that can be included? For example, requiring certain quality or material in coil wire to prevent short circuits, circuitry in the atomizer than can detect certain current levels or other things.

MR. HAWK: I'll start with that. I'd say, again, the outline that we prepared at UL was intended to be more performance-based. Certainly, if the atomizer, in its design or any component, provides that level of protection required to prevent the battery from going into that raceway mode or into a hazardous mode, that would suffice to fulfill that requirement.

So, again, the standard is trying not to design the

technology or constrain the technology, but from a certification standpoint or a standards development standpoint, that certainly could be a mechanism to comply with the standard.

MR. ALBERT: I'd say our experience in appliances has been that we assume that certain faults that could occur in the system that we know could occur, even though they might be unlikely, are things that we test for as part of that normal testing, and this -- for motor-operated appliances, this consists of usually a short-circuited motor or a locked rotor motor where there's no back EMF. Both of these create high-current conditions on discharge, although they have somewhat different current levels.

But they're still good tests to run because they then force the design to have to deal with these abnormal conditions. It doesn't necessarily have to survive the test, right, but it has to at least be safe at the conclusion.

So, in general, if you take that same philosophy and you were to apply it to electronic cigarettes, then I think the question would be are these events that shorted windings in atomizers, are they likely to occur and to what extent? And if so, then simulate that fault condition and determine what the

consequences are. It would be the kind of approach we'd apply if we were to take that same philosophy.

DR. YEAGER: Thank you. And I think we'll do one last question. It's for Larry Albert, but I believe a related question will be for the panel, too. You recommend not to use loose batteries. How strong is this recommendation, and what are the major reasons for the recommendation?

And the related question is if batteries in ENDS are required to use battery packs rather than loose cells, would there be a significant difference in cost? Would the design of the device circuitry change substantially?

MR. ALBERT: The recommendation, based upon our experience with appliances, has to do -- it comes from a different -- a number of different levels, one of which is 18650 cells, by their very nature there, with no additional circuitry or protection, provide no protection against external short circuits, at least for those that provide the kind of power levels that you'd expect to see in these kinds of loads.

Secondly, the cells themselves may not provide sufficient protection against physical abuse, and that can be mitigated by proper enclosure, battery pack enclosure design. Thirdly, to put protective circuitry in requires something in addition to

the cell, the bare cell, and so the enclosure of the battery pack provides that means. Fourthly, the enclosure then also provides the means of providing a more proprietary type of interface between the charging system and the load and therefore reduces the likelihood of having, you know, cells of various types, construction, quality, and so on being used in the end product.

By having a battery pack design that is specific to that end product, it puts the control of the battery, the cell choice in this case, right, in the hands of the manufacturer of the end product and not in the hands of the consumer who may treat these as being consumable commodities. And obviously, it's going to add additional costs, certainly, with respect to the enclosure.

With respect to the circuitry, I think the issue is the circuitry needs to be there regardless of whether you put it in an enclosure along with the cell or if you have it someplace else.

DR. YEAGER: Dr. Srinivasan or Mr. Hawk, go ahead.

MR. HAWK: Yeah, I echo the same thoughts. With regards to extend that to -- maybe part of the question is does this add to the expense? Well, you know, to build a system approach

that's going to be satisfactory, that cost is going to be the cost. Maybe the other side of the question not discussed is, well, how does that translate to the consumer? Does this mean the battery pack replacement that they're going to have to eventually purchase, is that going to be at a greater expense, is that going to be on the greater price point?

I think, in the early stages, that's going to be an interesting question. My assumption would be, like with most products, that's going to be the expectation that's going to have to be worked out in the industry, and the savings to the consumer for replaceable battery packs as opposed to loose batteries, that's just going to have to be worked through the manufacturing and the industry.

But the driver, hopefully, is that when manufacturers are driven to seek compliance for the due diligence or possibly even regulation, that will level the playing field so everyone is working from the same frame. But the initial period of time in initial years will be interesting with respect to those responses and cost.

DR. YEAGER: Dr. Srinivasan, any comment on that?

DR. SRINIVASAN: No, not at this time.

DR. YEAGER: Okay. And any last word, Mr. Lee, on the

question?

MR. LEE: Yeah, I think I agree with what's been said. In addition, the education piece is large on this, you know; we have bare cells out there. You know, you really don't want those in the hands of consumers, so we need to get the system approach, the enclosure, we need the battery management system.

I think that can be, you know, done fairly inexpensive as you get into volume pricing. You know, the basic circuitry is less than, like, a dollar on some of the smaller, but as you get into maybe higher current devices, it can add a little bit of cost, but I don't think we're talking large orders of magnitude.

DR. YEAGER: Okay. Well, I'd like to thank the panel. Thank you, Dr. Srinivasan, Mr. Albert, Mr. Lee, and Mr. Hawk. Thank you very much.

(Applause.)

DR. YEAGER: So as we have the Session 4 panel exiting, we'll start to call up our speakers for Session 5. That's Captain John DeLeeuw and Vickie Toman, and they're going to be starting Session 5, Current Practices of ENDS Battery-Related Risk Communication.

CAPT DeLEEUW: All right, well, can you all hear me okay?

Okay.

(Off microphone comment.)

CAPT DeLEEUW: What's that?

DR. YEAGER: I think you're good.

CAPT DeLEEUW: Oh, okay. Very good. Just to make sure. Well, good morning, everybody. My name is John DeLeeuw. I'm a captain for American Airlines, and this is Vickie Toman --

MS. TOMAN: Good morning.

CAPT DeLEEUW: -- who is the SMS manager for American Airlines. Just to say up front, we both work for American Airlines, but we do not represent American Airlines here. We've both been in the safety business at the airline industry for a long time, and we were at a conference about a year ago, we met somebody from the FDA, and they asked us if we'd come out and talk a little bit about e-cigarettes, not because I vape and neither does Vickie, but it's because of what has e-cigarettes done and what has been the implications to aviation. So good morning from me and --

MS. TOMAN: Good morning.

CAPT DeLEEUW: All right. So we'll start off. This is a 787, which as you probably know is all electric, for those of you who might be involved in the industry. That's currently

what I fly. This is a picture of a sunrise over Russia at 41,000 feet, and one of the concerns we always have when we fly is any hazards on our aircraft. And we check this; we have a very good process and every airline does.

But one of the issues that has started to pop up in the industry has been the use of e-cigarettes, not the use of in flight but the implications of having e-cigarettes on board an aircraft.

So if we go to the next slide, I'll let Vickie kind of talk a little bit about how we handle e-cigarettes in aviation.

MS. TOMAN: All right, good morning, everybody. As John said, we are starting to see this; this is a concern with all airlines, that we're seeing more and more events involving e-cigarettes and their batteries. So one of the things we wanted to look at is what guidance is there with the FAA. And so we went to the FAA website, and as you can read the screen, e-cigarettes are not allowed in checked baggage, but they are allowed in carry-on baggage, and this is one of the things that we really have to monitor on our flights. I'm sure all of you have flown recently; if you're in Group 2025 for boarding, all the overhead bins are going to be full. So you already know that your carry-on bag, you're going to have to check, and at

most airlines you will have -- the gate agent is going to ask each person individually do you have any loose lithium batteries in your bag, or do you have any e-cigarettes in your bag because you must remove them before you check in the back.

CAPT DeLEEUW: And if you'll notice, the way that the industry has gone is you cannot take an e-cigarette and check that in when you sign up for your flight; you have to carry in the overhead compartment, which leads to further issues as we go further on.

MS. TOMAN: So we got this information from the FAA Office of Security and Hazardous Materials Safety, and this is from 1991 to 2016, and there was actually 138 events that were reported, and these are all events that happened at airports. This does not include the three major aircraft accidents that were involving lithium batteries.

CAPT DeLEEUW: And we're talking about lithium batteries in e-cigarettes, not just lithium batteries as a group, because there's a lot more information on that.

If you'll go to the next slide.

So the big thing on this is, you know, can you carry it in your checked luggage? Like I said, you cannot check it in, but you can take it through security, and you can put it in your

overhead, the overhead compartments.

But that, in itself, leads a little bit to an issue because, and as we talk about it, think about the fact that some of the folks mentioned earlier about some modifications people make to their mods, to their e-cigarettes, and realize when you show up at the ticket counter and you can't check your e-cigarette in, you have to carry it with you, you now have to go through the TSA portals, and the TSA has their own requirements, and they're going to let you take your e-cigarette through, but the question is how will they let you take it through?

So here's what the TSA says, you know: You can take your e-cigarette through, but if you'll notice the last line, it prohibits loose lithium batteries from being transported in checked bags. So we talked about the checked bags not being loose, but what about you coming through security? So you go through the radar, the little detector there, and they look at your e-cigarette, and they go, you know, we're not quite sure what that is and you can figure out why. So they may make the customer dismantle his e-cigarette.

So go to the next slide.

Here it talks about e-cigarettes. Once again, notice the

line, as you read through the slide there, the last line of the first paragraph which says we recommend traveling with them in a designated carrying case.

So one of the issues that we've kind of discovered over time is, you know, you come through, you want to follow the rules, TSA tells you dismantle your e-cigarette because they want to take a better look at it through the radar -- or through the detectors, excuse me -- and you take it apart. Well, you know you're not going to be vaping in the terminal, you know you can't be vaping on the aircraft, so you're not going to put it back together once you've gone through security.

MS. TOMAN: Well, you probably stood in line for like 45 minutes to get through security, and now you have 10 minutes to run to your gate that's probably 40 gates away, so you're going to throw that in your bag and you're going to run.

CAPT DeLEEUW: Right. And realize, in your backpack, you may have already two or three, probably four rechargeable batteries are in your backpack. You just added two more you just threw in there with your loose change, potential dog tags, and now you've got a recipe for some of the issues that we've been discussing earlier.

Notice that, also, the airlines don't let you do recharging of these e-cigarette batteries in flight, the last line, "charging of electronic cigarettes and other related devices," during the actual flight itself. You all know what that is, of course.

MS. TOMAN: It's why we're here. Okay, these are just some random events, and this is just to kind of give you a perspective from the airline. These events are not happening just on the flight in the aircraft when you're at 28,000 feet in the air; they're also happening at the gate, they're happening in baggage claim, different areas on the bus going to the airport.

So this is one event, and these are all different airlines. In Atlanta, this made the news this fall or last fall, sorry. There was a flight that was delayed because an e-cigarette belonging to a passenger started a small fire on board. There are actually pictures of this. They were boarding the flight, and all of a sudden one of the passengers starts yelling, and there was a fire coming out of his carry-on bag.

CAPT DeLEEUW: And these are not one particular airline; these are all right off of the internet. These are no

surprise. Most of you probably know about some of these events here.

If you notice here, Little Rock, there was a flight that diverted there. A passenger's e-cigarette malfunctioned; it was in their possession, it was in their backpack. It appears the device went to thermal runaway, which resulted in a small fire. There was no clue of why it went to the runaway, probably because it was in a bag with other rechargeable batteries.

But the crew members are trained in this, and not just the airline we work for but every airline is trained on procedures how to handle a lithium-ion battery fire. We have specific ways to deal with it, but the reality is we don't want to deal with them.

MS. TOMAN: Right.

CAPT DeLEEUW: Because in our world at 35,000 feet or 41,000 over Russia with a fire in the back, that is a major problem. We can deal with it, but we don't want to find ourselves in that position. But this happened last year in Little Rock; it's all available on the internet.

MS. TOMAN: And the other thing, like what John was saying, we do have procedures for our flight attendants and our

pilots if there is a fire, but I mean, there's also putting out the fire. We don't know the potentials that -- is that battery going to explode? What kind of protection do we have for our crew members because we don't want it to be exploding in their face.

So at Bradley there was another event where the e-cigarette exploded in the passenger's bag while they were waiting to check in at the terminal, and they ended up actually evacuating the terminal because of this fire; they were unsecure -- or unsure if it was a security event or what was going on.

CAPT DeLEEUW: So here is another case, a cabin event. A passenger, they opened a carry-on, and the battery fully ignited, and it came shooting out and bouncing on the aft carpet. It was described like one of these firecrackers at the -- I'm not sure what the terminology is, but you light them up, and they go around like little spinning wheels; that's kind of what this was. It lighted the carpeting on fire along the way. It resembled one of those fireworks, of course, you throw in the street on the Fourth of July. But you can imagine if you're at 35,000 feet and you see this happening in the back, the potential risks to the flight and to the hysteria of the

passengers is of great concern to all airlines, not just the airline I'm with.

MS. TOMAN: Another event, this happened in customs, and this is in Mexico City, and they were waiting for their bags to come up on the conveyor belt, and all of a sudden, a passenger who just walked off the flight, his bag started smoking and started a strong burning smell, and he opened it up to find his e-cigarette, electric razor, and battery charger smoldering. And this is just minutes after they walked off the aircraft, so this could've happened on flight as well.

CAPT DeLEEUW: Yeah, a lot of the events that we're talking about, we're fortunate because we're talking about them because they happened either right prior to flight or after the flight. So draw your own conclusions about, you know, fortunately didn't happen at other times, although we've had a few.

Here's one where an e-cigarette began to smoke in the passenger's backpack on the seat. The fire was extinguished with a fire extinguisher; then the e-cigarette was submerged in water.

So one of the procedures that they use, which is an FAA-approved procedure where you have a lithium-ion battery

fire -- this is not just e-cigarettes but any kind of lithium-ion battery fire. The idea is to go ahead and secure the battery and put it in a bucket of water. And on the airplane, typically, there are pails -- not pails, but we have buckets that you put water in, and we emphasize not ice. Ice won't do it; you have to submerge it in water.

MS. TOMAN: Right.

CAPT DeLEEUW: And then we isolate it, and we'll put it, like, in the lavatory so it's away from the other customers.

MS. TOMAN: And then this last event, this was where a passenger was in baggage claim and an e-cigarette in her purse exploded. It actually burned her blouse, and it actually went out and hit other passengers that were waiting for their bags.

CAPT DeLEEUW: And this just came out about 4 or 5 days ago; some of you may know this, some of our colleagues in the audience from the U.S. Navy, but you can read it here. The U.S. Navy is going to be banning e-cigarettes and vaporizers from its aircraft, ships, and subs after receiving reports about the devices exploding, catching fire.

And one in particular, they mention in the second paragraph, was an incident on an aircraft, had to return to base because the e-cigarette batteries were creating smoke in

the cargo section. So it's surprising that you'd have e-cigarettes in the cargo section itself because we don't allow that in the airlines to be in checked baggage.

But this just came out, and it's going to be effective, I think, in about 3 weeks from now. And you know if the Navy's doing it, it's got to be good, right, although I'm an Air Force guy.

MS. TOMAN: All right. I don't know if you guys have seen this one.

CAPT DeLEEUW: I think you have to go back, go back one slide. And I think --

MS. TOMAN: There we go.

CAPT DeLEEUW: Go ahead.

MS. TOMAN: Okay, this was on an airport bus. Okay.

(Video played.)

CAPT DeLEEUW: That's the bus driver, by the way. He won't be vaping on the bus anymore.

(Laughter.)

MS. TOMAN: He might've been late to work as well.

CAPT DeLEEUW: And one of the things that -- and I didn't investigate or have complete knowledge of this event, but one of the things that was suggested is that the gentleman had some

rechargeable batteries in his pocket, and some of the batteries had the paper that holds the battery, on the outside was torn, and it had several exposed batteries that were not covered by the paper or anything. And so most of you who have been working with batteries know that there's a paper around it, and it's protection around it.

So because I don't vape and Vickie doesn't vape, and actually very few people I know vape, I thought it would be smart to be a little educated on this whole process, not because I was going to be talking here but also for my own benefit and edification. So I did go to a shop, just a random shop, and went over there, and I talked to a couple of the individuals there. I was quite informed about the process, and I actually learned quite a bit.

So if we go to the next slide here, I think that one thing that I found was interesting is this was a place that actually was taking safety very seriously, and not knowing anything about the process, the one thing that the individual mentioned right off the bat was, well, one thing you can solve in the aviation world is when you take the batteries out of your e-cigarette, which happens, that you put it in a battery carrying case.

And some of you have been talking about here, and I think it's well known, everybody probably agrees that this would be one gateway to mitigate the risk of having a battery issue. So if you look at the carrying case here, it allows the battery to go in there, you put three or four batteries at a time. And in a perfect world, if we were going to take and require passengers to take e-cigarettes, dismantle them before they went to security on an airplane, this would be probably an excellent solution to solve the issue about any kind of contact or anything.

You have to pay for these, they're not free, they don't come with the batteries, and this particular one was about $12. And so probably the younger generation is not going to shell up 12 bucks for a plastic case.

One thing I thought was interesting: They had cards at this vape store that they -- when you bought a battery there, they gave this out with the battery, and I thought it was very interesting. This is a couple of the warnings they had: Keep your batteries in approved battery cases when not in use. Keep your batteries in your pocket when you don't -- or don't keep your batteries in your pocket, purse, or other receptacles with loose change or keys.

And so when they sold the batteries there, this particular store individual was pretty adamant, because I was watching him when one of the people bought the batteries, he's very upfront about saying, hey, this is what you have to care for. Sir, would you like to buy a plastic carrying case with it? Of course, the answer was no, so I thought it would be interesting.

They do have a little piece of sheet -- a sheet of paper, I blew it up here for the picture, but you'll see that this is there; it's a little card you can buy or that they give out with the batteries, which has a lot of little m-o-d battery safety tips. It's actually quite informative, but it's a small card, you know, and you have to read it. But clearly posted was an FDA regulation. I don't know if any of you have seen this before. I was kind of surprised to see it, but they talked about free sampling no longer allowed, they talked about they can't take the -- they can no longer rebuild and repair the customers' devices, particularly their do-it-yourself type things they found on the internet.

This is an m-o-d. You can see they can charge it. And I was pretty impressed, not being a person who vapes. These are pretty electronic things. I was quite involved and quite

interested in how advanced these were. You know, you put the battery in there. You hook it and it charges it up. It tells you -- I mean, it's a pretty straightforward little digital, and it will show you exactly how much life is left on the battery there, if you noticed on the picture.

Of course, the RDAs. There's been discussions here in the group already, so I won't go into the RDAs.

This was another one here, and one of the things that the clerk was doing was -- I was surprised at how many batteries are coming in that were torn, the paper was torn. And the wrappers had to be replaced. So they sell the wrappers, and they sold them to the customers. They were not allowed to help them wrap the batteries, but they would tell them how to do it while they were in the store, but they themselves aren't allowed to do it.

So I have a few pictures of that. You can see how this came in; the battery was unwrapped and it was coming apart. So he takes the wrapper, they pull the wrapper completely off -- you can go to the next slide there -- and you can see how the battery on the left-hand side is taken apart. So you pull the wrapper off, you put the new wrapper on, and when the new wrapper goes around it, you basically heat it up.

And if you'll go the next slide, you'll see it comes together, and they can use it again because there's a lot of places where they were telling the customers don't have your wrappers come loose. When they come loose, come in and we'll sell you a new wrapper.

These are some of the flavors out there, for those of you who don't vape. Yeah, who knows. Interesting.

They also sell the charging stations. I did hear the -- because I was there for about an hour just kind of observing the transactions there, I think he thought I was a cop initially, but --

MS. TOMAN: Or the FDA.

CAPT DeLEEUW: Yeah. I told him I was with the FDA.

(Laughter.)

CAPT DeLEEUW: But they had sold the recharging station, and I was fairly impressed because the employee did make mention, hey, when you charge your batteries, don't just charge them and leave them all overnight. When they get full, unplug the device; don't charge them. And the guy said he was going on a trip, and the employee did mention you cannot be charging batteries on the airplane.

So I was surprised that this particular employee was very

good about mentioning the safety aspects, but I suspect that he was probably their topnotch guy. In fact, I'm pretty sure he was. So I'll let Vickie talk --

MS. TOMAN: Here there are some actual little pictures of some events that have happened. This was a fire where loose batteries were in the bag, and there actually was smoke started, coming from the overhead bin, and when they went to check, it was coming from this bag. There were dog tags in the bottom of the bag, and the battery was rubbing up against it. And you can see the little chain there.

This is another event where we had the batteries catch on fire, and that's actually the little case that they handed to the flight attendant, and it shows where it caught on fire at.

CAPT DeLEEUW: That was an actual e-cigarette. So, you know, in our world -- and both Vickie and me and a lot of my colleagues were involved in safety, and we're always looking at, you know, from everywhere from engine fires to all events across the spectrum.

The whole lithium-ion battery events have been relatively new to aviation, but now we're starting to see more of them, and we're starting to see more that are related specifically to e-cigarettes. And it's not that e-cigarettes themselves are

probably designed wrong, but it may be in the process of the way people are handling the batteries when they're taking them out at security or how they're traveling with them.

Someone mentioned earlier they don't just have two rechargeables; if they're a serious vaper, they've got a number of batteries because they, you know, when they -- when the other ones go bad, they don't have time to charge them up.

This is a typical day in the United States with a snapshot of aviation aircraft. And that, of course, isn't at 3:00 in the morning, but if you went at 3:00 in the afternoon, this is the type of traffic you see over the U.S. It's a totally saturated environment. And you can just see that the risk and the exposure to the airline industry is huge, and as we get more and more e-cigarettes on board, more do-it-yourself people modifying things, we talked this morning about, you know, battery packs, which is probably going to be a while, you can see where the risk is to the aviation community. So with that in mind --

MS. TOMAN: And I was going to mention, too, I was really surprised when we flew out here this week. I took the employee shuttle, and it drops you off on the bottom level of DFW, and I'm walking along, and I see all these people back in these

corners, and they're all vaping on their cigarettes. So I'm sure that they're going to be in a rush as soon as they get done to go up into the terminal, go through security, get to their flight. So we are seeing it more and more; it's something that a year ago you would have never heard about it on an airline, having an issue like this.

So we've gone through the hoverboards, the phones, all of that stuff. This is like our next big concern.

CAPT DeLEEUW: Yeah, I think in 2016 we had -- was it 13 events?

MS. TOMAN: Um-hum.

CAPT DeLEEUW: Thirteen events in the industry with e-cigarettes, specifically e-cigarettes, and that was just 2016. So this year we're on record probably to beat that, I believe.

So the next slide. And we'll show you -- these are just conclusions; these are not -- these are John and Vickie's conclusions. So I think one of the issues that we've kind of identified as we went through some events is what I mentioned earlier, lack of awareness about the dangers of the loose batteries in your carry-on bag. Go ahead.

MS. TOMAN: Security protocol for disassembling

e-cigarettes prior to boarding an aircraft. We've been kind of reaching out to different TSA agents at different airports, and it's kind of random, and of course, they have the right, if anything's in your bag, to tear it apart, to look at it if there is a concern, but that also kind of increases the risk.

CAPT DeLEEUW: And this may shock you, but we do have people who do try to vape on aircraft, and they'll go in the lavatory, and even though there's warnings and they've been told, they still vape, and the fire detectors do go off in flight. So the reality is there are still vaping machines that are being used in flight. Now, it's not -- you know, it's against the regulation, but they are being used.

MS. TOMAN: Right. And I think there is a perception out there, well, it's not a cigarette, so I'm not really smoking, but we do include that in our announcement, so they should know that it's not allowed.

CAPT DeLEEUW: So the last two probably are areas of discussion later after lunch, we're going to have a panel, but you know, should regulations mandate that e-cigarette lithium batteries be stored in an approved carrying case? That's just an opinion on my behalf, but if we had to make things safer in the airline world, that would be a start right there to make

sure we're not having loose batteries roaming around with other metal in a backpack or just in a purse or something like that. And the last one.

MS. TOMAN: And the last one is at that store that John went to, they had tons of warnings, and they had cards that they gave out, and they were very proactive to let you know the dangers. But when consumers purchase these products, whether it's on the internet or at a store, what kind of -- is that across the board that they're getting these warnings? Should something be printed on a label just like a pack of cigarettes telling you what the warnings are, to be careful?

CAPT DeLEEUW: And I'm going to be a little selfish, but I'd like those warnings to specifically mention aviation because I kind of enjoy it.

MS. TOMAN: Well, I think the bus driver would like to have a bus included, too.

CAPT DeLEEUW: Yes. I think we could probably find some testimonials out there.

MS. TOMAN: Yeah.

CAPT DeLEEUW: But anyways, our time is up, and I know we've got lunch, so there's going to be more discussion after the lunch, and we'll have a panel, and we'll certainly then

answer questions. But we're there for lunch, so if any of you have questions, you want to chat over lunch, certainly Vickie and me will answer them.

Thank you for your attention.

MS. TOMAN: Yes.

(Applause.)

DR. YEAGER: Thank you. Thank you, Captain DeLeeuw, and thank you, Ms. Toman.

At this point, we'll break for lunch and return at 1:00 p.m. Thank you.

(Whereupon, at 12:10 p.m., a lunch recess was taken.)

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

(1:03 p.m.)

DR. YEAGER: All right, we are restarting the CTP public workshop on Battery Safety Concerns in Electronic Nicotine Device Systems.

We're continuing Session 5, Current Practices of ENDS Battery-Related Risk Communication. Our next speaker is George Kerchner, Executive Director, Rechargeable Battery Association.

MR. KERCHNER: So thank you, everybody. Again, I'm George Kerchner with PRBA - The Rechargeable Battery Association. We're based here -- well, we're based in Washington, D.C. We represent -- let me see if I can move this ahead a little bit. Okay. Left click, right? There we go, all right. Thank you.

So, again, we're based here in Washington, D.C. Our members include many of the major manufacturers of lithium-ion cells and batteries, manufacturers of electronic products, medical devices, automobiles; also testing labs as well. They do a lot of tests, UN testing, IEC, UL testing on batteries; battery recyclers, as well; airlines, dangerous goods consultants, and packaging manufacturers are also members of PRBA.

So what I like to say when I make that introduction is the

great thing about our association is when you think of PRBA, of course you're thinking of us as a battery association when in fact it's a very diverse association, and that's a great thing for me, as the Executive Director, because I get to reach out to a lot of individuals in various industries that are not battery manufacturers but, for example, UPS and FedEx, who are members.

You know, I reach out to them a lot about the transport issues. I reach out to the testing labs about what they are finding in terms of their testing, talking about some of the standards that need to be updated, and the packaging manufacturers, automobile manufacturers, again, just a great diverse association with different memberships that all have one thing in common; that is, they're using battery-powered products or they're manufacturing batteries, and they're all regulated by various agencies, both domestically here in the U.S. as well as internationally.

So our role as the association is to get involved with regulatory legislative policy issues at the state, national, and international level. We're very, very active on transport issues at the United Nations Subcommittee of Experts on Dangerous Goods, the International Civil Aviation Organization,

as well as the International Maritime Organization. All three organizations are part of the United Nations, and they all deal with dangerous goods or hazardous materials transport issues.

So when I came into this meeting today, or this workshop, I was asked to talk about what do the cell manufacturers convey as far as the information they give to their customers. And when I say their customers, I mean the pack manufacturers or the product manufacturers who want to purchase their cells, you know, the product manufacturers are saying, okay, manufacture me a cell that can do X, Y, and Z for my notebook or my tablet or my power tool.

And so I go to those manufacturers, I was asked to go to the cell manufacturers and say come back to this workshop and tell us what the cell manufacturers tell those pack manufacturers and such; who are the intermediate users, for example.

So there's an industry out there they call battery assemblers or value-added distributors who will buy cells from Sony and Panasonic and Samsung and so forth. And when they build those battery packs, they get very specific information from the cell manufacturers about the capability of those cells. And so that information, I reached out to the cell

manufacturers, and they came back to me with information that they conveyed to their intermediate customers, and it's remarkably consistent from one cell manufacturer to the other.

So I just wanted to again share that information with you today. As I go through these slides, and I've been here -- I was here yesterday, and I've sat here since this morning. A lot of the information on the latter half of my presentation has already been addressed by multiple speakers. This whole idea of a systems approach, we are fully in support of that.

I mean, the idea that you can buy a bare 18650 cell and drop it into a device has many of our members very concerned. I mean, we have -- I'm getting e-mails and text messages from our members who are listening or watching this on the internet, and they are appalled, to be honest with you, that there's an industry out there that enables consumers, for example, to wrap 18650 cells at the retail level and drop these things into devices where that cell may have been designed for a different application, for example.

So we are in full support of this whole systems approach. The battery doesn't necessarily have to be integral to the vaping device, but the idea of a specific battery pack or a battery that's integral to the device, we are in full support

of that.

And, again, what I've told people after I've sat here for the last day and a half, we really don't have a dog in this fight because our members, for the most part, don't sell into this market. They don't manufacture vaping devices; they don't usually manufacture cells for vaping devices. But after sitting here for a day and a half, we actually do have a dog in this fight now because it's a safety issue; it's a lithium-ion battery issue. When there's an incident involving a lithium-ion battery, it doesn't matter whose battery it is, it's a black eye for the whole industry.

So when I see these pictures of incidents from the FAA from yesterday and from the airlines today and from -- one of the first speakers yesterday, they were showing patients who were injured by these devices -- that's bad for the whole industry. So it's not just a vaping industry issue, it's a lithium-ion battery issue, and certainly that has an impact on our members.

So just to give a little background, a historical perspective on the lithium battery world, if this is kind of new to you and you weren't old enough to be around in the early 1990s when lithium-ion batteries first came onto the market,

you know, when PRBA was first formed, the portable battery of choice was nickel-cadmium. And then in the early 1990s, lithium ion started to enter the marketplace. Sony was the first one into the market with lithium-ion batteries, and PRBA was actively involved at that time with how these batteries were being regulated.

But at that time, in the early '90s, there was Sony, Sanyo, and Panasonic, and maybe one or two other major manufacturers of lithium-ion batteries, and they had a very tight controlled supply chain and distribution of these cells. They knew where their cells were going. They knew who was using them and what products they were being used in. But it's a whole new ballgame now. Obviously, there are hundreds more manufacturers. You can buy these cells or all types of lithium-ion cells in the market.

And here's a couple examples I like to show people is that there's a company, believe it or not, in China who has a brand name called Ultrafire for their cells, okay? So someone at that marketing department needs to rethink about how they're manufacturing their cells. But if you go to their website, they actually will readily admit that people are counterfeiting their Ultrafire cells. So if you're a counterfeiter, you know,

and you're counterfeiting an Ultrafire cell, you would think they would probably want to raise their level, maybe go after a higher-end manufacturer.

But nonetheless, that's the challenge we as an industry face, is that you've got these manufacturers, mostly in Asia, who are manufacturing what can be poor quality cells, and then, of course, there's a lot of counterfeiting going on as well. So that's a big concern, is that you've got the ability actually to buy online thousands and thousands of 18650 cells and other lithium-ion cells as well, and there's a lot of counterfeiting going on.

The cell on the right there on your screen, I had to point this out because if you go to this company's website called Battery Junction, okay, some of you may recognize that cell, that's the cell from a tier one manufacturer, and that particular manufacturer doesn't sell into the marketplace like that. If you wanted to buy that cell from that cell manufacturer, you would have to have a relationship with that cell manufacturer. You can't go online and buy -- you shouldn't be able to go online and buy that cell. So that cell somehow has ended up on Battery Junction's website. I don't know how it got there, the manufacturer doesn't know how it got

there, but that's not how they sell their cells.

So for the most part, when you're buying what I'll call tier one cells, you have to have a relationship with that product. If I'm a product manufacturer or a battery assembler or a battery value-added distributor and I want a tier one cell, normally the process is you have to get that -- the cell manufacturer's blessing to use their cell in your product or to build battery packs from that cell.

So the challenge we face, as an industry, is the ubiquitous nature of lithium-ion cells these days, where you can buy off-the-shelf 18650s, you know, you name it, any type of lithium-ion cell, you know, on the internet, and that's a huge challenge for us as an industry, to ensure safe cells are being used in all types of products, not just vaping devices. But again, not to beat a dead horse here, but the idea that you can buy a bare 18650 cell, and there are products out there that people are using that they put up to their face, that's got a coil that gets up to 150 or 200 degrees C, again, has our members very, very nervous about just the general safety of those products.

So, again, we as an industry would certainly fully support the idea of a voluntary industry standard being drafted as

quickly as possible to address those core issues. And, again, that's coming from my members who are e-mailing me and texting me during this whole process here. And, again, I didn't come into this workshop with a particular position for the industry, but that's changed over the last, you know, 36 hours or so.

So getting back to my primary presentation here, you know, when I reached out to several cell manufacturers and said can you send to me, you know, the information you give to your vendors or to your customers, and they readily did that. Some of that is on the internet, and some of it's not on the internet. And I'm just going to share with you some of their core safety issues that they convey to their customers. Again, much of this has already been addressed here today, so I apologize for the redundancy, but I just wanted it just for -- to cover the association and the major cell manufacturers and the concerns that they have about their product being used in the marketplace. I'll just touch on these four or five core issues.

So, again, this kind of reinforces the whole systems approach that many of the manufacturers or many of the speakers have addressed over the last day and a half.

But again, getting to the first core issue, and that is

the charging of your cell, you know, charge the cell to a specified current, you know, charge current.

Do not exceed specified current or specified charge voltage; for example, for a 4.2 V cell, you know, you don't want to go above that. And in some cases, certain standards require that you, in fact, charge just right below that maximum specified voltage as an added layer of protection.

Charge cell at recommended temperature range: Again, we talked a lot about that.

Preventing cell from reverse polarity charging: And, again, that gets to that whole issue of you get a bare cell, you drop it into your device, you're assuming that the consumer knows which way that cell should be going, right? You're trusting a consumer to understand that.

Charging cells using specified cell charger: And, again, off-the-shelf chargers or bare 18650s has many of our members, again, very concerned about the way these are approached.

Do not attach cell to power supply plug or directly to car cigarette lighter.

Do not continue charging cell if it does not recharge within specified charging time. So, again, a consumer drops that cell into his charger, and it's not charging and it's not

charging and he continues to charge it, it's probably discharging, okay; it's creating an unsafe situation. He gets frustrated, and he puts it in his pocket, right, gets on a plane, and then you have an incident that way.

So, again, there are all types of, you know, potential latent problems that could occur that do not occur immediately from a charging or discharging standpoint but have this latent effect where this event could happen 2 or 3 hours later, which, of course, we have seen on some of the examples given today.

And in all cases, you know, these cell manufacturers will tell you up front that if you don't follow these recommendations, the cell may become hot, explode, or ignite resulting in injury. So they're right in your face about it, that if you're not properly using the cell, it has the potential to cause, you know, an explosion or become very, very hot. So there's nothing there they're hiding, but again, they're conveying this information to battery manufacturers and product manufacturers who are going to be using their product.

Other things: The other core issue on the discharging, and we've talked a lot about discharged cells over the last day and a half, and again some recommendations that come from the cell manufacturers, which again we touched on a lot.

Discharge cell at specified discharge current. Discharge cell within recommended temperature range. Higher than maximum discharge current reduces capacity. And, again, that compromises the integrity of the cell.

Discharge cell using only specified device. So, again, discharging a cell using only a specified device. As I said at the beginning, no cell manufacturers, tier one cell manufacturers are selling to a particular battery assembler or product manufacturer with the idea that it's going to power that device, and they are customized 18650 cells, all types of customized lithium-ion cells, for that very reason.

You know, again, that 18650 that's going to power my Makita drill -- I'm sorry, Stanley Black & Decker drill, there you go -- versus that same 18650, it's not going to be the same one that's going to power my notebook, for example. So the same form factor, maybe different chemistries, and absolutely different applications. So, again, there are a lot of variables involved here when you buy these bare cells.

Ensure equipment is designed to prevent overdischarge. And, again, that's the whole systems approach for batteries. Again, battery pack and equipment design. Use only cells for intended applications.

Contact cell manufacturer in advance when designing a device with the cell. So all of them are -- again, this is conveying that information that I said earlier. You've got a relationship with the cell manufacturer and with your customers, okay? So if I'm a consumer and I walk into a vape shop and I buy an 18650 cell, a bare cell, or I am the proprietor or I am the owner of that shop, and you know, they don't have a relationship with that cell manufacturer, certainly not. And maybe the vape device manufacturer does, but again, if I have a device that's suitable for multiple lithium-ion chemistries and multiple lithium-ion capacity cells but again it's a standard 18650 cell, you know, you don't have that ability to call the manufacturer up and say, hey, I had a problem with your cell. I just dropped it into my vape device; what am I supposed to do? That's not how it works. Well, that's not how it should work, I guess is my point.

Cells must be assembled in a pack with protection circuit. That's pretty standard.

Consult manufacturer regarding charging and discharging specifications. One of the speakers yesterday said he knows which cell to use in his devices that he uses or that he sells, and the product that he makes he sells to vape manufacturers,

and therefore he knows what cells can be used in that vape device because he can go online and look at the cell specifications. Not all cell manufacturers will put their specifications on the internet. A lot of that information is proprietary, and therefore you may not necessarily find those specifications that you're looking for. That cell that I showed earlier that was on Battery Junction's website, that was probably a cell specifically designed for a particular application. You probably can't go online and find the specifications for that particular cell, to understand what discharge, you know, what current, and what it's capable of doing.

So, again, while you will find some specifications for lithium-ion cells on the internet, in a lot of cases you won't as well. So you can't be assured that all of that information that is readily available by one manufacturer is going to be readily available by all manufacturers.

Ensure battery is positioned away from heat sources in equipment or in battery chargers. Well, they obviously didn't have vaping devices in mind, okay? And I've seen some of the really good designs of some of these e-cigarettes that do have that space between the battery and the coil.

So, again, I know there's some very well-manufactured e-cigarette devices out there that do take that into consideration. But the idea that, you know, again, from layman's terms, you've got a high energy cell next to a coil that can get up to 150 to 200 degrees C and a potentially flammable liquid, obviously, you know, keeping that battery away from that heat source is very important.

Prevent battery from being ejected when equipment is dropped or receives sudden impact. That's all part of a voluntary standard to ensure that happens.

Prevent short circuits and reversed connections. Design battery and terminals to ensure battery cannot be put in backwards, getting to the issue I talked about earlier, when installed in charger or equipment. And, of course, avoid designing airtight battery compartments.

So again standard, what I would consider, information that most cell and battery manufacturers are following today. But again, as we see, there is a variety of different manufacturers and a variety of different qualities as well.

As far as safe handling and use, I mean, very obvious stuff here. Do not solder directly onto cell. Do not expose cell to water or salt water. Do not carry or store cells

together with other metal objects. Well, we know that consumers are putting these bare 18650 cells in their pocket with keys and coins and that type of thing. When you have a battery pack, when you think about your battery pack, your cell phone battery, your power tool battery, your notebook battery, it's in a hard plastic case. So that shouldn't be as much a concern.

And oftentimes those terminals are recessed terminals. So even if you do put it in your pocket with coins and keys and such, that shouldn't be a big concern. But when you have a bare cell and you've got it in there with a bunch of other metal in your pocket, you've obviously got some problems on your hands.

Do not disassemble or modify cell. Well, that picture we saw earlier, and I've got a minute to go, where you're unwrapping a cell, that's not modifying a cell, per se, but the idea that you can do that at a retail level, that's not part of the cell technology, but that does provide some protection for the cell. So the idea that a consumer has the ability to do that obviously makes us a little bit nervous.

Some of the other information there, again, is just information that we're all very aware of.

And last but not least -- let's see, I thought there was on storage. Sorry. Let's see. That's okay. That's all right.

I'll just summarize here real quick again. There you go. Storage actually -- you know, this issue has come up a lot recently because, from a transport perspective, when you ship lithium-ion cells, just cells by air, they're limited to 30% state of charge. That's a new requirement that went in last year. And so when you have -- you're limited to 30% state of charge for air transport, and when you receive these cells at retail or at distribution centers or such, it's already at a fairly low -- a relatively low state of charge.

Lithium-ion cells and batteries have a very slow discharge rate, and I recognize that, but keeping these things in storage at certain temperatures is important as well. But again, if they're in storage for long periods of time, over 6 months, and you fall below that 30%, then down to 15%, and then it sits there for a long time, that overdischarge condition is obviously a concern for us as well. So, again, some recommendations as far as storage goes.

I'll just wrap it up here and summarize again. You know, with about six billion lithium-ion cells that were manufactured

last year, there's obviously a lot of cells in the marketplace. We're in full support of immediate voluntary industry standards to address this issue of drop-in cells for these vape devices. So if there's anything we as an association can do to get the message out about that, we obviously would welcome that opportunity and look forward to work with anybody in this industry if they're looking for help on that.

So thank you.

(Applause.)

DR. YEAGER: And our next speaker is Youn Ok Lee with RTI International.

DR. LEE: Hi, I'm Youn Ok Lee. I'm with RTI International. I'm a social scientist there, and today I'll be talking about battery-related information on ENDS packaging and websites.

First, I also wanted to acknowledge members of our research team who I collaborated with on this particular study. They include Jessica Pepper, Doris Gammon, and Margaret Cress.

So by now, I'm sure all of you are aware that there is increasing reports of ENDS battery-related fires, explosions, and injuries. This issue is receiving increasing attention from the public as well as the scientific community. Reports

of injuries due to battery failure are raising public concern about ENDS safety. And currently, there are no federally regulated standards for communicating battery-related safety, handling, and storage information for ENDS to consumers.

And so little is currently known about what information, if any, is really available and what formats and sources that information is available in. Consumers of ENDS may be interested in information such as the degree of risk of battery failure they may face, why battery failure occurs, consequences of battery failure, and preventive safety measures to prevent any kinds of battery failure, to name a few.

And there is also a wide range of potential sources for this information, and these sources include manufacturers as well as members of the public and others, in formats that include warning labels on packaging, product inserts and manuals that come with products, manufacturers' websites, as well as publicly maintained blogs and websites. And of course, there are also retailers, government agencies, advocacy organizations, and others.

So in this study, we really wanted to better understand what ENDS battery information consumers might be most commonly exposed to. So we focused primarily on information provided by

manufacturers, specifically information on (1) the packaging for ENDS products, that is, the external packaging in which the products are sold in, as well as any inserts or manuals that would be included with the products when they're purchased, as well as manufacturer product webpages specific to the product that can be found on the larger brand websites.

In the study, we also included top Google search results related to ENDS battery safety to provide some examples of other sources of information that ENDS consumers might be exposed to, especially if they were trying to seek out more information about this issue.

So in order to conduct these analyses, we used four data sources, which you can see listed here.

So, first, we used Nielsen company's Scantrack database. So we used this to rank order rechargeable ENDS starter kits by units sold in 2016. In the Scantrack database, sales of ENDS product are categorized. So for this particular analysis, we chose the starter kits because those reliably included the product, the battery, and some kind of charger for that rechargeable device.

Then using the scanner data, we identified top selling products from the 20 most popular brands. We purchased these

products between February and March of 2017, this year, so that these data would be recent. And then we analyzed the product packaging that we acquired with those products.

Third, we also analyzed the webpage devoted to each product found on its brand's website, and we really looked there just to see if there was any additional battery-related information that the manufacturers were making available that were not found on that specific product's package.

And then lastly, we examined Google search results. So these were retrieved using a set of key search terms that we developed, and we included the first page of results in our review.

So, first, I'll talk about our analysis of the ENDS packaging.

So as I mentioned, our first step was to identify a sample of ENDS products to analyze, so we used the Nielsen scanner data to capture the bestselling starter kits from the bestselling ENDS brands. We limited our list to the top 20 brands based on number of units sold in the year 2016, which you can see listed here.

For each brand, we selected the top selling starter kit product. Four brands sold two different starter kits with

unique contents, and in these cases we included both products for a total of 24 products from 20 different brands.

We then analyzed these 24 ENDS products to understand what battery-related safety, handling, and storage information the manufacturers communicate to consumers on ENDS packaging in particular.

So we used a content analysis approach, and we developed a coding scheme for reviewing these products. So our team then coded for the location of warnings and instructions, the presence and type of battery and charging information, as well as the presence and type of battery and charging warning, that is, information explicitly labeled under "Warning" or "Danger" or similar language.

To ensure reliability, two coders reviewed each product, and in any cases where their coding was discrepant, they met to resolve the discrepancy.

So just to give you some examples of some of the products that we analyzed, we found a range of information that can be illustrated here. So we found, among the 24 products, there was a varying amount of information provided in the packaging.

So as you can see in Figure 2, this is an example of what we are calling a minimal information package, where there might

be short instructions and a nicotine warning on the exterior of the package only.

In Figure 3 you can see what's more of a moderate level of information. This could include some information on the components, some use instructions, and the nicotine warning on the exterior of the package only.

And then in Figure 4, here's an example of a package that included a manual or an insert inside the package with a more extensive amount of information. We didn't do explicit word counts on the packages, but as you can see, there's more ability for there to be more information and more words communicated on a leaflet typically than on an actual package. This could include information on components, instructions for use, nicotine warnings, as well as battery warnings and other information.

So of the 24 products, 20 were closed systems, meaning that users could not refill the systems with a bottled liquid, and four were open systems that could be refilled using a bottled liquid.

The average price of the products that we purchased and included was $18.24.

And half the products had information listed only on the

exterior of the package, meaning there was no insert or manual found inside the package, so the only place that information was listed was on the exterior. The other half had inserts or manuals that were located inside the package.

And then here you can see results from our coding for presence and placement of instructions for use or assembly and charging.

So among products with exterior information only, 11 of 12 had instructions for use or assembly and then the same 11 out of 12 for charging.

Among the products with manuals, all had this information in the manual, but few listed it on the exterior of the packaging, as you can see here. It was only located in the manual in many of the cases.

So when turning to the presence and placement of warnings, we found all but one product provided some warning information, whether it was related to battery safety or not. Products with exterior information only had warning information that would likely be damaged or disposed of upon opening, so that's something to note with the exterior-only packaging. And then also these exterior-only packages rarely mentioned batteries or charging, as you can see here.

In contrast, products with manuals had warnings listed in the manual, and most had a warning that was related to batteries or charging. One thing to note there, that if information is only located on the insert or manual inside the package, consumers might not see that information before they make a purchase decision.

So here you can see the kinds of topics mentioned across all 24 products. ENDS product packaging mentioned a range of battery safety topics; however, some topics were more common than others, so there was a degree of variability of what kinds of topics were touched upon on the packaging.

For example, 13 of 24 products mentioned appropriate charging time, while only 2 of 24 products mentioned maximum battery lifetime. Similarly, 6 of 24 products explicitly warn of dangers related to device compatibility and using a compatible charger, while none of them had warnings related to maximum battery lifetime.

So to supplement our analysis of the ENDS packaging, we also looked at the product webpages found on ENDS brands websites to see if there was any other information being provided outside of the actual packaging or inserts or manuals.

So we analyzed these product webpages for the information

that they might provide to consumers specific to the products. So we adapted the same coding approach for these websites or webpages, and one thing to note is, due to the lack of web presence for the brand FIN, webpages for 2 of the 24 products were unavailable when we made our review, and that left a total of 22 product webpages that were maintained by a total of 19 brands.

So here you can see we found very little battery-related information on the webpages. Only compatibility, appropriate charging time, and maximum battery lifetime were mentioned on any page. And only two pages had any battery-related warning, and both of these were from products sold by the same brand. In this case it was Logic.

And so, finally, we analyzed Google search results to better understand what other information and sources consumers might be exposed to, particularly if they went seeking any kind of information about a product that they owned or were thinking about purchasing, related to battery safety.

So to do this, our team developed an ENDS battery safety information search syntax, basically a set of Google search terms to narrow the results that we would get. And so you can see those listed here. And also we made efforts to minimize

effects of prior browsing history. These included clearing cookies and history, we used Chrome in incognito mode, and we repeated the search on two different computers to ensure that we were receiving reliable results.

The first page results based on the Google search were coded by a single user. That first page yielded 10 total results, and then we coded the first page of each of those 10 results.

So here you can see the first page of Google search results that we retrieved and then subsequently coded. We found, of the top 10 webpages, they came from multiple sources. So four were blogs associated with retailers, so we identified retailers as a likely additional source of information about battery safety. Four were product review or vaping news sites. One was a general lifestyle blog. And then one was a scientific report that was done by the U.S. Fire Administration.

So here you can see the most common battery-related practices that we found mentioned on these webpages. These included use of manufacturer-approved chargers and components was found on 9 of the 10 pages. Not storing or exposing the products to extreme temperatures was found on seven. Do not

overcharge or charge for long periods of time was mentioned on 7 of the 10 webpages. Buying from a reputable vendor was mentioned on six. Using a battery case to keep batteries away from metal when not in use was mentioned on six as well. Not leaving unattended while charging was mentioned on six. And proper battery disposal was mentioned on 5 of the 10 webpages.

So these topics included practices on a range of battery safety issues such as charging, storage, purchasing, and disposal of ENDS. And here on Figure 5 you can see an example of the presentation of and format of the battery safety information found on one of the webpages that we coded. It's in kind of an infographic format in contrast with, say, the information that we find on the back of an ENDS product package.

So consequences of battery failure were also mentioned on many of these websites. Some of these consequences that were mentioned included fire, explosion, overheating, and injury. Four pages provided incident statistics related to some of these consequences. The sources that were cited here included trade associations, battery producers, and the U.S. Fire Administration reviews of media reports of incidents involving ENDS batteries.

One thing that's useful to note is that six of the pages also featured reader comments, and that provided a venue for users to share and get information related to battery safety, and many of it was anecdotal in nature.

So, just in brief, I just want to summarize and discuss a little bit of what our findings imply.

So, overall, we found that there was little product-specific information related to battery safety that was available to consumers. Only 10 of the 24 products that we analyzed featured a warning related to batteries, and this was particularly problematic for devices without manuals. Those with the exterior packaging only, only 1 of 12 had a warning. And webpages for the products had even less information, so that wasn't very useful if a consumer was to turn to a product-specific search. Generally useful safety information was available through Google search, but most websites did not cite sources, and the websites that did include sources typically cited industry-related sources or personal anecdotes. Only one independent scientific source appears in the top 10 search results, and that was an analysis of media reports.

So I also wanted to acknowledge that our study has several limitations that are important for interpreting what we found.

First, there's a limited range of ENDS products that were included in the Nielsen Scantrack data. Notably, products that are primarily bought online or in vape shops were not captured in the data and not analyzed in this particular study.

Also, the ENDS marketplace is rapidly evolving, so things can change, brands can come and go, and sales of particular brands can wax and wane.

And third, implementation of FDA regulation is currently in progress. So action there could also alter the types of communications and warnings that manufacturers put on their packaging or that other kinds of sources might share on the internet or other formats.

So our findings highlight several implications. Manufacturer efforts to inform consumers about potential harms due to battery failure could be standardized and improved. This could provide more consistency in the content and the format of battery safety information for consumers, especially information that might be specific to a particular product or product type.

Additional independent scientific research could also inform recommendations for product standards that include things like the identification of the most important battery-

related safety and handling information for ENDS manufacturers to communicate to consumers. This could include the potential risks or harm due to ENDS battery failure, as well as ENDS use behaviors that might mitigate these battery-related risks.

Further research could also develop the most effective messages and formats for ENDS manufacturer communication of battery-related information. This kind of information could be presented in different kinds of sizes, colors, the infographic versus having text. You know, all those things could matter in effective communication with consumers.

Thank you.

(Applause.)

DR. YEAGER: Thank you, Dr. Lee. And you can come back up, Dr. Lee. So if Captain DeLeeuw, Ms. Toman, Mr. Kerchner, and Dr. Lee could join us, we'll move to our Session 5 panel discussion around the Current Practices of ENDS Battery-Related Risk Communication. A game of musical chairs while they find their nameplates, right? All right.

So at this point I want to remind everyone that you're welcome to please come up to the microphone, and when I recognize you, to identify yourself and ask your question. You'll be able to do that if you want to do it verbally.

Otherwise, on the sides of the room there should be index cards you can write questions on.

So we'll start with the first question for John DeLeeuw and Vickie Toman. Can passengers charge their e-cigarettes while in flight? What can airlines do to limit passengers using bad chargers on board?

CAPT DeLEEUW: I think the guidance is pretty clear in the magazines on board, that they're not to recharge their batteries in flight. I mean, there's the handouts that are in the magazines in airplanes, and the FAA has a regulation, too, that says they're not supposed to recharge batteries in flight. I think if a flight attendant noticed it, they would have that passenger cease doing it.

DR. YEAGER: I think you presented that, too, in your presentation.

CAPT DeLEEUW: I did, I did. But that's okay, I just -- it may be something that folks are not aware of, but I think that the flight attendants, when they go through, if they see something like that or even a concern, they'll query the passenger.

DR. YEAGER: To get a clarification again, right?

CAPT DeLEEUW: Right, right. But it is listed in most

in-flight magazines about that.

DR. YEAGER: Okay, thank you.

This question is a general question. How many open-tank system e-cigarettes are sold including the battery, and how many require the user to purchase the battery separately?

MR. KERCHNER: I can't answer that question specifically, but it's a question I asked actually one of the panel members that was up yesterday. And there is some data out there, I don't know what it is, but I think that's a good question that would really help us to actually understand the risk. But again, I don't think that's a question for this particular panel.

DR. YEAGER: All right, thank you.

So John DeLeeuw and Vickie Toman, at what point would airlines begin to ban a certain type of device? What would the threshold be to start more restrictions, like the Samsung phone ban?

CAPT DeLEEUW: Well, I think -- and I can't speak for individual airlines, but being in the safety world, once you have enough data to indicate that you might have a potential hazard, you have to find ways to mitigate the risk, and one way to mitigate risk is to not allow, like, a hoverboard to get on

the airplane anymore.

The thing is, is I think the reason I'd say that we're here and other people in the audience are here is that we don't want to have an incident where they get banned because of an accident or an incident. So one of the things we're doing is trying to publicize that we have to have maybe some better controls now in place.

The evidence suggests that we do have issues, and I think the evidence is going to continue to grow as e-cigarettes start to grow. There comes a point where -- and I can't speak for the airlines, but if one airline was to ban e-cigarettes, the other airlines would be pretty quick behind it, which is what happened with the hoverboards. Vickie wants to add to that.

MS. TOMAN: Well, just the fact that there's also the guidance from the FAA. If the FAA says we're going to ban it, then we will ban it; we have to comply.

DR. YEAGER: Okay, thank you.

CAPT DeLEEUW: The regulator has a powerful way of getting things done.

DR. YEAGER: This is for all of the panel. What battery-related safety information, for example, replacement frequency, proper charging procedures, warnings about explosions, should

manufacturers communicate to consumers and end users, distributors, and the general public? And how can potential safety risks associated with ENDS patterns be effectively communicated and in which format, e.g., instructions? So what battery safety related information should be communicated, and how can safety risk be effectively communicated?

We can go across the panel if you're all answering; that's fine. Go ahead, Dr. Lee.

DR. LEE: I mean, I think that's a complicated question, and I think there's a lot of research that's still needed to really determine what the best practices and recommendations might be for the -- to have standardized content of what that kind of communication might include and also what it might look like. You know, in my presentation, I really just tried to summarize what's kind of out there, but I don't necessarily think that at this point we have a very clear recommendation on exactly what the most effective content and what the most effective format matched to that content is.

DR. YEAGER: Go ahead, Dr. -- Mr. Kerchner.

MR. KERCHNER: Dr. Kerchner, that's good, yeah.

DR. YEAGER: Oh, Dr. Kerchner.

MR. KERCHNER: I got promoted.

DR. YEAGER: You got elevated.

(Laughter.)

MR. KERCHNER: You know, this is where the standard, the voluntary standards come in handy. A lot of the standards, when they're written, have that kind of information on them, and I have to agree with the previous speaker that, you know, it's a little early to come up with some standardized language for these particular devices. I do find it interesting, though, that some of the information that was just presented about what consumers are being told about vape devices, what to do and what not to do, I wrote this down, one of them said don't leave -- when charging, don't leave unattended. Well, you know, I leave my notebook unattended all night when it's plugged in. I leave my power tool -- I hate to say it, but I charge it overnight, and everything's just fine. So, you know, if there's a concern about leaving these devices unattended while charging, I think that points to a much bigger problem for this particular industry.

So, again, I think if there's somebody in this room who doesn't leave something charging overnight, I'd be shocked. I mean, I know you're all -- a lot of battery experts here and maybe you do unplugged, but I leave my cell phone and my

notebook and, accidentally, my power tools sometimes when I'm using them over the weekend. But that's standard for any consumer.

DR. YEAGER: Ms. Toman?

MS. TOMAN: I don't really have any comment on that. I mean, I think we've seen from the packages. I was surprised when you showed breaking the packages apart, you just lost all of the warnings. And what we found when we went to the vape store, it's kind of across the board where the warnings are.

DR. YEAGER: Captain DeLeeuw?

CAPT DeLEEUW: Yeah. And I would add to that, really, is I think at this point e-cigarettes are here to stay, and in my world, people are going to continue flying. I don't think anybody intentionally wants to see something happen on an airplane, so it requires -- initially, it's going to require education on behalf of what we already do, but all of the warnings and everything are said in a magazine, and it's very small. More awareness maybe by the general public.

And I'm not sure it's the FDA folks to do that, but it's just more awareness of what the issues are with lithium-ion batteries, particularly in e-cigarettes and how we carry them and transport them. So I think, just right now, it's going to

be an education piece, because if the education piece doesn't work, the regulations will step in, I suspect.

DR. YEAGER: Okay. This is for John DeLeeuw and Vickie Toman. If an e-cigarette ignites in a passenger's pocket and that person happens to be sitting in a seat next to another person or a child, the explosion could inflict injury not only to the owner of the e-cigarette but to anyone nearby. Is there a way for airlines to check for proper storage of batteries and ENDS for anyone who is traveling with ENDS or loose batteries in carry-on baggage?

CAPT DeLEEUW: Well, I would say that the airlines don't know who is going to be carrying an ENDS product, just like you wouldn't know who's carrying a cell phone or a laptop; they're in their backpack or carrying case. So I would have to say that, you know, there's no ability to determine if they're carrying an e-cigarette or two e-cigarettes; there's just no way to know.

And to the question earlier, yeah, we've seen the video with the battery, I mean, on the bus. If it goes, it's going to go, and there's just nothing -- I don't see how you can ever -- you could never stop that issue because the risk will always be there. The only way to do that is to ban them, and I don't

think we're in an environment to discuss that right now, but that's it. But there's no way to track it, I mean.

MS. TOMAN: Right, the only person that might be able to see what's in the bag that's being carried on is going to be when they go through TSA, through security, and I don't know how much they can see and what kind of warnings they can give.

DR. YEAGER: Okay, thank you.

So, Dr. Lee, did you analyze the reading level of warning labels and inserts? If so, did the reading level vary by product or information presented? Will this information be published?

DR. LEE: Thank you for that question. We are looking at that. We have not completed our review of reading level, so I didn't report it here, but we do plan on publishing the results of a full review.

DR. YEAGER: Okay, thank you.

And this is a general question for the panel. Has anyone created a Wikipedia page on ENDS battery safety, and would associations be open to sharing safety tips as an interim solution to missing safety information from manufacturers?

DR. LEE: No, I have not created a Wikipedia page, and I would not know exactly what content would be most appropriate

for something like that.

MR. KERCHNER: Well, we'd be more than willing to share any information that we can through our association, you know, mining the information we get from our members over the years that's readily available through us. So, again, if a Wikipedia page is the way to get information out about the safe use of e-cigarettes, we're completely on board and would be glad to participate in that.

MS. TOMAN: And most airlines, through my research, have warnings on their webpages about what you can carry on and not carry on, and as far as having loose batteries, the FAA has a lot of information on their website and so does TSA, but it's a matter of getting the consumer to go and look at that.

CAPT DeLEEUW: I'd have to google my kids and ask what Wikipedia is. No, I'm just kidding; I know what it is.

(Laughter.)

CAPT DeLEEUW: But no, I don't have anything to add.

DR. YEAGER: Okay, thank you.

So can you explain the difference between tier one and other tier battery manufacturers? Are non-tier one battery manufacturers as discerning with the distribution of their product? For example, you need to have a relationship with the

company to purchase their batteries. I gather this is for you, Mr. Kerchner.

MR. KERCHNER: So yeah, the term "tier one" has been used for many years and that is -- it's not defined per se, but it's generally recognized as those top tier three, four, five, maybe six or seven manufacturers that are selling into the marketplace, the brand names that we're all very familiar with.

And in most cases they do have that direct relationship with the product manufacturer as opposed to -- tier one, tier two, tier three, I can't really discern where the dividing line is, but generally speaking, I would say that tier one is really the manufacturers of those consumer products that we're all using that do have a very established relationship with their customers.

So the cell manufacturer, the pack manufacturer, and the product manufacturer, that whole, I'll call, tier one level of products is probably a good way to do it.

DR. YEAGER: And so to follow up on that, were any of the non-tier one, the lower tier battery manufacturers, as discerning with the distribution of their products?

MR. KERCHNER: I think the short answer to that is no, and that's where you do find a dividing line where you can -- if

you go on the internet and someone's willing to sell you 5,000 18650s, that's not tier one, for sure.

But let me just clarify one thing. You know, I've learned a lot over the last day and a half, and I know there are some very, very well-manufactured e-cigarettes out there that the gentleman yesterday -- I apologize, I forgot your name -- who again is in that category where they visit cell manufacturing facilities, they do their due diligence and they know what the capability of a cell is for their product, and that's what you want for any product, not just a vape product or an e-cigarette, but you name it, any product powered by a lithium-ion battery. That whole systems approach is the key to the safety here.

DR. YEAGER: Thank you.

So introduce yourself and ask your question.

MR. ALARCON: Ramon Alarcon, Fontem USA.

Power banks are becoming more and more popular, and my intuition is that if they used loose 18650s that you could pop in and out of a power bank, we might be having a very similar discussion about or maybe read about some high-visibility occurrences of fires associated with those. So my question, though, is typically they're not, but as a comparison point for

power banks, especially on airlines, is there any data to show that there have been incidents with any power banks? I myself, I've recharged mine on airlines, and I know they're quite popular. It would be interesting as a comparison point. I'd like to hear your opinion on that.

CAPT DeLEEUW: I'm not aware of any data on that, and I'm not certain I've heard of any incidents with power banks having issues in flight. I'm not certain on the technology, if it's different or it holds it differently versus the e-cigarette batteries. I just don't know anything of it.

Maybe Vickie does, but I haven't seen anything or heard anything where the power banks themselves have had issues in flight yet currently, and it may be the way that it's manufactured different. I just wouldn't know; I just wouldn't. Maybe George has got some more info, but I don't know what the -- why it might be different than an e-cigarette recharge.

MR. KERCHNER: Yeah. So, unfortunately, I've heard about incidents on the power banks, and usually they are self-contained. I haven't seen any where you have a drop-in cell for power banks. But when you go to China, which I know you're headed over to China soon, when I was over there the last time and I was checking in, they had a picture of power banks, the

fact that you can't put those in your checked luggage because power banks are generally recognized as batteries. We all think of them as maybe equipment, but in fact, they're regulated as batteries by the international dangerous goods regulations and here in the U.S.

So those power banks, unfortunately, you know, going back a few years, there were quite a few incidents involving those because they were readily available 18650 sized and larger, and there was some questionable quality associated with them. Now, what has happened with that industry is, well, I know it has a standard and there are other standards as well that now these power banks are subject to. And so their quality has improved considerably over the last 2 or 3 years.

If you go to the FAA's website and you see those listed incidents that got there, as has been mentioned here, there are some power bank incidents listed there. But again, I think that the quality of that industry -- and actually, I spoke at their conference here in D.C., the trade association that represents them, and they're up to speed. You know, 2 years ago they didn't even realize they were regulated as dangerous goods, for example. But now they do know that, they know they're more stringently regulated now because of the transport

regulations, and therefore, they really have stepped up their game, I think, quite a bit the last couple of years.

DR. YEAGER: Thank you.

Please identify yourself and ask your question.

DR. SRINIVASAN: I'm Srinivasan from the Johns Hopkins Applied Physics Laboratory.

This question is for Captain John DeLeeuw and Vickie Toman. I walked into the airlines, the airplanes, and find people using charging and watching movies, etc., on their iPads and laptops. Why would the airline industry, the airlines, allow that while they may not allow some other devices, in this example, e-cigarettes? Has there been any reported incidents of fire when people are using, charging or using it through -- in a USB port, their iPhones or laptops or iPads?

CAPT DeLEEUW: I don't think I'm aware -- maybe Vickie would. I'm not aware of any that have happened during the recharging. I mean, it seems like I recall there was one or two incidents, but I don't know which airline. I don't know if that was so much -- but I mean, they're not supposed to do it in the first place, the rechargeables, but you're right, you do see people recharging their phones or iPhones in flight, and you'll see them do that. But I think, specifically, you

mentioned the rechargeable batteries for the e-cigarettes, but I don't know, have you seen anything? I can't say I have actually.

MS. TOMAN: No. I mean, I've heard of some events where maybe there was -- it got hot or there was a smell and you unplug it. But you're not supposed to just recharge it; you can plug it in while you're using it.

CAPT DeLEEUW: We don't really have enough data yet. Maybe George might have more data. I just don't have enough data. I have to research it first to give you an intelligent answer on that one.

MR. KERCHNER: I know that the whole charging issue was a big concern a few years ago because more and more airlines are offering that ability to recharge. But I know they've built in some safety features into those charging features on the aircraft. But keep in mind, the whole charging thing, if it's a properly designed device, you're not going to have that overcharge issue. I mean, just as a point of fact, a few years ago, correct me if I'm wrong, when the pilots got on the flight deck to get ready to go, they had their paper flight plans, but now they're all carrying Apple, you know, notebooks and everything is electronic. They bring it in, and they put it in

a docking station; the battery is charging, right? So lithium-ion batteries are safe if properly designed, and obviously the airlines recognize that, and that's a great example of where they're properly designed, properly used, and even in the flight deck.

DR. YEAGER: Thank you.

This is for John DeLeeuw and Vickie Toman. Will a plane always divert if there was a fire from an electronic device? What type of investigation takes place upon landing, if any, and what information is collected about those incidents, like the product types, date of use, loose battery, etc.?

CAPT DeLEEUW: That's a tough question. A couple -- that one. The first one, will they always divert with a fire? Generally, they will. If the fire is contained. Especially with a lithium-ion, we've had events where they've contained it, but they still diverted because they weren't sure what the outcome was, if it's going to flash back up. Generally, you know, when I'm flying and if we have a fire, we're more likely going to divert. The question is, if you're over the Pacific, I mean, it's not too easy to divert to too many places right up front, and there are some places we just don't want to divert, you know. But if there's a fire and you're still in domestic

U.S., the plane will almost always divert. It's just standard procedure for most airlines.

DR. YEAGER: Right, so the investigation that takes place?

CAPT DeLEEUW: Well, if it's a fire report on board, it's reportable to the National Transportation Safety Board, the NTSB. They generally will investigate it or request more information.

Sometimes I have just seen from my personal experience, and we recently had a conference to kind of, I think, to try to standardize it, but many times if you do divert and you have a laptop or a backpack that caught fire, the fire department normally will come on board to look at the fire, see if it's out, and they'll generally take that material off the airplane. So now the fire department might have the backpack. And I think that we talked at a recent conference where there may be some issues down the road where we do make sure that that particular battery that malfunctioned or caught fire gets back to a standardization where they can investigate that particular type of battery.

So I don't believe that's standard yet, but I think most carriers, once they were to get a battery that either caught fire or malfunctioned, the end result will be to get it back to

the manufacturer where there could be a teardown. Trust me, if it's an event that was -- that rose to a certain level where the NTSB got involved, then they would take care of that process and make sure there's an investigation done.

DR. YEAGER: And what information is collected about the incident?

CAPT DeLEEUW: What is captured?

DR. YEAGER: What information is collected about the incident?

CAPT DeLEEUW: Well, they collect just the stuff like we showed this morning. I mean, we try to capture -- because a lot of times if there's a fire, you know, we've been focusing on e-cigarettes, but you know, what kind of batteries were they? Was it an iPhone, was it a laptop? You know, there are lots different potential fires on an airplane. I mean, one airline had a camera battery that caught fire, so it wasn't really an e-cigarette, but it was camera battery. And I think that, ultimately, they would like to have a way where the -- after the fire department puts it out, there's a collection so they can grab the batteries. Remember, if you have a battery that malfunctions in flight, you can't just send it in the mail to somebody because they won't transport a battery that's been

damaged like that.

So maybe George can add something to it. We talked about the Battery Safety Council. There's no standardization. Unless it rose to the level where the NTSB got involved, smaller fires in there, I don't believe there's any data collection of that particular battery unless it went back to the -- to somebody to capture it.

MR. KERCHNER: In those cases where there are those incidents, I'll tell you the battery manufacturer wants that battery back as quickly as possible to do a failure analysis. But unfortunately, a lot of times that just gets -- that gets lost in the shuffle. The fire department takes it and throws it away, and capturing that battery is really key to determining why that battery had that event. And I know the manufacturer is more interested than anybody else to get it back to do that failure analysis. But unfortunately, a lot of times that data is lost.

DR. YEAGER: Any follow-up, Ms. Toman?

MS. TOMAN: No.

DR. YEAGER: Okay, thank you.

All right, this next question: Knowing how the FAA and Navy investigate issues thoroughly to identify root cause, what

are the causes of e-cigarette related incidents on planes and Navy ships?

CAPT DeLEEUW: Well, that's a good question. I only brought it up here because it was a news -- I believe it hit the news about 2 or 3 days ago, the slide I showed about the ban on the Navy ships and the submarines. I have no knowledge of what precipitated that, other than what I showed you here. There was a little bit more information that was in the article.

Just for the essence, so it wouldn't be such a large article, one page there, I took some of it out, but it didn't affect the outcome of what I showed. But I can't speak to why the Navy wanted to do that. I just don't know. I just assumed that they had enough data --

DR. YEAGER: Right.

CAPT DeLEEUW: -- or something to decide to do it. We might have one of our friends in the audience that might know.

DR. YEAGER: Okay. And then more a general question about the incidents or issues. Does the panel have ideas of what might be, like, reporting requirements and what type of information would the panel want to try and gather?

MR. KERCHNER: Well, I think from an industry perspective,

I think our biggest -- our most interesting data point that we'd want to get to the manufacturer, whether it's one of those drop-in 18650s, whether it's a full system, that type of thing, the capacity of the cell, those types of things, the use of that cell or battery within the last 5 or 10 or 20 minutes, was it charging and then someone put in their pocket and had an event.

You know, those kinds of data points are real key. But the type of battery, the manufacturer, and again the drop-in, if it's one of those batteries, that to me is a telltale sign. I think about all the incidents that have been shown on the screen here over the last day or day and a half. I would truly love to know, you know, what kind were they? Were they the drop-in 18650s? And if they were overwhelmingly that kind, then obviously you narrow your focus on those issues. But again, I just don't know. We just saw pictures, and we didn't see the battery.

DR. LEE: I'd be really interested to know more about user behaviors to tell us a little bit more about the kind of conditions that users might be putting the devices and the batteries under, especially when you're thinking about what kinds of communications might we need to develop to communicate

to users so that they can mitigate any potential risks. I mean that, I think, has to be made in light of how they're actually used and the range of that behavior.

MS. TOMAN: And one thing to note, too, we've talked about airlines, but also are these events happening on trains, buses? We saw the one bus, so I think it could affect all different modes of transportation.

CAPT DeLEEUW: Yeah, I would say, you know, from our perspective, my background is aviation safety, and so is Vickie's, and you know, folks like the NTSB, if there's an incident or an accident, the investigation that's done is very, very thorough. I mean, they look at things like -- talk about pilots, they'll go back 72 hours prior, what did they do, where did they sleep? The same for the flight attendants. It's an extremely in-depth interview process in the background.

I don't think we're there yet, but if we did have an incident with a battery, just what you're suggesting is exactly right on. What was the user pattern, what kind of battery, where was it manufactured? I mean, that is the kind of stuff you're going to need to do a detailed investigation. And as you collect the data sources, you may be able to pinpoint some of the issues. But we're just not there yet.

DR. YEAGER: So we've been through our questions, but what I'd like to do is if we could go down the panel, and we'll start in reverse order with Captain DeLeeuw this time, and any last comments on current practices of ENDS battery-related risk communications.

CAPT DeLEEUW: Well, I would say that, you know, just in getting involved in this process here, in my opinion, I think there's plenty of information out there, from what the airlines have put out, there's information from the FAA. If you google it, you know, just start googling different searches than what Dr. Lee did, but you know, aviation safety, there's plenty out there.

I just think it's a matter of education. I don't think people knowingly will want to get on board an aircraft causing an incident. It's just they show up at the TSA, for instance, or they just -- as Vickie had mentioned earlier, they're smoking just prior to flight, they dismantle it because that's their practice, and they throw the batteries in the backpack not realizing the potential that could happen from it. And the reality is you get this normalization of deviancy.

If they do that every day and nothing happens, then they think things are safe, and we get the one-offs and something

happens. So I still think probably education by the customers -- and Vickie makes a great point. We just talk to aviation safety, but you know, what's happening on maritime vessels and trains and buses and that type of thing? So that's it for me, I guess.

MS. TOMAN: Yeah. And the same thing, education to the consumers and especially with the loose batteries, on throwing them in a bag, I mean, that's where we see most of the issues with. So whether it be in a case -- and it's not just for the e-cigarette batteries, but when we're talking about all lithium batteries, that they're being protected so that they're not rubbing up against something else in the bag.

MR. KERCHNER: Well, I'll just add that I think, you know, you got a very diverse group here in this room, and everybody working together, whether it's FDA, CPSC, the battery industry, the product manufacturers, you know, working together to develop that standard as quickly as possible and getting good information out there to the consumer. I think it's going to take a real group effort because, as it was noted by John, this market is booming. I hate to use the word explosion.

(Laughter.)

MR. KERCHNER: It's just a fast-growing market, and it

kind of reminds me of the e-bike market about 10 years ago. I was like e-bikes, who's going to buy an e-bike? Well, that's a huge market right now, and they had some growing pains, and I kind of look at the e-cigarette industry as in that same light. You know, the e-bike market corrected their problems, and I'm sure the e-cigarette or the vape industry can correct some of the safety issues that we've seen. But again, I think working together, I think, is going to be the key, for sure.

DR. LEE: And I guess I'll end. One is that, you know, it would be really nice to have information that is standardized. There's a lot of information swirling around, and I would imagine that, you know, consumers probably have a hard time identifying and sorting through that information at the moment.

But I think a part of that is also going to be reflected by the fact that we have a variety in the devices, and so that will be, I think, a challenge, too, going forward, is kind of making sure that anything we communicate kind of matches and is appropriate for what devices are available.

DR. YEAGER: All right.

Well, I'd like to thank the panel. Thank you, Captain DeLeeuw, Ms. Toman, Mr. Kerchner, and Dr. Lee. Thank you.

(Applause.)

DR. YEAGER: So at this point, as the panel is exiting, we will transition to Session 6, Best Practices for Risk Communication. And our first speaker is Doug Rupert with the Center for Communication Science at RTI International.

MR. RUPERT: I was banking on that break we were supposed to get there, but that's okay.

(Laughter.)

MR. RUPERT: Very good. So hi, everybody. I am Doug Rupert, and on behalf of my colleagues Sima Razi and Jon Poehlman, I'm from the Center for Communication Science at RTI International, the same place where Youn Ok is, and you know, I really wanted to talk today about some of the behavioral issues.

So we started getting into those in this last session, and we've talked a lot during this workshop about how to design these products in a way that they are less likely to have fires, explosions, and other issues.

But the other side of that coin, of course, is how we address consumer behavior. A big part of what we want consumers to do is to be aware of the risks and to start changing their behavior to adopt protective behaviors as they use these products. But one of the challenges with that is

that this is an emerging market, and we don't really know a lot systematically about how consumers are using these products in terms of battery safety. We don't know a great deal about why they're adopting the behaviors that they currently have. And that makes it really challenging to communicate the risk in a way that is likely to change individuals' behaviors.

But one of the things that we can do to start is to look at best practices in risk communication from other areas. So for instance, other products that are regulated by FDA, what can we learn about effective risk communication from those fields, and how can we apply that to ENDS battery issues? So that's what I really wanted to talk about today.

You know, just as I said, we want -- and we've talked a little bit about this already in the last session. We really want consumers to be aware, number one, of the battery safety issues with ENDS products. And number two, we want them to adopt those protective behaviors, everything from using the correct charger, replacing batteries when they should, and you know, vaping within the amp limit. We don't want folks getting under the hood and trying to customize these things, you know, to get more nicotine, to get more power coming through.

But again, one of the challenges of doing that effectively

is we don't know a great deal. I mean, we know a little bit about how individuals use e-cigarettes and vaping products, but we don't know a great deal about it as it relates to the battery issues. You know, we really don't know the scope of the unsafe behaviors that individuals are doing, how aware individuals are of battery safety issues, and I think it's really key. We don't understand why individuals are adopting these behaviors.

Is it habit? You know, we talked in the last session about the habit of how we charge our notebooks and other devices. Are those habits carrying over, or are there other reasons that consumers are adopting these behaviors with the way the products are designed? We don't have an understanding of that, and without that understanding, it becomes really challenging to change individuals' behaviors or communicate the risk to them in a way that resonates.

And a final challenge, of course, is we haven't done any testing of different warning labels, which makes it really challenging to ensure that we're communicating the risk in a way that resonates. We saw, in one of the last presentations, and I think it was John and Vickie's presentation, they showed some of the infographics. Those look terrific, but do they

resonate with folks? You know, do individuals understand and comprehend the safe behaviors that we want them to adopt?

So what I wanted to talk about today, in terms of applying best practices, is really two different areas. Number one, I wanted to talk about product labeling. What do we know about best practices in risk communication as it relates to product labels from another area where there is a lot of research? And that's prescription drugs, so another area that FDA regulates where we do have a nice, solid body of evidence about what's effective in communicating risks to individuals.

And then, secondly, I wanted to talk more broadly about best practices in risk communication and behavior change and how we might apply those to ENDS products. And, again, the goal today is that even with some of the challenges I mentioned earlier, how can we use these best practices to get a jumpstart on communicating risks to individuals and helping them to adopt those best practices or those protective behaviors?

So let's talk first about the product labeling. This is my one nerd slide of the presentation, and I want to tell you a little bit about the methods that we used for this piece. You know, Jon, Sima, and I have a great understanding of the prescription drug literature and what happens there, but we

wanted to be systematic about our approach. And so we just conducted this literature review over the past 20 years and really identified 25 -- I'm sorry, 21 key articles that have really usable best practices about how we communicate risks on product labels. And I'll talk about those best practices now.

So the first one is plain language. There's been a great deal of research that shows if you use plain language on labels, consumers are more likely to understand the risks and adopt protective behaviors. And by plain language, we mean things like using active voice, using simple short sentences rather than long complex languages, being very concise and eliminating excess words, and really just communicating with individuals the same way we speak, right? I mean, we see -- you don't have to look too far, whether it's drugs or ENDS products or tobacco products, you know, there's a lot of safety information that is communicated in a way that you and I don't -- we don't talk like that on a daily basis. And so the more we can put this information in plain language, still being precise, of course, but put it into plain language, the more likely it is to resonate with ENDS users, and the more likely they are to understand what we're asking them to do and adopt those safe behaviors.

So what does that look like? Let's take an example from the health world about, you know, before and after, plain language versus not plain language, and look at some of the phrases that are bolded and think about which way you talk in your daily life.

You know, an "initial evaluation" versus an "appointment." You know, "Provide appropriate testing," "We're going to do some tests." You know, "Discuss treatment strategies designed to help you reach your optimal state of health and function." Anybody talk like that in their daily life? No, "We're going to talk about your treatment options." And, again, these are some before and after examples of how we can use plain language to communicate that information.

Number 2 best practice, explicit instructions. One of the defaults a lot of times with safety information is that we tell individuals what not to do, but we don't always tell them what to do, and that's part of being explicit in our instructions. So there's been a lot of research around, again, prescription drug labeling in this.

You know, we tell people take two pills twice a day prior to meals but avoid taking it on an empty stomach. Well, what does twice a day mean? Am I supposed to take it prior to

meals, or am I supposed to take it not on an empty stomach? You know, which of these do you want me to do? And so there's more and more movement towards being specific. We want you to take two pills at each of these times, and then after you take the pills, then we want you to eat.

So, again, another example: This is a made-up example as it might relate to ENDS products. So, again, we might tell people, you know, this product is not compatible with other batteries, chargers, accessories. It may become unstable after this time period. Okay, but what do you want them to do, right? We want you to use the charger that came with your product. We want you to replace the batteries every 3 months. We want you to use these types of batteries; the other ones are not going to work. The more we can be explicit, the more likely individuals are to adopt that behavior.

Number 3, low literacy structure and formatting, and this sort of goes hand in hand with plain language. When we use information that is dense, it's a lot of text, no visuals, it becomes really, really difficult for folks to understand what it is we're trying to ask them.

And this is especially true in our information environment. We do much more scanning than reading, and I

think most of us can probably relate to that as we look for information online. We're unlikely to read things verbatim. We're much more likely to scan and try and pick up the major points.

So here is another example from the prescription drug world, and this is actually an FDA-funded study that we worked on. You can see the difference between Version A and Version B. You know, Version B has headings, it has smaller chunks, it has bulleted lists. It's much easier to scan through that and get the key pieces of information.

Best Practice Number 4 is icons and visuals. How do we use these things to communicate to individuals the protective behaviors that we want them to adopt? And, again, this might be visuals that show folks how we want them to charge their ENDS products, how we want them to store batteries. These things are likely to lead to better comprehension and better use of safe behaviors than just using text alone.

Now, the key with icons and visuals, you know, there are some caveats. They have to be intuitive and recognizable, they have to be compatible with the text, and you really do have to test them with your audience to make sure that they get what we're trying to communicate when we use visuals and icons.

Best Practice Number 5 is using numeric risk information. You know, numbers can be hard for a lot of folks, but if we communicate numbers visually, individuals are more likely to understand the susceptibility and severity of a risk. And, again, we've seen this in the prescription drug literature.

So, you know, there's no one format or type of information and type of visual that works best, but using numeric risk information, especially with the visuals, helps individuals to get it at a glance. And so, again, here's an example; it's made up. These are not real numbers of the risk of battery explosion from unsafe behavior. But you can see, just at a glance, the difference. And when we're able to communicate that numeric risk information, folks are more likely to get it, too.

The last best practice from the prescription drug literature that I wanted to highlight is negative framing. So we talk about this sometimes in strategic communication, whether you're going to frame things positively or negatively. And, you know, the difference, of course, when we're talking about a positive frame, we're highlighting the potential gain or the potential benefits for individuals. When we're talking negative frame, we're talking about the potential loss for

individuals.

So, again, an example from the vape world. You know, are we going to highlight the benefits to folks when they store the battery safely, or are we going to highlight the potential damage that could be caused if they don't? Generally speaking, using a negative frame is going to be more effective in communicating those risks to folks.

So let's move on to the second piece and talk about the consumer education, right, because warning labels are important. We need to communicate the risk of battery issues to consumers through the warning labels, through the products, like Youn Ok talked about. But we also need to communicate proactively, right? The warning labels alone are an important step, but they're not sufficient on their own. We need to be proactive about helping consumers to understand how they can use these products, or the battery component of the product, safely.

So here is the ideal consumer behavior model, right? This is what we all -- well, this is what behavioral scientists dream about at night. If you give people risk information, they will be aware, they'll have the heightened risk perceptions, and they'll adopt a protective behavior. And so

these are the ideal circumstances; this is how we want people to behave in an ideal world.

And this is what real-life consumer behavior looks like, right? I mean, we give them risk information, but there's this huge, huge sphere of influence that ultimately affects consumer behavior. You know, there's self-efficacy; can individuals feel confident that they can adopt the behaviors that we're asking them to adopt? What are their intentions to do it? Are they ready to adopt these behaviors, or are they just in that contemplation stage? What are the barriers? What are the subjective norms? What do they see their peers doing? You know, are all their peers using the vape products incorrectly and they're not having damage? You know, that social norming aspect can be really strong.

And so, again, I think communicating that risk information is important, but we need to think about how consumer behavior happens in real life and all of the different influences on it. And so because of that, you know, risk communication is a necessary but insufficient step in changing behavior. It has to be there, but on its own, it's really not enough to change behavior.

So best practices from that broader sort of world of

behavioral change in risk communication: Number 1, listen to and engage the audience. We've got some smart people here from some different areas of expertise, but we need to be talking to people who vape. We need to be talking to the retailers, we need to be talking to the end consumers, and we need to understand why they behave the way they behave. You know, it's been shown that campaigns that leverage that stakeholder input, and again all types of stakeholders, are not just more effective but they're more authentic, you know, they're more believable. We talk to consumers in the same way they talk when we're able to tap in to those stakeholders.

So what does this mean for FDA and others working on this issue? I think it means, number 1, formative research, understanding audience needs, perceptions, behavior. But again, it means engaging that audience. We need to involve them in the planning process; we need to have the audience help develop solutions. You know, it's not enough just to get information from vape users and other end users and say, okay, we're going to go in the back room and come up with a solution now. We need to involve those people in the solution.

You know, I think, as John and others talked about, they have an interest in their products not exploding or catching on

fire when they use them or when they charge them. You know, so they have some skin in this game. How can we involve them in developing solutions?

Number 2, reframe messages. So what messages are going to resonate with our audience? And a lot of times safety is not the message that's going to resonate. So the example I always use is airplane mode for the phone. How many people know, before the plane takes off, that you're supposed to put your phone in airplane mode, right? Everybody knows that. How many people do it the first time we're asked? A couple. I never did. I got to tell you, I never did. I mean, I'm not trying to get the plane to go down, I'm not trying to interfere with the communications, but you know, I'm trying to get some stuff done.

Finally, one time one of the flight attendants said to me, you know, if you don't put that in airplane mode, you're going to drain your battery. What? Yeah, if you put it in airplane mode, it only lose like 5% of the battery. If you keep it in regular mode, you're going to lose 30% of that thing. Every time I put my phone in airplane mode now. You know, that's real-world behavior. Sometimes safety doesn't resonate.

And so the question is what resonates with people who

vape? You know, what aspect of this is going to resonate with them? Maybe the fire, the explosion, but likely there are going to be other issues, too, and we need to find out what those are, and that's the message that we need to be framing around.

Number 3, audience segmentation. You know, people who vape are a big audience, and they are not all the same. They are different ages, they are different ethnicities, they have different reasons for engaging in this behavior, and they've been doing it for different amounts of time.

It's important for us to start looking at that, that group, and divide them into distinct audience segments so that we can have a better understanding of who they are and why they behave the way they do because, again, the messages that resonate may not be the same for each segment. Some folks may be concerned about safety, but for others it may be cost, convenience, or other issues that are really going to resonate with them. And audience segmentation is one of those tools that helps us to get there.

Best Practice 4 is multiple channels, right? We know that just as we can't put something on a product label and expect it to do the job, we need to use multiple channels to reach folks

because that's how we communicate. And some of those channels are, you know, media related, but a lot of them are interpersonal as well. Who do vape users trust? Who do they listen to? Maybe it's the retailer. Likely, their friends and peers are a part of it, too. How do we start communicating the message about protective behaviors and safe behaviors through all of these different channels, because one channel alone is not going to do it. We need to reinforce the message. Just like any effective marketing campaign, you need to reinforce the message through multiple channels.

So where do we go from here? What are the next steps? I'd like to propose that there are three big ones we need to focus on.

Number one is that formative research. We really need to start investigating what consumers do with vape products as it relates to the battery issues. But moreover, why they do it. You know, what are the factors that drive that behavior? Because the more we understand those, the more likely we are able to change consumers' behaviors.

Number two, the warning labels, starting to create and test those warnings labels with consumers and see what resonates with them. We have a sense of these best practices,

but we need to get in the field, and we need to see what's going to resonate with folks. You know, a best practice in terms of doing that is what's known as rapid prototyping. So rather than, again, sitting in that back room and coming up with something that we just think is fabulous and then going out and testing it -- no. Quick drafts, put something together, get out there, test it with consumers, find out what doesn't work, come back, another quick draft. And the more we can rapid prototype these things, the more likely we are to get close to something that's really going to resonate.

And then, finally, that consumer education piece. It's not just the warning labels; we really need to think more broadly about education and safety campaigns around this issue. You know, FDA has put together several well-known and effective campaigns as it relates to tobacco use. I think there was one that just won an award recently. And there are other opportunities for that around battery safety, you know, around safe behavior of ENDS batteries.

So I think, you know, those are at least the next steps that I would propose for us to think about today.

Oh, I said I only had one nerd slide; I lied. So I included the references from the lit review just so that you

have them available, and I know you're all looking them up right now, but they're here in case you want access to them. I could not in good conscience skip over that.

And then here's my contact information. If you have questions, I'm happy to be in touch. You're welcome to e-mail me, but my inbox is usually a hazmat zone, so I would -- connecting on Twitter is usually a much more effective and efficient way to get in touch with me.

So thanks. Within time? All right.

DR. YEAGER: You might give yourself a break.

MR. RUPERT: All right. Yeah, I can take that break. Oh, at least we get a break.

(Applause.)

DR. YEAGER: All right. So our next speaker is Dr. Gary Kreps from George Mason University.

DR. KREPS: All right, thank you very much for having me today. I'm glad to speak, and I'm really glad to have followed Doug because I'm going to amplify and reinforce a lot of what he said. I was getting a little upset because he kept saying all the things I wanted to say, until the very last slide. I saw that he cited one of my articles, so everything is okay now.

(Laughter.)

DR. KREPS: I want to start with the main issue that risk communication is not something that's easy to do; it's complicated. It's not easy to, you know, warn people about risk, and it's even more difficult to get them to follow your recommendations.

Most people operate under the path of least resistance. They want to do what's easy to do, what's comfortable to do, and most people don't like being told what to do. I know I don't like being told what to do. So when people say to me don't do that, go into the airplane mode, I don't want to do it, and I'm glad not to do it, and I'm glad to resist.

And so we've got to really think about what to do. And so I'm a big believer in using evidence to guide intervention, and the more evidence, the better. So I'm going to talk a little bit about Doug's strategies for gathering evidence.

What did I do? I killed it. We're going to have the presentations over again.

DR. YEAGER: Can you set me up for them? Sorry.

(Off microphone discussion.)

DR. KREPS: All right. So the first thing I'm going to do, okay, I want to ask some questions. Here are some key

questions that we want to ask. I find that more often than not, that risk communication is based on very good intentions but a very limited amount of data. And while people really want to achieve their goals, because they don't ask the right questions and don't really respond to the right issues, they often actually make things worse. They make people reactive to their kinds of requests, they give them the wrong information, they create enemies, they disempower people, they frustrate them. And so risk communication is often a very ineffective science.

So what influences do risk communication programs have? How are your risk communication programs working? What do people know now about battery safety? The truth of the matter is I really did not know how many problems there were with batteries with different products, and some of the things I learned today really scared me, and it made me think twice about carrying my cell phone in my pocket and doing things and making sure that I don't have loose batteries. But I didn't know any of these things, and I don't think most of the public really understands.

Is anybody paying attention to this risk information? And from my experience, I don't think they are.

How do diverse audiences respond? So different audiences from different backgrounds have different ways of perceiving information and use different channels of communication, respond in different ways, and when we have a really important risk message like the one we want to send about battery safety, we want to try to reach different populations. So we need to figure what are the different ways to communicate. What are the channels that these people are using? What are the messages that will resonate with them?

What has been learned from these programs? What do people know? What do they think is right? Most people just assume that their batteries are safe. They can keep them plugged in, and they can use them on the plane. You know, they believe this; they've thought that. And so it's not just providing them with the information; it's relearning what we already think is right. And so we've got to figure out where they're coming from.

Are there any unintended influences from current messages? Are we telling people that their batteries are safe and there's nothing to worry about? Do we need to provide counter-information?

Why do some risk communication programs work, and why do

others not work? All right. So one of the first things we need is we need to do formative research. We need to figure out who are our key audiences. So Doug talked about audience segmentation, and we know that different audiences have different backgrounds, different needs, different orientations, different languages, different perspectives, different choice points, different motivators. But if we treat all of our audiences the same, we're probably not going to come up with a good message.

So we need to figure out what are the different demographics of the audiences we want to reach? What are their current health behaviors? What are their communication characteristics in terms of what media do they use, what channels do they use, what languages do they use, what examples do they use? Who do they look up to? Who do they pay attention to? Who do they find credible? What is their current knowledge, attitudes, values, and emotions? What kind of cultural habits and preferences do they have?

What are the effective motivators? So you want to be very specific about how to persuade people. And when you're doing risk communication, you're not just doing a blind kind of educational effort; you're really trying to influence people.

You want them not only to think differently about these issues, you want them to behave differently. So you need to think about influence patterns and influence strategies. And what kinds of barriers are there to behavior change?

So there are different strategies for collecting audience analysis research. I do a lot of advising to federal agencies who are doing risk communication campaigns, and often they tell me they really don't have the time, they don't have the money, they don't have the inclination, they don't know how to do risk communication research, they don't really believe in it.

And so I tell them that you don't always have to go out and collect new data. There's a lot of existing data out there about the audiences you want to reach. There's a lot of information about what they believe and what they think. So you can review existing data about key audiences. And if that's not enough, then you can go collect new data. So, you know, it's a matter of getting some information so you're not just going into the situation blind. I think this is like driving down the highway at 60 miles an hour, and all of a sudden your windshield goes black. You can't see anything; you don't know where you're going. This is really frightening. This is exactly the way a lot of risk communication is being

done. We need to see the light, and we need to see what's going on. And so the data let you see what's happening so you can make good choices.

So audience analysis data should guide program development. Interviews, focus groups, surveys, textual analyses, analyses of documents, and observations are all really good tools to use to gather that information. Interviews and focus groups are often good for setting up later surveys, and they provide really good baseline data to determine where people are, because one of the things you want to do when you're doing risk communication is you want to determine what influence you're making and what you've accomplished. So the baseline data provide a guide for evaluating progress for the future.

Surveys provide good audience characteristic information. Interviews are best for generating information for programs. Doug talked about involving your audience. So one of the really good ideas for developing strategies is user-centered design, a participant design, and when you're conducting interviews and focus groups, you can ask people what kinds of messages would resonate with you, what would influence you.

A couple years ago I did a study for the CDC about getting

the women of childbearing age to use vitamins to avoid birth defects, and for years the CDC was having trouble getting young women to take the vitamins, and they had been using a safety strategy to say, well, you don't want birth defects. Well, it turned out that women were really not that concerned. Many of them weren't planning on having children; it wasn't on their agenda.

And so when we asked them what it would take for them to, you know, use vitamins on a daily basis, they said if it improves my appearance, if it makes me thin, you know, then I'll take it. So we tried to change the -- we unfortunately couldn't find any good evidence that vitamins would make them thin, but we did find out that it would give them strong nails and thick hair, and that was good enough. And so the new messages -- and they were much more effective than the safety messages because we identified what it was that the women really wanted, and we came up with messages that made sense to them, and we did that by involving them and getting their input.

Once you've done your formative analysis and your needs analysis to figure out what the issues are, you need to guide and evaluate your development of the strategies. So process

evaluation is really important, and primarily that involves message testing and also tracking whether people are paying attention to your message.

What do they know what's going on and how are they responding? Are they understanding what you're telling them? Are they liking what you're telling them? Do they believe what you're telling them? Are they following your recommendations?

Often you'll be really surprised that none of these things are happening. They're not hearing you. Most of the biggest problems with risk communication is very limited exposure. The people are just not paying attention and they're not hearing the message. It's a very crowded media environment. They'd much rather listen to somebody else than you, and risk messages are not particularly interesting unless you design them in ways that will really attract your attention.

What kind of user responses are going on? Are you achieving your goals? Are you having negative effects? Are you having boomerang effects where people go in the opposite direction? You need to know that right away, and it's amazing how often, with risk campaigns, we've had negative effects.

There was a very famous campaign several years ago. This is your brain on drugs. Do you remember the commercials with

the sizzling eggs? You know, this is your brain. And it was very effective with people who were not intending to use drugs, but it was terrible with people who wanted to use drugs because they were high-risk takers, and they said that's cool; I want my brain to sizzle like that. And every time they showed the commercial, people would be -- these at-risk, you know, youth who were high risk takers were more and more, you know, interested in using drugs because they wanted that sizzling brain effect, and it was having a very negative effect. Not only that, they were spending all of this money on this campaign, and they were actually making the outcomes worse.

Test message/channel strategies and program usability to see how users -- are they paying attention? There's a lot of interest right now in social media. Social media has become the new buzz for intervention. But what social media channels are people using? Are they paying attention? How are they using them? Are they using them for health information? Probably not.

And so you need to figure out how to utilize the right channels in the right ways with the right people, which may mean you need to do a variety of different campaign strategies targeting different groups using different media channels.

Track responses to refine program features. So as you're improving the program and as you're making progress, you know how to change because it's an evolutionary process. So when you're doing risk communication, you're not just making one change; you're moving people, you're moving them towards where you want them to go. And as you move them, you want to try to come up with new messages that allow them to take the next step.

We're also living in a changing environment where there are lots of new issues going on, and so you can't provide the same messages over and over again. People become bored of the same message; they don't want to hear it anymore. You know, maybe they liked it the first time they heard it, but the tenth time is a bit too much. I don't want it anymore. They want something different, and so you need to figure out how to move your campaign as you're building your relationship with your audience.

All right, summative evaluation is the last part, and it's where you try to figure out whether you've actually moved the needle or not. And so I'm a really big believer in trying to track what has happened, what has occurred, what have you accomplished, what's working best, what's not working. You

want to come up with the most parsimonious strategies as possible so you're not wasting money and time.

So you want to identify what's working and what's not working, what channels are most effective, what messages are most effective. What is the cost-benefit analysis? And if you have those data, you can actually invest wisely and also sell your program to people who want to invest in it. You want people to have confidence in what you're doing, and you want to demonstrate how this works so you can guide future interventions as well.

So one of the things that I'm hoping that I'm going to convince you of is that evaluation and data collection needs to be built into every risk communication effort. It needs to be, you know, inseparable with every time you want to do any kind of communication to identify a risk to an audience that you have good data to guide what you're doing.

There always seems to be this tendency to put on a show to get out there and do it, you know, to build a website, to develop a commercial, to have a jingle. But, you know, I think the issue becomes, before you go to the field, figure out what's going on, figure out who you're dealing with, and engage your audience actively so you can develop a program that makes

sense to them.

I think I'm on the wrong message. Let's go to the last one, best evaluation research practices. So evaluation is better than no evaluation at all. Always have some data to guide you.

The best evaluation efforts are longitudinal, and there are multi-stages along the way. The best approaches use multiple methods, both quantitative and qualitative.

I love the use of unobtrusive methods that are nonreactive where you're not asking people, but you're observing what's going on and using natural data.

Make sure that you look at really good health outcomes data. Don't look at really shallow -- like web hits don't really tell you very much. What did they do when they got there? What did it mean to them? How did it influence them? You really need to dig deep to get that information.

Try to identify data that will demonstrate progress and that leads to direct action.

Make sure you do a cost-to-benefit analysis so you know how much it costs and how much you're gaining.

I like to use a controlled field experimental design for my summative research where I use the basic information from

formative and needs analysis and the process analysis to evaluate what goes on later on in terms of outcomes. And I do that at multiple points in time so I know whether it's working and whether it needs to be changed over time.

And I really think we need to think about using an engaged user-centered participant approach to our health promotion.

That's my position, and I'm going to stick with it. Thank you very much.

(Applause.)

DR. YEAGER: Thank you, Dr. Kreps.

Our next speaker is Dr. Tonya Smith-Jackson from North Carolina Agricultural and Technical State University.

DR. SMITH-JACKSON: Okay. Hello, everyone. And I have to apologize because there's going to be some overlaps with my talk and the two previous folks, but it tells you that there is some convergence in the field of risk communications, and convergence is based on not anecdotal information but on information acquired from research, and really good research.

All right, so this is a bit of an overview. I'm going to talk a bit about the aspects of my area of specialty. I am an ergonomist. I use cognitive ergonomics, and I apply it to the design of risk communications, the design of products, any kind

of products, and then, of course, the subsequent evaluation.

So I'm going to talk a bit about the hazard control protocol, which is something that guides, it basically serves as a framework for us, and then talk about hazard perception in a sociotechnical systems context. I'm heavily a cognitive person, but more so a social cognitive person. So my expertise based on my training and education has focused on social cognitive and not the sort of old way of looking at how people think and reason. And then suggestions for ENDS risk communications.

So the hazard control protocol is pretty well known in engineering. We use it as a way of understanding how to integrate safety and health into context, whether they're products or whether they're other kinds of more complex systems. But one of the things that is most important to understand is that when we're looking at cost and research and development and return on investment, it's important to note that, first and foremost, we need to look at this top tier of "designing out" the hazard, and that's our -- that's very much so the initial goal.

So if we can get a hazard out of a product, we don't have to so much focus on efforts for behavioral change, except as it

might relate to something else peripheral. But for the most part, if the hazard isn't there in the product, we won't have a problem. So engineering controls are sort of at the top of our pyramid, and that's where we like to start.

And then "guarding against" is the second layer. In this case, if we're talking about e-cigarettes, I don't know if we can convince people to wear, you know, flame-retardant face masks and mouthpieces and whatever, but guard against does mean that you do something in that environment where the hazard will still be there but you guard or you protect or you cover in some way so that the consequences will not be as severe if they're exposed to the hazard. But that's another engineering control.

But sometimes we're not at a place, particularly in early product design where products have moved into the marketplace and they're still evolving. At times, people will often overlook hazards, they don't design them out, and they don't guard against unfortunately, and so they hit the market, and those hazards are there. And like our former presenters have said, our users don't understand the hazards, and in some cases the hazards might actually be hidden from the user.

So we do find ourselves moving to the "warn" stage, which

is where warning or risk communications happen. It doesn't mean all of these things can't happen in parallel; they can all happen in parallel obviously.

And then "train" is sort of the last part of that pyramid where you're actually training people to use a particular product, which is occurring from, what I understand, in some of the e-cigarette and vaping industries.

But I'm going to focus on "warn." So that's what we call an administrative control, which is trying to change behavior, getting people to use different ways of interacting with the product or interfacing with the product.

And I want to make a distinction. Risk communications are sort of the broad name. Many of you, of course, already know this, but risk communications are quite broad. That's the name we use for information you might find anywhere. It might be on the product, but it also might be on a website. It might be information communicated on a blog, or it could be in collateral materials, safety instructions that go along with a product, for instance.

And then risk communications are delivered in multiple ways. You can deliver -- you know, sounds can communicate warnings. The urgency patterns have been tested in the warning

industry for quite a long time. We know what pulses, we know what frequencies to communicate different types of urgency to get the user to do certain things. So that's also, you know, part of the risk communications.

And risk communications, warnings are included in risk communications. But what I'm going to focus on today is first, initially, some information about warnings which are more specific, and warnings tend to focus on a particular hazard. And then I'll move into a little more about risk communications. But very much like risk communications -- well, warnings can be on product or also collateral, very like risk communications.

Now, one thing to note is that I'm going to be talking about what makes warnings and even, in general, risk communications effective. And there are some warnings on actual products that really aren't effective, and you may have seen some. These are some products that actually did exist at one time, and they've been removed.

Tesco fruit juice carton, on bottom side: "Keep Upright." Now, I'm not sure if that's -- we're not sure what the purpose of that warning actually is.

Sainsbury's mineral water: "Suitable for vegetarians."

Why do we need that information, right? Unless it has some kind of pork drippings or something in it, I don't know.

And then there's an unknown Japanese food processor that was going around in our practice community for a long time: "Not to be used for anything else." It was on a food processor. So, again, we're not sure -- oh, I'm advancing for no reason here. Okay, again, I'm not sure -- some warnings we're not sure why they're there, okay.

Oh, the tiramisu dessert: "Do not turn upside down." It was on the bottom of the box. So some warnings can actually lead to other problems.

Okay. So I'm talking about a sociotechnical systems perspective, and I see something's happening with my slides here. In my profession, we have moved -- well, we moved a long time ago, like 1910, to what we call the sociotechnical systems perspective.

So in industrial and systems engineering, we're designing using sociotechnical systems. We don't just design a product, for example, simply from a cold engineering perspective. We design it with an understanding of who's going to be using it, under what context they're going to use it, and when there's strong emphasis on that, that area is known as human factors,

which is also my area.

But in the sociotechnical systems perspective, it's actually used as a way of seeing how you consider various components of the whole design challenge that you are faced with. So there are three primary sort of modes where you have to be able to, you know, apply your knowledge and do your research in order to design something that's going to be effective and usable.

And the first is consider your users. So you've heard many of our previous presenters talk about the importance of users and knowing your users and knowing your audience. Users bring certain types of capabilities with them. You know, some users read better than others. Okay, some users cannot read at all. Some users have certain resources available, while others may not, which might incline them to rig something or modify a technology which may introduce additional hazards. So capabilities differ, and then experiences and culture obviously.

So everyone comes in with different experiences. We made the mistake in the past -- actually, it's getting better -- of designing for the average, all right, and the average wasn't representative of everyone, and in fact, once you do your

statistics, the average doesn't exist. Okay, there's no real person after you've come up with your various averages. But unfortunately, we design for the average in many instances, and that has put many users at even higher risk than they were before.

And then culture matters. So we like to talk about the commonalities. There are plenty of commonalities across people, but the variations are very important. We're a highly socially segregated society in this country. Not all countries are like that, but we're pretty socially segregated.

And so people have different customs and socializations that are occurring. They may come together and interact in the workplace, for example, but they go back, okay, to their cultural areas, and certain behaviors are predominant in those areas that may not happen when they are together and mixed. So we have to really consider culture because culture impacts how people think, how they interact, what assumptions they bring.

And then the technology, in this case the electronic nicotine delivery systems. But familiarity with previous products will also need to be considered because if there are previous technologies that are similar to a technology that is introduced, then people are going to take some of the

assumptions from the previous technologies and transfer them to the new technology. That transfer could be deadly.

And then affordances and culture, the technical term we sort of use to say that objects by their shape or color or coupling will communicate something to the user about whether the product is really dangerous or whether the product is safe. It's called an affordance, and it comes from 1973 Gibsonian research on how we perceive things and how perception and cognition work together.

And then context matters; context always matters. Where do people use the products, because the context changes how they perceive the hazards of that particular product. So when people are in a maverick culture, for example, the macho, you know, machismo maverick cultures, they may take more risks, okay, typically a male-gendered culture will take more risks under certain circumstances because of the context, the social context.

And then object coupling in situ in the point or at the point of where it's going to be used, whether it's in the home or at a bar, in a vape shop, really does matter as well as part of context.

So looking at the users, you know, I pulled some of this

information from the FDA website to kind of look at who we're designing for. We're designing for any potential users obviously, and users we don't quite know about or have never counted. But if you look at some of the statistics, we're looking about 16% users who are high school students, 5.3% middle school student, and 12.6% are adults. And that was just 2015. There's probably more updated information that I couldn't find, but more updated information at this point.

But these are our users, and one of the things that we have in human factors is we do have some voluntary standards, pretty much, that have based themselves on usability and primarily for adults. Unfortunately, there isn't a lot for children.

But when we look at usability in particular and we want to look at the usability of a warning -- that's what this applies to -- you do have ANSI Z535.1 through .6 standards, and I used to be on that standards committee, but I got too busy and had to come off the standards committee and learn to say no to certain things. But there has been empirical research on what makes a warning effective. So it's not just about designing warnings, but it's about designing effective warnings, because we ultimately want to modify behavior. We want to convince the

user, persuade the user to take on a safe behavior and always practice that safe behavior.

It's down to four elements. An effective warning captures attention, it uses a signal word, an icon, a color of some sort, but it captures the user's attention. It communicates the hazard, so it tells them what's dangerous here, okay, what the problem is. And then it communicates the consequences, you know, an explosion could occur, etc. Okay, don't just tell them about the danger; you tell them about what's going to happen if that hazard occurs, so the consequences, and then provide information to avoid the consequences.

So those four steps still hold true since 1991, I believe it was, since 1991. So it's replicated and replicated and not just in laboratory studies but also in field environments.

And then ISO 9241, 41-11 actually, the guidance on usability has provided more information about how to design warnings with, you have to understand, for example, the goals of the user, what they're trying to do, the context of use, etc. And that's very much like I had mentioned before actually about context. I'm going to get to user expectations in a moment.

There are a number of research-based guidelines, as well,

for warnings, and I, on my last slide, have some contact information so that I can send you a reference list, if you'd like.

So back to other aspects of the user, I'm going to go -- I don't want to go too deeply into this, but cognitive ergonomics, of course, is my particular area, and we have evolved since the 1800s, trying to understand how people think. We made a lot of mistakes in the beginning because we first studied rich people, European people, and then we studied a lot of psychology students. Okay, quite a long time, all right, from 1920 to -- you know, some of it's still happening now. And psychology students, especially early on, weren't representative of the entire population.

So, initially, if you look at that middle diagram on your right, you'll see that the initial is something that might be very familiar; it's cold cognition, what we call cold cognition. You know, people perceive -- you know, they sense something, they perceive it, and then it goes into the short-term working memory, and then it goes to long-term memory, etc., etc., etc., right? And we just knew that we were right. I mean, we just knew this is happening, okay, especially when you had them in the laboratory and if they were a psychology

student or a rich European, a person of European descent, okay, but we controlled the environment so much that really what we were pulling out from cold cognition fell apart in the field.

And a lot of that started with people in the military, thank goodness, who actually started applying it out in the field on naval ships and on aircraft and etc., and realized, whoa, wait a minute, these theories aren't working the way we thought they were.

So we have something now that we call hot cognition, and hot cognition says, yes, okay, you still have a memory and you still have all of this stuff, you know, encoding and all of this other stuff happening. But what happens in parallel -- it's very connectionist. What happens in parallel are your cultural metaschemas, whether it's the multiple metaschemas, you have your gender, your ethnicity, your socioeconomic status, any prototypical images that you hold in your mind that might be related to that technology, your expectations and assumptions, whether you're stressed or aroused at that particular time, etc. All of those things happen together and that's what determines how you're going to process the information, whatever information it actually is.

So we also know that people have certain ways of thinking,

then. With our understanding of hot cognition, we know now how to design certain things for people.

So the third bullet. If I can't see it, it's not there, right? Those are hidden hazards. But we have something called object permanence and expectation. If something is not -- I mean, if we don't see it, then it's really not there, okay?

Where there are lots of people in a great place or a familiar place, it's all good. What bad things could actually happen? So our beliefs and our affect or emotion and the context in which we are will change our decision making, changes our risk perception, and that's something we have to consider when we're designing.

And then this last one is pretty important, too. I trust my networks; they're all like me. I don't trust anyone outside of my networks. Identity is a big driver in how you process information. So the bottom line is we really don't see the world the way it is. We see the world the way we believe it is, the way we've been socialized to believe it is, okay? And that's important to remember, and that again goes back to why it's so important to talk to our audiences.

All right, I'll go through this one a little more quickly. More about users, things that -- if you see these bottles at

the top, one of these bottles is actually soda, it's a soda drink, and the other is an alcohol drink. I'm trying to bring up the point here that what we know through Gestalt principles and through Gibsonian affordances is that shape causes people to -- and colors and things like that, if things are familiar to something previous, then they're going to make assumptions.

So if a soft drink is considered safe and then you produce something that's an alcohol beverage that looks about the same, okay, the same container, the same color, they might drink several of those and not realize that they are -- you know, that they are actually putting themselves at risk for intoxication.

I guess I'll hit another point here. Under the learned behaviors and learned assumptions, a lot of things are coupled or learned through classical conditioning. Well, we learned this goes together with that and that goes with that. These are all important to understand when we're designing a technology because, again, if technologies are brought together from this systems perspective, the battery charger plus the e-cigarette, then that coupling, if the battery charger looks like other battery chargers, for example, it's going to be assumed that that battery charger is safe and coupling the

battery charger with the e-cigarette, it doesn't matter, it's something safe, it's going to be the same thing.

And my yellow light is on, so I will rush through a little more.

This is making the same point about affordances, similarity to safer products and the likelihood of understanding the hazards -- of underestimating the hazards, sorry. When something is very similar to a previous product that was relatively or less hazardous, then they're going to underestimate a similar product that comes along.

And these are just showing you some of the similarities between phone chargers, for example, some that might be a little safer than chargers that are used for e-cigarettes, and that's an affordance problem that we have.

And inhalers, you know, asthma inhalers and in the shape of some of the vape products that are out there. And interestingly, you can see that some are marked in ways that will cater to children or draw the attention of children.

And then the environments in which things are used. Okay, so people are using e-cigarettes in all kinds of social environments, again, where their risk perception may change. And the little boy who's on the lower right, you know, maybe he

may end up having to charge very quickly because he needs to smoke before his parents get home. He might be a latchkey kid. So those are things about context that we need to understand.

I'm going to provide you with a paper that explains this, but you talked about the boomerang, Gary talked about the boomerang effect before. There is an effect that we call critical confusion, where people think that an icon that's used that is trying to tell you something that's hazardous is actually a friendly icon telling you to do just the opposite.

So this is a study we used -- we did in West Africa actually, and then we brought it back to the United States, the same thing. Mr. Yuk is a poison -- you know, a poison hazard-communicating icon, and we had quite a number of people, though, in West Africa who thought it meant you should drink whatever it is that you find that icon pasted to. And so a few people out of that 22% who had that critical confusion actually explained that it looks like the Laughing Cow, and Laughing Cow is a big deal in West Africa, it's cheese, it's milk, it's everything.

All right, so some final things. I think I'll go to some suggestions. Learn your users and their context. I think we've already said this. You know, it's important to

understand who they are and where they're using the products.

And some suggestions for the ENDS risk -- other risk communications that I can provide you with, in terms of literature, if you e-mail me for the references. Some of these are very basic, so our former presenter already covered them. But the text should be simple, the arrangement is important, and user readability formulas, and there are plenty of great readability formulas out there.

And communities of color: Obviously, you know, we know that it's been our history that we tend to do research, and we over-generalize to all groups, and if you note that in much of the research, there's typically under-representation of minority groups, then that leads to certain problems in overgeneralizations.

So this last section just brings up the point that it's important to interact with communities of color and have people who know how to interact. So I make a reference to partnering with minority serving institutions. We have a rich knowledge base, we have a lot of trust in our communities, and we're able to do the research that different organizations might need.

And I think this is my last point. If you're going to use social media, social media is a big -- a very popular way to

communicate risk, in fact, if you are in any blogs or you use Twitter. Many communities talk to each other about the risks and about health information, but it is important to be strategic about how you do it and be very careful about how you do it. And so there are assessment metrics we've been using for dementia that relates to social media, and we can share those.

And so, finally, if you would like me to share my reference list, feel free to contact me. You have my e-mail address. Thank you.

(Applause.)

DR. YEAGER: Thank you, Dr. Smith-Jackson.

Our next speaker is Spike Babaian from Vape New York.

MS. BABAIAN: How are you? Thank you for staying so long. Usually, there's no one left by this time. My name is Spike Babaian. I am a Technical Analysis Director for New York State Vapor Association. I'm also a retail shop owner, and I own Vape New York.

Most of the slides that I have in here have been covered way too extensively to spend too much time on them, so I'm going to skip through them very quickly and then talk about other issues that were brought up during this that maybe should

be addressed.

As a retailer, we see a lot of different people who have a lot of different experiences. A lot of -- the last three people who talked, talked about knowing your user, and this is a really big thing. If we're going to try to prevent these things from happening, we have to know who the people are that are using it and what they're doing wrong and why they're doing it wrong.

One of the ways that we can prevent some of these incidents from happening is by talking to the people who are dealing with the consumers, talking to the retailers, finding out what mistakes they're making, finding out why, which is, I guess, why I'm here.

So one of the mistakes we have -- obviously, the number one mistake discussed today, because the majority of the incidents that cause e-cigarette explosions are because people take loose batteries and put them in their pocket with metal keys and change. We've talked about this all day, and we talked about it all day yesterday. This is a huge deal.

As a consumer, I didn't know for, you know, most of -- until I was 30-something, I guess, that you couldn't take a double A battery and put it in your pocket with your change.

That didn't occur to me that that was a problem. Most people even now don't understand that, obviously, or we wouldn't have all of these incidents. And frequently, when we go over the risk agreement that our store does with our consumers, they have no idea. They're like, you mean I can't take a battery and put it in my pocket with my keys? No, you can't. Why not? They don't know, and this is not a common thing.

Most vape shops carry a battery case for less than a dollar or a dollar. In our store we give them away for free because we will not let you take a battery out of the store without a case. But the shops that do charge for them typically don't charge more than a dollar or a dollar fifty maximum. So it's really not a big thing to get one.

Another mistake that is frequently made is using the wrong charger. People take a battery that is an e-cigarette, and they go, well, it fits into this charger, so I'm going to use this charger, even though I bought this charger at a gas station or airport or wherever. So using the improper charger we already talked about a number of times. We're going to skip past this one.

This was one of the issues that I had disagreement with some people on, that they say charging a battery inside of a

device, if the battery charges, is not necessarily an issue. However, maybe some of the devices are not made well enough because it seems that some of the battery ports that are charging, some of the USB ports that are charging batteries are not charging them properly. Or people are using the incorrect USB charger. The device should limit how much power goes into it to not allow the batteries to overcharge, but sometimes in very bad manufacturing circumstances, it doesn't, and that's a problem.

I did, however, have an argument with John, who spoke yesterday, about the battery chargers, and I said all batteries should be removed and charged in a charger and not in the device because people can't use the wrong charger that way, and he said every time you take it out, the battery skin tears more and more. And we've already seen a whole bunch of pictures of torn battery skins, and this does increase the risk level if the person is not careful, and as people, we are inherently not careful. So I guess maybe it's better to charge it in and take your chances and hope they're using the correct charger.

Okay, can you go forward, please? Thank you.

We've seen this picture about a dozen times in the last 2 days. We're all using the same picture. I did kind of want to

bring up the point that we're all using the same picture. There's a reason for that. There are not a whole lot of other pictures. We all choose this one. The reason there's really only one good picture that explains -- that shows what happens to an e-cigarette when the battery explodes in it is because this is not a common occurrence. If it was, there would be hundreds of pictures online, and each of us would have used a different picture.

So I'm not saying it's not a problem. If I didn't think it was a problem, I wouldn't be here. However, it's not as common an occurrence as we all think that it is, and this is one of the few pictures where there's actually an e-cigarette in the photograph, not just a battery that exploded in someone's pocket.

The mistaken solution in this one is don't interchange parts of a device. Don't take one top from one device and one bottom from another device and put them together. We talk about open systems and refillable tanks, and these open systems are meant to be used with the package that they come with. If they're not purchased together, they shouldn't be used together. And people frequently say, well, this fits; I think I'm going to try this.

One way to prevent that is to contact the manufacturer and say can I use this particular product with these specifications with this particular product? And that way the battery manufacturer can tell you whether or not they're compatible.

Using batteries that have ripped skin, dented tops and bottoms, damage on them, have been dropped, have been exposed -- you know, engulfed in water, have been exposed to salt water, have been corroded, have been rusted -- if your battery is damaged, it shouldn't be used. This is a simple thing. We explain it to people.

Again, every day I go over at least three or four dozen risk agreements we call them in our shop, where people accept this risk, and we explain to them how to avoid the risk and how to not have these problems happen. But when we do that, we make sure that they understand if you can see metal through the wrapper that is on your battery, do not use it.

Someone showed re-skinning of a battery, which we sometimes tell people if you refuse to buy a new battery, at least please re-skin your battery; do not continue to use it in that fashion. And we do everything we can not to get them to take that battery out of the store with them.

We also encourage them to, please, if they are not going

to keep that battery, put it into our "call to recycle" box. Most vape shops have recycling programs where they recycle used batteries, because they should not be tossed in the garbage, which is something that did get discussed a little bit but not a super lot the last couple days.

Obviously, we've already talked about TSA and FAA and on the planes way too much, so we're not going to talk about that too much, with exception of the fact that a pretty easy solution, again, would be to make the TSA enforce using battery cases on the batteries. And maybe that's not an easy thing to do, but they can see the batteries going through the scanners, and it's very simple for them to say can you please remove the batteries so that I can see that it's inside of a proper case so that it's not going into a plane without any packaging?

These are poor cell quality batteries, knockoff batteries, fake batteries, all sorts of things that people buy on eBay. Obviously, this one says Ultrafire, and we talked about TrustFire earlier today. TrustFire and Ultrafire were made as flashlight batteries, from what I understand, and were not intended ever to be in an e-cigarette, but somehow they find their way into e-cigarettes somehow.

So, again, should batteries be built in? Well, that's

something that I don't want to talk about until the end because I feel pretty strongly about that.

Using old batteries, batteries that have been charged and discharged too many times, people don't understand that they have to replace the batteries after a length of time, and it's a very simple solution to explain to the consumers when you're going to use this battery, after you've charged it 300 times, you need to replace the battery.

We say 12 months, and it depends on the size of the battery. Someone just before me put 3 to 6 months, but they had a picture of a very, very tiny battery, much lower milliamp hour, and obviously that one will need to be charged two to three times a day, so that would be 3 to 6 months instead of 12 months. These batteries typically are charged once a day.

For customer education, we have a long 12-point list that we actually read to the customers and make them initial next to each one so that we can be sure that they understood what we were saying. If they don't speak English, we use the online Google translator to translate to them all of the different points, to make sure that they understand what to do and what not to do.

Charging batteries unattended. Obviously, using the wrong

chargers, using devices without built-in safety protections, like mechanical mods that were shown in the other devices. Mechanical mods are not e-cigarettes; they're metal tubes that have no electronics. They're not electronic cigarettes because there are no electronics. They're just metal tubes that have batteries inside of them. They don't have any safety features, they don't have any protection, and we make sure people understand that. We don't sell those products in my store. We're not saying you shouldn't. We're saying you shouldn't use them without proper education.

Obviously, tell them not to put batteries into their pocket loose without a case, not to use damaged batteries, not to put the device in their pocket with the device still turned on. Almost every advanced-level device, the larger-sized devices have on/off switches where you can turn them on and off. If you don't turn them off, they can get hot. When they get hot, the battery gets hot. When the battery gets hot, we see what happens.

Interchanging parts from other devices we talked about. Rebuilding their own devices, we strongly warn against that. There are some people that are going to do it anyway. We encourage them to do it as safely as possible, but we don't

encourage them to do it at all in our store. Unfortunately, there's not really a good safe way to make your own stuff unless you are an electronics person or an electrical engineer, so we don't think that consumers should be doing that. The devices should be used as they come and not modified.

Leaving batteries in extreme temperatures, like leaving it in a hot car, obviously dangerous. And these are simple things that you can tell people.

Obviously, we talked -- the last three people that spoke, spoke a little bit about how to get that message across and how to get it across properly to people. We own a domain, modbatterysafety.com, that we have a video on, and it's just a very short -- you know, it's a workshop video that we had at a workshop about 6 or 7 years ago where they went over 18650 battery safety and all of these "what to do" and "what not to do" things.

And it does seem that the majority of e-cigarette users are much more likely to watch a video that's 5 or 10 minutes or 20 minutes than they are to read anything. Maybe they're listening to it in the bathroom while they're doing other work. Maybe they're multitasking, maybe they're making dinner, but they're listening to it or they're watching it. So we do think

that a video message or YouTube videos are a good way to get that across to the users, that they actually pay attention and recognize what they're being told without just skimming through something without actually reading it.

We always warn about marrying batteries and devices using multiple -- if you're using batteries, multiple cells, to mate them, buy them together, use them together, charge them together so they maintain the same lifespan. But people don't really understand that, and frequently they will come into the shop and open their device and have three different batteries inside of it, which is not good. So we do go over that with them and make sure that they understand.

Our suggested store policies: These are things that we do in our store that we would encourage other stores, you know, retailers, to do. Of course, we can't really demand that they do it, and it would be very hard to reach them all, except maybe through trade associations like Smoke Free Alternatives Trade Association. Amy spoke earlier about them. But the trade associations can reach out to their shops to make sure that they're being responsible and having responsible policies about educating the consumers and about helping the consumers.

Steering new users away from advanced-level devices,

encouraging them not to use products that are maybe a little bit too much for them or maybe have too many complicated features. Only selling advanced-level products with the battery safety lesson or education and a risk agreement being gone over so that they understand what things they should and shouldn't do before they have an advanced-level product instead of them buying it on eBay, going home, making the mistake, and then coming into the shop and saying I bought this on eBay but it's getting really hot and I don't understand why.

So this is a problem as well. And, you know, it's not that they shouldn't be able to buy a device, but wherever they're buying the device should be providing the education to them before they actually get the device and go home with it, so that they're educated and they know what to do.

Warning customers about using batteries that are damaged, warning them about using high-powered or fast-charging sources: Most well-made devices have something that will limit the amount of power that can go into the device, but there are very poorly made devices that don't necessarily do that, or they're older model devices that just happen to still be on the market, and this is a problem.

So, you know, this goes back to the whole situation that

we're in right now, is that older model devices didn't necessarily stop the charging when the device -- when the cell got full, and so it would overcharge the batteries causing, you know, obvious explosions.

Well, right now we're not allowed to make any improvements to our products. The FDA has said this is where you're at, and you can sell these products exactly the way they are; there are no changes allowed without submitting another multimillion dollar PMTA. And so none of these problems with any of these products can be fixed.

And so I feel like we've been here for 2 days wasting our time talking about how we can fix this problem, but we're not actually allowed to do any of those things with e-cigarettes. So I don't manufacture anything, I don't make anything, I don't go to China and talk to manufacturers. I mean, I talk to them on the phone and I make suggestions, but I don't actually manufacture anything. I'm frustrated, however, that the people who are manufacturing cannot improve the products so this doesn't happen anymore. This is not the way it's supposed to be. The regulations were not put out correctly, and we understand there was pressure from Congress to get some kind of regulations out, but it was not done properly. So they need to

be revamped and made so that that way people can improve and fix the products that are out there that are dangerous. It doesn't make any sense.

Another suggested store policy we have is to give a free battery case away with all loose batteries, which we do and we encourage everyone else to do.

The first point here is actually kind of covered over because my slides got messed up, but doing public service announcements is what we think would be the most beneficial to people. We have spent multiple millions of dollars -- well, not I guess -- yeah, we have, as taxpayers we've spent multiple millions of dollars putting ads on television telling people they shouldn't use e-cigarettes because they're dangerous and that children shouldn't use e-cigarettes and children shouldn't smoke and we should all stay away from e-cigarettes, and that's great. But that hasn't saved any lives yet. What we need is for someone to pay for lots of television PSAs and advertising to tell people to put the batteries inside the case, to tell people not to step on or smash their batteries, to tell people not to use batteries that are ripped or torn or damaged.

We need to have PSAs that encourage shops and manufacturers to use -- you know, to get UL certification of

their devices or get their batteries tested or, you know, their products tested to make sure that they are not going to overcharge or overdischarge, that they're not going to be damaged.

We need better instructions. We need someone to require hey, listen, we need to have instructions included with the device and warnings included with the device. Obviously, how the warnings are written is going to be important, but there are plenty of ways to get a standardized way of setting regulations and sending warnings out to people that they'll understand.

Replacing old batteries: One of the suggestions that we do is we encourage people to put a little sticker with the date of purchase on the batteries so that they don't forget which batteries are which and not replace the battery soon enough. A lot of times people have batteries and they have eight of them. E-cigarette users don't use just one battery or two batteries. Sometimes they have a whole bunch of them, which is why they end up with them in their bags exploding because they forget they had one in there sometimes.

And having a date on it, with a sticker on it with the date will tell them, hey, I've had this battery for 2 years. I

can't believe I'm still using this. This is not a safe battery anymore. I need to recycle this and move on to a new battery. So that was a big issue.

Obviously, we're here addressing battery safety, and it needs to be addressed, but it needs to be addressed to the people who are making the errors. I don't think there's anyone in this room who's exploded an e-cigarette. So we need to find a way to get the message to the people who need to hear it, and we think that PSAs may be helpful, we think that getting the word out may be helpful, we think that having some kind of advertisements or commercials may be helpful. Encouraging people to do that or offering some kind of incentive for them to do that may be helpful.

There are no known deaths from using an e-cigarette properly, as it's intended to be used. No one ever vaped an e-cigarette and then died from it. However, there are a lot of people dying from using combustible tobacco, and I'm only bringing it up because we're all sitting here talking about, you know, the hundred people that may have been injured by a battery explosion and have a burn on their leg or maybe they aren't able, you know, to look the same anymore because they burned their arm or their hand. And we're not talking about

all of these people that are dying every year from smoking cigarettes.

These people who have been injured are injured, but they're not smoking, and they're not getting cancer. They're not -- except for actually I did see a commercial for an attorney who said my client went back to smoking cigarettes because he was burned by an e-cigarette. So he was willing to go back to cigarette smoking because he burned his leg because no one educated him. This can't be happening; it can't keep happening. We can't have a product that has the potential to save millions of lives and just say, well, let's just make it go away because, you know, some guy burnt his leg because no one educated him properly. That's not fair. People need to be educated.

In London, they put out something saying that they were going to -- that it was reducing -- e-cigarettes were reducing the risk of fires. Here, I apologize that I missed the first 2 hours of the meeting yesterday, so I was not here for the fire marshal or the person from the fire department that came. But in London, they're very excited that the number of fires have been reduced because the number of cigarette smokers has been reduced.

Here, we think e-cigarette fires are dangerous, but there are not that many e-cigarette fires, and there are lots and lots and lots of -- I think the UK said 3,500 fires related to tobacco and 14 or 18, 14 or 18 related to e-cigarettes. So if everyone was using e-cigarettes instead of smoking cigarettes, we would reduce the number significantly.

Nearly every e-cigarette mishap can be avoided by proper education and safe products, and there are ways to do that. I think there needs to be a working group of people sitting around -- obviously, the UL has made a framework and the framework is great, but there needs to be a working group of people sitting around making the standards. They need to be talking to retailers to find out what people are doing, when I have a consumer come in my store and they open their e-cigarette and there's a piece of aluminum foil stuffed in it because the battery wasn't reaching the contact, and I tried to explain to them that you can't do that, and they don't know that that's a really big problem.

So there needs to be someone talking to the retailers, finding out what mistakes are being made, finding out what's causing the problems, and writing standards and education programs that will stop these problems.

I also really quickly wanted to make sure I did not skip by addressing this. And I think I'm done with my slides here. But it was pretty important to me that I bring it up because, again, a couple of people have brought it up.

The Navy has decided that the risk of e-cigarettes exploding on ships and on planes is too much and that they are going to temporarily restrict use of e-cigarettes on their properties. Well, on their mobile properties, I guess. We understand the safety risks, we understand this is a problem, but there are many, many devices that are not that risky. And to ask these people who are serving our country to tell them it's okay to smoke cigarettes, but they can't use an e-cigarette is dangerous to our country.

(Applause.)

DR. YEAGER: Thank you, Ms. Babaian. You can join us up here, Ms. Babaian, for the panel. Can we bring up Mr. Rupert, Dr. Kreps, Dr. Smith-Jackson, and Ms. Babaian for the Session 6 panel discussion on the Best Practices for Risk Communication?

I'd like to remind people that you're welcome to come up to the microphone and ask your question verbally. We also have people on the sides that have index cards if you'd rather write your question and submit it. I think we have someone on this

side right now. Can you raise your hand with the index cards so people know? Yeah, okay. So if you need one, just flag them down.

Okay, so the first question: Is there an altered risk perception when communicating with an audience like former smokers, many of whom have engaged in an unsafe behavior knowing the risk? How do you successfully communicate the risk to this group?

(Off microphone comment.)

DR. YEAGER: It's for general, anyone on the panel. You guys can go down the line, if you wish.

MR. RUPERT: I can start. I think it's a good question, so a couple thoughts. And I don't know the answer. I don't know personally how folks who -- they perceive the risk of battery damage or battery explosion. And I think that's an empirical question that we need to answer.

But a couple thoughts: You know, number one, yeah, I think that it's likely that individuals who knowingly -- yeah, not everyone, but many individuals who vape were former smokers, not all, that those individuals have a different risk perception than individuals who are not former smokers.

But, you know, the other point I would make is that I

don't think it necessarily means that they are desensitized to it, right, because a health risk from using tobacco is different from the injury, the potential injury risk of a fire or an explosion. And so I think it's a mistake to assume that those two risks are the same and that individuals perceive those two risks as the same. Maybe they do, but I don't think we should assume that that's the case.

DR. KREPS: I think this becomes the reason why you need to do formative analysis of your audience. You don't really know, up front, whether former smokers are any different from any other audience until you survey them, until you speak with them and find out what their issues are. And so, you know, rather than coming up with a strategy before talking to your audience, your intended audience, is a really big mistake. You've got to figure out what's going on with them and then adapt your strategy to the audience.

DR. SMITH-JACKSON: So the question is specific to whether former smokers have a different risk perception of vaping than nonsmokers who vape. Is that the question?

DR. YEAGER: Is there an altered risk perception when communicating with an audience like former smokers?

DR. SMITH-JACKSON: Oh, so just in general, is there an

altered risk perception? And, again, you know, I agree. The issue is we need much more research in this area to really even understand, in a more systematic way, people's risk perceptions. But if you look at anecdotally the discourse around vaping, e-cigarettes, etc., there's a lot of discussion out there.

People are communicating their own risk perceptions through blogs and forums and, you know, other collective groups in the cyberspace. So that's one way to understand it, although I'm not sure many people are actually studying this. But what I have seen is that -- and there have been even protests actually, and photos of protests from some of these user groups, that people do -- former smokers perceive e-cigarettes to be less hazardous than combustible cigarettes. So that's their conversation.

In my presentation, I showed a sign where someone was protesting against further regulations of e-cigarettes, and the sign said -- I think it was -- I think on her sign she said something like e-cigarettes saved me from smoking, from being a smoker. And so even the language there tells you that the risk perception is somewhat different.

So, again, it's in cyberspace, but we need to, of course,

go out there as researchers and make sure that we can fully understand it and then again, you know, talk to our users.

MS. BABAIAN: So there are already -- I mean, I'm sure that we all know that maybe you use research that's already out there, which there is tons of research on risk-taking behavior and cigarette smokers. Obviously, they're risk takers; they smoke cigarettes. So we already know that that's an issue, and I feel like that's what the question was that was asked, is how do we deal with people who are already willing to accept risk because they're smokers? How do we address them with those risks? Well, it's a different kind of risk, and I think that if you ask any e-cigarette user are you okay with risking your battery exploding near your face, most of them are going to say, no, because that's not the same kind of risk.

We're not talking -- we're talking about immediate harm or immediate harm risk rather than, you know, potential for risk down the road or potential health issues coming up later on. In numerous surveys, the number of e-cigarettes users who are former smokers is greater than 99%. When we say smokers, we mean cigar smokers, hookah smokers, cigarette smokers.

The studies that show any less than 99% only asked if the person smoked cigarettes. It did not ask if they smoked. So

if you look at every survey that asked whether or not people actually smoked at all, you'll see that 99% of e-cigarette users were smokers. So the risk to them of explosion, when they know there's a 50/50 chance of death from a cigarette-related illness, they're willing to take that chance. So yes, there is a different audience and a different way of addressing that.

DR. KREPS: I think the issue is you want to try to address the audience that is at greatest risk for abusing batteries, and you've got to figure out who that is. We don't know whether or not former smokers are a part of that audience or not, so we've got to identify who's the audience that we want to reach, and it's the audience that really doesn't utilize batteries safely. And so once we figure that out, then we figure out the best way to communicate with them.

DR. SMITH-JACKSON: But I still think we need specific studies on risk perception. So the behaviors and the use frequency doesn't always tell us about the cognitive risk perception. So we still need to get into the minds to get that information.

DR. YEAGER: Thank you.

So go ahead, please, identify yourself, and ask your

question.

MS. CLARK-ESPOSITO: Okay. Hi, everyone. My name is Deanna Clark-Esposito, Clark-Esposito Law Firm. Several of you expressed the importance of speaking with that group to whom is directly impacted by the message you're trying to communicate. So I would like to ask each of you how many e-cigarette users did you personally speak to in preparation of your presentation?

Thank you.

DR. SMITH-JACKSON: I spoke to 12. That's the amount of time I had. But I would like to talk to a whole lot more.

DR. KREPS: I didn't speak to any because I really wasn't talking about, you know, what to do specifically. I was talking about the process to use.

MR. RUPERT: Yeah, I have about five or six friends who vape, and I didn't really bring this. They were not very interested in whether I'd be talking to the FDA about vaping, but I do know folks socially who do and have that context.

MS. BABAIAN: I didn't feel like I had to really answer that. I've spoken to over 150,000, so yeah.

(Laughter.)

MS. CLARK-ESPOSITO: Thank you.

DR. SMITH-JACKSON: But we are very open to anyone who will support our research so we can talk to many more users.

MS. CLARK-ESPOSITO: Do you have grants for that?

MS. BABAIAN: If anybody does have research that they have grants for and they're looking to do it, we've dealt with Columbia and we've dealt with Cornell; we've dealt with at least a dozen universities doing e-cigarette research, and we're happy to have you come in and sit down and talk to users or gather users for studies or whatever you need. Happy to do a Vape New York -- happy to give you a card.

DR. YEAGER: Thank you.

This is a general question for the panel. Could "brand ambassadors" be used to influence change among people who vape, like well-known vloggers or bloggers?

DR. SMITH-JACKSON: Yes, the messenger matters a great deal. You know, I couldn't walk in and actually convince people to be more careful about their battery usage, but certainly there are different people from different areas who could be considered advocates because they have a great deal of credibility. So yes.

MR. RUPERT: Yeah, I agree. I think it's important to understand who -- folks who they consider as influential in

their network. You know, who are they going to listen to, and who are they going to listen to for what types of information? You know, I think there can be cases where vape shop owners are a reliable and trusted source of information for certain things, and in other cases it may be peers who are a more trusted and reliable source of information. So I think being able to disentangle that a bit and understand who is most trusted for what types of information is really important in changing behavior.

DR. KREPS: I would keep all potential message strategies on the table, but I wouldn't enact any of them until I found out what it was that audiences were interested in hearing, who they wanted to hear from, and what they wanted to hear. I would allow the data to guide me.

So, you know, the question about coming up with a strategy before you do your analysis is part of the problem that we can't put together a cogent strategy until we've gone out and figured out what's going to work, and then we need to kind of track it to make sure it's working the way we want.

MS. BABAIAN: I would just say that if there -- I did suggest PSAs and getting the word out there. Those messages should not necessarily be coming from government bodies, I

guess, but from people, because I've found that the majority of vapers don't trust the people who told them that e-cigarettes were worse for them than cigarettes. They realize that's asinine, and they have a hard time believing anything that comes from the government now. So maybe use, you know, popular figures or something like that to get the message across a little better.

DR. YEAGER: Thank you.

So this next question is for Spike Babaian. How would you characterize a segment of e-cigarette users?

(Off microphone comment.)

DR. YEAGER: It says how would you characterize a segment of e-cigarette users?

MS. BABAIAN: So there are definitely different groups within the e-cigarette users. There are people that were very, very heavy smokers that are very much about using e-cigarettes as an alternative to smoking cigarettes, and these people are generally not so much into the hobbyist and fun aspect of it. They're more into using the product for what works for them. Then there are people who are more hobbyists, and some of them were either social smokers where they didn't really smoke daily or they weren't as heavy smokers, or they were hookah smokers

where they did it for flavors and for fun, and there is that segment of the population, but I would say that it's diminishing very, very quickly over the past year or two. I would say from 2014 to '15 or maybe '13 to '14, somewhere in there, we had a growing segment of hobbyists who really were interested in playing with them and building them and making them, and it's kind of dying off.

I mean, the hoverboards kind of came in, and that was more interesting then, so that became popular. And then light-up sneakers. And I don't really know what the newest thing is, but there are always new things. So the people who were hobbyists or were into it for the fun of it have kind of started to go find other interests, and I think that the majority of the people left that are serious about using e-cigarettes are people that were former smokers.

An average e-cigarette user, if we're looking at audience, which we're talking about how to get the message across to that audience, it seems to be between 30 and 50. Well, we say 35 to 45, but generally 30 to 50 would be like the majority of new e-cigarette users or people that are kind of learning about the product. Typically, racially, mostly white, but we definitely have a more diverse population in New York City than we do in a

lot of the other states. I mean, there's been a number of research studies that show the average user, and I think that's important to look at maybe. But again, the person who's exploding their e-cigarette is probably not the average user.

DR. YEAGER: Go ahead.

DR. SMITH-JACKSON: I just wanted to add, also, there are -- of a couple of individuals who took me to places that I could observe, there are users who are smoking other things besides -- so they're using hashish liquid, and actually, there is some use now of downers and liquid forms of heroin that people are trying to incorporate into these devices. What I referred to early about grassroots sort of modifications to products, it's already happening in certain areas. And that's another, you know, subpopulation.

MS. BABAIAN: Just to be clear, the other products that are put into e-cigarettes, they don't function with typical e-cigarette products. So they have to make like special or buy special items that are not sold in e-cigarette shops. So they have to actually make something or find something that works with it, so it's not a standard thing.

DR. YEAGER: Okay, thank you.

Please go ahead and identify yourself, and then ask your

question.

DR. BARNES: Yeah, Jim Barnes, independent consultant.

As I've listened to this, I see two things being mixed up, so frankly this is more of a comment, but I'd like your feedback, and that is the issue of risk from vaping and the risk from issues from misusing batteries. As an ex-Navy guy, you know, when you're working with the military, you're dealing with people who all the time have to do dangerous things, but they were not interested in getting a battery that blew up on them unexpectedly.

So I would argue, picking up on what Spike has been saying, you know, many vapers or e-cigarette users are actually trying to reduce their risk by getting away from tobacco. So to say that they are risk takers, in one way you might say they're risk adverse. So I think the problem, and I need your comment, is that they don't realize how dangerous the batteries are. I mean, if we had blowing up cell phones or blowing up flashlights, you know --

MS. BABAIAN: I have people coming in every time there's a news story that says e-cigarette exploded in a man's pocket, e-cigarette exploded on a plane, e-cigarette exploded here, every day the day afterwards, I spend the whole day explaining

to people that they didn't have an e-cigarette in their pocket; they had a battery in their pocket. And the person I'm talking to is typically using a pen-style or ego-style, we call them, device, which is a skinny device that looks like a pen. The battery is built into the device; it is not removable, it is not at risk of having the contacts meet because it is built into the device.

They're completely different devices, and it takes me all day to explain to people that's not the kind of thing that's going to happen with this battery. This is not that kind of a situation. Yes, you can charge your battery. No, you shouldn't leave it in your daughter's room next to her bed; you should charge it, you know, next to a sink or in a garage or somewhere where it's not going to be touching anything that's cloth or a rug or, you know, near your children. And you don't want to leave it charging and go out of your house. But it takes so much time to explain to people that this is not the type of situation. If there was some kind of a public message explaining to them what caused this, they would be less uncomfortable, and we would not be in this position.

MR. RUPERT: I mean, I think that goes back to what we talked about earlier, which is that they are different risks,

and we should not assume that somebody who is willing to take, you know, a health risk related with tobacco use is willing to accept an injury risk related with explosion. And the other piece of it is -- and frankly, I'm sure there are folks here who are much more steeped in this than I am, but I think it's a fallacy to assume that all, you know, vapers or former smokers who are vapers are risk takers.

You know, it's likely that many of them were risk takers when they first started, and 30 years on it's a habit, it's an addiction. So I think it's a false assumption to say that anyone who currently uses either combustible tobacco or a vaping product is, by their nature, a risk taker. I don't think that's a fair assumption.

DR. YEAGER: Okay, thank you.

So this next question is for the panel. What is an example of a message that could potentially result in a behavior change for someone to keep spare batteries in a storage case?

DR. SMITH-JACKSON: Okay, I'm going to sort of walk around that question. I spend a lot of time testifying, giving court testimony on product litigation and safety issues, so I don't tend to design on the fly. I would actually, you know, test

something, mock it up based on what we know from research, use participatory design, as Gary had mentioned before, and then take it out into the field for testing. And then I would show an example of a prototype, you know, rapid prototyping. But yeah, I spend a lot of time in court with some of these types of cases.

DR. KREPS: The use of the plastic, you know, package sounds like a really good solution to me, but you know, I'd have to see whether or not it resonates with other people as well. And if it does, then that would be an ideal strategy to pitch to them. But you've got to figure out, you know, what are the impediments, what barriers are there? Is there a cost issue; is there some other issue? Does it make the product more bulky for them? What kinds of concerns do people have? And once you identify that, then you can come up with a strategy for trying to convince them that this is a really good solution to reduce their risk.

MS. BABAIAN: Over the last 8 years, we've used a number of ways to try to get people's attention to figure out what would work to keep them carrying enough, from putting batteries into their pocket without a case, what was going to make them pay the dollar for the case and put the batteries in the case.

And what we found was that with the majority of our customers, and consumers being male, when we tell them that the battery is going into their pocket and there's something else that's very close to their pocket, and if it explodes it's in their pocket, they understand that very quickly, and they typically spend a dollar for the case.

(Laughter.)

DR. KREPS: Spike, I love the idea. I love the idea you had of giving away for free the cases. I wish that was going on all the time. I think more people would use it.

MS. BABAIAN: Just to be clear, we charge a dollar extra for our batteries. People complain about how high the battery price is, and we say, oh, no, that includes the case. Then they say, oh, okay.

DR. YEAGER: Thank you.

So another general question. There are many vaping online forums, video bloggers, and other online communities that discuss at great length vape products and components and their use. How can this vibrant user community be tapped to communicate risk for behavior change?

DR. SMITH-JACKSON: There's a lot there, and you can certainly do the research, you know, the -- RTI, you described

their systematic method for going through websites, but I think that can also be applied to the blogs, the forums, etc. The information is out there. The users are telling us some things about their risk perceptions, and they're doing it in multiple ways, and they argue back and forth.

If you remember Andrew Hall in Idaho who, in January 2017, you know, experienced the explosion and it knocked out 17 -- I mean no, not 17 -- 7 of his teeth, and you know, he had some other injuries, burn injuries, etc. Andrew Hall, when he posted it on Facebook and showed, you know, the bloody face and then showed -- there were pictures of him in intensive care, etc. You know, it wasn't just the story and the news stories about -- the formal news stories about Andrew Hall and the battery explosion. What it actually was, was the risk discourse around Andrew Hall's story. So when you look at the arguments back and forth that happened on certain Facebook pages, in communities of practice for e-cigarette use and other products, you'll see where people are saying different things about -- that indicate that either they don't believe what happened, or they don't think the risk was there, or it was the user's fault, or it was the design of the product, so it's kind of everywhere.

But there is so much information out there, and it's very raw. A lot of it is quite raw, which really does help us from the cognitive perspective because when we saw raw language as social cognitivists, we're thinking we're getting closer to the truth.

MS. BABAIAN: But you didn't know what some of them were saying, and they were angry because it was public. They are so afraid to have their e-cigarettes taken away and end up smoking cigarettes again, that there are so many people -- and we talked about underreporting and overreporting of battery explosions. There is a significant underreporting -- I don't want to say that; they'll get mad at me. But there is a significant underreporting of battery explosions because the users are afraid that this product that they feel saved their life is going to be taken away if they tell anyone that their battery got hot or that it exploded and burned their carpet. So they don't tell anybody because they're afraid, and that's a problem, too.

DR. SMITH-JACKSON: And you are getting an underground community. I agree, sorry. And just one last thing. There's so much anger out there. They accused Andrew Hall's wife of being a makeup artist, and she was called a [expletive

removed]. The wife, by the way, okay, because people are angry and afraid that they're going to lose their product.

MR. RUPERT: And I think that type of backlash underscores the point some of us had talked about earlier, which is figuring out which message is going to resonate, right? Based on past experience, it's unlikely to be the safety message. That may resonate with a certain segment of the population, but there is always, you know, not just in this area but in many areas, sort of that suspension of belief that something is going to happen to individuals. I mean, there's great literature on risk that individuals are more attuned to, if they're more catastrophic, if they are more likely to be -- you know, cause really permanent damage or things like that. But likelihood of the risk and -- you know, is not really one of them. So I think, again, we have to figure out what the message is that's going to resonate with this audience. It might be safety for a slice of it, but I think it's unlikely to be a safety message that resonates with most.

DR. KREPS: There's a lot of evidence that social networks are extremely influential. The members of these social networks have a lot in common with each other. They speak the same language; they build trust and relationships with each

other. So it's a potentially good channel. The problem is it's very difficult to control communication on these channels, and people may end up saying exactly the opposite from what you want them to say.

They may refute the evidence; they may encourage people to engage in risky behavior. And so if you go and use these social networks, you need to build collaborations with influential members of the networks and be confident that they will provide accurate and consistent information in support of a position. If not, you can actually make things a lot worse.

DR. YEAGER: Thank you.

Another general question: One presentation mentioned that a vaping store provided wrappers for users to repair the wrapping on their battery. If this process requires heat to shrink-wrap the battery, is this really a safe practice to be suggesting to users? Shouldn't users just buy new batteries?

MS. BABAIAN: When the cost difference is a dollar or $15, it's very hard to get them to do it. So the question becomes is it more risky to let them heat the battery momentarily to get the new wrapper, or is it more risky for them to use the battery that is obviously ripped and very likely to explode? So there's a question of what's more risky, and you cannot take

a consumer's product away from them that they paid for and that they own. And believe me, I've tried.

I'm like, you're not leaving the store with that battery; that's dangerous. No, that's mine I bought; give it back. You're going to blow up. I don't care. Okay, fine, blow up. So, you know, what can you do? At that point, you have a choice. You either give them a free battery skin and you say, please, at least put a new skin on it if you're going to use that the way it is. So for those of us who need our nicotine, at least let us use e-cigarettes instead of smoking cigarettes. It's kind of a risk. You know, make a choice; what's more dangerous?

DR. YEAGER: Okay, thank you.

Another general question for the panel. Do you know of examples of products where people have ignored warnings in pamphlets and on packaging and how users were successfully "forced" to read warnings before using the product? It's looking like that's not resonating with anyone.

MS. BABAIAN: The McDonald's coffee comes to mind; that's the only thing. They made it so that when you're drinking the coffee, you actually see, "Caution: Hot," like right in your eye, which I guess you're forced to read it, but that's the

only one I can think of.

DR. KREPS: I think there are a lot of examples of people ignoring risk messages. I think it's probably more common for people to ignore risk messages than to follow the risk messages. The trick becomes how you actually break down that resistance. How do you get people to follow the risk messages? The FDA puts out warnings all the time about risks associated with medications. They have a website that lists that. Very few consumers pay any attention to those risk messages. It's just not salient to them. And so you need to find the best channels, the best strategies, and the best sources to provide that information to make it really resonate and to make it work.

MR. RUPERT: I agree. I mean, forced exposure, even if it could be done, is not the solution. It's not going to make a dent.

DR. SMITH-JACKSON: Yeah. And I'm still trying to think of a product that's been designed that way, and I cannot think of one that has forced -- designed in such a way -- I don't even know how you force a user to read a warning.

But either way, even if -- you know, the user, before they use the product, if they're forced to read the warning, at some

point they're going to habituate. They might be forced to still look at the warning, but they're not reading it. They're not, you know, integrating and encoding and processing it.

DR. YEAGER: Thank you.

Another general question: For teens who are of legal smoking age, how can risk be communicated to them, knowing that providing information about safe use and handling of ENDS may be misconstrued as condoning their use of ENDS? Is the better option to promote safe use if the ultimate goal is no use at all?

MS. BABAIAN: So, basically, should we not warn them because they might use them, or should we warn them so that when they use them they don't explode? That's the question?

DR. YEAGER: I can repeat. Is the better option to promote safe use --

MS. BABAIAN: I'll let somebody else answer that. I'm not --

DR. YEAGER: -- if the ultimate goal is no use at all?

DR. KREPS: You know, I think that it's a population that you've got to learn about, and you've got to figure out what are the issues for them, what are their concerns, what are their worries, what are their motivations, and once you learn

about that, then you can devise a strategy for interacting with them. Unless you're a member of that population, you really don't know what's motivating them.

And so I think that there are strategies that can be used, but you've got to figure out who they are and then work with that population to come up with the best strategies that fulfill their needs but also reduce their risk.

MR. RUPERT: And I recognize the contradiction in the question there. But, you know, I think that we, as a society, have kind of resolved that and landed on the side of information. I mean, we have many public education campaigns around teen and adolescent drinking and other drug use. I mean, I think as -- I mean, really, it's a value question and I think, as a society, we have decided that it's worthwhile to provide information to people, even if they shouldn't be legally using a product, to help them reduce harm and be safe as much as possible.

DR. SMITH-JACKSON: And that's exactly where I was going. We have a history of dealing with situations like this, and we have, like you said, erred on the side of information. You know, as a former HIV/AIDS case worker, where I had to deal with teenagers who were already HIV positive, this was back in

the '90s -- but when we're talking about whether they abstain from sex or we provide safer sex behaviors, you know, we provided safer sex behaviors. So, again, yes, I like the way you said it, err on the side of information.

DR. YEAGER: Thank you.

A general question: How do you explain to a consumer what an "incorrect" charger is? I would think that many people will use a charger if it fits.

MS. BABAIAN: We always say please use the one that came with your device. If you do not have the one that came with your device, go back to the place where you purchased your device and ask for the same charger that came with your device.

We also encourage people to purchase chargers that are brand name chargers or well-known and respected manufacturer chargers. There are a lot of -- you know, there are less knockoff or fake or, you know, counterfeit chargers than there are batteries because they're a little bit less expensive than the batteries to make well, I guess. But they still happen, and we always encourage people to use a respected source and a good manufacturer.

DR. YEAGER: Okay, thank you.

A question for Spike Babaian: Yesterday a question was

asked regarding waste and disposal practices. One panelist responded that they would assume, as a manufacturer, a retailer business would follow waste and disposal procedures according to their local or state environmental guidelines. In your experience and opinion, do you think retailers or manufacturers have knowledge of these procedures?

MS. BABAIAN: I think that there are two different processes for disposing of empty nicotine liquid bottles, which are significantly empty or full ones, and it does seem that the majority of the waste that an e-cigarette store has would be old batteries. The majority of them seem to follow their state recycling laws. Typically, the state has their own recycling center set up for batteries and dangerous products, and people seem to bring them from the shop once a month or once every few months to drop them off.

DR. YEAGER: Okay, thank you.

This one's general: Is there a good way for retailers and users to ensure their ENDS have safety features like overcharge or overdischarge protection? And do you have suggestions on how users identify counterfeit or copycat devices?

DR. SMITH-JACKSON: Repeat the first part of the question again.

DR. YEAGER: Is there a good way for retailers and users to ensure their ENDS have safety features like overcharge or overdischarge protection?

DR. SMITH-JACKSON: There is a way for the manufacturer to design, definitely. Manufacturers could design those features. And then the other part of the question was?

DR. YEAGER: The other part is do you have suggestions on how users identify counterfeit or copycat devices?

MS. BABAIAN: It seems that, for the most part, you're asking people to use respectable manufactured products. So there's not currently a standard. Yeah, there's not currently, you know, one trade association for the whole vaping industry. There are a couple different groups. So how do you know who's making a product that has proper overcharge and overdischarge protection?

I mean, you can do research, you can ask manufacturers do you have this, can you explain to me if this does that? But most consumers don't. They trust their retailer, and that's one of the issues, that the retailer has to do their homework to make sure the product they're selling is not -- you know, has proper safety features built in. What was the second part?

DR. YEAGER: The second part was identifying counterfeit

or copycats.

MS. BABAIAN: To be honest, I've been doing this for 8 years, and typically, I google it and look at -- I say fake this, and then I start looking for pictures, and I try to find people who have the real one and the fake one next to each other so that I can see what the differences are. And that seems to be the easiest way to find them. The other way is to contact the manufacturer and say are there any identifying marks, serial numbers, anything that I can find about your product that would be different if it were not -- you know, if it was a counterfeit device?

DR. YEAGER: Okay, thank you.

DR. KREPS: A clever intervention strategy might be to work directly with the retailers rather than going to the consumers to see if we can get the retailers to enact different safety features, like providing cases and providing information and encouraging use and providing safety features that might increase the loyalty of their customers. I'm not sure that the consumers are wary enough to make good choices about the use of these products. But if they're provided with safer products right from the retailer, it's more likely to be enacted. It's not a choice point; it just becomes the safer product to start

with.

MR. RUPERT: And I guess I would just add, I mean, I think one of the goals is to make the safer products easier to obtain than the unsafe products, right, because at some point -- I mean, the question becomes do consumers care, right? Especially when it comes to batteries, if they're buying an inferior product, if it seems to work and it costs less, do they care if it's an inferior product? And so the ease of making the reliable products easier to obtain, I think, is key.

MS. BABAIAN: Well, the more people that get hurt and the more stores that get legal action taken against them, the less they want to sell the products that are more dangerous. So even though the consumers don't want to pay the extra money, like you said, if the stores aren't selling the products that are more dangerous, we're in a better situation.

DR. KREPS: But auto dealers have been doing this pretty successfully with selling cars with safety features with rear mirrors and other factors, and that becomes part of their marketing strategy.

DR. YEAGER: And I want to let the panel know we are out of time, but there are two questions left, and I wonder if the panel will indulge me. All right, great, they're indicating

yes.

So the first one is, Spike, what proportion of your customers still smoke cigarettes in addition to using e-cigs?

MS. BABAIAN: We've seen that the number is typically lower than 10%, but that is not universally standard, so that's for our store specifically. But we spend a lot of time teaching people. We've seen, with the surveys that have been done, that the average number of people using e-cigarettes that are still smoking, in self-respondents -- which, of course, we know response surveys you're going to get a special type of group of people that are responding, so you're not always going to have a representative sample for that. It's generally between 70 and 90%.

But for certain places where the education is higher, it's a little bit different. For people who are purchasing the product online, it's very different than people purchasing in a retail store. When you don't have the support to learn how to use the product, fix the product when it doesn't work, deal with products that are malfunctioning or not working or running out of product or running out of battery, that's when people end up smoking, you know, in dual use with e-cigarettes.

DR. YEAGER: All right, thank you.

The last question is how effective are infographics at producing behavior change? What makes the difference between an effective or non-effective infographic?

DR. SMITH-JACKSON: There are a whole lot of studies on infographics, pictorials, icons, you know, dating back to the early '60s actually, for empirical studies. But there are several different metrics that we use to do assessments of the effectiveness. If you look at ANSI Z535.3, even in the appendix, actually, they even outline for you different ways of assessing pictorials and icons in this case.

But in general, the effectiveness of a pictorial, an icon, or an infographic is going to go back to some of the simple design principles for designing things that are meaningful to people, that are culturally relevant. In cases of infographics, it should be simple, and also it should be salient and the salience is all about not just capturing attention but conveying the consequences of the hazard in a way that it immediately captures their attention and hits home, okay, or resonates, as people are saying.

DR. KREPS: I'd like to add to that. I really like the use of graphics and visuals, but alone by themselves they don't work very well. They've got to be embedded in a larger

multimedia, multi-channel strategy. So, you know, I think that the visuals, because they don't have a lot of depth of information, are good for reinforcement and at helping people to recall and to think about it again.

But if they're used by themselves and they don't have that background, they're not going to work very well. So I think you've got to come up with a larger strategy for providing information and then reinforcing and encouraging over time. And so the visuals, I think, are helpful, but not by themselves.

MR. RUPERT: I agree. I mean, I think if well designed and tested with the audience, infographics and visuals can be very effective at communicating information, but in and of themselves they're not going to change behavior. That's a much bigger step.

DR. YEAGER: Spike Babaian, any comment?

MS. BABAIAN: I think that, again, I feel like something that's moving or a video seems to get -- the people that we're trying to reach seem more entertained by video and moving and colors and action rather than still images.

DR. YEAGER: I think that last question was relevant to FDA's information-gathering efforts because they recently had

infographic release that's tips to help avoid vape battery explosions. So that's a good informative piece for the FDA.

Oh, did you have a last comment, Dr. --

DR. SMITH-JACKSON: Going back to video and dynamic movement of images, video in the digital space, in cyberspace seems to be very effective, and there are a lot of excellent, really excellent social psychology studies that have gone on and looked at the impacts at least of reported behavioral change or behavioral intent, intent to change after exposure to videos that have been well designed to convey hazards.

So those studies are showing some promise, but it matters what's in the video, how the video is delivered, etc., etc. Videos appeal to younger audiences, in particular. I should say generationally. Okay, so Gen X, Millennials, and Gen Zs. Baby boomers, not so much.

DR. KREPS: I think the trick to the use of the video is to have an embedded narrative or a story. If it's dramatic, if it's exciting, if people can identify with it, if there's a lesson to be learned, then I think that the videos are really powerful. But you've got to really make sure that it's an appropriate video and an appropriate story for the different audiences and that people can identify with the information

being provided.

DR. SMITH-JACKSON: And please don't count video watches as the only way to try to test effectiveness. That is not a good measure. Okay, there are many measures, and social psychologists are showing some great studies and ways in which to measure the effectiveness of a video, you know, better than just how many people watched it.

DR. YEAGER: Well, I'd like to thank the panel. Thank you, Mr. Rupert, Dr. Kreps, Dr. Smith-Jackson, and Ms. Babaian. Thank you.

(Applause.)

DR. YEAGER: And we would like to thank all of the speakers and panelists that came to give information on Battery Safety Concerns in Electronic Nicotine Device Systems. And this is the close of the workshop.

Thank you very much.

(Whereupon, at 4:17 p.m., the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

BATTERY SAFETY CONCERNS IN ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS): A PUBLIC WORKSHOP

April 20, 2017

Silver Spring, Maryland

were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Tobacco Products.

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TOM BOWMAN

Official Reporter