UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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CENTER FOR TOBACCO PRODUCTS

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

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April 19, 2017
8:30 a.m.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Building 31 Conference Center, Room 1503
Silver Spring, MD 20993

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SESSION 1: SCOPE AND IMPACT OF ENDS BATTERY-RELATED FIRES AND EXPLOSIONS

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SESSION 2: CELL, BATTERY PACK, CHARGING SAFETY, AND RISK CONTROL

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SESSION 3: FAILURE MODES AND DESIGN STRATEGIES

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M E E T I N G

(8:47 a.m.)

DR. YEAGER: I'd like to welcome everyone to the FDA for the public meeting on Battery Safety Concerns in Electronic Nicotine Delivery Systems. This is a public workshop and information-gathering session by the FDA.

I'm your moderator, Phil Yeager, supervisory toxicologist, and we're going to get right under way with the agenda.

So I would like to first introduce to you Matthew Holman. He's the Director for the Office of Science at CTP since January of 2017, and he'll be introducing the workshop for us here.

Thank you, Dr. Holman.

(Applause.)

DR. HOLMAN: Thanks, Phil. And good morning, everyone. On behalf of the FDA Center for Tobacco Products, I welcome you, everyone in the room as well as those viewing online, to our first public workshop on battery concerns in electronic nicotine delivery systems, or ENDS.

Although FDA has held three workshops previously regarding the impact of ENDS products on public health, this is the first workshop focused specifically on battery safety concerns related to ENDS products.

ENDS products are a novel and diverse category of tobacco products making up a broad range of products from disposable cigalike e-cigarettes to rechargeable/reusable tank systems.

ENDS products have gained significant attention in the marketplace and in the media over the past few years. Unfortunately, a lot of that attention has been highlighting the potential for these products to catch fire, explode without warning, posing a threat to public health to both the users of the products as well as bystanders.

We at the FDA have been collecting data and information on explosions, fires, and overheating of these products. However, additional data and information would significantly help us better understand these products and how to regulate them in order to minimize this acute public health concern. That is why we are here today.

Over the next 2 days, the workshop will focus on gathering scientific information and stimulating discussion regarding batteries used in e-cigarettes. Specifically, FDA would like this workshop to gather information about the incidence of ENDS fires, overheating and explosions, strategies for risk mitigation, and design parameters related to e-cigarettes.

We'd also like to gather information about the best ways to communicate information regarding the risks associated with e-cigarette batteries to different populations of people who need to know, including distributors, retailers, consumers, and the general public.  All the information over the next 2 days will help FDA in carrying out our responsibilities under the law and regulating these products.

We would like to emphasize that FDA intends to use the information presented and discussed during the workshop, as well as ongoing research efforts, to help inform future regulatory actions and decisions related to these products. FDA makes decisions based on science, and we'll use the best available science to inform regulations.  FDA intends to carefully consider the evidence and make full use of our regulatory authorities to protect the public health.

I'd like to point out that this workshop is just one of numerous actions that FDA is taking to address this significant public health concern.  In addition to this workshop, we have established a public docket to gather data and information on the hazards and risks associated with the use of batteries and ENDS products.  And we've been collecting adverse event reports in an ongoing capacity through our safety reporting portal.

And most recently, we introduced tips to help avoid vape battery explosions on our website, communication to help users of these products.

So I welcome you all again to this 2-day workshop. We are aware of the level of interest in ENDS products, and there are many interests represented today. FDA is a science-based organization, and all of our regulatory decisions are based on and grounded in science. So while many may hold strong opinions, we at the FDA continue to focus on the scientific evidence that could help inform our future actions related to these products and the unforeseeable safety issues they pose to public health.

I would now like to introduce Dr. Julie Morabito from our Office of Science. She will provide an overview of the workshop proceedings.

Thank you again for your participation in this workshop.

DR. MORABITO: Good morning. Thank you, Dr. Holman.

I, too, want to welcome you to our first workshop on battery safety concerns in e-cigarettes or ENDS products. I also want to apologize for any of you who were routed all around campus this morning, trying to find the room. That workout is on the house.

(Laughter.)

DR. MORABITO: I would like to spend a few minutes setting the stage today and going over some logistical information.

The purpose of this workshop is to gather scientific information and stimulate fact-based discussion about battery concerns in ENDS products. We're not looking for advice or full consensus, but we are interested in an open exchange and discussion of scientific information.

We acknowledge that ENDS products present complex regulatory and scientific challenges, and there are strong opinions about these products and the potential impact on the public health. However, we request that all workshop participants be considerate and respectful of all other participants, the information being presented, and the opinions expressed by others.

We have asked all speakers and panelists to voluntarily disclose any financial interests and relationships that they have in e-cigarettes, other electronic nicotine delivery systems, or other relevant companies or products.

As Dr. Holman mentioned, the focus of this workshop is on the scope and impact of ENDS battery-related hazards, as well as ways in which these safety concerns can be mitigated and the best ways to communicate risks to consumers and the general public.

We have a total of six sessions of presentations over the next 2 days. Each day has three sessions, and each session has between five and three presentations. Following each session, we will have roughly half an hour for panel discussions where the audience may ask questions and the presenters can continue discussion on their topics.

Our first session today is focused on the scope and impact of ENDS battery-related fires and explosions. The second session will discuss the safety of cell, battery pack, and charging systems. And finally today, Session 3 will be focused on failure modes and design strategies.

Tomorrow we'll start the day with a public comment session, followed by presentations focused on safety features for risk mitigation, and we will have two sessions to discuss risk communication strategies for ENDS battery safety concerns.

As mentioned, our agenda is very full. Our presenters have been asked to keep their presentations within the time allotted. And Phil is very serious in his role of keeping our presenters on track with their time.

We will have two 15-minute breaks and approximately an hour for lunch and end the day today around 4:30 p.m.

For those of you who have clarifying questions either for a speaker or a question for the panelists, we ask that you wait until the panel discussion following each session, and either approach the microphone in the center of the room or alternately write down your questions on some of the cards that are available and pass them to one of our volunteers in the room. If you could write legibly, that helps Phil a lot, so it would help us move forward more quickly.

If you are participating by webcast, you can e-mail your questions to our workshop e-mail address. You should all have that e-mail address, but in case you don't, it's workshop -- w-o-r-k-s-h-o-p -- .CTPOS@fda.hhs.gov.

This workshop is being recorded. The transcript and webcast will be available on our website when they become available.

For any media inquiries, we have Michael Felberbaum here as our press contact. Michael, are you here? He's back in the back corner, and so you can contact him if you have any inquiries.

Thank you. So now I'll turn the podium over to our moderator, Dr. Phil Yeager.

(Applause.)

DR. YEAGER: Thank you. I'd like to thank Dr. Holman for framing why this ENDS battery issue is so important, and thank Dr. Morabito for explaining the progress of the technical details we're going to be covering.

So as a reminder, this is an information-gathering session. There may be times where you may have questions, and I want everyone to be aware in the audience that the FDA is responsive to questions, but some may not be appropriate for this forum. At that time I may direct you to ask CTP rather than asking here, because we're trying to gather information. So if it's more regulatory, I'd like you to ask CTP.

A couple other technical details. A reminder for lunch: If you want to avoid a long line, get your order in to the kiosk, right out here, for sandwiches for lunch before 9:30 or 10:00. Otherwise, you may have a long wait.

The last issue is each speaker will speak, and then we will save questions for the panel discussion after that group of speakers speak.

And with that, we will just launch into our first session. So this is the Scope and Impact of ENDS Battery-Related Fires and Explosions, and I'd like to introduce Dr. Felicia Williams from the University of North Carolina.

(Applause.)

DR. WILLIAMS: Good morning. I'm one of the burn surgeons, actually, at the University of North Carolina, and we're one of the busiest burn centers in the country, and we see a bunch of cases. And I'm just going to talk about the scope and the impact of those cases on our patient population, and hopefully, this is some valuable information.

I have absolutely nothing to disclose.

Let's see. So smoking remains the leading cause of preventable death. There are about six million in the world every year, and in the U.S., about half a million. That's about 1,300 a day. And there has been a lot of public health initiatives and legislation, from after-school programs to warning labels to preventing access or limiting access, and all of those things have been helpful for trying to decrease the number of people that are smoking cigarettes, and just really led to innovative ways for people to deliver nicotine to others or to their population.

Electronic cigarettes were originally marketed in 2003, and the actual original patent license was in 1963, and it was to be a smoking cessation tool and a healthier way to deliver nicotine in hopes that people would decrease their intake and eventually come off of cigarette use or nicotine use. There are an estimated nine million people -- adults using them and three million teens.

The basic design is a cartridge, which is nicotine and flavorant, as in flavor. People that have come to us were using candy flavored, alcohol flavored, and cigarette flavored, which seems weird, and any flavor you can think of, chocolate, anything. And then atomizers, or an atomizer that's attached, is a heating source, and then there's a battery for power. There are over 500 different brands marketed in the U.S.

(Off microphone comment.)

DR. WILLIAMS: Sure, I'm sorry. I'll try to speak up a little bit.

And this is just -- this is from the U.S. Department of Health and Human Services, and these are the different forms that we see, and I'll tell you that the fourth one from the right is one we've seen very often for our patients.

And these are the different pieces, parts, and I'm sure that this is going to be explained in the other presentations. But again, this is what we actually see a lot of for our patients.

There are different injuries. People have had nicotine poisoning, toxin ingestions, but for us, as burn surgeons, the multiple fires and explosions are where we come in. And the idea is there's this thermal runaway where there's a chemical reaction that results in a rapid heating. It's an uncontrolled, positive feedback, and so it's a rapid heating that leads to an explosion.

We just got back from our American Burn Association meeting, and that was the end of March, and there are multiple case reports that are from across the country: 9 in Irvine, 30 in Sacramento, 16 from USC and UAB, 9 from New York, and 11 from us and UNC. And these are patients that required surgery, not the number of patients that have presented to our clinics. You're talking about 100 patients overall that present to the different clinics with minor injuries that don't require hospital admission.

The majority of the patients that required hospital admission and surgery were males. In all of the studies, the average ages were in the 30s; burns to the hands, buttocks, genitalia, thighs, and faces; and less than 1% of them were during charging phases. So they were either in use or in their pockets, and the overwhelming majority of these injuries had been while they're in their pockets.  And the majority required surgery.

And interestingly, the majority happened within the first six months of 2016.  So they would see maybe two or three come into the clinics at the end of 2015, and then the majority of the operations in the patients that required surgery came in, in 2016.  And I'm going to be showing you some graphic pictures, and I apologize, but I'm a surgeon and that's how we think.

So the burns are thermal, so they're heat, they're chemical.  If they're exploding, they're getting alkali burns plus flame injuries, and it's a contact burn because it becomes so hot, and if it touches or they touch, it burns them.

There's an exploding component, so there are particles we have to take out.

And there's a psychological component: scarring.  This is forever.  They are scarred.  They were trying to quit smoking in some instances, and they suffered permanent injury from something that was supposed to be healthier.

So this is a typical injury from the e-cigarette exploding in their pocket.  They had the device in their pants pocket, walking around, and all of a sudden there was an explosion.

They said they weren't charging, they weren't running into things, they were just doing their normal duties. In the central portion of this, the black and white area, these are full-thickness injuries. These required skin grafting, so surgery.

Another instance: You can see a very similar pattern, in their pocket, again idle.

This gentleman unfortunately lost his eye. He was using the e-cigarette when it just exploded, he said. He was driving at the time, and so luckily, nobody else was hurt during this incident, but you can see how that could have led to a mass casualty situation. He suffered severe injury to the area of his nose, and I'm going to show you a picture of that later, and he lost his eye.

This is a closer picture of the eye. You can see the damage. This is not a normal picture of an eye. This is a traumatic injury for him. And this is despite healing so well around his nose. You can see the permanent damage around his nose from this explosion.

So the overwhelming majority of these are treatable injuries for us as burn surgeons. There are patient visits where it's just local wound care, which is still an inconvenience to patients, but losses of eyes and teeth. A lot of centers had patients that lost teeth and required surgery for those because they exploded in their mouths as they were trying to use them.

Variable morbidity: Small injuries where they will heal and have minimal to no scarring. Blindness; you know, at our center this gentleman lost his eye. Permanent scars. Permanent disability over the age of 30; that patient was 37 years old. And currently, there are no reports from any of the centers or the media or from us of mass casualties, but as you can see, this could have led to that.

Psychologically, it's more difficult to treat. You know, burns is a multidisciplinary field, so psychiatrists or medicine doctors, everybody -- but this is an aspect of treatment that is more difficult for patients. They have permanent scarring from a healthier product. They're using this either to try to quit smoking or a means to take their products with them everywhere they went.

You can see people on planes even though, you know, there's people talking about don't use your e-cigarette, you can't have them. But people can walk into restaurants with them; there are some restaurants that allow that. Buildings, malls, anywhere, people are vaping their e-cigarettes, and just imagine an explosion during those times.

We have our addiction counselors round on and meet with all of our patients that have substance abuse issues or want to talk about tobacco cessation.  Most of these patients return to their cigarettes after their ENDS explosions, for a variety of reasons, but they usually say I'm 30 years old and now I have a scar, I'm stressed out, I'm just going back to what worked before, which is not what we want to hear, but unfortunately, that's what we're hearing.

So there's an increasing incidence of devastating cases nationally, public health issues from ease of use and acquisition to potential public harm.  The gentleman that lost his eye was driving.  Again, I want to stress that he was driving, and it was very lucky that no one else was hurt.

It is clinically a resource-heavy injury.  We have surgery, medicines, psychiatry, physical or occupational therapy, all of those things, and some of these patients are often disabled.  When these explosions happened in a hand, that's a functional deficit that's unfortunately often lifelong.  As a surgeon, I need my hands, so imagine how difficult of an injury that would be, having a burn on your hand.

And that's it.

(Applause.)

DR. YEAGER: Thank you very much.

So a little slight change in the agenda. Dr. White has been slightly delayed, so we'll be moving up. Oh, as long as you're ready, jump up, Dr. White. All right. So then we will move on to Dr. White from Exponent. Sir, you can come on up and give your talk. Thank you.

DR. WHITE: Hi, my name is Kevin White. I am an electrochemist by training, and I've spent most of my career working with lithium-ion batteries, and currently I spend a lot of time helping people understand the performance, safety, and performance aspects of lithium-ion batteries. And what the folks here asked me to do today was kind of peel the onion back a little bit. Most of us don't really know what goes on inside the can of a lithium-ion cell, so I thought it would be instructive to just kind of show you what's inside the black box, so to speak.

So lithium-ion batteries are kind of interesting. They're very young in the grand scheme of things. The lead acid battery in your car, for example, was first commercialized in the late 1800s, and other rechargeable chemistries that we're pretty familiar with, nickel-cadmium, nickel-metal hydride, are close to 100 years old.

Lithium-ion batteries were first commercialized in 1991, so they're about 26, 27 years old at this point. It's a fledgling industry, but they've gained incredible traction because they are so much better at storing energy than most of the -- well, all of the other chemistries that are commercially viable. Therein lies the problem. You've got a whole bunch of energy in a very small space, and if it comes out in an uncontrolled fashion, it can be a devastating consequence.

You can see the market numbers down there. The industry is actually exploding. These numbers are about a year old at this point. The projection for 30 billion in 2019, it's more like 100 billion at this point, depending on which market analyst you believe. So there is a lot of money to be made, and a lot of folks are trying to get their hands into the pot. Some are making very nice lithium-ion cells, and some are making questionable lithium-ion cells, and that, again, is a problem.

Lithium ion is a game changer; that's for sure. It's a technology that puts a lot more power into a small space than we've ever been able to do before, and it's one of the things that enables these nicotine delivery devices to work well. But it is not without risks, and it can be a very safe product if those risks are understood and mitigated. And the industry is maturing to the point where that is possible and could be so for this particular application as well.

So the basic outline for my talk will be to go over some really fundamental battery concepts. You guys are going to hear from a couple more speakers today regarding batteries, so I'll get the terminology straight with you. We'll go through some general construction aspects, like I said, peel back the onion and take a look at what's on the inside. And then we'll take a brief look at lithium-ion cell failure and thermal runaway, and I'm not going to go too deep into this because the next speaker is going to look at some of the finer aspects of lithium-ion failure, but I'll get that ball rolling with a couple of videos.

So let's start out easy and go back to high school physics. We're going to talk in terms of energy, and in this case, it's essentially potential energy.

So if you imagine that the bucket on the top is full of water, you can actually do work with that bucket, right, and the amount of work that you can do is related to how much water is in there, right, its capacity. The quality of the work that you can do, how much energy you can get out of it, has to do with how high it is off the ground, and that's its potential energy, right? And these are all terms that fit with batteries as well.

If you poke a hole in that bucket and let the water out, you can do work with the stream of water that's coming out of there, and the size of the hole is related to how fast you can do work with that water, right? It's the power associated with the potential energy stored in that bucket.

So if we start making these same comparisons to batteries, you can see that the terminology is pretty interchangeable. Potential in a battery is the voltage. The capacity is measured in milliamp hours, and there's typically a power rating associated with batteries as well.

And it goes back through these comparisons again. As I said, the units of capacity for lithium-ion cells are amp hours; it's essentially a count of the number of electrons that are in the cell, and it's equated to the amount of water in the bucket.

The voltage is the potential, right, the potential energy, the height of that bucket.

And if you dig deep, deep into the cobwebs, you might remember a couple of pretty fundamental formulas, and they translate straight across from the normal kind of work that we know about from potential energy stored in the bucket to the potential energy stored in the cell. And again, power is just the rate at which that energy can come out of the cell.

So those are the things you kind of need to remember. Capacity is the number of electrons, the amount of energy that's stored. Power is how fast you can use those electrons. And potential is the energy that those electrons have, their capability to do work.

So now that we've got that basic terminology down, we're going to start looking inside the cell can.

Lithium-ion batteries come in three basic form factors. There's a cell called prismatic, kind of roughly a deck of playing cards sort of form factor. Those models can be either stacked electrodes, so kind of exactly like a deck of playing cards, or spirally wound inside that can.

There are also cylindrical cells. These are typically the types of cells that are used in vaping devices.

And then there's pouch cells, and these are the ones that are most commonly used in your mobile phone, for example.

All of the chemistries are essentially the same, and we'll talk a little bit about the chemistry that's inside each of these cans.  And they all share different performance -- they share different aspects of construction and chemistry, but they all have different uses in the real world.

So lithium-ion batteries start out as raw materials, and it's hard to think about this if you just look at a finished cell can.  But the active materials that comprise the electrodes that we generate the energy from are actually ground powders, and we'll talk just a little bit about what those powders actually are in just a minute.

So on each electrode there's an active material, typically a metal oxide for the positive electrode and carbon, graphite, for the negative electrode.  That's mixed with carbon black to increase the electronic conductivity so you can move energy easily through this deposition of material, and they mix in a polymer binder as well, essentially glue to stick it to the surface.  The positive electrode substrate is made of aluminum. The negative electrode substrate is made of copper.

And then all of these materials get put together in very sophisticated plants.  They're fully automated assembly lines.

In less sophisticated plants, humans actually do all the work. And the quality of those systems varies somewhat between the fully automatic and handmade, as you might imagine.

I need to start this video.

(Video played.)

DR. WHITE: So this is a computed tomography x-ray image, a 3D representation of an 18650 lithium-ion cell. Right now, the contrast is optimized for the steel of the can, and in just a minute we're going to change the contrast so you can see the electrodes inside.

So this is a spirally wound cell. That will become more evident as we virtually remove the top from it in the next bit of this video.

So the way that these are made is the active materials are coated on long strips of foil, and the foil runs through a machine that winds them around a mandrel, which you can see, kind of, in the middle there. And then that whole assembly gets placed into a can, gets filled with electrolyte, and the top gets put on it.

The process is slightly different for the other form factors, of course, but nuts and bolts, they're the same on the inside, right; it's the same sort of active materials, the same sort of electrolytes and other inactive materials inside the cell.

Can we go to the next slide?

(Off microphone response.)

DR. WHITE: Okay. Oh, somebody's got it.

(Off microphone comment.)

DR. WHITE: Yeah. Oh, he said don't use the mouse; we're going to get in trouble.

Okay, so we'll take a closer look now at what this looks like in the fully assembled state. You remember from the x-ray imagery we just saw, it was a spiral-wound kind of system. This is a physical cross-section of the exact same thing. So this particular lithium-ion cell had the electrolyte removed from it, rendered it inert, in effect, and it was backfilled with epoxy so we could polish it down to a fine surface to image with microscopy.

So it's pretty easy to see the winding structure in that image on the top left. The bottom right image is just a close-up view of what's going on with the different layers, and in the next slide we'll try and define what those layers actually are.

So you remember back a couple slides ago I said that the positive electrode substrate was aluminum, and you can see, at the very top of this image, the kind of shiny metallic-colored line there; that's the aluminum current collector.

The next layer going down is the positive electrode active material. So this is a combination of some sort of metal oxide that has the capability to store lithium ions. The darker regions in that portion of the image are the carbon black that are in there to increase the conductivity of that porous matrix. And what you can't see but is in there is the binder material as well.

The next layer down is called the separator. This is a very, very important part of the lithium-ion battery. It keeps the positive electrode from touching the negative electrode. You can imagine that that would become a short circuit. We can't transfer energy outside of the cell in the presence of a short circuit. Most of the energy flows through the short when that occurs.

So the separator has a very important job. It's very important because it's that short circuit that causes the explosions that we read about in the newspaper and see on YouTube. The short circuit causes the energy to be dissipated inside the cell, and that energy heats the cell up, and then some uncontrolled chemical reactions occur that result in flames and the production of gases in a very rapid fashion. And we'll talk about that a little bit more in detail as we go on through the talk.

The separator is quite thin. Modern battery cells, they're about anywhere from 10 to 20 microns thick. So you're talking skinnier than a human hair kind of thickness, right? And they're porous; they've got a bunch of holes in them so lithium ions can move from the positive electrode to the negative electrode fairly readily.

The next layer down is the negative electrode. Again, it started out as a powder, a graphite powder in this case. So the larger, lighter colored sort of flake-like structures in there are the actual graphite particles, and they look like potato chips, if you look at them under a microscope before they're coated into an electrode. The darker material is the carbon black, again, for conductivity enhancement, and a binder holding it together and holding it onto the copper current collector, which is the last layer in this image.

So a little bit of what goes on to make electrons come out of this thing, right? So in the as-manufactured state, all of the lithium ions in a lithium-ion cell exist in the positive electrode material. The first thing that happens after the cell is assembled is what they call a formation cycle. It's nothing more than charging and discharging the cell a little bit. But what happens there is the lithium ions move from the positive electrode to the negative electrode where they're stored inside the crystal structure of the material. And the same is true of the positive as well. So they exist in the spaces between the atoms that make up the material. So there are voids in this material where the lithium resides.

The reason this whole thing works is the potential difference between the materials, right? So the graphite is a relatively negative material, and the metal oxides are relatively positive material. So if you put energy into the system through charging and move the lithium ions from the positive to the negative, you're elevating their potential, and they spontaneously want to go back the other direction. So if you provide a path for the electrons to flow outside the cell, you can cause the lithium ions inside the cell to move back to where they started from, and that's essentially what's going on.

So to charge up the cell, you push electrons into it and move lithium ions to the negative side, and when you discharge the cell when you use it, those lithium ions spontaneously want to go back to the positive side, and they'll give up an electron to do it. So that's kind of the basic functionality of a lithium-ion charge and discharge cycle.

So positive materials -- this is a little bit chemistry heavy. Positive materials, as I said, are typically metal oxides. There are some examples of phosphate materials. The lithium-ion phosphate was popularized by A123 a little while ago; now it's pretty readily used by many different manufacturers. But you can see that there's a common theme here, right? There's some transition metal and oxygen to make up the matrix of these materials.

And the eye-popping chart on the right is just a rundown of who makes these materials and who uses the materials. You can see battery manufacturers and component manufacturers in that chart.

The negative material is a little bit more simple. There are some alternatives to graphite in the market. They're not readily used because they're substantially more expensive than graphite. And there are different flavors of graphite, so to speak: artificial, synthetic, and natural graphites. And they all have applications in different places in the battery using space. Some of these materials are better at some functions than other materials. And again, if you're interested, you can probably go on the website to see these charts and study them in detail, but I won't bore you with those right now.

The last critical component in a lithium-ion cell is the electrolyte, and it's critical from a functionality standpoint because it provides a medium for the lithium ions to essentially diffuse through when they're making their trip from positive to negative and back and forth.

They're typically organic materials of linear or cyclic carbonates, most typically. Some other more exotic additives in there. The one thing that all lithium-ion batteries have in common at this point is the salt that's used as the source of lithium ions, and this material is called lithium hexafluorophosphate.

The composition of the electrolyte mixture will vary from manufacturer to manufacturer and from application to application. You can engineer the electrolyte to work better at high temperatures or better at low temperatures or, you know, places in between. But the one thing that's consistent from across all manufacturers is the use of lithium hexafluorophosphate, and it actually has to do with passivating layers that it forms on the surfaces during that formation cycle that we talked briefly about that makes the lithium-ion battery functional.

It's important to point out, the electrolyte is largely the bad actor when it comes to thermal runaway and explosion sorts of events, and the reason it's a bad actor is more than 50% of the energy that's generated during a thermal runaway event, a battery explosion, is simply combustion of the electrolyte material.  So in the absence of combustibility, the severity of lithium-ion events would be substantially lower.

Okay, so this is the last bit of my talk.  We'll talk just a little bit about lithium-ion cell failure.

At its most basic sense, the only thing that is required for a lithium-ion battery to fail is for the chemistry inside the pouch or the can or whatever it is that's containing it to get hot.  There are a bunch of different ways to do that.  You can heat it externally, you know, with a blowtorch or something like that.  Even more subtly, just leave it on your stovetop, and that will get it to go off.  But more insidious is what happens when some sort of failure occurs inside the cell can and causes an internal cell fault, a short circuit that we talked about at the beginning of this talk.  When a short circuit is established, you don't know it's happening, and the energy that's stored inside the cell gets dissipated across that short circuit, raises the temperature of the cell, and then these uncontrolled chemical reactions occur.

Those cell faults can happen because of manufacturing defects, poor design, user abuse -- that's a big problem in any kind of consumer device; no amount of engineering can really curtail the creativity of the human mind to do terrible things to perfectly engineered equipment -- and as I said, again, external heating.

Let's take a look kind of graphically at what's going on. So this is an experiment called accelerating rate calorimetry, and it's a big bunch of words for a really sensitive oven. So what we do is a lithium-ion cell goes into this instrument, and it's able to very carefully control the temperature and monitor both the temperature that it's applying to the cell and the temperature of the cell itself.

So in the beginning here, in that time between 0 and 500 minutes, the machine is increasing the temperature a little bit and then waiting to see if the cell does anything, then increasing the temperature a little bit and waiting. Eventually, just past that 500-minute point, you see that the curve smoothes out and starts to increase in slope on its own. That's what we call the onset temperature. It's typically around 100 to 150 degrees.

And what happens there is that you begin to excite the chemical reactions that start off the thermal runaway event. Initially, they're very slow, and you can see, in this particular experiment, it takes quite some time for them to generate enough heat to cause a problem.

But during that time period, what's happening is the surface films on the negative electrode are breaking down, and they're doing so exothermically in a way that generates heat. That increases to the point where you cross kind of a point-of-no-return threshold where you involve the positive electrode, as well, and that's typically at around 180 degrees C.

At that point, once the positive electrode is involved, it can cause oxidation reactions to occur that dramatically increase the heat in a short time frame. And that's what's depicted by that quick spike in temperature.

We actually, with this particular experiment, didn't catch the peak temperature; it was above 600 degrees. The timing of the measurements didn't allow us to. But you can see that it happens very, very quickly.

And in the next two slides we're going to take a look at what that looks like in real life. So this is -- it's going to be a video that I'll start in just a second, but let me lay the groundwork for it first.

So in that lab stand, in the tongs of that lab stand is a lithium-ion cell, an 18650, the most ubiquitous lithium-ion cell in the market right now, and around that we've wrapped a resistance heater. It's a flexible heating coil. So what happens during this experiment is we increase the temperature of the cell using the heating coil, and you can see what happens.

Can you guys start the video?

(Video played.)

DR. WHITE: Hopefully it won't get squished like this for the next one. So this is just kind of to set the playing field. Let's skip to the next video, which is a high-speed version of that exact same event. We're now just looking at the top of the cell can. So the heater is engaged, it's turned on, and oh, it's doing something funny. So that mess coming out is vaporized electrolyte, and it left the cell under pressure because, as it gets hot, it expands in volume and causes the safety mechanisms to operate.

The next thing we're going to see is the generation of smoke. We're combusting things inside the cell can at this point, and you're going to see material being ejected. Those kind of tracer-looking things here, that's actually molten aluminum from the positive electrodes being ejected. So aluminum melts at about 650 degrees C. Water boils at 100 degrees C. So this continues on until all the fuel in the cell is exhausted.

This is a situation where the cell is vented to the atmosphere so additional pressure isn't building up. You can imagine, if this was inside some sort of an enclosure and all of this energy was escaping in an uncontrolled fashion, you could build up enough pressure to essentially turn that enclosure into something akin to a grenade.

Okay. Well, I'm just going to end on that happy note for you guys to think about.

(Laughter.)

DR. WHITE: And I guess we're going to have a panel discussion later, so I'll be happy to answer questions at that point, if you have any.

(Applause.)

DR. YEAGER: And while our next speaker comes up, I just want to remind everyone if you want to get an order in, I'd do it before 10:00 at the kiosk for lunch.

Next up is Dr. Barnes from Barnes Technical Advising. Thank you, Dr. Barnes.

DR. BARNES: All right. First, I'd like to thank the organizers for pulling this meeting together and allowing me to participate. I feel like I've come home. I started my government career and my career in batteries right here on this site, but it was a Navy lab at the time. You can still see Navy Ordnance Lab in the stone above the main door, and that's when I first came.

And finally, for the battery folks in the room, this is a really good time for you to go and put in your order for food because this is going to be a relatively basic item.

Now, the nature of this talk is really very general in the sense that the failure modes that I'm going to discuss would apply to any lithium-ion battery, not just those in electronic nicotine delivery devices. And, in general, they would apply to all chemistries and all cell designs. Some make bigger bangs than others, but the generalization is there.

In light of the first speaker, I will comment that based on my personal experience with over 30 years worrying about the safety of batteries, the number of incidents, failures, sometimes violent failures that have occurred, probably are many, many times the incidents that put people at a hospital. People do not normally report to the hospital if the only thing that's happened is they get scared out of their wits. In fact, they often just throw things away.

So the other comment is that many of the things that we're going to talk about here can happen with other chemistries. Years ago, when what we now would call a 9 V transistor battery, the little 9 V battery with two connectors on top, first came out, I had a colleague here at the lab who was doing some experiments with them, and they were brand new, and at the end of the day, he put a couple in his pocket to go home with them. Well, at that point they didn't have any caps on them, and he had some keys in the pocket. He had to jerk his pants off halfway home because those batteries, those little alkaline batteries had gotten hot enough to burn him. He didn't end up at the hospital, but it made a good story later.

All right, let's go on. Which button do I want to --

UNIDENTIFIED SPEAKER: A left click.

DR. BARNES: A left click. Okay, all right. Okay, now to pick up on what you heard just a minute ago, failures, they all start with heat. If you take a lithium-ion cell and you get it hot, you have a series of reactions that occur. As shown in the accelerating rate calorimetry and many, many other experiments, it tends to start at the negative electrode over on the so-called anode, and if that produces enough heat, then you begin to get reactions over at the cathodes that also get involved.

And an important comment here is you will see manufacturers who will tout their cathode material as being particularly safe. And yes, if you do the experiments, some of the cathode materials do give off more heat when they fail than other cathode materials. But if you beat a lithium-ion battery hard enough, any of the cathode materials will fail.

If you get the electrolyte burning -- you've already heard this about a minute ago -- the heat associated with the electrolyte burning, the energy stored in the electrolyte that can be released by burning actually overwhelms the electrical energy in the battery.

And although it's a generalization or it's a fact that you can make a lithium-ion battery fail, period, it's more likely to fail, and more likely to fail with vigor, if it's fully charged simply because it's got more electrical energy in there. And more importantly, as was shown, all of the energy in the buckets -- you've got the bucket up high, filled. And so that's a situation that's less stable than if all the water is in the bottom bucket.

Okay, let's see. I've got to go over here to the side to click it. There we go. Okay. There we go. More delicate than I thought.

Okay now, thermal runaway: we already heard about it. Any lithium battery can be -- ion battery can be forced into thermal runaway. You start with something providing a source of heat. Now, if the heat is less than what can be -- if the heat exceeds what can be dissipated, then the cell begins to get hotter, and eventually you begin to get the reactions that we've already alluded to: they begin to cascade, they speed up, and at some point the cell gets hot enough to vent.

Now, as was already mentioned, how the cell vents partly depends on how the cell is constructed and how it's constrained. A pouch cell, a lithium in a polymer bag, tends to expand and blow up like a balloon. A cell in a metal can is more likely to go pop. If the cell has a vent and the vent gets obstructed, then it comes about -- comes apart with great vigor.

The implication here is, and we'll say it again, it's a balance of heat, and as long as you're taking the heat away from the cell faster than it's being generated, for whatever reason, things are okay. And when the heat begins to build up, things go awry.

Okay. Now, we've already said electrolyte. You saw it already. All common cells today contain that mix of electrolyte or organic carbonates. You will hear about some polymer cells or gelled cells; they've still got liquid electrolyte. Now, if you go to the research literature, there are truly solid electrolytes coming along. Some of them are organic solids, polymers, and some are inorganic solids, glasses, or ceramics. They are in development. I do not think any of them are in routine, high-volume commercial cells.

Now, we've already said it, the electrolyte and its vapors can burn. You'll hear sometimes of people who put flame retardants into the electrolyte; that may have some effect, but it doesn't solve the problem.

And if you heat the cell enough, either externally or internally, it will vent. And the only question is does it vent benignly and with some grace, or does it explode with a big bang? Because cell manufacturers like benignly and grace, they tend to try to put a vent in there. But if the vent gets clogged, uh-uh.

Okay. Now, you got to have heat. The simplest experiment for heat we saw in the video, simple external heating. But you can also have heat produced by electrical effects, and I've listed them there: overcharge, overdischarge, and short circuits. And we'll talk more about them in a minute.

But the external heating, I'll point out, in an experiment -- we saw the experiment. You wrap the cell with heating wire or you put the cell in an oven and push it too hot, or you install the cell in a piece of equipment that has a heater right next to it, and things don't work quite right.

This is very delicate. Okay. Now, in batteries other than ENDS, external heating, and if it's not coming from something gross like a fire, are often associated with external electronics, external wiring, things like that. If the external wiring is not well designed, it might get hot. If it's placed in the wrong place, it behaves inadvertently like the intentional heating wire wrapped around a cell. The heat, by itself, is no problem. It's only that it begins to produce reactions inside the cell, and eventually you get thermal runaway.

Again I'll repeat, you can get a cell to fail even if it's dead 0 V, but if it's fully charged, it's much less stable, and the reactions can be more dramatic.

The issue of venting electrolyte was already mentioned, and I'll mention it again and again. Interestingly enough, for those of you who are working with larger batteries, this probably is not an issue with the single cells in cigarettes. But if you get a large battery to vent and the electrolyte doesn't burn, you have to be very, very careful because a closed chamber full of electrolyte vapors and air is an explosive mixture.

Okay. Now, we're going to talk about other things. Overcharging is another thing that can cause a cell to fail. Overcharging does several things. First of all, as you push a cell beyond its normal top of charge, you're messing up the chemistry, and it's not designed to be at those voltages, and so you're going to get some resistive heating.

Also, in some chemistries, overcharging means that you produce unstable reactive species, which means that after a while, they go off and do their own thing and push the cell into runaway.

Overcharging can decompose the electrolyte. If a cell is designed for 4.1 V charging and your charger goes a little crazy and pushes the cell up to 4.5 V, you will also begin to tear up your electrolyte.

If you push overcharging enough, you will get the cell to fail; it will vent, and you may get thermal runaway.

One of the generalizations here is that when you're abusing a cell, except perhaps for really, really guaranteed gross abuse like heating it to 500 degrees C, you will have -- if you test 10 cells, you may not get all 10 to behave exactly the same way. Again, it has to do with heat balance, heat dissipation, and subtleties of cell design.

Okay. Overdischarge, letting a cell drop below where it should go, is less common than overcharge. If you allow a cell to get to 0 V by simply draining it down, the copper current collector in the anode -- you saw it in pictures -- can begin to react and dissolve. This is not good. If you're lucky, your cell becomes a brick and is just useless, and from a safety point of view, that's pretty good.

If your cell happens to be in your Tesla, that can be really disappointing. And early on, before Tesla redesigned some of their -- in their very, very, very first vehicles they had some that were parked in an airport, and the people let the batteries run to zero, and when they came back, the battery was a brick.

Some cells are marketed saying they can tolerate 0 V. The real issue when a cell has been taken to 0 V when it shouldn't have been is if somebody tries to charge it. Now, you say, well, why wouldn't they want to do that? Well, hey, come on, these are rechargeable batteries, and they're expensive, and they're often embedded in the equipment, and if it goes down to zero and your equipment isn't working, the first thing you do is you put it on the charger.

Now, if you've got a really, really good charger, the charger is not going to let you do anything stupid. But if you've got a really dumb charger, it may just push at the cell until something happens. And if you're really inventive, you'll say oh, well, this charger isn't any good, but I'm going to go out and hook it up to the charger I've got for my car battery because that's really powerful. And, of course, it's also 12 V, and if you put a 12 V charge on a 4 V cell, uh-uh. Yes, okay.

If you have a multi-cell battery, you can get what is called forced overdischarge into voltage reversal. This is not a problem with single-cell batteries of the sort that are in typical e-cigarettes, but it would be a problem in bigger batteries. I won't bother with it today because we're talking about e-cigarettes.

Okay, short circuits: Short circuit means that the cell is being discharged in a way that it's not designed. When you discharge a cell rapidly, you get heat, and you drain the cell electrically. Pretty self-evident. Now, if the heat is less, the heat that's generated is less than the heat that can be dissipated, all you get is a dead cell or a poorly performing cell.

Many of you have experienced cells with soft short circuits in them and not had to go to the hospital. If you've got a cell phone that used to run for 24 hours and now somehow the battery seems to dribble away after 4 or 5 hours or takes longer to charge, although that may be normal aging, it may also mean that that cell has a soft short in it, that is, a small short. Now, it's not producing enough heat to cause the cell to blow up, but it is producing enough heat to drain -- electrical pathway to allow the cell to drain. Now, as soon as this heat generated exceeds what can be dissipated, you get thermal runaway.

Now, an external short circuit means that the cell is undamaged, but it's discharged between the positive and negative tabs in an unexpectedly high rate, besides being able to produce unstable species inside the cell, because as in the picture, we saw lithium ions, during discharge lithium ions have to move, and if you're trying to move those lithium ions faster than the cell is designed or allow them to move, weird things can happen. But the real issue is you produce a lot of resistive heating. And again, as soon as the resistive heating gets to the point that you begin to trigger that cascading set of reactions, you go up the curve shown in the arc experiment and you get runaway.

And externally short-circuiting is a real problem with -- all right -- with cells -- frankly, more of a big problem with big batteries. But that's what happens when you put the 9 V battery in your pocket. That was an external short circuit.

An internal short circuit. This is the most insidious one, and this is also the one that's most likely to show up in field failures that cause great concern. In this case, the current flows through an inappropriate pathway within the cell; that is, instead of going out one terminal and around to the other side, through a light bulb or an e-cigarette, the current is simply going inside the cell. We saw, in the previous presentation, a chart that showed the different ways that can happen.

Now, an internal short circuit will produce heat, and it's often quite localized. Now, there are two ways to get an internal short circuit. One is to take a perfectly good cell and do something rude to it, like crush it or ram a nail through it or shake it until parts stop flopping around. So these will be external damage to the cell that produces an internal discharge pathway that gives rise to heat, and it gives rise to runaway.

Or it can be caused by a failure mode that grows inside the cell. The details are more than I've got in the next 2 minutes, but if you have material in a cell that shouldn't be there, like a metal particle from the manufacturing process, or you have a cell designed so that material rubs or whatever, you can get electrochemical processes that grow a short inside the cell. And when this short grows to a big enough point, you get a short circuit, and then eventually you get thermal runaway. Or can get thermal runaway.

Now, it's this last situation where you have a cell that has passed all the quality control steps, you've used it for several months with no problems, and then suddenly one day the battery burns up and you can promise people that you did not abuse it.

Now, I note that you can increase the probability of an internal short circuit by having poor cell design or poor manufacturing. For example, the Samsung phone fiasco probably included these two things. One, they worked so hard to make the cell hold as much energy as possible, they cut a couple of corners in their design, and then they had some manufacturing problems.

Now, these things can be very fast. A nail penetration produces a very sudden, very high-current short circuit inside a cell or can. And studies on nail penetration show that from the point where the nail penetrates the cell to the cell taking off in six different directions can be significantly under a second. So it doesn't take hours for this heat to build up. If you get a major short, it can go very, very rapidly.

Now, short circuits are particularly insidious if the cell is on the charger because, of course, if the cell is sitting off by itself, the maximum amount of electrical energy that can be dissipated through the short circuit is whatever the cell can store. But if you're plugged into the charger, then you've got an infinite supply of energy to go through that short circuit and to build up heat.

Now, to summarize in 20 seconds, all of these things are general.  There are specifics to each cell design, to each cell use, but they're all ways that cells can fail.

Thank you.

(Applause.)

DR. YEAGER:  Thank you, Dr. Barnes.

So next up is Dr. Lawrence McKenna from the U.S. Fire Administration.

DR. McKENNA:  Good morning, everyone.  I'm going to add a little fun to this, maybe.  My work at the U.S. Fire Administration as a resident physicist/engineer is to do research on a lot of fires, fire cause and origin, product development in terms of new techniques and tools for the fire service to use.

About 2 years ago I started to get calls from fire marshals around the country saying, hey, we got these e-cig things that seem to be blowing up; what's going on?  So that initiated our research at the time.

Part of what we do at the Fire Administration is we operate the National Fire Incident Reporting System.  Basically, when a fire department goes out on an emergency run, they fill out a report that eventually finds its way into my office, or into the statisticians that I work with, for analysis to identify trends and incidents and changes in society that may implicate that national fire problem.

So my first thought was, okay, let me just pull up the database, there are several hundred million incidents in this database by now, and see if I can find anything about e-cigs, and I came up with a great big fat goose egg. The database was compiled or started in the early '90s. The data fields that you collect and click on as you're filling out the reports, there's nothing there for e-cigs. There's a battery field, but it's nonspecific for lithium-ion or nickel-metal hydride or any of the battery technologies.

And certainly, very few fire departments are going to be able to know what the difference is in the battery chemistries, and it's irrelevant to them frankly.

So with the absence of detailed information in NFIRS, we started looking for data from wherever we could find it, and it turns out that the most readily available, largest amount of data on these incidents is in the media. Now, I'm very, very familiar with the problems in trusting what we read in the paper and online today, and so this was something we undertook with a great deal of trepidation initially, and we put out a report in late 2014 that summarized what we found. About probably 2 weeks before Julie reached out to me about this workshop, we had started to update that report, and whatever you're going to see here is an update for what we did in 2014. And I'll tell you now, the conclusions have changed, and I'll tell you why in a bit.

With the 2014 report, we put out guidance to the fire service that said we're really interested in e-cigarette types of things. So if you would, please do this, this, and this when you're filling out the report so that we can start to cull the data. And indeed, between the 2015 and 2016 datasets, we do have some e-cig or ENDS product fires showing up in the NFIRS database. The vast majority of the incidents I'm going to report on here came out of the media.

We did not have opportunity at this point in time to look at other datasets. One of the datasets that we want to query, and we're working with the appropriate people, is the national emergency medical incident dataset. You know, when an ambulance goes out, they fill out a report. And that's up on the web, summary reports and things, but these kind of details don't show up in that. So I don't think the data that I'm about to present represents the total universe of incidents, which is typical of fire reporting in this country and in every other nation that has a nationwide fire reporting system.

So what did we find? We found 195 discrete incidents of explosion or fire involving ENDS devices between 2009 through 2016. A lot of the media reports particularly showed up in multiple media outlets. Some of them showed up, and we had reporting in the NFIRS report as well as in the media, so we had to carefully go through every one of these to make sure we were culling out discrete incidents, and we were pretty successful with these.

No deaths were reported in this nation. There's been a death attributed or reported in the UK, but that had less to do with the ENDS device than it did with the medical device that was being used. The individual was in an oxygen tent smoking.

Out of these 195 incidents, we found 133 acute injuries, some of which were reported earlier.

What was going on in the device? It's important from a fire service perspective to find out what's happening, what's the source or the root cause of the device or the incident, and we found most of it, 60 or 61 incidents, both were either in somebody's pocket or in their hand or mouth in use when they happened. So this is the largest variety.

The next step was 48 incidents where the device was being charged, so whether it was the battery was removed from the device to put it in a separate charger or the device was plugged in. It really varied from device to device.

Eighteen incidents were in storage, and these would be things in a purse or on a tabletop or on a countertop. I just kind of statistically called it storage for lack of a more descriptive term.

And we had one incident on an aircraft, which gained a lot of notoriety a couple of years back.

The fire service is, of course, interested in where does this go, because this is a finite source of energy, and it all depends on where it happens, whether a fire is going to go somewhere else and create death or injury or damage. Most of them had very minor fire spread, and by minor, it created a burn pattern of typically 6 inches or less diameter circle. Fairly small. These are fast. As you saw in the video, they're energetic events; they happen quickly. The electrolyte and the polymer separators burn up pretty quickly, and there's just not much material, not much mass there to burn and continue a fire. So it depends on whether it's in contact with something that's more combustible than the battery itself.

There was moderate fire spread, which tended to require some interaction to put out the fire in 27 of the incidents. And in 10 of the incidents, we have what we call major fire spread, which would be a room and contents, or beyond a room, a bedroom or into the rest of the home.

Is this a major source of fires in the United States?  No. And that helps us field that.

How were they suppressed?  How did these fires go out? Most of them went out by themselves.  Limited amounts of energy, limited amount of fuel to burn; it's just not going anywhere unless it lands on something that will burn.

Eighteen incidents, the fire department had to do something.  A number of other incidents, the fire department was called because people often will call the fire department right away, but there was nothing necessary for them to do when they got there.

There was one incident, and this was on the aircraft cargo hold of a Federal Express aircraft landing in Minneapolis. Fortunately, the aircraft was on the landing pattern and about to land when the incident occurred in the cargo hold, and the onboard fire suppression system controlled the fire in that case.

What FDA is probably rightly more concerned about is the injuries. We grouped these into minor, moderate, and severe.

Basically, a minor injury we thought would be something that caused smoke inhalation, minor lacerations, or first-degree burns.

A moderate injury in this chart would be second-degree burns, something requiring treatment at the ER, or lacerations requiring stitches, and we had quite a few of those.

And severe required hospitalization. These typically reflected the life-changing events, loss of body parts, third-degree burns, facial injuries, things of that nature that really upset us.

So the severe injuries, we had 38. We had 80 moderates, 62 incidents where no injuries were reported, and that's a good thing, and 15 incidents with some minor injuries.

So scientists always want to see trends and see what's going on in the world, and we see an increasing number of trends from -- of events from 2009 through 2016. It makes a nice little trend plot. If you do the curve analysis, it's pretty simple; it's increasing.

Wondering why it was increasing, I went to that always-accurate StatisticsBrain.com and pulled up ENDS sales information and plotted it, laid it on the plot against the incidents, and there's a pretty interesting parallel which one would expect for a manufactured device with probably a set failure rate because of manufacturing defects, or a fairly constant failure rate typically of most devices. You would see more devices means more incidents in the field.

So let's take a look at differences now between the initial report in October '14 and what we found in January and February of 2017.

The big change, the enlightening change here, happens in where they're happening and when these devices are failing. We had none occurring reported in the pocket in 2014. Today it's up to 61 incidents.

We had nine reported incidents in use with some severe injuries, two severe injuries in that dataset. Today it's up to 60. This is the major change in what we found.

Charging was the major cause of incidents at the time, and at that point in time we were implicating improper charging techniques, which is still going on. Because many of these devices come with a USB port for charging, people will plug them into any USB port they can find, whether it's in their automobile or their computer or their laptop computer, and not all USB ports produce the same amount of voltage. And we were seeing with some of the lower-end devices overcharging incidents when you plug a device in that's meant for 3 V or 1 V charging and you plug it into a 3 or 5 V USB port, and you overcharge the device, and interesting things begin to happen.

The fire spread stayed pretty steady. Most of them went -- the fires went nowhere. The trend is fairly typical and not terribly informative here.

The fire suppression, similarly, most of the fires go out by themselves. It's a limited amount of energy, and it all depends on where it goes.

The injury trends changed a bit, and this is reflected largely in the number of incidents, the increase in the number of incidents that we've seen -- or quite a few more injuries across the board in every category that I've created here.

In 2014 I characterized these in a summary as rare events because, at the time, we were looking at 20 events or so in the country. I no longer believe that they fall into the statistical category of rare events. Having done rare events analysis for many years, and probabilistic risk assessments, these are much more frequently occurring than rare events. I would call them uncommon.

The number of acute injuries per incident, the ratio of acute injuries to number of incidents has increased considerably.

However, an interesting thing fell out of, particularly, the analysis of the NFIRS database.  We're seeing similar events in terms of the lithium-ion failure rates and the fires and explosions in a wide variety of consumer products: radio-controlled cars or remote-controlled cars and airplanes. Drones, we're seeing lots of drones start to catch fire now, in flight or on the ground during charge.  Or some of the battery packs for power tools.  Typically, they seem to be a better product, a better designed product because they've come to market after some of these lessons learned, but we're seeing this happening in all of these product categories.  And it appears, without having the opportunity to do a real statistical analysis, that the failures are occurring at a roughly similar frequency.

One of the things that makes ENDS devices different, and I'll go a little more into why it's so that we're seeing the severe injuries, is the failure mode.  Typically, if you get an internal fault, as has been very well described, you get overheating, buildup of pressure within the cell -- this is a cutaway of the cell -- and eventually when the internal pressure reaches the relief point for the pressure vents, the gas is vented out the top of the cell.

If you have a cheaply constructed cell without a rigid tube down the center, as Dr. White showed in the photo that he had, the pressure will relieve at the top of the cell, but the pressure at the bottom of the cell continues to build, and eventually, fairly quickly, you can see the ejection of the core out of the can.  And that is indeed what you see in this photograph, a reasonably intact core and one that was ejected out of the can.  We're finding these all over the place.

Now, if you take this failure mode, whether it ejects out of the can or not, and wrapping inside a cylindrical container made of metal or rigid polymer, you basically put this fuel device inside of a rocket nozzle.  And that's what we see; these things fly across the rooms, from the front seat of the car to the very back seat of the car.  They'll bounce off the wall and land on bedding and start fires there.

Looking at the physics, it's not that surprising.  Coming to this without that background of knowledge on these devices and how they're developed, it was kind of an eye-opener to me.

But they do tend to do this, and you can go on YouTube and watch lots of really interesting videos of these things failing in pockets as they dance, the people dance around the rooms, and the sparks are flying all around.

We also get container ruptures where the physics of what's going on inside the can, the distribution of pressures, the manufacturing of the container itself, then aluminum stampings, we can see containers rupture. And this one rocketed a little bit before it failed. And we also get ruptures in the ENDS device itself as the containers fail.

And this is what makes ENDS different from every other consumer product that we're seeing using lithium-ion batteries.

In a typical laptop computer power pack, we have the same 18650 batteries as we do also in power tools or different sized batteries, but we've glued them together, and we soldered them together, or welding them together, more correctly, and wrapped them in a rigid polymer enclosure.

When the battery fails, and they do, you probably recall years ago a whole spate of battery failures in laptop computers, and the computers would catch fire on a conference table or on an airplane or something. These rigid enclosures and the construction of that battery pack keep it from going anywhere. They retain it and, you know, we get battery failure progressive, as it goes from battery to battery to battery, but it doesn't go rocketing across the room, and it's certainly not in close physical contact with the person.

The cell phone industry, the laptop computer industry, after experiencing a number of these kinds of high-profile incidents, they got together and they formed industry standards for battery safety, and they've addressed this problem and have done very well at it. The folks in the ENDS community, in the power bank community haven't done such a good job of this to date.

It's important to understand that the design of the product informs the failure mode. We heard about how the prismatic and the pouch batteries fail differently, similarly but differently, and it's all in the enclosure.

A flammable liquid or a combustible liquid electrolyte is going to expand when it gets hot. That's fairly simple physics. When it starts to combust, you're going to get combustion gases and expansion, fairly simple, fairly well-understood physics.

So the batteries are held well together here. The core issue that separates ENDS from all of these other products --

and we're going to hear from some of the other producers about what they do and how we can make these batteries safe -- is intimacy. My power drill is not -- I don't have my lips wrapped around my power drill battery pack when I'm using it, okay, nor my laptop computer or anything. It's intimate with the human body, in a place on the body where severe injuries can occur, and that's what sets this different from all the other products out there.

The consequences: I mean risk, we talk about risk, and typically, automatically, we say risk equals the probability of occurrence times the consequences. Well, probability of occurrence here, failure of the battery, is fairly small. Given the number of batteries and the number of incidents, the consequences far outweigh that, as we've seen.

There are also behavioral considerations. This is a Wild West. As part of my research, I spent some time in a vape shop. It's a hoot; it really was. It was an eye-opener. Some great people, absolutely wonderful people, but they have a whole different environment, and what we're doing here -- and you can go on YouTube and look at this. People will take scavenged batteries from a laptop battery pack.

This laptop battery pack I took apart. Here is the protection circuit to keep it from exploding and catching fire, and a thermistor here, a temperature sensor, as part of that circuit. When they go into these battery packs to take it apart to get a free battery, they throw these away, and they've got an unregulated, unsafe battery. You can buy protected batteries with an overcurrent/overcharging circuit in them. But here's the kinds of things you can buy on eBay, with a battery charger, separate battery safety circuit, and you can gin up things like this. I've seen this, this particular thing floating around in somebody's pocket, not a particularly safe thing to do. And most of your vape shops will sell you devices to keep that under control.

We've seen most of it, the conclusions, already. In the end of the day, if the goal is to reduce the incidence of severity of acute injuries from these devices, then the current generation of lithium-ion batteries is not the right power source for these devices.

I do not think you can make, with the current technology and widespread use -- and there's other stuff out there that might be better, but I do not think you can eliminate these injuries with the current technology.

Thank you.

(Applause.)

DR. YEAGER: Thank you, Dr. McKenna.

So our next speaker is Douglas Burton from Altria Client Services.

MR. BURTON: Good morning. So I am a principal engineer working at Altria Client Services, and one of my primary responsibilities is to assess or lead the assessment of mitigation of the hazards that we've been talking about this morning. So what I'm going to talk to you about this morning is a little bit from the designers', manufacturers' and distributors' perspective. But make no mistake, this is an engineering issue.

So I'm going to describe the process that we developed to effectively assess and provide information to mitigate the causes of these battery issues.

So I'm going to talk a little bit about why these ENDS devices seem to perform a little differently than a lot of other things you have in your house. I'll briefly touch on causes of battery incidents, just to tie all of this together to the process that we developed to try to get ahead of this. I'll talk a little bit about standards because it presents an opportunity for us to get control of this activity. And then

I'll leave you with some conclusions and considerations to take home with you.

Yeah, it is very sensitive, isn't it?

(Off microphone comment.)

MR. BURTON: Okay. So by now we've established that we have houses and offices full of lithium-ion battery products. But we seem to see a lot more of failure reports in the media on ENDS devices than you typically see for the other devices that you have in your house. I mean, on average, each of you has two to three of them with you right now.

So part of the reason they tend to perform a little differently: These batteries -- or the ENDS devices work their batteries very hard, okay. In some cases, an ENDS device will actually draw more current from the battery assembly than a power tool. This is because they operate at low voltages, so the current has to be higher to get the energy involved in aerosolizing the e-liquid.

The battery cells in general tend to be inexpensive. Sometimes they are actually hand-wound. Now, this is not, in itself, an intrinsic weakness, but it does cause these batteries to be very variable. So winding quality, filling of electrolyte, sealing of the pouch can be pretty variable.

In the absence of standards in the development of these devices, there's been relatively low design guidance on what constitutes a reasonably safe device. The architectures are all over the place and where, for example, your cell phone is designed to a standard which leads to the development of fault tolerance, the ability of the device to tolerate an internal failure or fail in a benign way, this guidance is relatively rare in ENDS devices.

By the same token, testing of these devices tends to be quite variable, from virtually none to, in some cases, pretty well-based testing programs. But the testing doesn't always make a good prediction of the performance of the device in the market because it's not particularly repeatable or structured.

So manufacturing controls and quality systems: We have designed quite a few devices, we have looked at many places to have devices manufactured, and what we see is variability in how these manufacturing facilities control their processes, how they control their incoming materials, and the sophistication and degree of diligence in their quality system operations.

So what this means is you could have two or three companies making a very similar device, but they will perform very differently, and it's difficult to actually figure out because of lack of traceability when these devices were manufactured.

So to touch on the causes. So we know that the outcome of battery failures, venting, flames, content release, rupture, can create a spectrum of personal injury and property damage. And the external causes of issues in the battery have been discussed pretty well here, but there are a couple things I would like you to take away from this slide.

The first is that second column of issues that can be developed in the battery cell. If you are not careful, you can design those into your device. You can overdischarge, you can place conductors in a way that they impinge on the cell body, you can place the cell in thermal stress. So you can actually design problems into a device rather than have them be an effective manufacturing error.

The second thing I'd like you to take away is -- and we don't always discuss this, but a cell internal fault, there's almost nothing you can do in device design that will protect you from the consequences of an internal fault. I can't put a fuse in; I can't regulate the current if the short is internal. About the only thing I can do is try to manage the release such that I don't build up so much pressure that I cause, essentially, issues of shrapnel or direct the content release in a direction towards the consumer.

So given this -- yeah, let's do this. Okay. I'm going to share with you a process that we developed to help us navigate this space.

Now, there are two outcomes from this process. It gives you a very well-characterized, understood device, and it gives you engineering-based user instructions that tie directly back to what might be happening in a device if something is going wrong.

So it's cross-disciplinary. It involves the engineering group, it involves a third-party failure analysis company, it involves cross-disciplinary review, principally to combat bias. If you're designing this and you've got a schedule to keep, you need somebody to work as an ombudsman for you a little bit. And finally, the user guide development process comes directly from the testing of the device.

So we design some products from the ground up, but we also evaluate pre-built products from other places that perhaps we would like to sell under our brand.

So when we start from a clean sheet of paper, so to speak, we start with design control, and we go to prototyping, and we develop a data package. Now, this data package is build material, specifications, schematics, algorithms, printed circuit board designs, everything that we can put together, and we do this before we build the prototype.

If we are considering purchasing a device, then that device comes into the process at the technical data package stage where we go to the manufacturer of that device and we basically say give us everything you have.

When we get that information, the first thing we do with it before we spend money on building things is we put the device technical data through a paper hazards analysis test, the idea being that if we have all of this information, we can find out if the electrical components are properly rated for the power required, if the parts that may or may not get warm are too close to the battery cell. We can evaluate all of that, and frequently at this stage, which is very early, we will make design changes even in things that we're buying.

So from there, after we've built a few prototypes, enough to support testing, we will go into our hazards testing process again with our third-party failure analysis company.

So this process is built around a standard called IEEE 1725, and that is a standard for single-cell lithium-ion cell phones. So you might ask why are you using a cell phone standard to test an ENDS device? Well, this standard is built around a very comprehensive model of the universe that a user of a cell phone and a cell phone live in, starting with the environment, the user, then the charging system or the power system in the wall, then the charging system, then the host device, all the way down to the cell.

And interestingly enough, as Dr. McKenna said, when you use these, if you're using a cell phone or using an ENDS device, when you're using it, it's close to your face. When you're not using it, it's in your pocket. When you're charging it, it's probably on your nightstand or maybe in your car. But the universe of use is very similar, even though perhaps the current operating limits are different, but it works well for us.

So we take the battery cell by itself, and we evaluate it using destructive tests to see how robust the cell itself is. Then we combine the cell with our devices and our intended charging systems, and we verify that the ENDS device is treating the battery well, it's not operating the battery out of its normal operating range. And then we will add additional accessories. And interestingly enough, power accessories fill two roles in this model. Yes, they're accessories that support the use of the device. They also happen to be part of the threat environment because, as Dr. McKenna mentioned, these are charged by USB power sources. And so if you have a USB socket and a USB plug, they will always get mated together, and we have no control over what people mate them to.

So part of this evaluation process involves simulating and inducing failures in the device to understand the consequences if external charging devices don't work, if internal safety devices fail. The idea is basically you expose the system to the next layer of voltage up the path.

So when this work is done, our third-party failure firm provides us with a report, and they have three obligations to us. The first one is to do the right tests, the second one is to do the tests right, and the third one is to provide us feedback in a way that we can act on it. That is the extent of their responsibility. What we do with the information is our responsibility.

So to illustrate that or illuminate our decision process, the change tracking matrix lists the observations from the failure analysis company. This is the consequences, this is what we decided to do about it, and it lists any comments that we need to make to clarify why we did what we did. So we have a very clear picture of how we made our decisions so we can go back to it, if we have to.

So from the engineering change matrix and the third-party work, we have another third party come in and help us do a human factors analysis because we believe that you cannot understand fully how these devices are going to act unless you understand how people are going to interact with them because, as has been mentioned already this morning, people are very innovative, and they will find interesting ways to use your device that your engineers never really anticipated.

So once we have done this cross-functional activity where we get people that are not just engineers, we have lawyers and brand people and everybody come in, it's a large meeting and we've done that, and we've done a cross-discipline review to make sure that the decisions that we've made are properly supported by what we learned, we use a commercialization gateway. Basically, you have to be able to complete this gauntlet before you can go to commercialization. If you can't complete the gauntlet with acceptable results, you have two choices. You can redesign the device or you can -- and then put it back through the test loop again, or you can stop your project, archive your results, and put the information in your engineering practices archive for the next time you try to go through it.

If you get an acceptable result, you get a positive engineering recommendation; you can continue commercialization, and you can then go to include the outcomes of this work into your instructions to the consumers, if they require specific instructions. So what we tell the consumer is properly vetted to go with the device.

So I've been talking about standards. Standards, as has also been observed, have made a big positive impact in the safety of other devices that you have. Development of appropriate standards for e-vapor devices could do the same thing. The two that I'm offering you for consideration, because we have experience with them, is IEEE 1725 or something designed in scope for ENDS devices like it, and IEEE [sic] 62133, which is a very common but pretty effective standard for cells.

UL just released its 8139 Outline of Investigation, which we are studying very carefully. We think it would benefit from industry input. Consensus makes these standards work much better.

So, in conclusion, we need standards. If we don't have them, we can expect to see the same type of reports that we are currently seeing for adverse events.

Good manufacturing practices can improve manufacturing quality. They can improve, perhaps more importantly, traceability so we can find out, if there is an event in the field, where we have to go to get things back if we have to.

Regulatory practice: These are tobacco products by classification, but by nature they're electronic products. And the process required to maintain electrical quality in a changing and dynamic availability picture of parts and pieces is not the same as controlling a tobacco blend and its ingredients. And right now we would have to do a PMTA to make changes to the system or improve it or even maintain it.

And finally, adopting standards for design and testing can serve as the foundation for perhaps a faster and effective and reliable process for authorizing changes to maintain and improve safety for these devices without potentially taking 2 years to get an authorization for improvement, because 2 years is forever in the electronics business.

So thanks for your attention. It's a privilege to be here today with a very impressive group of folks here. So thank you.

(Applause.)

DR. YEAGER: Thank you, Mr. Burton.

So at this point, we're going to take a break, and we're a few minutes ahead of schedule, and that's good. So we'll come back at 10:55. Then we'll have Drs. Williams, White, Barnes, McKenna, and Mr. Burton up here for the panel discussion. We'll have index cards on the side, if you're looking for those during the break. And we'll come back at 10:55.

Thank you.

(Off the record at 10:36 a.m.)

(On the record at 10:57 a.m.)

DR. YEAGER: So for our first question for Dr. Williams, do you see any evidence to suggest that the e-liquid exacerbates the injury, i.e., spilling out and expanding the burn area, preventing the fire from extinguishing?

DR. WILLIAMS: Yeah, just to -- I'm going to break that question up. The actual liquid inside can -- am I still on -- serves as another for a chemical burn on top of the flame injury from the explosion. So you could actually have two components to that burn, a chemical burn, a flame burn, which makes it worse, deepens the injury, worsens the injury and leads to surgery.

As far as a retardant or limiting the extent of the burn, that I can't really answer.

DR. YEAGER: Okay. So Dr. McKenna, what portion of in-pocket explosions involved ENDS devices, and how many are batteries intended for use in ENDS?

DR. McKENNA: Approximately 45% of the devices or the incidents we looked at were batteries alone, spare batteries thrown in a pocket with their keys or change, and of course, we know what happens. There was probably 10% of the total number of devices in pockets where the report was specific enough to say the ENDS device itself was in the pocket. The rest of the devices, the reports were nonspecific.

DR. YEAGER: Okay, thank you.

Mr. Burton, the use of a cell phone is different from the use of an e-cigarette. One is running continuously, and the other draws a large amount of current in short bursts as the user is puffing. How do these differences influence assumptions made when designing e-cigarettes and safety?

MR. BURTON: So, yes, a cell phone has effectively a sleep mode where it's continually drawing current. It also generally has pretty sophisticated management systems to manage that current. So your principal concern on a cell phone is don't bring it down to the point where it shouldn't be recharged, and there is circuitry in there to take care of that.

So some e-vapor ENDS devices are continually active, and the ones I'm aware of have similar minimum discharge level controls. Basically, your battery spec has a minimum voltage beyond which it should not be recharged. That's part of the normal operating envelope for the battery. Below that, there are safety issues that can occur because you can plate lithium out of the battery-caused dendrites that pierce the separator and end up with an adverse event.

But frankly, the cell phone/ENDS difference in terms of continuous operation, I don't see that as being a driver for the frequency of events difference.

DR. YEAGER: Okay, thank you.

Would any other panelists like to comment on that?

(No response.)

DR. YEAGER: Okay, thank you.

So the next question is general. Why are explosions in pockets more likely? Does electrostatic buildup have something to do with it? Are ENDS just in people's pockets more of the time?

(Off microphone comment.)

DR. YEAGER: Go ahead.

DR. WHITE: I'll take a swing at that. The environment in your pocket is what does it, and it's not static electricity; it's the fact that you have keys and coins and things like that in your pocket, right? I mean, in an 18650 cell, the separation in the top cap between the positive portion of the cell and the negative portion of the cell is very small. So if you have something conductive in your pocket and the protective sleeve that's around the cell is compromised, you can cause a short circuit to occur in your pocket, and you get heating because of that.

DR. BARNES: I've said this to a couple of my colleagues. The other issue is that if a cell explodes in your -- or vents vigorously, even gets really hot in your pocket, you're likely to notice it and report it. If the same type of failure occurs in a more benign location, you may mumble something under your breath and throw the darn thing away.

Based on studies of battery failures that others have done, the ratio between incidents that get reported and are really serious and incidents that didn't get reported but would've been serious except that the person wasn't holding it in their hand at the time or something like that can be 100 to 1. And the ratio between those that result in reportable incidents and those that could have or almost were reportable incidents and instead it was just a dead battery can be 1,000 to 1.

So we only see or hear about those things that are so damaging or so dramatic that they get talked about. I mean, a great many people were surprised 2 or 3 weeks ago when almost 45,000 people a year are involuntarily denied transportation by the domestic airlines. It's been happening for years; it's in your ticket fine print. But there was one incident that suddenly made the news because it was much more dramatic than the other 44,999. And the same is true for battery failures.

DR. YEAGER: Okay, thank you.

Go ahead and identify yourself and proceed with your question.

MR. TYLER: I'm Matthew Tyler. Sorry, I'll stand back. My disclosure is that I work for a semiconductor company, and we are one of if not the world leading supplier for battery protection solutions.

Now, have you or any of the panel members been able to correlate design criteria or design thresholds in these systems with failure rates or thermal events that seem very tightly correlated to the number of devices in the market?

And the reason I ask that is that we see a very wide range of requirements coming in from different manufacturers. Some of them are very conservative, and some of them are very thoughtful and careful, and others are absolutely the Wild, Wild West. And it's deeply concerning for us as a solution provider, but I think that's an important piece of this discussion is to be able to correlate this back to are simply these failure rates coming because people are overstressing the batteries or damaging them by how they're using them?

DR. YEAGER: Repeat the question for the panel one more time.

MR. TYLER: So have any of the panel members been able to correlate engineering thresholds, discharge/charge currents, thermal limits, with failure rates in the field?

After we see a thermal event in the field, then we look at the device and we say, okay, let's characterize this device as it was intended to be used or as it was being used and look to see if there was any systemic design issues.

DR. McKENNA: I would love to be able to do that. It was tough enough. We tried to get, from the reports and reaching out, tried to get data on what the manufacturer or what the product number was, and it was just nearly impossible to do --

MR. TYLER: Right.

DR. McKENNA: -- in this environment.

MR. TYLER: In my experience, we actually just purchased several of these devices and did some lab characterization, and we found that the overwhelming majority of them were exercising the battery beyond its design criteria. And some of the components inside have tolerances that are irrationally large and will not protect the battery.

So in reference to Mr. Burton's presentation and looking at having thresholds or having a very clear process for characterizing and qualifying a design, I think this is an essential piece of the discussion because without that we're seeing a data trend and we're responding, but we have to have scientifically based, fact-based discussion around how we prevent that and how we keep people safe. I'll hold my other comments.

DR. YEAGER: All right. Dr. White, you showed a cross-section x-ray of a cell that was clearly made on a properly tensioned winding machine. Does he also have x-rays that can show a handmade cell for comparative purposes?

DR. WHITE: That data is available, but it didn't appear in this particular report. I think I can make it available if you -- if whoever asked the question approaches me afterwards.

DR. YEAGER: Okay, thank you.

Another general question: How often do people come in with a device that harmed them, and do you see patterns of injury associated with certain types of e-cigs, cigalikes versus tank mod systems? So how often do people come in with a device that harmed them, and do you see patterns of injury associated with certain types of e-cigs?

DR. WILLIAMS: I think that one is really for me to start. They come in often enough for us to want to look at the devices, and I'll say that -- I will say that when we had a large surge of incidences, they were during a time where -- and this is my ignorance, I don't know how to describe this, except that there was sort of a buffalo hump, that's what we call it, and the actual tube and then there is an extra component. I think you'll call it the tank system. A large amount of the patients that had injuries significant enough to warrant surgery, it was that particular device.

But we've seen them with, I'll say, all the ones that I have seen on TV. And it's not just e-cigarettes, but in particular for us, it becomes a huge issue just because of the resources required to fully treat the patient.

But the numbers, there's the number that requires hospital admission, and then there's the numbers of patients that don't. The numbers that don't far outreach the numbers that do, and I'd say about 10 to 20 a month in a clinic will come and don't require surgery, and that's pretty significant.

DR. YEAGER: This question is for Dr. McKenna. Does the NFIRS database currently have unique coding whereby firefighters can report fires attributed to ENDS devices, cell phones, and other battery-operated devices? If not, are there any plans to move in that direction?

DR. McKENNA: At present, the NFIRS coding system does not have a check field for these concerns. We've issued guidance to the fire service with how we could help. We asked them to code it certain ways and to put ENDS or e-cigarettes or lithium-ion batteries, as appropriate, in the comments field, and we can use data-mining tools to go through for that. But at present, we don't have an easy way to do that without the data mining.

It is unlikely that there will be any revision to the NFIRS system in the near term. It's a rather expensive and a rather lengthy process. There's a whole lot of people with their fingers in the pot and no money to do the job. So we would love to do this and several other things, but we just don't have the resources at this point in time.

DR. WILLIAMS: I'd like to comment on that as well. For physicians and the coding systems in the hospitals nationally, when we switched from one coding system to another back in October of last year, a lot of the burn diagnoses were dropped, and it was very difficult to delineate whether somebody had a burn from a flame injury, a chemical injury, or these products or battery-related products. When this was brought to the attention to the medical coding system nationally, there was a change and a shift, and we're able to capture those more, but I think that contributed to a lot of the data that was missing for national databases, and that's why you sort of have to talk to all the burn surgeons and trauma surgeons to try to figure out what they're seeing. But hopefully, that will be changed and fixed for everybody.

DR. YEAGER: The next question is a general question. What design strategies can help to prevent the battery from acting like a rocket? For example, do the prismatic battery explosions look different from explosions of other forms of battery cells or battery packs?

DR. McKENNA: The rocketing effect is caused largely by the rigid metal enclosure, the can. The prismatic batteries don't have that, or the pouch batteries don't have that. They're probably not a practical solution to use pouch or prismatic batteries in the ENDS devices simply because of how things are used. Under the current technology, maybe some really smart folks could come up with a way to do it.

DR. YEAGER: Thank you.

This next question is for Dr. Williams. You showed a slide with a number of admitted operated burn cases from a number of burn centers, when totaled about 75 cases. So can you explain -- and this is a three-part question -- how the numbers were obtained? (2) What time frame is represented in the count? And (3) what type of databases are typically available at U.S. burn centers in keeping this data? So how the numbers were obtained, what the time frame is of the count, and the type of databases.

DR. WILLIAMS: Okay, the numbers are obtained from the different burn centers and what they saw and what they were choosing to write up as their case reports. And since I was present at that meeting, you know, you talk to the other centers that are choosing to write up their case reports and case series, and we discussed what's happening, what they were seeing, and what we can do differently.

I will tell you that the American Burn Association is currently trying to do a multicenter trial looking at the injuries of e-cigarettes, and I know that because I'm a part of that group that wants to do that.

As far as nationally, there is the National Burn Registry that gets information from all of the U.S. burn centers and collects it, but it also requires that the different centers send that information. But if you talk to us, all of us are willing to share that information because all of us want to treat patients and make things better for them.

What was the second question?

DR. YEAGER: Time frame.

DR. WILLIAMS: For example, from Sacramento, they looked for the last 10 years, and they had 1 about 8 years ago and 29 from 2015 and '16. It's really been a surge in the last 2 years with the number of cases that have been seen nationally.

DR. YEAGER: And I think you already mentioned the database, so thank you.

All right. Then I have a general question. When are cells vented or not vented? How does venting work, and why would a cell be vented or not be vented? How does venting influence a potential for failure or explosion? So when are cells vented or not vented, and how does venting work, and why would a cell be vented or not vented?

DR. WHITE: The cell vent is a design aspect, and it's in there as a safety feature to help the cell fail gracefully. We obviously don't want cells to fail, but if they do tend to build up pressure, when they do so, we want to have a way for the pressure to get out that doesn't cause pieces of metal to come loose from the can, for example.

So they're designed to activate at a pressure that's below the bursting pressure of the can itself and typically the bursting pressure of the seal that holds the top cap in. That's for cylindrical cells. Prismatic cells are typically vented by making an engineered weakness in some portion of the cell can; a coin slot, for example, or a burst disk that's stamped in to the actual can that the cell resides in.

Pouch cells typically aren't vented because their failure pressures are quite low. You know, it's essentially a foil bag with polymer on both sides of the bag that's heat-sealed together. So as the cell warms up, it melts that heat-seal glue, and the pouch just tends to open up rather than to over-pressurize and burst. Did I catch everything?

DR. YEAGER: Yes, I think you got them.

DR. WHITE: All right, thank you.

DR. YEAGER: Thank you very much.

Okay, so the next question is for Dr. Williams. Were ENDS involved in incidents, those containing disposable batteries or rechargeable ones? So I think they're asking, for the incidents involved, were the ENDS -- did they have disposable batteries or rechargeable batteries?

DR. WILLIAMS: The majority were the rechargeable batteries, but we did have patients with disposable ones.

DR. YEAGER: Okay, thank you.

So then, this is a general question. To what extent could the incidence of ENDS battery incidents be underestimated and why? It's a general question for the whole panel. To what extent could the incidence of ENDS battery incidents be underestimated and why?

DR. McKENNA: Based on what we see as -- or we believe is the trend in underreporting and fire incidents in general, I would expect that we are -- the numbers I flashed up, in terms of the number of incidents, not to do with the severities involved, but in terms of the total number of incidents, I'm guessing we're down by a magnitude of 10, an order of magnitude, that most of these things happen and they're not a big deal. They stomp on it and they walk away from it and pick it up and throw it in the garbage.

DR. BARNES: I have no data on ENDS systems, but in other battery systems that we have tracked, that's exactly what we learned, that most of the incidents didn't get reported. And as I said earlier, based on one or two studies where they did teardowns of batteries that were flagged as behaving peculiarly but did not fail, they found that there was a very large ratio between vigorous failures and almost failures, something on the order of 100 to 1. So for every one that, if you'll allow the usage, blew up, there were another 100 that were not healthy but didn't blow up. But this is not ENDS generally, and this was other technologies.

DR. YEAGER: Thank you very much.

Please identify yourself and proceed.

MR. TYLER: I'm Matthew Tyler. I apologize for asking two questions. So a lot of work has been done to characterize these cells under their most catastrophic circumstances. We heat them up, and they explode. It's, you know, exciting. I think what's more important to understand is what happens on, you know, the tail of the distribution of a new manufacturer of tens of millions or hundreds of millions of these cells, what's happening? What are the manufacturing tolerances that could lead to slow degradation, and how do we identify those in the ENDS system?

And I'm curious if any of you have experience or have been looking at what are, you know, the dielectric thicknesses, you know, voids or damage to the separator or any of these physical things that may lead to accelerated degradation of the battery and what that might manifest itself as in the system.

DR. WHITE: The literature that addresses that question is really thick. It's essentially what's been going on for the last 25 years in the lithium-ion battery industry. The industry has evolved through a learning process about how these materials interact in all the environments, right, not just in exciting hot environments where sparks shoot out of them, right? I mean, there's no one easy answer to that question, but the knowledge is out there, and it, I think, simply needs to be applied in the right way to any system, not ENDS, exclusively in ENDS systems, but in all the systems, you know. And the mobile device community and the mobile computing community, I think, are probably doing the best job of understanding the breadth of knowledge that exists about lithium-ion cells and then implementing that in the design and engineering of their devices, and it could be that just an evolution of these new industries is timely.

MR. TYLER: May I ask a follow-on question?

DR. YEAGER: You may.

MR. TYLER: All right. So, Mr. McKenna, you made some comments about, you know, the current generation of devices or how they're used and that the form factor or the user preferences are kind of dictating the use of these 18650 style cylindrical, you know, metal can cells.

As we look at other industries that use lithium-ion batteries in tremendous numbers and, I think, have a very good safety record, you know, in terms of the number of devices per million that actually have an issue, do we see any correlations to failure rates and the style of cells or the energy that tends to get released per unit area of battery? What I'm thinking is, is there ultimately, for safety reasons, a transition coming where we have to start looking at ENDS devices that get designed with lithium polymer pouch cells because the vapor pressures are lower and they're less likely to be energetic, even if that's a form factor that may be less attractive to the end user?

DR. WHITE: So I think the fairest way to characterize the severity of a battery is simply by its capability to store energy, right? And the reason I say that is because the capacity correlates really well with the size of the cell.

And as I mentioned, the biggest problem isn't the chemistry or the electrochemistry; it's the fuels that are present in the system along with the thing that's able to start those fuels on fire, right?

So there are engineering tradeoffs in every design space for every type of product, and that includes ENDS products as well. And it may be that there is some viable design space that uses a different form factor. The bottom line is the amount of energy in there is part of the design, right? And that, to some extent, is going to dictate the severity of what happens. You also have to appreciate that a lot of the problems come from the enclosure itself. So taking away the steel can of an 18650 and replacing it with a pouch cell but still wrapping that in a metal container really doesn't get you any further.

MR. TYLER: One more if we've got time.

MR. BURTON: I'd like to talk a little bit about that briefly. Your question seemed to address opportunities for design approaches, and what we need to remember, I think, is that these cells become reality because the design is translated through manufacturing.

And so to go back to some things I said earlier, if your manufacturing process is not in control, if you don't have appropriate statistical evaluation of what you're making, you can establish very effective parameters in design that won't actually make it to the product. And I think that that plays a larger role in the failure rate for these batteries than we've figured out how to measure.

MR. TYLER: I would completely agree with that comment. And the last question, and then I promise I'll stop. In some regions of the world, there's a limit on battery capacity that you can take with you and travel, you know, air travel. Do we anticipate a need for a battery size limit with ENDS devices? Do we anticipate that for safety reasons, that there should be or there is a need for a battery size limit or a capacity limit with these sorts of devices?

DR. YEAGER: Dr. McKenna, back and forth, yes or no, maybe?

DR. McKENNA: Well, that's certainly been the approach the airline industry has taken and the FAA in general. Whether they're going to take it to say -- let me step back. Part of the calculation that's used often, as we talk about energy capacity, they tend to look at what's on a label that says milliamp hours. The bulk of the energy capacity is in the flammable liquid or the combustible liquid, and that's the electrolyte that produces a bit more energy than the electrical energy.

So when they look at that calculus for how much energy is in that container, it has not, in my experience, included the total of the energy present or the total potential energy. And will we see something in the future in the airlines or even in the shipping industry, I can't begin to guess.

DR. YEAGER: Thank you.

MR. TYLER: Thank you very much.

DR. YEAGER: Thank you very much.

We have a couple questions. Can I get 5 more minutes on the clock, please? So there's a clarifying question. If the venting is flammable or toxic gas, is there an alternative safety feature to vent holes to prevent rocketing? And that question is for anyone on the panel. So if the venting is a flammable or toxic gas, is there an alternative safety feature to vent holes to prevent rocketing?

DR. McKENNA: I imagine one could design the cell so that the pressure relief would be more abrupt and less focused. There are tradeoffs in designs for that. I'm aware of a number of people who are desperately working on alternative chemistries to eliminate the flammable and combustible electrolytes that are used. They're not going to happen in the near term. It's just too tough a problem to solve.

DR. YEAGER: Thank you.

So Dr. Felicia Williams stated that the majority of battery explosion injuries happened at the beginning of 2016. Is there a theory of why the rate of injuries from battery explosions decreased in the second half of 2016?

DR. WILLIAMS: I'm assuming that one's for me, too. We were speculating, we, being my partners and I, that it was associated with the control of the products being better regulated, but that's just speculation. I don't have a concrete answer for you.

DR. YEAGER: Go ahead, Dr. McKenna.

DR. McKENNA: Typical with emergency incidents of this type and fires in general, they tend to be -- occur in clusters. It's not unusual. You have the full moon effect or the butterfly in New Zealand effect. It tends to impact just about all of the kinds of incidents. We'll see a cluster of e-cig problems and we'll see a cluster of idiots running around with a can of gas and pouring it on a camp fire and we'll see a cluster of each of these general types of events.

So I tried to look at this as I went through the data, particularly with respect to the severe injuries, and I saw your cluster. But then, as your cluster started to fade, I saw a cluster pop up in Seattle. So it's probably just randomness.

DR. YEAGER: Okay.

DR. WILLIAMS: Oh, I do want to -- just one thing about the data about severity. So clinically, inhalation injury increases a patient's risk of death 20 times. So while it's designated as a minor injury for the U.S. Fire Administration, for us that is a significant injury. And so I think that's important just to put out there that a minor injury for a database is relative to what you're studying, the question you're asking, and how it impacts patient care.

DR. YEAGER: Thank you very much.

And then this, again, is a general question. What are some examples of user abuse, and is there a way or ways to design lithium-ion cells to resist this abuse?

DR. WHITE: So as I stated during my talk, there's really no end to the creative ways that people mess with consumer electronic devices. I mean, examples of user abuse are leaving your laptop computer on your stovetop while it's still hot or, you know, running over your cell phone with the car or putting it in a microwave. So that's an example of one that we've seen.

So that equates to user abuse, right? I mean it's, generally speaking, doing something with the device that it was never designed to have done to it. So examples, and then what was the other part of that question?

DR. YEAGER: So are there ways to design lithium-ion cells to resist this abuse?

DR. WHITE: Yeah. And that's the goal of all of these device manufacturers, is to come up with some kind of a design that provides a safe environment for the lithium-ion cell to exist in. But there's a limit to the amount of safety you can put around something and still make it useful. If you make it so safe that you can't touch it anymore, it's not a useful product. So there are tradeoffs that have to be considered all along the way.

DR. YEAGER: All right. Well, I'd like to thank the panel, and we'll move to our next session. Thank you very much.

So as the panel is clearing out, we will transition to Session 2, which is Cell, Battery Pack, Charging Safety, and Risk Control. And we will be starting off with Jeremy Carlson with Lenovo Strategic Technology Innovation Center.

MR. CARLSON: Okay, the first thing is just I'd like to thank the organizers for inviting me here. It's been great already today to see the previous discussions, and some of the questions, people are thinking about the right things and asking the right questions. So I'll talk a little bit about just an overall design for safety idea, not specifically for ENDS devices because I'm not an expert and shouldn't be speaking about it. But my expertise comes from the mobile side and the notebook computer side.

(Off microphone discussion.)

MR. CARLSON: Oh, now we're at the end. Oh, jeez.

(Off microphone comment.)

MR. CARLSON: All right, that's what I was doing, but -- yeah, now we're at the end. Okay, I'm going to let somebody else touch this.

UNIDENTIFIED SPEAKER: I got it.

(Pause.)

MR. CARLSON: Okay, all right. So just a quick overview of what I'm going to talk about. We'll talk about the idea of a system-level design, and I'll look at the cell itself, the battery pack, the charging system, as well as the host device. And then just very quickly, I'll speak about failure analysis.

So, initially, I wasn't going to talk much about the cell. There was supposed to be a speaker going in front of me that was going to spend some time on the cell, but he wasn't able to come. So the cell is really the most critical part of this system. Adding circuitry and designing the system, it can't make up for a poorly designed or a poorly manufactured cell. So I can't overstate that enough. The manufacturing of these cells is where most of the events I see, where it goes wrong. And these are companies that, you know, manufacture millions and billions of cells with no problems, and there's one excursion with a single machine that has a problem, and that translates to failures in the field.

So while all of this other design that we're talking about is great, that it has to be focused on the manufacturing side is extremely important.

Then this little diagram over here, this comes from IEEE 1625 and IEEE 1725 was mentioned earlier. It's very important. While that's not directly applicable to ENDS devices, they're very similar applications as this idea of thinking of the whole system to keep the battery safe.

It's also very important to know that these standards were written by cell manufacturers, battery pack companies, you know, OEMs. They all got together and worked on this together and came to a single conclusion. And that's a huge, huge thing. It's not easy. It's a room bigger than this, more people than are in this room right now, all got together and worked on this for years. And those lessons, you know, that were put into that should be utilized by everybody moving forward. You know, industries don't need to relearn these things because they had more problems.

So one of the most important parts is that the cell must be kept in its safe operating range that is defined by the cell manufacturer. It's not designed -- you know, defined by me or somebody else who maybe knows about batteries. It's defined by the people that designed and made those batteries.

And doing that will limit the degradation and the changes to the cell that can lead to a reduction in the safety overhead. We've talked about, you know, cells that -- you know, what happens when you heat them or when you overcharge them. It changes from Day 1 to Day 300, and that change will be different, that if it's always charged to its proper voltage or it's overcharged a little bit each time, that changes, the safety margin changes.

And then every portion of the system, the cell, the battery pack, the host device, the charging, the power supply, all of these things have to work together to keep the battery in a safe operating range under normal use and as safe as possible under foreseeable misuse.

Some comments that were made a little bit earlier, you know, there's no end to what people will do to these things. I've seen a laptop computer run through a table saw. There's nothing you can do about that. But as far as, you know, using it in a hot environment or using it in a cold environment, that's foreseeable kind of misuse. Not the way we want to, but it's going to happen.

So looking at the battery pack, we call it the BMU, the battery management unit. It's the last line of defense to protect the cell, and it protects against overvoltage, undervoltage, and overcurrent. So it's really there to protect against faults in the charging system and the host device. This isn't something you want activating under normal use. It should be designed -- all of your system tolerances should be designed so that this is only there as a last resort.

For battery packs that are removable, they should also protect against incorrect chargers, that if you plug it into anything else -- people are inventive, they'll figure out ways to charge, you know, a USB device with a 12-volt charger. I've seen it. They'll figure out a way. And then also to protect against short circuits, you know, because people do carry these things around in their pocket.

And then the last thing is, when possible, the battery pack should be permanently disabled when it's exposed to conditions that change or compromise the safety of the battery. That's a hard thing for device manufacturers to swallow, but it's extremely important. I know the next speaker will talk about what happens when batteries are overcharged or charged in low temperatures.

These things make a significant change in the safety of the battery, and when that happens, to protect the user, the best thing you can do for them is say you can't use this battery anymore. You did something bad to it, and you need to get a new one.

So looking at the next kind of layer of the onion, the charge system, so the charge control should be designed to keep the charge voltage and current in spec and to properly terminate charge.  You don't want to just continually charge these cells.  And a very important factor is that needs to change based on the cell temperature.

Again, we've got a nice diagram here from IEEE.  But at low temperatures, you need to lower the charge current.  The cells cannot accept charge as quickly, so you need to lower that charge current.  At high cell temperatures, you need to lower the charge voltage.  And below the minimum voltage and above the maximum -- I'm sorry, below the minimum temperature and above maximum temperature, you don't charge.

Again, this is just how you have to treat this battery to keep it safe.  And these temperature charge limits, again, are defined by the cell manufacturer.  This will change based on, you know, every different cell will have a different set of parameters here.

And then this should not depend on the BMU that I mentioned in the last page, to keep this in the operating range.  You shouldn't be depending on those, you know, last line of protections to say, oh, the voltage is too high. The charge circuit should never get above that, and that's taking all of these tolerances into account.

Okay, I hit the button, but I don't want to hit it again, so I'm going to wait. There we go. I've learned. Oh, no, wait, I backed up.

(Off microphone comment.)

MR. CARLSON: Yeah, okay. And then to look at the host device, so the host device needs to be designed so that under normal use the cell was kept within its operating parameters for voltage, discharge current, and cell temperature. So one of the first things is, you know, when the cell gets below its end-of-discharge voltage, you can't discharge it anymore. It's typically 3 V, but it can change.

And then the discharge current is one where I see, with my very limited amount of research into these devices, that could be a major problem. You know, the discharge current should remain under the maximum discharge current specification for the entire discharge.

So a cell will typically have, you know, a maximum discharge current for a short period of time. Sometimes that's in seconds, and sometimes it's in minutes, but you need to stay within that. And a lot of devices that are constant-power devices, at the end of the discharge, the voltage is lower and the current goes up a little bit. So you need to make sure that during the entire discharge, you stay in that range.

And then also, you need to make sure that the battery is kept in its operating temperature range. The batteries themselves will heat up as you discharge them, just due to self-heating. They'll heat up from other things in the device. You know, for my devices, it's typically a processor or a GPU. In these devices, you're heating up a coil that's going to be fairly near to the battery, so you need to make sure that everything is -- that the batteries are in the right temperature range.

And then under foreseeable misuse scenarios, you should design it to keep the battery as safe as possible. I know, in this industry, a lot of modifications happen. So you take a coil that was designed for a certain resistance, and now it's, you know, a third of that or a fourth of that. That's going to make the battery heat up. You can have a much higher discharge current. You're going to have more heating in wires and contacts. You know, it's not just one thing; you're changing the entire system.

And then you have accidental activation. I know some devices, you know, you can only activate for a certain amount of time. Some devices have no intelligence whatsoever, and if you're holding down the button, it's just going to be discharging the battery.

Okay, now I'll spend a little bit of time on failure analysis. I was asked about this. That's one major portion of my job; I do investigations for any of our reported safety cases.

So all battery failures need to be fully investigated by all applicable parties. So we had a question about, you know, basically the battery safety chip that's used in there. You know, you need to look at -- you have a failure. You start going through this failure analysis, and anybody who's done this knows failure analysis work can take months. Sometimes you can figure out a root cause very definitively in a number of days. Sometimes you work for 4 to 6 months, and the best you get is, you know, a most likely root cause.

But you have to have the host device manufacturer. You need to have anybody that's giving you circuitry, whether it's your charger designer, your cell company, and all of these companies need to work together to go through this, and there needs to be a feedback loop much like we saw the design feedback. But there's a separate loop there that once you start to have a failure, it needs to come back into that loop as well.

So there are really three categories of failures that I deal with. We have internal cell failure, electrical abuse, and what we call mechanical abuse or thermal abuse.

So in an internal cell failure, that's typically a manufacturing problem. You get foreign materials inside these cells, and over time and over many cycles of charging and discharging, it creates an internal short, and you have a failure.

So the type of analysis you do on these is you do the same type of x-ray work we saw, CT scans, and cell disassembly. If you take a battery apart, even though it's had a failure, and we've seen pictures of cells with failures, you can learn a lot by taking them apart.

And then from that your corrective actions, you know, you can improve the cell design. If you look at what cells look like, the 18650 cells in 2003 to what they look like now, it's quite a change. I mean, they're the same size from the outside, but internally there's a lot of differences. And it's really amazing to consider that they've about doubled in energy density as well.

And then also, really, the important one that I've seen and done a lot work with myself is improving the manufacturing process. Almost every time that I deal with a cell failure, that translates to something that happens in -- some improvement that happens in cell manufacturing. You know, 6 months later you find out that a machine had a problem; you go and fix that machine and you fix every other machine that that company has.

So electrical abuse, you know, the analysis, a lot of it is electrical testing and failure mode analysis. So this is typically, you know, once you start looking at all of your tolerances, maybe you missed something or maybe something was unexpected or somebody plugged it into something you didn't know you could plug it into.

So these are typically the corrective actions: You improve your circuit design. Do you have to beef something up because somebody could plug in a different USB adapter? Or also you can again improve manufacturing. We've had some problems at my company that we just didn't see a certain thing, you know, we didn't think it could happen, but we had to improve the manufacturing the way we designed some battery packs to protect against some electrical abuse situations.

And then the last one, mechanical abuse and thermal abuse. A lot of this is simulation and reproduction testing. This is a difficult one because you can't test and simulate for everything that people can do. But you can go and look at what's the most likely scenarios. With laptop computers, people drop them, people put them in bags and bang them into stuff, so you have to test for that. And then corrective actions, they are typically improving the cell protection and improving the way you inform your users what they can and can't do.

You know, at Lenovo, we actually had a recall because we had a system that if you dropped it one way everything was fine, but if you dropped it at, like, a very specific angle, it just wasn't protected against it. So, you know, we had to go through and figure out how to improve the overall cell protection and improve our testing, and now we do a lot more testing, kind of random drops to see what we get.

And then it's also very important that every time there's a failure analysis, you check what you just learned against what you learned over the past 10 years because you have to look for patterns, and that's really where, when you have a manufacturing excursion, it doesn't happen once.  You know, you don't have that these cells are made, you know, 50,000 a day and if you have a manufacturing excursion there's not just one that's bad that day.  You get lots of them that are bad that day.

So you have to keep looking at this again and again and again to find these patterns, and then you start to realize, oh, we had a problem here.  Then you start digging into manufacturing data and you go in there, and that's when it gets -- you know, it starts taking a very long time to go through these things.  But you have to do that to figure out where a problem existed so you can fix it and potentially go get things out of the field, if necessary.

And then, also, you need to continuously improve all aspects of the manufacturing design as you go along.  Again, don't just learn from your own mistakes, learn from the mistakes and the lessons learned from the notebook industry or the cell phone industry.

All right.  And I'm on the yellow light, so this is working out pretty well.  So, in summary, again, the entire system has to be designed to work together to keep the cell in the safe operating area.

Any excursions outside the safe operating area have a cumulative effect. You know, the first time you overcharge it by a tenth of a volt, it's not going to start a fire. But the more you do that, the more that cell changes.

And then the last point, I can't say this enough, continuous improvement is absolutely necessary. Learn from past mistakes and learn from other industries.

Thank you.

(Applause.)

DR. YEAGER: Thank you, Mr. Carlson.

So the next speaker will be Judith Jeevarajan from Underwriters Laboratories.

DR. JEEVARAJAN: Thank you. Okay, so today I'm going to talk about the chemistry basics. You heard quite a bit about it, so I'll just touch on it: some of the typical charge protocols we've seen in the commercial industry and in commercial products, some hazards associated with charging, concerns with the charger proliferation we're seeing today, and summary and recommendations.

You've seen this chart before; someone else presented this, this morning. The lithium-ion chemistry is a very simple one. If you look at battery chemistries, it's got a cathode and an anode, and the cathode is usually lithium metal oxide. And today we have several different types of cathodes in the market. We do have high voltage, the typical traditional voltage, as well as the voltage cathodes.

And the anode is carbon, and it's a very simple system where all we have is lithium-ion going between the cathode and the anode, and there is no other chemical reaction that's actually happening.

And the lithium is held in between the layers of the carbon during the intercalation process or the charging process, by what is called van der Waals attraction. There is really no chemical reaction again happening there. And during the discharge process, the lithium ion goes back to the parent compound.

We do have several types of electrolytes you can have, but the main changes are in the components of the solids. In most cases, the lithium hexafluorophosphate salt is very common through all the combinations of electrolyte that you can see.

So I mentioned that there are many different types of cathodes that people can use, and of course, there a few different anodes also that can be used, but I'm going to focus a little bit more on the cathodes.

So the lithium cobalt oxide with the carbon is what was first used starting from the early commercial products, and that's the one at the top left end.

(Off microphone discussion.)

DR. JEEVARAJAN: I'm trying to find -- okay. So that's the cobaltate, where your rate of charge voltage is 4.2 V. Once it reaches 4.2 V, then we hold it at a constant voltage until the current falls off. And it's usually a predetermined value when we start the charge.

If you look at the NMC, which is a more recent development, we can actually charge it up to 4.35 V, and several commercial cells allow you or give you that specification that says that you can charge to 4.35 V.

Then you go down to the iron phosphate system, the LiFePO4, again with the carbon, and that is charged only to 3.6 V.

So you can see that different cathode chemistries can give you different end-of-charge voltages.

Going on to the next slide, okay, this is a typical charge profile that we recorded with traditional consumer equipment. This is what I actually recorded in the early 2000s. The one on the left is a laptop lithium-ion battery, and the one on the right is a camcorder lithium-ion battery, and what you will notice is that in all of these cases, the current that is used to charge the cell actually starts dropping off even before the cell or the battery pack reaches end-of-charge voltage.

That actually is a feature that had been incorporated into pretty much all the current consumer equipment in the past. I don't see that much -- I don't see that design in the more recent ones because of the way these things are built cheaply, and also, they don't follow the traditional safe mechanisms.

So this is another charge profile that I wanted to show you between what it looks like for a fresh and cycled cell. If you look at the picture on the left, actually there's this aging test with cells and modules, where I used a full manufacturer's voltage range, and what we found is that the one on the left is 4.2 to 2.7 V, which the manufacturer recommends, cell manufacturer recommends. And with aging, you can see that the profile actually changes, even profile, meaning the time it takes for a cell to reach a certain voltage is much shorter in an aged cell than it is with a cycled cell. But the charger, even if you're using a regular charger, that charger does not recognize the difference between a fresh or an aged battery or an aged cell.

I also wanted to show that if you actually reduce the range that the manufacturer recommends, for instance, in this plot on the right we had the same cell that was exposed -- or that was cycled between 2.9 V and 4.0 V while we reduced 200 mV on each end, and you can see that the number of cycles we got was almost triple that of the one we got where we used the entire manufacturer's voltage range.

This is just one incident where I was given this information by a friend, a colleague of mine.  Her niece had a failure with an e-cigarette battery.  She had just, you know, picked it up and was going to turn it on, and she had this explosion where actually the battery flew out.  She was burned, and you can see that a lot of furniture was also damaged, the furniture, there were marks on the ceiling, the drapes were burned, and so on.

So what I had done was -- and I'll talk a little bit about this.  I actually took that same set of battery, e-cigarette, and the charger, and that combination, and I did some testing, and I'll show you just one result from that.

But I wanted to go back to the hazards that are associated with lithium-ion batteries.  There are several different hazards. Of course, overcharge is one of the catastrophic ones. External shorts or internal shorts are the other types that can cause really catastrophic events. And, of course, extreme thermal environments.

I wanted to focus on overcharge and overdischarge. If you look at overdischarge, overdischarge by itself actually just kills the cell. You have dissolution of copper, which spreads on all the cathode, anode, and electrolyte and separator, and it becomes a dead cell.

But when you have subtle overdischarges, then -- and if you have a string of cells and you're not monitoring every cell voltage, you could have an instance where one of the cells is inadvertently overcharged.

The other thing that can also happen, which I'll talk in more detail in the next couple of charts, is that you could actually cover the intercalation sites with the copper, and so there is no area for the lithium ion to intercalate.

All of these hazard causes can also lead to what I call misuse in the field leading to internal shorts. So internal shorts can be caused either by manufacturing defects or by misusing them or by design.

So with overcharge, we rarely have either overvoltage or a high-rate charge. You could have electrolyte decomposition, and you could also have cathode destabilization. In some cases, like lithium cobalt oxide, when you go above a certain voltage, you actually destabilize the cathode, and so the oxygen is released very quickly from the cathode.

But in some cases, like the iron phosphates, where the oxygen is actually attached to the phosphors rather than the metal, it's more difficult to get the oxygen out. It also happens with the spinels where they're meant for cathodes. It's more difficult to remove the oxygen from that spinel compound.

But with respect to the cobalt oxide or the NMCs, it's very easy to release oxygen. And so when you're at high voltage and you have oxygen that is released and you have a warm electrolyte, that's a good recipe for a catastrophic thermal runaway.

One of the things I wanted to show here was the lithium dendrites. If you look at the picture on the right, you actually see a really good cathode -- sorry, a really good anode which has lithium intercalated, and so it has a really smooth gold appearance.

But when you have a design where the design of the cell is really not done well -- in this case, where you see these gray areas in the electrode, it's where the current collector fingers were actually covering the cathodes.  And so -- sorry, were covering the anode.

And so when the lithium intercalates, it could not really intercalate into the anode itself because of the metallic current collector fingers that are on top of it.  So it actually formed lithium metal dendrites; it can actually form metal dendrites very close to the areas where it was -- where it had been prevented from intercalating into the electrode itself.

So some of the things that you would see in commercial cells are safety features that are internal to the cell.  With the cylindrical cell, for overcharge protection there is what is called a current interrupt device.  It's actually two disks that are touching each other in just one location, and it's a mechanical design.  And when you have gas buildup inside the cell, in cylindrical cells as well as in prismatic metal can cells, there's actually a compound that is added to the cell so that when the cell gets to a certain voltage, there is a release of gas.  Carbon dioxide is actually produced to activate this current interrupt device while the two disks then move apart due to the increased pressure and you have a disconnect. This is a permanent disconnect in the cell, and so you -- electrically it is disconnected, it is safe, but then you have to remember that internally it is actually overcharged.

But in many cases or I would say traditionally this current interrupt device, at a single cell level, always works. It has worked traditionally in all cases.

The same feature actually exists in the prismatic metal can cell also. It has a current interrupt device that works extremely well.

But in the case of the pouch cell, you do not have those types of features. So when you have a pouch that is overcharged, depending on the current that you're using to overcharge, it can actually go into pretty big -- into a pretty big fire and thermal runaway. And the pouch actually expands and since the vent -- sorry, the pressure at which the pouch actually opens is very low, which is like 50 PSI, you can have the gas and electrolyte come out of the pouch, fall on the hard pouch, and then have another flash point, which can lead to a catastrophic runaway, too.

Some pouch cells are actually fitted between the two tabs with this protective circuit board that will protect for overvoltage, undervoltage, and overcurrent. But in most cases you won't find that. If you're using pouches, I would recommend that that additional safety feature will actually help you be safer.

Some of the challenges we've seen with more recent cell designs, this is the latest, I would say the highest capacity cell that you see in the commercial market, and it is also from a top-tier manufacturer. What we found is that the CID activates, but it does take a longer time to activate in some cases.

And what we also found is that the temperature still keeps increasing even after CID activation.

What we also found when we opened up the cell is that there was charring that was observed under the header of the cell, and there were parts of the electrode that were also charred. When we did a short-circuit test again, you know, we found that there were edges of the electrode that were actually affected even though the safety feature inside the cell activated.

This is the overdischarge hazard that I talked about. Even though the cell is what we would call dead at the end of a complete overdischarge, that can be subtle overdischarges that can actually cause dissolution of copper in very small ways, where it covers up electrode surfaces or the separator surface and prevents intercalation.

Though, I think Jeremy mentioned, he talked about how you have a constant power load sometimes, and as your voltage goes down, your current goes up.  But your voltage is going to react to the excessive current.

So in some cases, if you're not recording or if you don't understand and characterize your loads completely, you might have small excursions where your voltage actually goes to very low values and you do have copper dissolution taking place.  So you can have either a benign situation where you really kill the cell, or you could have a situation where you've actually deposited so much copper that now -- and also you've decomposed your electrolyte at the lower voltages, that you start building up heat, and you also start having lithium dendrite deposition rather than intercalation.

So this is a test that I mentioned.  I used a combination that I was given by my colleague that had the incident, and we did some tests; quite a number of tests were done on this.  And what we found in the particular combination that we used was that there is really no undervoltage control in the device that we used, in the e-cigarette that we tested. But of course, at a certain point, because the e-cigarette needs a certain power to work, it stops drawing power from the cell.

But there really is no protection for undervoltage at the equipment level. And so this particular cell was actually overdischarged below 2 V, and in general, lithium ion should not be discharged below 2.7 V, maybe 2.5 at the lowest, depending -- again depending on the chemistry.

I just wanted to say a few things about low temperature hazards again. As you lower the temperature, you've got to -- I think someone talked about it. Jeremy mentioned it again. As you lower the temperature, you've got to lower the charge current, unless your electrolyte is actually capable of performing at low temperatures. Like the cells we designed for Mars applications, they used a low temperature electrolyte that was very good even down to -30 degrees.

But in most cases, in traditional lithium-ion cells, even at 10 degrees C, you can see that there is increased viscosity in the cell, and so you can start depositing lithium metal rather than having lithium-ion intercalation.

And I just have a couple of pictures that I can show you.

One is to show you that lithium dendrites can be found, and that picture was actually from a cell that was exposed or charged at 10 degrees C. We could see the lithium dendrite formation in that.

And the one on the bottom is an aging study again, where I looked at cell resistance changes with temperature.

So the other issue that I wanted to mention was the proliferation of chargers. This is just from one vendor selling e-cigarettes. There's a whole bunch of chargers, and as I had mentioned before, depending on whether you're using an iron phosphate cell or a cobaltate cell or an NMC cell, the end-of-charge voltage can be very different.

So how does this charger know when you're just taking a cylindrical cell and plugging it into the charger, how does the charger know what type of chemistry you're actually working with? How does a charger know that you've got to charge only to a certain end-of-charge voltage? How does a charger know that you've got to change the charge current based on the capability of the cell itself? So there are a lot of concerns with the proliferation of chargers.

One of the things that I also wanted to point out, this is another e-cigarette battery vendor, again -- you know, I think they have a whole bunch of chargers that you need to have so you can have it everywhere you want to use it and have the flexibility of charging it at any time. That's what they advertise.

This particular one in the middle was a big concern for me. It actually says you can put any cell in it, any sized cell even, and use it to charge it. So like I just said, you know, there are so many chemistries, so many end-of-charge voltages, so many rate capabilities that these cells, you know, have limitations on, and if you are going to use a universal charger to charge up any and all of these batteries, then that can be a huge safety concern.

I just wanted to reiterate it and show you the slide again. There are different chemistries, and so they have different end-of-charge voltages.

So what are the concerns? The chargers should actually take into account the different end-of-charge voltages. It should be based on the cell chemistry. And a lack of this type of feature will lead to overcharge of some of the chemistries.

And it should be dedicated to charging the specific product and should not be a generic charger. You know, it should be based on the rate capability of that cell, you know, what chemistry, like I said, it should be. And also what it's being designed for, what is its pulse capabilities and so on.

And it also needs to be able to cut off charge current as soon as the current falls off. You shouldn't have, like, a small trickle charge on it all the time.

The charger also needs to have protective features for voltage and current, as well as temperature, and it should be able to carry out a health check on the battery before charging is attempted, for instance, a new fresh cell was in each one.

In addition to all of this, the battery itself, I think, should be independently fault tolerant.

I just wanted to conclude with some approaches. You should be using it within the cell or battery manufacturer's specification for current, voltage, and temperature.

And it should be qualified. One should understand, you know, what the requirements are for the application and also design the charger with respect to that.

And a faulty design doesn't always lead to an immediate failure. It's a cumulative effect. As you slowly take it beyond its limits, you will accumulate the effect, and then it ends in a very big catastrophic failure.

And reducing the voltage range is actually good. Complete characterization is necessary, and testing stringently and the relevant configuration is also important.

And thank you.

(Applause.)

DR. YEAGER: Thank you, Dr. Jeevarajan.

At this point we're going to break for lunch, and we'll return at 1:00 p.m. for a continuation of Session 2. Thank you.

(Whereupon, at 12:15 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: Okay, good afternoon. We will be resuming Session 2, Cell, Battery Pack, Charging Safety, and Risk Control, and our next speaker is Jonathan Carter from the Federal Aviation Administration.

MR. CARTER: Okay. Now, how am I driving? I heard that I can use arrows, something simple.

(Off microphone comment.)

MR. CARTER: All right, I'll try that. Thank you. Notice he didn't say Ph.D. or PE or anything after my name, so this is going to be a significant drop from the technical, from the last presentation.

FAA obviously has lots of brilliant engineering and technical folks; I'm just not one of them. I work, you know, explaining regulations to people and trying to make those better for everybody involved.

We do have a great FAA technical center in Atlantic City, New Jersey that's done a lot of testing on lithium batteries, particularly bulk ship, cargo shipments of lithium batteries, which is not really the focus here today.

And let's see. So the overview. We'll talk about the

FAA's role in e-cigarette and lithium battery safety in general because we've been dealing with lithium battery fires both in passenger baggage, in the cabin of the aircraft, and in cargo for many years.  We'll talk a little bit about FAA testing and research on the lithium batteries.

The DOT has its materials regulations that we enforce and how e-cigarettes and lithium batteries fall under them both as cargo and, more specifically today, what people are allowed to carry with them.

UN transport testing for lithium batteries, that's a transport standards testing that's come to be the default for batteries, lithium batteries, in general.

I'll talk to you about some of the aviation incidents that we've had and some of the outreach and guidance that we try to do to the industry.  And to the users.  All right, I'm not having success on the clicking.

(Off microphone discussion.)

MR. CARTER:  So as I said before, we -- FAA Office of Hazardous Material Safety, we do responsibility and oversight of air transportation hazardous materials.  Traditionally, most of that work is in cargo, large cargo shipments, small cargo shipments, either on cargo aircraft, like your FedEx, UPS, but also on passenger aircraft. They make significant revenue putting cargo on their aircraft, even more so today since so many people don't want to pay to check their bags; there's more room for actual cargo on that plane you're flying on.

Anything carried into the cabin by passengers, that, too, is a subcategory of the whole cargo baggage. You are basically paying to bring that from Point A to Point B, so that is hazardous materials in commerce if it is an e-cigarette or lithium battery.

So hazmat inspectors for the FAA, we do a lot of follow-up on cargo shipments. If something happens in the cabin or in a checked bag involving a lithium battery, a fire or something like that, we inspect that, too.

We will bring a civil penalty against an airline passenger depending on the culpability of their actions. We have fined airline passengers at least once, a civil penalty, because of the reckless disregard for the way they had packed an e-cigarette in their baggage, causing a fire to evacuate -- then the airplane had to be evacuated. It doesn't happen that often, just because sometimes you don't know why the incident happened and you can't really prove the negligence or the culpability of the person who owned the device. I went the wrong way. I hope the last people feel better about this, seeing me struggle.

(Off microphone comment.)

MR. CARTER: Yeah. And we were going to link to this on the internet, but I think we're just going to bring up one video. We have a lot of videos, but as I said before, they are -- most of our testing is on cargo shipments, palletfuls, so I have just one quick video of kind of one our lesser technical ones where we put fire under lithium metal, lithium-ion, and nickel-metal hydride batteries just to do a flammable comparison of what happens in a fire.

So we're also concerned at FAA if we have these below deck, if there's an unrelated fire and we have lithium batteries present, what would happen, because we've had three aircraft lost to lithium battery fires where they were implicated either as the cause or contributing to the fire, and two air crews lost and three cargo aircraft lost.

So lithium primary is the same thing. If you're not familiar with the terminology, it's a lithium metal, a non-rechargeable battery. I'll cite, too, that there are differences in the lithium. Lithium chemistry differences will yield different results depending on -- in tests, too. So will the state of charge. Larger state of charge, you get more --

(Off microphone comment.)

MR. CARTER: I'm sorry. A larger state of charge will give you a more volatile incident when there is an incident.

One of the things we discovered at the FAA tech center was that a lithium metal fire, lithium primary batteries, the halon fire extinguishing system on an aircraft cannot put that fire out, and that is why cargo shipments, not baggage but cargo shipments, of lithium metal batteries cannot go on a passenger aircraft.

We've recently discovered that lithium-ion battery fires, although the halon can put it out, it can still produce enough explosives of flammable gases where there could be a catastrophic explosion, and we're talking again cargo shipments, a palletful of these batteries. So lithium-ion batteries, the large cargo shipments have been banned from most passenger aircraft. That's not the law in the United States yet. The rulemaking has been delayed, but a lot of airlines, passenger airlines, have already voluntarily stopped carrying cargo shipments of lithium-ion batteries.

And obviously, in these tests, we purposely put a fire under these. These were not -- you know, these did not go into thermal runaway on their own.

All right, now we'll try to go to the next slide. That is what we just saw. Yeah, if someone else could drive for me, that would probably be easier on everybody here. So we can go to --

(Off microphone comment.)

MR. CARTER: Okay, I can stand near the microphone. All right, so what we're enforcing is the Hazardous Materials Regulations out of 49 C.F.R. Those regulations govern what you can put on an aircraft and cargo as far as hazardous materials go, including lithium batteries, and as well as what you can carry as a passenger.

For Department of Transportation purposes and worldwide transportation purposes, lithium batteries are in Hazard Class 9 - Miscellaneous. You see there's a brand new lithium battery label in Class 9 that just got introduced, and it's being grandfathered in. But 49 C.F.R. is what we enforce. We do accept the international regulations in aviation, the International Civil Aviation Organization's regulations, their technical instructions, which are pretty much the same regulation.

Next slide.

So we've been talking in the last presentations about the people who use them and the human behavior. We do allow people to carry e-cigarettes and their batteries onto the aircraft. It's got to be in carry-on baggage or on their person. That's because we've had fires in checked baggage.

One of the problems we have is the device, itself. Let's set the battery aside for a minute. The device itself heats up. If the device is not protected from accidental activation, someone slides it in a bag, checks the bag, if the device itself heats up, it can cause a fire down in the baggage hold.

If there is going to be a fire, we'd actually like it to be in the cabin. Even though that would be a very scary experience for people, at least the flight attendants have training to put that fire out immediately. And that's what has happened in the in-air incidents we've had. The flight attendants acted just as their training directs them to.

One of the things that -- I was at an airline industry meeting yesterday, and one of the things we were driving home to them is when you check a bag at the gate, your carry-on bag at the gate or at planeside because there's no more room, that is a checked bag now. The airlines, and we're working with them, they need to be telling people to remove any e-cigarettes or spare lithium batteries.  And if it's a spare battery, lithium battery, for a laptop or any device, any spare lithium battery has to come out of the checked bag.

And the batteries, according to our regulations, all have to pass the UN transport tests, Series 38.3.

So go to the next slide, please.

So the cargo shipments I talked about briefly.  If the battery is in the equipment, experience has shown that it's less likely to be damaged, it's less likely to cause an incident, so batteries in equipment can still go in cargo shipments on a passenger aircraft.  It's the uninstalled lithium metal batteries that traditionally we're the most afraid of because the halon is ineffective.  If we have a lithium metal fire on the aircraft, the best you can do is land that aircraft as quick as you can.  The lithium-ion batteries, as I said, we're starting to see those banned from passenger aircraft as well.  And I'm talking about large cargo shipments of these.

Next slide, please.

So I spoke earlier about the United Nations *Manual of Tests and Criteria*.  These are what our transport regulations require batteries to have passed.  And you'll see often that

38.3 will be marked on the outside of a package, "meets UN test."  Sometimes it will say "FAA approved," which is really not a thing, but I'm sure FDA and every other government organization has seen that type of thing.

If you wanted a series of tests for transportation, this is exactly what you want.  All these tests simulate the types of shocks and hazards and treatments something might go through, including in air transportation.  They have the altitude simulation, the thermal test, the vibration, shock, external short circuit, impact and crush as is pictured there, overcharge for the rechargeable batteries, and forced discharge.  I'm not an expert in these tests, so when we get to the panel and you're asking questions, there's probably other people in the room that could speak to these a lot better than I can.

Next slide.

Our concern and the concern, you know, of other people in the industry with this is these tests are for brand new batteries to be transported to the distributor, to the vendors, and ultimately gets to the consumer.  So this is a transport test for new batteries; it's not, you know, an end-all and be-all lithium battery test.

Manufacturers can self-certify, you know, they can -- we can ask, oh, let's see your test report; that test report can be in Chinese, okay. You see "UN38.3 PASSED, Transport Safety Certified," and these I just cribbed from the internet from different companies.

That doesn't mean anyone from the Department of Transportation has verified this. The FAA does not go over to China or Japan or Korea and look at their factories. The DOT does have a multi-modal hazmat agency, the Pipeline and Hazardous Material Safety Administration; they're the ones who put out the hazardous material regulations that we enforce. They have gone over and worked with the Chinese, but again, you cannot think that the DOT is over there making sure UN 38.3 tested means something on the outside of that box. All the hoverboards that caught fire had these things stamped on the outside them, so you know, it's -- you got to take it for what it really means.

We've seen, you know, world-class companies have battery problems. These batteries all passed UN 38.3. So it doesn't guarantee the quality control or the quality assurance in the factory the very next week, the very next month, the very next year, because you can keep making the same cell year after year after year and not retest.

People need to be aware that there are some -- quality assurance is really the industry standard more than a government standard. You know, I saw the new Samsung commercial the other day, and they talked about all of the things that they're doing and it showed, okay, that's -- that looks like a whole lot of quality assurance going on beyond what the UN test has asked them to do.

Next slide, please.

For us, there are two hazards for an e-cigarette. Obviously, there's the battery. Every lithium battery is a hazardous material. If it has been made poorly or if it's been used by someone and/or abused by someone or has been in their pocket, bad things can happen. But the device itself, any self-heating device is capable of starting a fire; it's a hazardous material. So we have concerns with the device itself being protected against accidental activation.

Cigarette lighters, for instance, have two things that have to happen before that flame comes out of that little -- even the cheapest Bic lighter.

We allow a self-defense spray to be carried in checked baggage, but our rules has two means to protect against accidental activation. So that's one of the things that we look for, for devices.

And right now we have a general DOT regulation that says anything that can cause a fire, there's -- or any battery or battery-powered device that is not properly protected is forbidden, except we can't enforce that until it actually causes the fire, and that type of post-mortem enforcement doesn't do anybody any good really.

The larger vape pen style is responsible for all the incidents we're seeing. We did have one cargo incident of the smaller one several years ago, but as far as passengers, it's these larger vape pens and they come -- obviously, as we -- I saw another presentation today. It's a wide world out there. There's a lot of renegades, you know. There could be very responsible people with a responsibly made device that causes an incident, or there could be a homemade device that causes an incident.

So we've seen incidents caused by the device accidentally activating and heating up in a bag and probably just as many, if not a few more, of the same old shove the battery in a pocket of your pants, shove the battery in the pocket of a backpack, and the external short circuits.

So we're seeing both; we're seeing the e-cigarette as a unit start a fire, and we're seeing the battery start a fire.

Next slide.

Lithium batteries in general, we count the ones reported. "Reported" I should have underlined as a theme from one of the discussions earlier. We don't know what we don't know, and yesterday when I was speaking to a crowd that had a lot of the airline flight attendants associations in it, I reminded them of their actual legal responsibility; the airlines have to report any of these incidents to the Department of Transportation.

So last year we had 31 reported incidents of lithium batteries in air transportation. "Incidents" means fired, exploded, something in that nature. Twenty-eight of those were passenger related, which is an up-tick. Twelve of those were either e-cigarettes or their batteries, so once a month.

We talked about clusters; seven of those happened within, like, a 6-week period last spring, about this time last year. I don't know why. But that's how it happened. Seven in carry-on, five in checked baggage.

Four out of the seven carry-on incidents occurred during boarding or just before boarding. They were still in the concourse. I don't know what to draw from that either. Maybe they had just charged it and the battery was already in thermal runaway. Maybe they had just -- they were getting ready to get on the plane so they just shoved the spare battery into the bag.

We do see a couple of ones where it was the battery, we see that the battery is being just put in its charging device and the whole thing put into the carry-on bag. So not really the best protection for -- you know, protecting against external short circuits.

The most recent one, we had one last week in Las Vegas, a guy got burnt, you know, at least from the hip to the knee. It looked pretty bad. It looked like third-degree burns. I'm not a medical professional; I mean, it was black all the way up and down his leg. He was still in the concourse and shoved a battery in his front pocket.

Next slide.

This has really opened up a new or broadened a new area for us. I mean, the human factor is always there. FAA has an entire division devoted to human factors, you know, pilots, air traffic controllers, and things like that. We have never seen this level of renegade behavior.

You know, when we started looking, we had our first incident, I think, 2½ years ago. We started googling this and couldn't believe what we were seeing. You know, bloggers giving advice on how to manufacture their own batteries. Get the old laptop battery, you can buy the -- you know, really cheap, strip it down, hey presto, you've got six or nine e-cigarette batteries. It's scary stuff, people building their own e-cigarettes out of, you know, flashlight bodies and stuff. I don't even, you know, know where to start to communicate with these people.

Obviously, we think at least half the incidents could have been prevented if somebody had a battery case, and there's lots of them out there, but unfortunately they don't come automatically with the battery when you buy it.

It's scary that the 18650 cell is the e-cigarette battery of choice because it is the building block of lithium batteries throughout industry, that size, and that's just 18 mm by 65 mm. So, obviously, one of the last presenters said there's all kinds of batteries in that size. It's just like double A batteries; there's all kinds of double A batteries.

The unsophisticated vaper does not know that. So we see on the internet these batteries, some with the raised terminals that are designed for a flashlight being sold as e-cigarette batteries, which a lot of them don't have the raised terminals, aren't designed for that, you know. It is quite frightening to us, and we've seen a lot of bad hazardous materials carried by passengers.

But the FAA is data driven and risk based as far as what we concentrate on. Most of our fires are lithium batteries. Most of our passenger-related lithium battery fires are now e-cigarettes. And so this has become, in just 2 years, all of a sudden a whole new area to focus on, and we're well behind some of the other government agencies on this probably.

Next slide.

So we've been doing a lot of outreach as much as we can. We have a captive audience in the airlines because we -- you know, they have an FAA certificate from us to operate, so they kind of have to listen to us. Passengers, less so. You know, you don't need an FAA certificate to get onto an airplane as a passenger or to put something in a bag.

We do have a website that we have airlines and airports point people to when they want hazardous material guidance. We've made posters and brochures to distribute out. We've gone out to some of the vaping shows, the industry shows. We go to the Consumer Electronics Show in Las Vegas. So we do a lot of outreach.

What's different about the FAA Office of Hazardous Material Safety is we regulate passengers; most of the FAA does not do that. We also regulate shippers. If you drop a battery into a FedEx envelope or UPS package and drop that in the box on a corner, you just became a hazmat shipper, and we regulate you. So we have millions of regulated entities. So our outreach in our awareness campaigns are much broader and always coming into new areas.

E-commerce has really elevated the universe of hazardous materials because everybody can buy everything now, and it's not just lithium batteries. We've had people selling industrial drain cleaner on eBay to people and not marking it as hazardous materials, and of course, bad things happen when it doesn't get handled right.

But obviously e-cigarettes and lithium batteries, the batteries, at least, are big on the internet. A lot of the big sites won't sell if they can't sell to people under 21, but even the major sites, e-commerce sites, have conflicting information on the batteries and the chargers, as you saw in the last presentation.

Next slide.

We also put a lot of battery guidance on our website for the air carriers. We do an illustrated guidance to passenger regulations. We've done lithium batteries for the airlines for their cargo handlers and baggage handlers for years. We also, you know, try -- I try to do the IKEA version of explaining things to people, you know; you should be able to look at the picture and know what we're trying to tell you, and that way the language doesn't -- the language barrier doesn't really matter. So we have battery charts on our website that explain, in pictures, to people what they can have and not have.

The important thing to remember is people can have e-cigarettes and they can have lithium batteries for all the most common consumer devices out there. They just have to follow the rules. So if it's new or used but it's not in a device, it doesn't matter if it's new or used, if it is a spare lithium battery, we absolutely want it in carry-on bags.

That's one of the things, the most important things that we can tell people because we want -- unlike TSA, they're trying to get everything in the checked baggage, we're trying to get everything into the cabin because the flight attendants have very good training, and in every incident so far, they've done the exact right thing. They've hit it with the fire extinguisher, and then they dumped water on it because you've got to cool down the battery pack before you -- people are selling a lot of these very expensive fire containment bags, so the airlines -- we've let the flight attendants know don't go pick up the laptop just because you put the first fire out because there's six more fires, nine more fires or explosions that could come with that. FAA has put out guidance that -- take water, take coffee, take Coke, whatever it is, cool down that battery pack after you've hit it with the fire extinguisher.

Next slide, please.

I mentioned before we have a website for the passengers. That's the illustrated -- and if they click, any element they click on, any hazmat listing there, they can get more detailed information and a link to the actual regulation itself.

It's confusing to have TSA and FAA both telling you what you can bring on a plane, so we're fine if most people start off with the TSA what can I -- you know, can I bring this, website. We work closely with TSA to make sure their information is accurate; they've got a lot of good information on lithium batteries on their website. It's just with the more exotic hazardous materials, TSA is glad to link to us and refer people to us.

People can also e-mail questions directly to us. Sometimes we get some very technical questions from people, people telling themselves a lot by asking questions, you know, oh, yeah, I'm assembling this battery, and I've done this many cells in serial and this many in parallel, and I'm going to put it on in, you know, I'm going to put it on a bicycle and put the bike in, check the bike. And we do the math and, you know, you're up to over 300 Wh, and it's no, you're not.

Next slide, please.

So that's my contact information as well as our executive director, Janet McLaughlin's, and if we can put you in touch with our engineering folks who do a lot of testing in Atlantic City, we'll be glad to do that. Like I said, they've done a lot of technical testing on that, mostly aimed at cargo and fires and fire suppression, but there may be an opportunity to work collaboratively, and certainly, we'd be interested in something like that as well.

Thank you.

(Applause.)

DR. YEAGER: So at this point, we'll move to the Session 2 panel discussion. So if Mr. Carlson and Dr. Jeevarajan can come up, please.

And we do have cards being passed out, but if you do have a question, you can come up to the microphone and -- can we get the microphone raised up a little? I don't think we'll have any four-foot questions.

So we'll start off with a question for Jeremy Carlson. What was the failure mode in the Lenovo laptops, and what design or manufacturing changes took place to mitigate the cause of failure?

MR. CARLSON: I guess I don't -- I don't know exactly what failure mode that's being asked about here, but typically, what we see in our safety incidents is what I referred to as a manufacturing excursion. Something at the cell manufacturer, some process that went out of control for, you know, maybe a few days, maybe it was a little bit longer than that, that caused an abnormal cell to be produced.

Typically, that is foreign materials that get inside the cell and, you know, in some cases can make it completely through manufacturing without looking abnormal, passing all the tests, and then anywhere from 6 months to a couple of years later, after many charge and discharge cycles, ends up being a failure and a thermal runaway in the field. So as far as what changes are made, that's why you work very closely with the cell manufacturer to do the failure analysis. Okay, I'll be closer now. You do these failure analysis activities with the manufacturer so that you can identify down to what machine it was that had this problem and, you know, and make changes to that machine or the process or the downstream testing to beef that up so that you don't have that problem again.

DR. YEAGER: Dr. Jeevarajan, do you know whether the injury/damage caused by the e-cigarette case study you showed was reported to any databases? Was the person hospitalized, and what type of device was it that exploded?

DR. JEEVARAJAN: So the person did go to the emergency, and they had really not reported it until I had asked them if they had reported it, and I think they did, but I don't know the details other than that.

DR. YEAGER: Was the person hospitalized?

DR. JEEVARAJAN: They just went to the emergency and got some treatment.

DR. YEAGER: And do you know what type of device it was that exploded?

DR. JEEVARAJAN: I have the details. I think it was an

Excalibur, and I have the whole -- the details of every manufacturer, you know, for each of those parts, including the cells. We tried two different cells. One was what was used by them, but we also got another one that would go with that particular vaping device, so we tested both types of cells.

DR. YEAGER: And then early on, was it reported to any database?

DR. JEEVARAJAN: I think they did, but I'm not very sure. I can confirm.

DR. YEAGER: Thank you very much.

So the next question: What information is submitted to the FAA after an incident of ENDS fire or explosion? Is there coding for ENDS specifically? I gather that's for you, Mr. Carter.

MR. CARTER: It varies. After an incident, sometimes we find out about it through the media unfortunately. Sometimes we find about it right away, sometimes the fire department has already disposed of the device, sometimes the device has been returned to the passenger. So most of the time, however, we get a photograph or two that the airline or the airport rescue firefighters have taken of the device.

We, as far as coding of the -- you know, it's -- we keep a list of all the lithium battery incidents, and we make that public just to -- the media and Congress finds that helpful to inform their efforts.

It is a hazardous material incident just like, you know, if battery acid leaked from a different type of battery.  Most of the time it doesn't become an enforcement case because there was no negligence on the person.

But other than keeping track of the number of incidents, we don't have it sophisticated enough to it was this brand of e-cigarette, or generally the device, if it happened in the device, the device and the battery are both severely damaged. Even if we had it, we don't have the wherewithal to do, you know, an engineering, a reverse engineering of what happened to it.

And we're coming to -- we're pretty new at this.  Lithium batteries as cargo, big cargo shipments, has been a concern for a long time; it's just been the last 2 years that the e-cigarettes have been on our radar.

So if I understand the question, you know, other than keeping a listing of the types of lithium battery incidents, we don't go beyond that.

DR. YEAGER:  Okay.  And coding for ENDS specifically?

MR. CARTER: Coding?

DR. YEAGER: Coding, yeah. Coded. That it's coded it's an ENDS incident.

MR. CARTER: In our listing, we will say the type of device.

DR. YEAGER: Okay.

MR. CARTER: And in our unsophisticated way, we'll call it an e-cigarette or a vape pen basically. You know, we haven't gotten to the level of, oh, it was this style, and this was the manufacturer of the battery. Usually, a battery, you can't even tell the manufacturer.

DR. YEAGER: Okay, thank you.

So the next one is for Mr. Carter. You mentioned there's a new sticker. Does that mean a shipper of e-cigs must use a sticker now versus the one shown in your slides?

MR. CARTER: The hazardous material label, that Class 9 label, if anyone is shipping lithium batteries and lithium battery devices, they should avail themselves of the hazardous materials regulations. And if they're shipping by air, if they have the IATA Dangerous Goods Regulations, which the airlines put out which are based on the actual regulations, they should be in good shape. That particular Class 9 label is brand new, people can start using it, but there's -- I don't think in the United States you need to use it for another year or so. And that is for cargo shipments.

If you're putting that diamond, that big diamond on there with the black and white stripes, you are a person with hazardous material training, and you can prove that you've had that training, and you were filling out shipping papers when you shipped these.

I'm glad someone asked the question. It lets us remind people that lithium batteries and the devices are hazardous materials, and if you engage in shipping them, you need to check the hazardous materials regulations.

DR. YEAGER: Dr. Jeevarajan, the same battery chemistry is claimed to be "safer" and often come without circuit protections. Is it sufficient to use one of these "safer" batteries in place of protections like CID or PTCs?

DR. JEEVARAJAN: So the CIDs and PTCs have a specific function. The PTC, for instance, is used to protect against external short circuits. So when you have a high-rate cell, that cell is specifically designed to provide high rate, so there's no point in putting a PTC in it and -- so there's no point in putting a PTC in a cell that is designed for a high-rate application.

But that doesn't mean that, you know, you don't have to have protection for the battery. The battery should have the appropriate protection, and also the cell can be tested to the max current or load for the particular application and then determined if it's going to provide that function. And if it does not, then it probably shouldn't be used for that particular application.

So there are many levels. Like as, you know, Jeremy had pointed out, it's a system-level effort, and so if you cannot put the protection at the cell level, then it has to be placed at the appropriate levels. So as a system, it is safe.

If the battery is replaceable and, you know, it can be affected in some manner, then the protection should be at the battery level. But if it is embedded inside a laptop or it cannot be removed from a laptop, then again you can look at other levels of protection other than from the cell or the battery. I hope that answers the question.

DR. YEAGER: Okay, thank you.

So, Mr. Carlson, what communication channels do battery manufacturers rely on to learn about failures of their batteries? How is this info shared with consumers and companies that use the batteries in their devices?

MR. CARLSON: All of our failure analysis is done with the cell manufacturer, so that --

(Off microphone comment.)

MR. CARLSON: Sorry. So that is our communication channel. As soon as I am notified of something I can find out either through pictures or having my hands on the hardware, as soon as I know what battery manufacturer is involved, they're notified because, as I mentioned, you have to do this, you know, in hand with all of the suppliers. So I don't know how other people do it; that's certainly how we do it.

And then I can't remember the second part of that question.

DR. YEAGER: The second part is how is this information shared with consumers and companies that use the batteries in their devices?

MR. CARLSON: I guess I'm not sure exactly what that question -- you know. Typically, when it comes to safety incidents, you know, we get that through our call centers. As far as how do we tell customers what to do and how to handle their batteries, that's usually in user guides. On the label of the batteries themselves we'll, you know, tell you things, not to put in fire and not to stick it with a screwdriver.

Typically, I know a lot of cell phones with embedded batteries have specific stickers on them with, you know, a screwdriver and a little line through it so that people don't try to remove batteries that can't be removed. But that's really all you can do is try to warn them in the normal places on how to use their devices.

DR. YEAGER: Okay, thank you.

And I think, with the AV activity I've seen, we probably need to be a little closer to the microphones than we think so people online can hear us, too.

So, Mr. Carter, does an e-cig seller who ships quantities of, say, 500 pieces need to register with FAA as a hazmat shipper?

MR. CARTER: No. As I said, passengers and shippers are not certificated by the FAA and anyone who -- the scary thing is anybody can ship hazardous materials, though depending on what exceptions are in place, most hazmat shippers have to have training and complete hazmat shipping papers and have labels. There are a lot of exceptions, however, for very small quantities of hazardous materials. Historically, that's included lithium batteries.

So you also often see on e-commerce, you'll see something that says Section 2, because that's Section 2 of the ICAO/IATA packing instruction, where the shipper does not have to fully comply, doesn't get the full shipment paper, doesn't get the hazard label you saw there, and doesn't have to have the full training; they just have to be aware of the requirements. That has been a problem. Now, that's been great for the shippers, and it's made it more affordable to engage in commerce.

The big problem for us is the -- without having the full hazmat declaration, the pilot did not know there was 100,000 lithium batteries on his or her aircraft sometimes. As you can imagine, the Air Line Pilots Association was not a fan of that exception.

There are so many exceptions in the regulations that I can't say that, yes, if you sell hazardous materials, you have to do this type of training and do this type of shipper's declaration on a shipping paper. But the short answer is nobody has to register with the FAA to be a hazmat shipper.

You do have to register with the Department of Transportation. The Pipeline and Hazardous Materials Safety Administration has a threshold for really large quantities of hazardous materials where you might have to placard a truck for it. That's not your eBay sellers; you're not selling 30,000 pounds of something usually. Usually, that's a large -- you know, you're talking about a thousand kilograms of hazardous material, a little bit less if it's something like Radioactive 3 or some, you know, 1.1 or 1.2 explosive.

So as you can tell, the regulations have a lot of gradients and exceptions to them, but the simple answer is no, you don't have to register with the FAA, but please, please, look at the hazardous materials regulations before you ship.

DR. YEAGER: So what kind of new charger-specific technologies are out there? What protection should be located in the charger versus the device, and what protection should be involved? So it's a general question.

DR. JEEVARAJAN: I can speak a little bit on that. What we have seen is that chargers and batteries sometimes have a double E prong. So when you have, you know, a device or a battery with that and you plug it into a charger, the charger can read the chemistry, it can read the voltage, it can read the capacity and so on.

So if you have that capability, I think that would be really good so the charger and the battery can talk to each other and recognize what chemistry, what voltage, how it needs to be charged and so on. That's what I would recommend as a general practice.

MR. CARLSON: I agree with that, and that's how especially notebook computers are done. The battery knows what it needs, and that's communicated to the system, the host, and you know, that gets communicated to the charger.

As far as, you know, what protections need to be in the charger and what protections need to be in the battery pack, it really comes down to how your system is designed, and it needs to -- you need to look at how everything functions together and where you might have faults. The closer you put the protections to the cell itself, the less room you have for faults to affect the battery. So that's typically where you move the most critical things close to the battery, and then as you get further away from that, you have a little more fault tolerance. I know in some of our devices when it comes to overcharge, we have four or five different levels of protection against that, but the most basic one is basically sitting right next to the cell so that you can't have those problems.

But there's a lot of flexibility in how this is done, and it really depends on the entire architecture, the power architecture, of the device. And that's why it's very important; like one of the speakers talked about early this morning, you need to do this design review and look at it and have other people outside of your organization look at it and say, you know, if something -- if this fault happens, how does that impact everything else, and go through that cycle a few times so that you have a robust system.

MR. CARTER: Dealing with passenger behavior and traveler behavior, they are going to, and I speak from personal experience, leave the original charger or charger cord plugged in at the hotel room and stop at Five Below on the way to the airport and get one for five dollars. That's going to happen. So sometimes we hear, well, it was -- you know, they didn't use the OEM charging equipment, but we know they're not going to; that's human behavior. So we would certainly, from the FAA perspective, like to see the protection in the device itself as much as possible because they are going to use an after-market charger or charging cord, and as we saw on one of the presentations this morning, there are all types of quality out there in all types of claims that the vendors are making.

DR. YEAGER: So another general question: The most catastrophic failures are difficult to do forensics on because the cells are often destroyed beyond the point where examination to the mode of failure can be done. However, this type of failure warrants perhaps the most investigation as it has the most potential for harm. In these cases, what can be deduced about the failure mode to inform design and manufacturing changes?

MR. CARLSON: So even in the cases of, you know, catastrophic thermal runaway, there is still a lot you can learn. You know, often in a thermal runaway, you lose about half of the materials. The aluminum current collector melts and gets, you know, expelled out of the top. So, you know, these things are very difficult to unroll. In a lot of cases, you can still unroll them, you can pinpoint where they started, so you have an idea of inside this, called the jellyroll, you have about 1 m long leftover copper foil. You can pinpoint roughly where this internal short started, so you can tell if it's on the top or the bottom, that it could be either a foreign material sitting on top of the jellyroll, so you have an idea of where in the manufacturing step this started.

It's not as nice as when you can do disassembly and pinpoint where exactly it happened and do some material analysis and understand that it's -- you know, there is some chromium there and get down to it's this specific type of stainless steel that's only put on this one part, piece of equipment, and getting to that point.

But you can get some idea of where in the manufacturing step something went wrong, and that's where you start focusing on, you know, the manufacturing data and what days did something go wrong or when was some maintenance done. So it's not as clean as some of them, but, you know, in every case there's something you can learn from it.

DR. JEEVARAJAN: I would like to add to that, talking about the internal problems. You could also have other types of defects like -- you know, like what we had, what we saw with the Samsung. But apart from that, there are also other parts of the battery, other components of the battery. So if you disassemble the battery or if you just look at it at the system level and test every part, you'll actually find out where the problem is, whether it is with the external or with the internal or something that was internal to the cell.

I was talking earlier to someone here, and I said, you know, we've done tests on these circuit boards and the controls. In the past, we found that they worked really well, but today what we find is that some of them actually crack when we do the test at the battery level to test the controls, some of the IC chip fuses actually char. So those are not supposed to happen, and people really don't test those.

So what we are finding out is they're not -- it's probably because they're not using the appropriate parts or the appropriate -- for that particular application they're not using the right components. So I think, you know, it's a system, again, system-level process. You've got to go through every step, every component, and it would be good to do, as they pointed out this morning, to do a system-level analysis and go through every step and find out what the cause was. And you have many samples to work with from the same lot, so you can start at that and then come down to figure out what happened at the cell level, if it did happen at the cell level.

DR. YEAGER: Thank you.

I have another general question: Is there a way for a consumer to know whether their cell or charger is poorly designed or manufactured?

MR. CARTER: I'll start with a non-technical answer. As I pointed to in my presentation, a lot of vendors and manufacturers are going to say "meets UN 38.3 standards." However, there's no government guarantee behind that from the United States' perspective. We can tell you that the Chinese government, Japanese government, Korean government do have inspectors, and they take it seriously, but this is a very, very large industry.

I think the simple answer to that question is no, stick with a reputable brand and a reputable vendor.  We at the FAA have seen, with e-commerce, not just with lithium batteries but all manners of products, there is a wide variety out there. Even with the hoverboard fires of 2 years ago, when they had the big rash of them, there were some reputable brands with counterfeit batteries, you know; Samsung was misspelled on the battery pack.  So sometimes if you're on the internet looking at stuff, look very carefully.  If you see really poor grammar and misspellings and stuff like that, that might tip you off, but unfortunately, you know, there's not a guaranteed way.

Obviously, if I'm buying, you know, let's say camera batteries, double A batteries, and I see something that says Evercraft instead of Eveready, but it's the exact same logo and appearance and I know, okay, I'm staying away from that one, but you don't always know.  And certainly, the industry has been fighting counterfeiting for a long time, and so sticking with reputable vendors and names is the best and the un-technical recommendation I could make.

DR. YEAGER: Thank you.

Another general question, although maybe FAA related: Airline staff do not always recheck that no lithium batteries are in gate-checked baggage. How can policy be executed so that all staff ensure safe handling of e-cigs in gate-checked baggage?

MR. CARTER: That's a new effort we're making. The rule that we held airlines to in general advising passengers of hazardous materials in their baggage, that rule has just changed. For the hazmat reg nerds in the crowd, that's 49 C.F.R. 175.25. That was the regulation that said when you checked in a bag, you had to be able to see prominently displayed a notice about 49 C.F.R. blah-blah-blah forbids this, and the airports didn't like any type of warning, so they usually had that sign right on the side of the baggage well where you weighed your bag.

When we started seeing e-check-in at airports and we saw the airlines said, okay, you had this, print that button that -- yeah, I read that and they had pictograms, which was not a legal requirement, but something they started doing internationally. We think that works a lot better.

So the rule has just changed that instead of telling the airlines exactly what you say, the rule has changed that you're going to go to pictograms and make sure it's effective. Now, the airlines don't like you saying, okay, you just got to do this and make sure it's effective; we're not going to tell you how to do it. They want no, no, what are you going to inspect against, what do you want to see? So what we'll probably end up doing is in the FAA we put out an advisory circular. It's not a regulation, but it tells them this is what we expect to see, this is the result, you know, it's more of a performance metric. We want to make sure that the passengers will know this once they've seen your warning. So we'll be doing that.

We've already started with our principal hazmat inspectors going to the airports and witnessing it, all right, when the overhead bins are full, listening to what the gate agent says. And so we'll be doing that, we'll be physically, visually, orally inspecting what is going on out there and providing guidance to the airlines on what we expect to see.

And I was at an airline, an aviation symposium yesterday and delivered that same message to the airline associations present, that they -- that although there's no regulation that says, okay, when you start gate check and carry-on, you have to say this, it is a performance standard we expect them to make, and we'll probably have that in an advisory circular within the year, telling them, you know, laying it out a little bit more clearly.

DR. YEAGER: Thank you.

And a general question: How reproducible are different failure modes? If the relative likelihood of failure of lithium-ion cells is low, then how much testing needs to be done to confirm a particular design or manufacturing issue as the reason for failure?

MR. CARLSON: So when it comes to manufacturing problems, you're looking at, you know, kind of a normal failure rate of maybe 1 in 10 million, 1 in 50 million cells. So at least for me, when you start seeing numbers above that that are kind of, as I mentioned in my talk, you can kind of see a pattern, that's when you start -- you can't really recreate some of these failure modes.

If you have a manufacturing problem that's putting a foreign material in a cell and it takes 3 years for it to happen, you can't recreate that cell really because all those cells are 3 years old. You can't open them up and put foreign material in them because you've changed the system. So you have to look -- if you're going to say, you know, here is my root cause, it has to be based on all of your evidence in the failure analysis, not so much, you know, I recreated it by putting this little particle in this part of the cell, although you can do that; there's a forced internal short test that kind of tries to do that. But it's, again, you're changing the system which then changes the cell and what you're actually testing.

DR. YEAGER: Well, I appreciate it. Did you have a last comment?

DR. JEEVARAJAN: Other than that there are many ways you can induce a failure external to the cell or the battery and test it. And those are more defined than the ones that we open up a cell and try to find out if there's a problem that's internal to it.

DR. YEAGER: All right. Well, I want to thank the panel. Thank you, Mr. Carlson, Dr. Jeevarajan, and Mr. Carter. I appreciate it. And we'll move on to our Session 3. And thank you very much.

(Applause.)

DR. YEAGER: And for Session 3, we're moving to Failure Modes and Design Strategies, and our first speaker will be John Bellinger with Evolv, LLC. Thank you.

MR. BELLINGER: And see, here I was terrified of making a fool of myself with the mouse. All right, so -- all right, left click doesn't do anything?

(Off microphone response.)

MR. BELLINGER: Oh, got you. Got you, got you. So for disclosures, I'm co-owner and chief technologist of Evolv. Evolv makes the circuit boards that run high-end electronic cigarettes. You know, we're sort of up at the top end of the market. If you have a device that's sort of boxy-looking with a screen and it costs more than 100 dollars and you bought it in this country, there's a very good chance that we made the circuit board there.

And we're the largest domestic manufacturer of ENDS control circuitry. At this point, we may actually be the only one. Everybody else is manufacturing in Shenzhen. We were founded in 2010, and we've sort of grown up with the industry; it doesn't seem like a long time, but it is. And I personally designed 21 ENDS controller families.

We were the first people to introduce direct wattage control for ENDS, which is important for battery safety for reasons I'll get into later, and we were also the first people to have a multi-cell battery management system.

All right. Okay, so we've really gone over what makes batteries explode, so I can get through this pretty fast, but essentially if you beat them up, they explode or burn or fail.

And so the question is, as a control circuitry manufacturer, what can we do to prevent this from happening? We're sort of what stands between the cell, which is getting taxed really hard, and the user who will do whatever they want.

And a lot of these things are -- you can mitigate the hazards to a large degree, and you can also do it sort of cost-effectively for, you know, we're the expensive end of the market, levels of cost effectively, so, you know, it's not, oh, oh, wouldn't it be nice if we had that, wouldn't it be nice if we have that? A lot of these things you can do and are being done by companies using our boards and some other companies that are responsible actors.

And, you know, lithium-ion batteries do power the entire world and, you know, if we are being half of the fires on airplanes, you know, that's a problem for us, not, oh, well, who could prevent any of this? The cells just go bad. All right.

(Off microphone comment.)

MR. BELLINGER: There we go. Okay, so the absolute craziest thing that the market still has a large number of, and it's especially crazy to me as a circuit board manufacturer, is non-regulated devices. These are literally you've got to sell with no protection, you've got a switch, whether it's a pressure switch on a little cigalike or it's a mechanical switch, and you've got a coil of wire, and that system, with the inherent safety that we've heard about with lithium-ion batteries, we have users putting them in their pocket, taking out, putting up to their face, pulling God knows how much current out of it because it's not regulated, putting it back in their pocket, and repeating that two to three hundred times a day.

They don't have any protection against short circuits, they don't have any detection of, you know, the health of the battery, they really can't -- they don't know anything; they cannot be made safe. You can put a fuse on them, but that protects against, yeah, kind of half of one of the litany of failure modes we've heard about that I'll get through.

So non-regulated devices: It's not just the big, big bro, giant tube, pipe bomb-looking thing. There are a number of -- especially the really cheap disposables tend to be non-regulated. You know, some of the cigalikes tend to be non-regulated. And even with disposables, that's a problem because even though they aren't recharged and you can say, well, we'll do this, one of the failure modes for electronic cigarettes is the coils can short simply from mechanical abuse. So even if you've only got a one-shot and you're hitting the button, you could be firing that directly into a short.

All right, regulated devices have electronics and can be as safe as you're willing to spend money on electronics. Protections that they should include is current and voltage limits on the output and on the battery side, short and open circuit detection, weak and damaged battery output limiting.

So if you have a replaceable cell or even just an old and degraded cell, you need to be able to have mechanisms in place to know that that cell isn't able to provide the amount of power the user wants and to throttle back. And we do that by sort of measuring discharge voltages and reducing power to keep that above about 3 V.

One of the things that's really nice is this is a very user-driven industry. If you can annoy the users into replacing the cell, they'll do it. If it's sort of working until it goes bang, they'll work it until it goes bang. So if you can have performance drop off faster than, you know, cell damages increasing hazard, the users will voluntarily stop using that.

You really should have your battery charge and discharge protections on board and you know, saying, well, charge it off board somewhere and, like we saw, some charger somewhere, and then we'll kind of hope that it was okay. As a device manufacturer, you at least know the sorts of loads you're putting on it and the sorts of batteries that should be in it. You have more information than the 5.99 charger that charges four batteries.

Thermal cut-outs are really important. You need to have temperature monitoring for, you know, high temperature ambient, low temperature ambient for charging, for discharging, for all the rest of that because really, heat is the enemy.

The downside to regulated devices is they tend to be software controlled, and they all have electronics. If you have 300 components and, you know, 200 kB of code, you got a lot more places where you could have a glitch. I mean, the one thing with I've got a switch, I've got a battery, I've got a coil is I know where it went wrong because one, two, three or all three of them sometimes. So yeah, regulated devices aren't a panacea if you do them badly, and they have a lot more opportunities to do them badly.

All right, wattage controlled devices, most of the large battery stuff like this are wattage controlled. Wattage control is actually really important because it decouples the atomizer parameters from the battery parameters.

So if your active control loop is going to 20 W, it doesn't matter if you put on 100 milliohm coil or a 3 ohm coil; the device will figure out, and it will only pull 20 W out of the battery. So then you can say this battery is spec'd for 20 W, and we're in a good spot.

And this is important because users do modify their coils, they do make their own coils, they do screw up. I mean, all of these things have a standard what's called a 510 connector, so atomizers are interchangeable whether the manufacturer envisions it or not. And wattage control really has become ubiquitous among the large regulated mods. So you can decouple the "well, what's wrong with the atomizer" from "well, what's wrong with the battery," and anytime you can, you know, reduce interactions, you're in a better place from a safety standpoint.

Built-in chargers are a good thing on devices; they need to be properly engineered, they need to have constant current, constant voltage charging, and they need to have low and high temperature cutouts. They need to limit the charge rate, and they need to detect damaged cells and decline the charge.

And if you have multiple cells, they need multi-cell balancing, and they really have to do this internally because USB sources, the users, like we've heard, are going to plug in anything with a USB port to anything with a USB port.

We've seen stuff as stupid as custom chargers happening to be using a micro B with a 12-volt output. I don't know why somebody thought that was a good idea. It's basically a guaranteed "kill your devices," but it needs to kill the devices, not kill the boards or not kill anything. Or not the boards, not kill the batteries.

All right, it's a new way to go. Replaceable batteries. Most of the large devices do use replaceable cells. I don't have -- I mean, I have an opinion, but I don't control that as a circuit manufacturer, but the market really drives in high-end stuff replaceable batteries, and it makes sense because you say, well, I spent 100 dollars on this device and, I mean, as e-cigarettes we're really hammering on these batteries. So if you get 6 months out of one before the capacity's falling off, that's pretty good.

So if I buy this device for 100 bucks, 6 months from now I'm throwing it out, but if I buy this device for 100 bucks, 6 months from now I'm spending 7 bucks on another battery, and I'm back in business.  I mean, that's a pretty obvious value proposition for the customer, so we need to do everything we can, you know, in a world before PMTA.

And FDA is definitely free to say, hey, if you don't, you know, they could get rid of that, but until then, you know, the customer's going to drive a need for replaceable batteries, so you need to have protection against reverse polarity.  You need to sense your battery voltage and current, not just your output.  You need to, you know, limit.

Fuses are really key between parallel cells.  Some of the devices, because they're designed -- electronics tend to be designed to run from single cells, but people want more capacity and say, well, we'll just put two in parallel.  Well, that's great; it works fine-ish.  You've got some charging problems.  The problem is a lot of these devices with parallel cells, the parallel cells are just a bar and a bar of copper.

And so if somebody puts one of them in backwards, then now you've got a battery shorted to another battery and, you know, you may not be able to pull it out before stuff gets real exciting. So anything with parallel cells really needs to have a disconnect or a fuse or some way so when you plug them in backwards, they go. And you have to work with whatever cells they picked, even if they picked some out of laptops because they're going to do it.

So as much as you can, make it safe with whatever cell. Fortunately, the low discharge cells tend to have high internal resistance and work poorly anyway. So the users, I mean, they will try to find decent batteries; they may be counterfeit decent batteries, they may be decent batteries that somebody said, hey, that's great. But yeah, you really have to try to protect against that because people are going to do it if you have replaceable batteries.

All right, here we go. So one of the things we do at Evolv is all of our devices require statistical data of our users, and we started doing that because our goal is to sort of perfect the electronic cigarette, and to the degree that we know what they're doing, we can design stuff around that.

So, you know, some of our data is publicly available at ECigStats.org. We've got 180,000 or so devices reporting anonymous statistical data. We've got about a billion and a half puffs.

So, for example, for batteries, we know what the profiles look like. You know, you've got a distribution for puff time, you've got a distribution for puff power, you got distribution for puff energy and puffs per day. You can use this to sort of build a battery test regime and -- you know, because they're not constant discharge. They're bang, off, wait some time, bang, off, wait some time. You know, that's where you need to be testing them, not, well, it says it's at 15 A discharge continuously so, you know, great.

Anytime. All right. And really, this is, as a battery, what an electronic cigarette looks like. You've got very high peak power, you have 2- to 3-second bursts with some time in between, you have 5 to 20 minutes of total active time per day. So, you know, why are they exploding in your pocket? Because they're in your pocket the rest of the day and then they're in nightstands all night.

And typically, in the large devices pulling 40 to 70 W per cell, which is very much, you know, within the good high-end power tool oriented cell ratings -- so, you know, if the power tools aren't exploding, there's no reason we need to be, there's no reason we should be, we are not exercising the cells any worse than, you know, Black & Decker are there.

Okay. So we make devices that are single-cell powered. We also make devices that are multi-cell powered. And the interesting thing is the users of both devices -- and this is off our recordings. The users of both devices put out about the same amount of power because to simulate a cigarette you need a certain amount of, you know, energy generating a certain amount of vapor.

So the multi-cell devices are actually stressing the cells considerably less because the average power is less and even if you go way out to the tail; the right-side tail of the multi-cell device is still less power than the single-cell device. Of course, the trick is multi-cell devices cost about twice as much to charge and protect.

I was just going to talk through -- this is our highest spec board, sort of talk through what we're doing as Evolv. This is commercially available, it's commercially viable; you know, these are things that you can get on the market.

So this board is wattage controlled, it's two or three cells, and it has a complete battery management system which I'll get into. It has a built-in USB balance charger. It puts out between 5 and 250 W, which is rather a lot. And it's temperature sensing up at the coil. And the precursor of this has been around since 2015.

So at a system level, we have a fuse between the battery and the power electronics. It's protected against reversed packs or reversed individual cells with a whole bunch of effects and comparators and whatnot. And it's hardware comparators against output short circuit and a watchdog against software lockup.

We also have -- this is a screenshot off of our device. You can configure the boards because we sell to manufacturers. The manufacturers configure the boards for max peak battery current or max sustained battery current. They can set the charging mode for different low cutoffs and high cutoffs. They can pick different cell types, they can set the discharge curves, they can actually do capacity analysis of the battery and field gauge it and things like that. So those tools are available to the manufacturers.

And this is just sort of from a board -- standpoint. About half of the cost of this board is in the charging and battery protection circuit. So, you know, they're monitoring each individual cell with an end-lock front end. It's balancing each cell.

The reason balancing cells and multi-cell stacks matters is because if one cell has less capacity than the other, if you don't do that, by the time that one -- by the time the average pack voltage is charged up, that cell is overcharged for voltage and will overcharge every cycle, and that will actually get progressive.

So in a multi-cell pack, you need to measure them and then bleed off energy so they stay at the same state of charge just by having different capacities. I mean, that's especially important if you have replaceable cells because if you think people would say, oh, well, all the cells have to match, no, I got two cells here and that one's pretty bad, so let me just grab this other one, it's brown, but I think it's fine. I mean, that really is a case you have to protect against, which you can do; it just costs money.

You know, we monitor and limit the charge current, and we monitor and limit USB voltage. We do temperature monitoring to slow or terminate the charge if the ambient temperature is above or below the operating range, like we heard in the laptop case. And we've also got hardware clamps on total battery voltage and other layers of protection on charging.

All right. And then while we're operating, we're measuring each cell's voltage. We have programmable peak and sustained battery current limits, like I mentioned.

So if you're building a device with this that uses little batteries, you can say, okay, I can throttle this down to where it comes off the battery datasheet to say, okay, this is a 15 A battery I'm building with, limit it to 15 A; if it's a 30 A battery, limit it there. We have programmable device power limits, we have temperature sensors, system monitors. None of that's actually popular in the market because, for example, we do internal calibrations. People would much rather, instead of saying -- you know, having the device flash warranty service or return to manufacturer or whatever, they're like, oh, no, you guys' devices are much less reliable. Well, maybe, or maybe the other guy just doesn't care if he's charging more than 2% out of a voltage spec, things like that.

You know, a lot of the safety stuff is going to have to happen regulatorily because it adds costs. You know, most of the users aren't going to get blown up. Most of the users don't want to spend an extra 10 bucks, because if you remember, most of our users are former smokers, so they're very comfortable with, you know, this will eventually kill me.

So, you know, there's a 1 in 100,000 chance that this might burn me. You know, if they've been able to get over the one, they can kind of get over the other. So, you know, safety's nice, but so is that extra 10 bucks.

So really, that's where some regulatory authority should say no, you can't do this or this or this or this or this because it's beneficial to the guy who got blown up, but everybody feels it won't happen to them.

Traceability is also really important because we -- you know, I've been just sitting in the audience here, and you're like, oh, yeah, we have a cluster and then it goes away, we have a cluster and it goes away, we have a cluster and it goes away. Knowing what I know about manufacturing, are those all the same device, from the same batch, from the same panel, from the same lot, because, you know, if a vape shop gets, you know, a batch of devices with a design failure or a manufacturing fault or something like that, you could very easily get a cluster, and that may not be a butterfly flapping its wings. It's just if we don't have any traceability and we don't have anybody sort of looking at that, you can't say, well, you know, that guy was just having an off day and soldered all of those wrong and they all blew up, you know, and then it's like, well, it's that guy, that device, that company or that industry problem, and right now it's being seen as that industry problem because nobody's looking at specifics.

So on our side, every board of ours is serialized; it undergoes a variety of automatic tests which are stored in a database and can be looked up off of the serial number of the device if there's an issue or even just if the user's interested. And then the other thing is we manufacture all of our electronics here, which doesn't mean that they're inherently higher quality than something manufactured in China. But it does mean we're a lot easier to find, and it's a lot easier to verify what's going on.

So if you hear a lot of, oh, well, we couldn't possibly know what our manufacturing partners blah-blah-blah-blah-blah, you could just open a factory and make them. It's not impossible; it's not even prohibitively expensive. We make about a million boards a year with six production employees and a ton of robots.

But, you know, the labor costs in the control of electronics, which really define the safety profile of the devices, is pretty trivial compared to everything else. So you do not have to outsource that which may or may not make, you know, easier safety. But if there is an issue, it's a lot easier traceability; you don't say, well, that one's kind of black and had a camel hump, so maybe it's, you know, this or that.

Out of time, all right. And that's really all I had, but just the takeaway from this is these protections do exist on the market, and there are any number of manufacturers that are using them. So it's not -- you know, it's not, well, wouldn't it be nice if we had this and this and this pie in the sky; there are people making responsible devices.

(Applause.)

DR. YEAGER: Thank you very much.

Our next speaker is Eddie Forouzan with ARTIN Engineering and Consulting Group.

DR. FOROUZAN: Thank you. So I'm an electrochemist, and I've been involved with batteries for over 20 years, more like 25 years; experience with many chemistries, not only lithium-ion batteries. And I'm here to kind of maybe put a twist onto the presentations a little bit because I've been involved with the development of multiple standards that have to do with the safety aspect of lithium batteries.

But unfortunately, none of them are bulletproof, and for the past -- since the introduction of IEEE 1725 that Mr. Burton was discussing in 2006, we're still experiencing failures in the cellular phone industry, including what happened at the end of last year, a multi-billion dollar recall. So maybe the fundamentally -- resolving these failure rates that we're seeing right now and what the FDA is interested in addressing or the FAA is interested in addressing can't be achieved by having some more standards published. I think, unfortunately, a more heavy-handed approach needs to be taken, especially by the government, where significant fines and penalties should be imposed on entities that are knowingly, willingly compromising the safety of the devices that are being introduced into the market. So that's what I'm going to be talking about to some extent.

Okay. So this isn't advertisement, but I'm just trying to explain, ARTIN Engineering's background has to do with multiple tiers of categories of clients. We're involved with procurement departments that call us, and they are basically yelling and begging for a 2-cent price reduction in the -- cost, a 2-cent reduction in the cost of the lithium cell that they're getting.

At the same time, we're involved with engineers that call us and they say, hey, where do I go to get a lithium cell that has more power, more voltage, more capacity?

And finally, we're also involved with lawyers who call us and say, hey, listen, you know, this device that went through all these different certifications failed, and I have a client here who was harmed, and can you investigate the situation for us?

So we see this approach of the evolution of these devices, especially now specifically talking about the e-cigarettes from many different aspects. I'm very happy to see that the mechanical e-cigarettes are kind of dying out. They should've died out immediately because most of the failures that we've investigated have to do with those mechanical devices. And I'll talk about that a little bit more.

So the cells and the battery packs is really the focal point right now, and we have already seen the presentations before, earlier today, talking about the fundamental chemistry that goes on in a lithium cell.

The point that we need to understand is lithium is the most electronegative element on the periodic table. It is the most -- it's critical to deal with it in an appropriate manner where you don't expose it to a situation where it would want to do things that you don't want it to do. It's there, it's intercalated when you charge a lithium cell into the anode, into the graphite, into the carbonaceous material, but again it's readily available to react. Now, you can induce it and tip that scale, tip the balance by forcing the cell to experience or be in a situation that makes it thermodynamically unstable.

Okay. So we talked about -- we have heard about different cathodes, different anodes, and the different electrolytes. The only reason I have this chart up here is just to show you how many options there are, and it's not just one chemistry on the anode and one chemistry on the cathode; it's a combination of a whole bunch of different factors.

And then on top of that, in addition to this variability, you have the manufacturing process, which has many different aspects to it as well. And in addition to that, you have the manufacturing process of the device, and then in addition to that, you've got the users. So there are multiple levels of know-how that we have to deal with, know-how or lack of know-how.

Okay, so, you know, the benefits of the lithium batteries are -- the most important is really the high energy density. For the minimum weight, minimum volume, it holds a lot of charge compared to any other chemistry that we have -- any other commercially available chemistry that we have available to us. It doesn't have any memory effect. People are very happy with the performance, the overall performance of that chemistry. Low self-discharge, you can keep a lithium battery charged for very long periods of time. You can cycle them a relatively high number of cycles, 1,000 cycles, 800 cycles, and it's not atypical. And because they're mainstream in the market, you have many producers, manufacturers of the product, so it's readily available.

Now, mostly the balance has actually tipped towards Asia, so mostly the production is all Asian production when it comes to lithium batteries.

Now, the shortcoming is that it's a higher cost product, but again, it's worth it because of the high energy density. It's got some sensitivities, thermal sensitivities. Again, you know, you have to cushion it and baby it, if you will, in order to avoid any kind of catastrophic failures.

It's really not suitable for any type of a deep discharge mechanism, so these mechanical ENDS where you can keep pressing that button until it dies and even more, I mean, it's just really not meant for devices like that.

Now, protection circuitry is definitely a must, in our opinion. And then it also has its restrictions. Unfortunately, just because of the nature of the cell, it has inevitably been categorized as a Class 9 because once it fails, it fails dramatically.

So the typical safety tests that safety labs like us do really are only meant to verify the design, and that's another critical point that I think we all need to understand, that it is impossible to manufacture a lithium cell or integrate systems-engineered lithium cells in a product and expect to have a 100% safe product with zero failures. It's just not going to happen because of all the levels and all those variables that go into the production of the cell and the device and then again the user.

So the tests that we have earlier on discussed regarding 1725, 1625, IEC 62133, the newly released UL version of that which is basically a mimic of it, the UL 6133, UL 1642, UN/DOT 38.3, all those -- 2054, UL 2054, all those standards really have to do with design verification. You take five samples, and you run a test on them. You take 10 samples, and you run a test. Well, the minimum number of cells that are produced are in the millions, hundreds of thousands to millions of that same model. So how can you guarantee, by testing five samples, that you're never going to have an internal short circuit?

So the exposure to fire, which we saw a very nice video of earlier on; hotplate testing; oven testing, which we saw some data presented earlier; drop/shock; crush test, which we again showed the crush bar that was demoed up here, a picture of it was there.

The nail penetration, it really evolved from the Battery Association of Japan by penetrating a 2½ mm diameter steel nail at the rate of 1 cm/s into the cell to induce shorts, internal shorts.  It basically only shows you once the cell fails, the extent of damage, how much smoke, what temperature, how loud of a bang, etc., etc.  But none of these are geared towards producing a zero failure product.

So the other point that we need to stress, that even if you have the best designed cell, again, just by the nature of the chemistry and the usage pattern, you may induce a premature failure, a safety issue.

So manufacturing issues:  I decided to kind of throw these slides in last minute.  This is what we've seen.  I mean, physically we have seen these types of shortcomings. Manufacturer A, this is a prismatic type cell, an x-ray image of the inside, and you can see the jelly rolls. And this is what they call a goose neck; it's usually a nickel tab that is bent very nicely, and it's supposed to be coming out, protruding the jelly roll straight up and typically spot welded. So this would form one of your contacts, and then the canister would be the other contact.

Manufacturer A has invested a lot of money, a lot of know-how, and a lot of patience in designing equipment that can reproducibly form these goose necks.

Manufacturer B is not automated, semi-automated, I should say. End line, this is the product that they were producing. And we, as American consumers, were purchasing these things unknowingly because most of these devices are now not only designed elsewhere, they're made elsewhere as well. And they were flooding the market with this type of a goose neck.

This fold, inevitably what it does, it pushes down on the electrodes, and it may induce a short circuit failure, okay? So this is the separator, usually a polyethylene separator; it's a porous membrane where the lithium could actually shuttle back and forth, the electrolyte is freely -- free to impregnate it and lithium penetrates it, gets shuttled back and forth.

There are some critical dimensions that need to be taken into account. Fortunately, IEEE 1725 really clearly explains all of that. So at the very least the cells should be going through those standards, again, for design verification, is that the separator must protrude both the anode and the cathode. And the cathode must always be -- the anode must always be wider than the cathode in order to fundamentally have a safer cell available to us.

But keeping all of these in alignment, and these overlaps we're talking about, maybe a tenth of a millimeter, sometimes half a millimeter, sometimes a millimeter, but keeping it in alignment throughout the production lifespan of a product is an art by itself. So knowing really who you deal with, who you source the product from is very critical if you want to be able to sleep at night without having to worry about catastrophic failures as much.

Other failures that we've seen are spot welds that weren't holding, right, that there was no check on it. So these -- where's my mouse here? Okay. Like this is an indentation, the electrode has been pushed onto it, but the actual nickel tab was never welded onto it, right? So there was a lack of -- so the current was actually just being -- going through this spot weld and whatever else of that lithium plate that was in touch with this piece of metal.

Other things that we've seen, and this is a picture that I personally took; I was there, believe it or not. There was a presentation, I think, earlier that talked about the raw material that goes into the construction of a lithium cell where you have all the powders and then everything gets pasted on these current collectors, the aluminum and the copper current collector.

So they usually come in a very wide -- they call it the jumbo roll. And in order to be able to slit this into the right lengths in order to be able to make the jellyroll and insert it into a canister, you need to be able to cut that jumbo roll to size.

This specific manufacturer was using -- and I blackened this out just because there was a name brand on it, I don't want to get sued, but they were using a razor blade that's meant for shaving, soft steel, right here, super stainless, Shanghai, China, to cut the jumbo rolls. It blew my mind. This is a new blade that I got from them to take a picture of, but the actual blades that they were using had dull edges, it was missing this corner, they were holding it at a 45-degree angle, and the jumbo roll is being pulled from the other side.

Because of wear and tear, just the friction, this blade was missing, it was just worn out.

An hour before going to the line to do this inspection, they were pulling out documentation claiming how thorough they are to ensure that the raw material that's coming to their lab, that powder stuff, is extremely clean and it has iron less than 30 parts per million.

But an hour later, in their own process, they were using a shaver blade to cut the jellyrolls, and all those pieces of metal that comes off of this was flaking right into -- this is an SEM micrographic, so basically right onto the electrodes.

So what do you do with people who do this? I mean, how do we, as a community, do we train them, do we -- I think they need to be penalized. It's just ridiculous. I've got a whole list of pictures to show you. We don't have time but -- okay.

So when you have manufacturers that produce that type of a product, now that product is more susceptible to failure due to an overcharge situation, due to mechanical stress. It's just not supposed to be like that.

So any type of fundamental testing that we do based on those five samples that is meant to be a design verification inevitably basically has no significance whatsoever because that product is coming from a manufacturing facility that is producing products that none of these tests would ever be able to catch, right?

So instead of the low part per million or hopefully part per billion failure rates, which we all need to accept that there is going to be some failure involved, now we're going to be dwelling in the hundreds of parts per million, thousands of parts per million, but yet again, none of those standards are really meant to address this.

So bottom line, I think that really the only way for us to move on, move forward and not have to worry about -- not have to worry as much about the incidents that we are here to discuss is to be heavy-handed with them and penalize them. If they are introducing products that are made like this into the U.S. market, the government should heftily fine. The banking industry does it. Why can't the FDA do that or the FAA do that? I'm sure you can.

And this is, you know, we simulated a failure in our lab. This is a pouch-type cell. It doesn't even have to be a canister-type cell; it doesn't have to be an 18650 that we've been discussing so much and focusing on earlier today. Even a pouch-type cell can still fail catastrophically, right?

So as you can see, in a very quick time span, you will reach temperatures -- and this was the minimum temperature that we measured out of all the samples -- of at least 550-ish degrees Celsius. Very quickly. You don't have a chance to pull that e-cig out of your pocket, you don't have a chance to, you know, run away, I don't know, take your pants off, throw in the trash can. It's not going to happen. You're going to get burnt. And these damages are inevitable.

And you can see that, you know, it starts cooling down, and as it cools down -- and I think the FAA's process of cooling down a potentially -- a battery fire, especially a lithium battery fire, by extinguishing the flame and then cooling it down is very appropriate, is actually one of the best approaches that there is to take. I'm trying to be gentle with this mouse because I know -- okay.

So these are fires that I've investigated myself. It's a house fire; literally, a two-story house was burnt down because of a tiny battery with a protection circuit, mind you. Top right. I can't get the mouse to go there. It's going the other way. So sensitive.

Okay. So this is the protection circuit of the battery that I need to say allegedly causing the house fire.

This is another failure on a medical device, 18650. It doesn't have to be in an electric cigarette, an e-cigarette; it fails if you abuse it.

Okay, so now -- so our experience. Now, this comes to ARTIN Engineering's experience specifically with e-cigarettes, right? Mostly we get called in by the lawyers, not by the manufacturers. Mostly it's the lawyers who come to us and say what happened here, do I have a case?

So money talks, right? As I mentioned on the very first slide, one of our -- a portion of people that we have to deal with are the procurement people. People want to increase their profit margins, they want to save that 2 cents, 3 cents in cost. They go and buy source lithium cells from no-name brand manufacturers that use stainless steel shaving razor blades to cut their electrodes. So fundamentally, we've seen a lot of cases that have to do with cheap, cheap, cheap stuff that's being used, cheap components on the electronic circuitry or cheap manufacturers of lithium cells, relatively unknown sources. Again, that's a key factor. When there's a name brand to protect, at least they try to protect it.

Especially on the mechanical ENDS, the failures that we've experienced, it's directly because of the heating coil. Now, it doesn't mean that the heating coil is heating the cell for it to fail, but it's because the heating coils are messed around with by the end user, by the vape shop that sells it, because as we saw in one of the first -- Dr. Williams's presentation earlier, the average age of an e-cig user is around 30.  They're mavericks; they modify it, they play with it, they come up with, you know, different types of fun stuff to do with these.  One of them is called dripping.  It's something -- apparently it's been around in the industry for a while, but I just heard about it, where they take out the coils, the factory-installed coils, and they fiddle around with it so it doesn't glow red hot, it glows white hot.  So when they -- and they keep it dry and then they drip the e-liquid on it.  What that does is that the e-liquid goes into vapor phase immediately, the smoke is whiter, it's denser, it's -- there's much -- a lot of smoke that they can inhale.

Then they do what they call tapping.  So then they, you know, they tap on their mouth and they make these geometric shapes, and because the density of the smoke is now so much, those geometric shapes stay and they float away from them.  So it's a game.  So they come up with these things, and they alter the device.

And so let me just go to some -- I'm worried that I'm going to run out of time, so let me go to -- jump and go to -- I guess this is typical; I mean, I concur. Most of the headaches that we've seen come from -- this is an actual sample from one of the e-cigs that we investigated. We got permission from the lawyers to share this with you. There's a lot more, but, you know, they were okay with it. The middle picture is that 18650 cell. It sits in a very rigid structure, which is the right picture; it's typically brass or copper or something like that, typically made in a machine shop and without a lot of engineering, no protection of circuitry. A hard button dumps all the current from the cell to the coil, and unfortunately, in order to save cost, they actually go and break their old laptop battery pack, take that cell out of it and reuse it, as we saw earlier in the presentation.

And this is what I'm telling you, you know; these coils are not meant to be like this. The factory typically doesn't sell coils like that.

These are off of people's blogs. These are pictures that we found off of people's blogs. I mean, they're intricate, beautiful geometric designs, but completely senseless from an electrical perspective. This is the star shape that the guy was claiming to have made. Where is it? Right over here.

You know, they sit down for, I assume, hours maybe or a long while to come up with a coil that looks like this, but they don't know how much current is required by this coil, how much discharge the cell is. They don't -- not necessarily quantify that.

This is a typical coil that comes with many of the cigarettes that we've seen, and then they go take that, loosen these two screws, and they come up with this type of a coil design. I mean, just look at it, right? How do you know what battery, what cell needs to be there to safely power the coil like this?

And sometimes, in order for it to glow white hot, they actually cut the coil, they shorten the length of it so the current path is less so the heating would be -- the IR heating would be -- would increase.

And this was off of another person's blog. It's the same e-cig with different coils on it, and I used his numbers. The top one is a stacked quad, parallel 28G is the middle one, the zipper coil. So it's all these fancy names and all that. And he had measured the impedance of the coils. The top one is .14 ohms; middle one is .35; the bottom one is .25, a quarter of an ohm.

So basically what this does is that that same cell, at the very minimum, at a charge voltage of 4 V, has to -- is providing 11.4 A and at a full state of charge is providing 12 A, granted for 2 seconds or so, 3 seconds or so, and at the same time, when he changed the coil on it, you're discharging that same cell at 28.6 to 30 A. These cells are not meant to do this; mostly they're not, especially the ones that come out of laptop -- you know, battery packs are not meant to do this.

Now, there are some high-rate discharge cells available, you know, RC, radio-controlled airplanes; they've been doing that for a long time, but it's costly, and you need to have the know-how to make that. But not necessarily are all the 18650s available to the e-cig people capable of these types of currents, so you're just asking for trouble.

So I think I need to rush it. I only have 2 minutes, but you know, these are some testings that we do specifically for devices. It pertains to cell phones, e-cigarettes, laptops, notebooks; it doesn't matter. I mean, as long as there's a lithium battery in there, these are the types of testings that -- I just wanted to kind of -- there's a teardown, you can tear the cell down, verify the design again, the design, make sure that all the insulating tapes are available, have been placed there appropriately and correctly.

And you've got some data acquisition going on with different types of testing. If this mouse was a little bit more friendly, I would've been able to explain them better, but we take samples from protection circuitry, and we induce a failure, and we kind of make sure that they're supposed to fail where they are -- or supposed to activate, not fail, activate when they're supposed to, so at a certain voltage, at a certain current threshold.

So there are things that need to be done, and I think the industry should be able to -- should follow this and just do a sanity check.

But just not necessarily because there is a protection circuit involved. This is another physical measurement that we've taken. Does it mean that protection circuit is used appropriately when assembling the e-cigarette or the device as a whole? This particular protection circuit was rated to trip within 11 ms of the type of failure that it saw. But our measurements, and that's a physical scope measurement, it was taking 210 ms for it to activate.

So you need to verify these things. You know, if you're designing and if you're procuring e-cigarettes to sell in your shop or you need to ask for certification, there needs to be some sort of a sanity check done.

And these were just examples of some of the other -- oh, another type of testing that needs to be done; this is from another ENDS device. Believe it or not, this had a thermistor in there, which is really fancy, but it wasn't really calibrated to measure the temperature correctly. It had an output, but the output wasn't being calculated appropriately by the electronics.

So next slide.

So, you know, educate yourselves. Don't buy junk; don't go buy whatever is available. Cost reduction of 2 cents, 3 cents, ultimately when you have a $20 million recall on your hand, doesn't really mean much.

Thank you.

(Applause.)

DR. YEAGER: Thank you, Dr. Forouzan.

Our next speaker is Paul Shawcross from Battelle.

MR. SHAWCROSS: Good afternoon. My name is Paul Shawcross. I work for Battelle in Columbus, Ohio.

And I think we already discussed some of this earlier in the presentations, but some definitions on failure mode and effects analysis. Failures are referred to throughout this presentation as reactions internal to the battery becoming uncontrolled and leading to something that's self-propagating.

Damage, as referred to throughout this presentation, any irreversible reaction or process in which the capability of the battery management system is stressed or it's incapable of preventing thermal runaway or some sort of failure.

And then the failure modes and effects criticality analysis, that's what I'll run through today, as it applies to a project we supported more than, say, 5 years ago. And then hopefully I can take some of those lessons we learned and apply it to how you would do a general failure modes and effects analysis for e-cigarette batteries.

So like I said, we did a study a few years ago for -- on lithium-ion battery, electric/plug-in hybrid electric vehicles, and that report, this was a very -- this is kind of the scope of my presentation as well. It was a very top-level failure modes and effects analysis because what we were trying to do is help give people who set the standards and regulations for the batteries that go into vehicles, how to help them identify data gaps, safety issues with these batteries so that they can go back and update the standards or make recommendations for required tests. So what I'd like to do today is kind of show what we did there and what lessons we can learn and what can translate over to e-cigarette batteries for that same type of approach; help identify where some shortcomings may be, what gaps need to be addressed, what standards may need to be evolved.

So with our general FMECA approach, we had basically seven tenets we stuck to. One was start simple, start at a very basic level of our battery and work our way up. Especially within vehicles, we go from individual batteries to packs, modules, to the entire vehicle system. So start simple and involve as many different backgrounds as you can with the analysis.

Along with starting simple, you have to work your way up, so we started down at the battery level, worked our way up to different components throughout the vehicle.

Determine what can go wrong, internal and external to the battery. Not as easy as it sounds because it kind of starts off as this shotgun spread of what all can go wrong within a battery, and it can be a very daunting task going into it. You may find yourself asking what have I gotten into and how serious are all these consequences, but as you start to work through it, you start to develop a feel for the probability of how often things could occur, what the severity could be, and then you go through some practical means to mitigate some of these hazards.

With the general FMECA, we kept it very discreet. We didn't apply it to any specific battery manufacturer or vehicle manufacturer. Like I said, it was more of a shotgun spread, sort of, to make sure we covered as much of battery and vehicle designs as we could, so we didn't kind of trap ourselves into one mode of thinking or just looking at one battery design.

And after we did that, we assigned severity rankings for what could happen if a battery failed, how severe the injury or the risk would be to the user, to the battery, to the equipment, to the vehicle.

And we made sure we covered every aspect of a design. So not necessarily looking at just injury to a vehicle, a driver, the passengers, but also the vehicle itself, every aspect of the vehicle design, the battery design, was taken into account.

And after we summarized that, we made recommendations on existing data gaps and ways to develop standards or tests to address those gaps.

So I said start simple. When we started off our FMECA, we brought in a very diverse group of engineers, including chemical engineers, electrical engineers, technicians, and we all just started with that basic diagram of a battery. I'm sure a lot of us, most of us in the audience understand how a battery works, but it's always great just to start from scratch and get everyone involved and make sure everyone's on the same page on what the approach is and then see if anyone has some insight, some questions, some ideas that you may not have thought of yourself that you can then apply to the FMECA.

So then we get into predicting what could go wrong and how, and that's where we apply our "work your way up" approach, starting with the individual batteries and going up to the different systems, modules, and rates associated with that.

So with failures on the battery, they are usually caused by heating or what we call hot spots. Some impulse or insult to the battery makes the battery perform outside of its range. There's something, there's some heat generated in there; we call those the hot spots.

This heating can trigger the onset of additional exothermic reactions. You can create, either through chemical decomposition or other means, more flammable or oxidizing materials or chemicals that can come into contact with each other and react. These reactions can continue to build and build and build; they become self-sustaining and propagating, and before you know it, you're reaching thermal runaway.

These damage effects can then start at the cell level, and then if you have several batteries together, they can spread from battery to battery in kind of a sympathetic reaction, so spreading from one battery to the next battery and then up to the module level or pack level if you have a whole system of batteries in place. And without any means to check or mitigate these failures, that's when you run into trouble with the thermal runaway occurring.

So thermal runaway, we talked about this earlier, that's the rapid heating of the battery that's going to outpace the rate of heat dissipation to cause some issues. So it's important to know the rate of heat generation and how quickly you can remove it. There's a lot that goes into the design of a battery from the materials, the size, and the quantities of the materials that you use, the design of the battery itself, to look at where heat is generated and how quickly is it removed. And that's why your dT/dt, your change in your temperature over time, is so critical because you want to know how that rate influences the response of the battery.

My background is in energetics, so I always like to kind of equate these ideas to some nice pictures I have put down there at the bottom.

A good example of change in temperature versus time is metal oxidation. So I can have a very safe reaction, just a piece of iron there that rusts over time, or I could have like an almost pyrotechnic charge, which iron is again being oxidized. We're getting the same end product there, which is just rust, but they're occurring at much, much different rates, and one is very -- one you don't want to have happen.

In our FMECA we also included this chart here. It kind of gives an overview of what could go wrong in events that typically lead up to thermal runaway and at what temperature ranges they happen. It's not all-encompassing. We took case studies from literature, from references, and included those examples here in this chart. And the idea is that you can have, you know, reactions like the SEI layer decomposition. That can occur at lower temperatures, like at 60 to 120 degrees or so there at the bottom, bottom left, I believe. And they can give off oxygen, flammable materials, sources of heat that can then grow into these other columns as you go from left to right.

So you can have these failure reactions that build into other reactions, that build into worse reactions, and before you know it, you have several processes going on at the same time that can be catastrophic.

With our thermal runaway analysis, that's when our heating becomes self-sustained. So we have all these, like I said, cascading reactions. So a good example of that is your SEI layer decomposition. If it decomposes at relatively low temperature, on that slide I just showed you, it can produce flammable materials and as well as oxygen.

So those can go out and react with other materials within the battery, and before you know it, you have pressure generated, heat generated from all these reactions that can cause issues with your battery.

And an important thing here to note, too, is you can have global conditions that seem okay, you can have your oxygen level or your fuel level well below what's considered hazardous or it's well below your explosive limit, but in a local area it may not be that safe.

And when we were preparing this report, we had one of our senior technical reviewers take a look at this and he asked --

he saw this chart here with the hydrogen and the oxygen molecules, and he said to me, he said, so if I understand this right, if I'm in my garage and there's a small pool of gasoline that's just collected on the garage floor and I strike a match, the whole room is going to explode. I said no, but what could happen is if you bring the match in close contact with that small pool of gasoline, even though you're in this large garage and you have a piece of paper that's near the gasoline and that could ignite, you could have a reaction that you were just not ready for.

So things could look safe from the outside, from the global conditions, but you have to look at those local conditions and get a feel for, you know, a probability rank of things to go wrong.

So I know we talked about this a little bit earlier, too. It's important to know what insults can cause thermal runaway in your system and what is designed in the batteries or the packs and modules to mitigate against thermal runaway from happening. So things you would look at include your mechanical damage, probability of an external short, internal short, cell overcharge or discharge, low temperature recharge, and high temperature storage.

It's important here along the way to also assess the probability of things occurring. Probability goes a long way with your failure modes and effects analysis, especially with trying to identify just what level of safety you have to be at in order to be at a certain probability of risk not occurring.

So then you can have design features in your battery at the pack level. I know a lot these we've already talked about, but fuses, shutdown separators, vent disks or plugs, those should always be incorporated into your design to prevent catastrophic failure from occurring.

So getting into our failure modes and effects analyses, the first part of our approach was to analyze those failure modes, the sources and their effects, for all of the elements of the lithium-ion battery system.

So we kept it general, and we made -- we had the largest reasonable set of probabilities to occur in our failure modes and effects analysis, and again, we tried not to be manufacturer specific.

In Part 2 we look at what we created in Part 1, and we looked at factors that are more external to the battery, so more related to the environment of its use; especially for vehicles, how often do you recharge it, how often is it driven between charges; and then how do you tie that back to a failure mode.

And then after we had that summarized, we classified the failure modes using our severity ranking.

So this is a little bit of an eye chart, but I just wanted to show you how in-depth our failure modes and effects analysis was.  This was about an 800-page document or so that I hopefully summarized in about a 20-minute presentation, so I left a few details out.

But the idea is that we took each individual component of a battery and tied it into, you know, what causes of failure there could be and what effects those had starting at the cell to the pack to the module all the way up to the vehicle and the user.

On the second page, this is where I identified kind of those environmental conditions, so how often you charge, how often you drive your car.  I think a lot of the information that John presented earlier with the statistics on, you know, e-cigarette use, number of average puffs or number of puffs per day, that's good information to have because then you can quantify its use or its environment and then hopefully tie it back and assign some probability factors and severity ranks to the failure modes.

So having that data on use or what types of environment it's used on, they're useful for the failure modes and effects analysis.

So after you've defined your failure modes and then your environment in which you would use them or use your battery, it's important to have a severity rank and then a path forward.

The severity rank that's presented here is specific to the vehicles, and we identified kind of those low-risk, low-severity examples. We gave it a value going from 0 to 7, 0 being no effect from the insult or from the failure mode, up to an explosion of the battery, so the worst-case condition. So with each failure mode we identified on the previous two slides, we identified or we assigned a severity rank to each. And for that, after you do that, you get a feel for where your path forward should go. So if you have any severity ranks that are in the 4, 5, 6, 7 range, that tells you that need to identify or develop standards or tests to help bring those severity ranks back down or lower the probability of those ever occurring.

And as an example, you may see that the standards may need lifecycle durability and damage tolerance testing because there's so much of the data on lifecycle that says, okay, if lifecycle may be an issue, you may run into, you know, venting or fire or flame of your battery if unchecked after a while.

So in translating this from what we've done with the vehicles to e-cigarettes, the approach that we basically recommend is to identify your primary hazard, which is the battery failure, heating and rupture, identifying which -- a lot of the same things we discussed before with batteries. What are the likely damage sources? How can the battery fail as a result of this damage? And then how are the controls and safeguards designed to mitigate risk? What is in there already to prevent these failure modes from occurring? And like I said, it's likely to be similar to what's been done already for other lithium-ion battery FMECAs.

The secondary hazard is more -- pertains more to how the e-cigarette is used. You have to take it into what I call environmental conditions, environment and use conditions. So if you store it in your pocket, if there's any faulty controls or safeguards or after-market modifications, you have to take all those into account and know that some user somewhere may modify their e-cigarette device or have it in their pocket 20 hours a day, 24 hours a day, and you have to know what those conditions can do to how the battery is going to perform.

Also, you have to look at the overall e-cigarette design and if there's any designs that can help or design changes that can help mitigate risk.

So we talked about how the e-cigarette, too, can almost act like a rocket when the battery fails, and you have a lot of pressure coming out one end; it's tube-shaped, it's going to shoot right back up into your face, so you have to take that into account and look at different designs.

Also, the proximity of your battery to the heating coil and the flammable vaping liquid, especially if you're looking at a worst-case scenario where you have your battery failing, but also you have a secondary factor from a flammable vaping liquid creating this large fireball right next to your face; that's another factor specific to e-cigarette use that you have to take into account.

So for the severity rank for e-cigarettes, you have to -- I haven't seen anywhere where severity rank was already defined, so you would have to establish your own severity rank definitions, similar to what we had presented for the vehicle batteries.

You have to consider all the scenarios, even the ones that are unlikely to occur, like I said taking into account the ignition of the flammable vape liquids and identifying what could be your MCE, or your maximum credible event. That helps shape where the worst-case scenario is, and this gives you a starting point to how dangerous e-cigarettes can be or how safe you need to build it, either way.

And then you have to do an exercise in identifying the data gaps, know what existing regulations and standards are out there, compare them with the results that you developed for the e-cigarette FMECA and severity rank, and then once you have your severity rank established and you have a knowledge of the existing regulations, you need to identify those areas where the severity rank is high and there is not an applicable safeguard control or standard that's out there to help address that severity rank.

And then from that you can help set the standard, you can propose a new set of tests, you know, identify new or revised standards, or put on other supporting safety documentation to help make for a safe e-cigarette design.

So, to summarize, to perform the failure modes and effects and criticality analysis, you have to understand all the failures and damage that can occur and initiate these failures.

You have to identify the primary and secondary effects, you know, those effects that are particular to the battery design or those that will come out from use in your environment and how the e-cigarette is usually handled.

And you have to use the results to perform that data gap analysis and understand what needs to be done next.

I think that's it.

(Applause.)

DR. YEAGER:  Thank you very much, Mr. Shawcross.

At this time we'll take a break, and we'll resume again at 3:30.

(Off the record at 3:14 p.m.)

(On the record at 3:31 p.m.)

DR. YEAGER:  And our next speaker is Ramon Alarcon from Fontem USA.

MR. ALARCON:  Good afternoon.  I guess I'm fortunate, maybe you're fortunate, and I'm the last speaker of the day. So we'll get going here.

What I'd like to do is, you know, we've had a lot of people speaking today and have hopefully given you a great background about some of the theoretical and the basic design principles, and what I'd like to do is give you a little bit of perspective from a manufacturer, perhaps a very practical perspective.

So if I can have the next slide, please. Next one.

Just to introduce Fontem to you, for those who don't know, Fontem designs and manufactures electronic cigarettes, and we're a global company. We do our R&D and design in Silicon Valley, we do our e-liquid manufacturing in the U.S., we have operations in Europe, and our battery production is done in Asia. And over the last 8 years, we've shipped approximately 70 million devices containing lithium-ion pouch-type cell batteries.

Next slide, please.

And we sell these products under the blu brand both in the United States and several key European markets. And that gives us good insight into not just some of the requirements and regulations in the U.S. but also in the European market, and that informs our design as well.

Next slide, please.

And then to give you a little bit of a sense about where we play, a lot of the discussion today, I think, when we hear about 18650s and that style of battery, that's really on the far right-hand side of the spectrum. Where we play is a little bit different than a lot of what we talked about today.

On the left-hand side of the slide are rechargeable cigalikes and disposables, and what I've tried to plot out for you is if you look at the x-axis on this graph, it's the capacity in milliamp hours. So these cigalikes and disposables are more in the order of, you know, 100 to 300 mAh is the amount of energy that you have in those. Then you get into these pen-style refillables; they're approximately in the 1000 mAh range. We sell some accessories roughly in the 1500 mAh range, and then we have these other typical mod devices, maybe anywhere from 2000 on up to 4000 mAh.

And as a designer, you know, we think that where you are on this graph, you want to take an approach that's aware of how much energy you have, and you may take different risk mitigation actions in your design based on where you are in the spectrum.

Next slide, please. And the next one.

So I have a couple slides on the basic principles, but I'm not going to go too deeply into them because we had all these great presenters talking about it before.

The first example, though, is you have to select a battery that's properly rated for your application. A very simple example is if I have a cell that can be charged to 4.2 V, and I have 1 ohm coil, well, I'll get 4.2 A of max current.

Well, if you have a device where, perhaps, you can change the coil, let's say you cut it to half an ohm, well, you've just doubled the amount of current. And I think, as Eddie -- if he's still in the audience, he pointed out in his slide, that yeah, you will have higher and higher current, max current draws on your battery, and you just need to make sure that the battery is sized appropriately for that, that it can support it.

Some other things other people touched on, don't discharge too aggressively. That can be, you know, too high of a load or short circuits. You want to charge the battery correctly; we had a lot of discussion on that.

You need to provide space, especially in our application where we use primarily pouch cell styles, provide space for those batteries to swell a little bit. You get a little bit of a thermal expansion as the device heats up, and you don't want compression on those layers.

So, again, this is kind of Design 101 principles, just reinforcing again and again and again.

And then if we could go on to the next slide.

This is, again, a basic kind of overview of what we think should be in most e-cig systems. In the center you'll see there is a microcontroller. This could be an e-cig, some dedicated IC, but pretty much every e-cig, except for these mechanical mods that are just switch based, will have a controller at its heart. And then if you look at the bottom right-hand side, you'll see a transistor that usually controls the heating coil, and a battery cell.

And the two things I want to draw your attention to are at the top and the top right. At the top is a lithium-ion battery charge IC. What this does is this controls the charging of the device, and then the battery protection IC controls short circuits as well as overdischarge.

And the nice thing is, as a manufacturer, there are a lot of vendors out there that sell solutions, chip vendors, IC vendors, that sell solutions that you don't need to be a battery expert. They have great designs; they've done the work. You need to understand, as a designer, how to use these and implement them properly, but they've done the work of making sure they have chips that work not just for e-cigs, but for any lithium-ion battery applications if you follow their design guide properly.

Now, that's not to say you have to use those. In certain applications, you can actually design them, incorporate their functionality into your main circuit design, but as a manufacturer, if you choose to do that, you need to take the responsibility of the additional testing to make sure that you've really achieved equivalent functionality.

Okay, so if I can have the next slide, please. All right.

So I've gone over some basics, and what I'd like to do now is turn to a couple of perhaps lesser-known examples. And it's not that I want you to remember the gory details of everything, it's just to point out some of the nature, some of the types of problems or issues that can arise and how we might want to deal with them.

So the first one is ESD and fast transients. Really quickly, ESD is when you get a shock. When you run across the carpet, you build up static electricity. Fast transients are essentially what happens if you plug a device in, especially to some third-party adapters, you may get a momentary power surge on that line.

So the example I'd like to walk through here is we had a scenario where we had a vendor for our charge IC that was discontinuing the part, which is common in the electronics industry. So what do you do? You go and you find another vendor, and you ask for a drop-in replacement, which we did. Now, what we found in our lab before releasing this product with the drop-in replacement was that the built-in ESD protection and fast transient protection in this replacement chip really didn't match the performance of the original vendor.

So what we did in this case is -- you can see these circuits that are drawn at the very bottom of the screen. The circuit on the bottom left has -- you're just connecting your charge input directly into that charge IC. That was the old design.

And what we did to accommodate this other chip, this replacement chip, was we added essentially some ESD protection, that's this ESD diode that you see on the bottom right, and some ferrites. You know, I think that was, I'm going to guess, in the 5- to 10-cent range in terms of the bill of materials. But what it did was it allowed us to then have the freedom to pop in these replacements and have a more robust design that was tolerant to any manufacturer of this equivalent chip.

So next slide, please.

The second of the lesser-known considerations. We know that sometimes users, especially on refillable devices, have -- you have to anticipate the user scenarios where they may overfill or fill in the wrong port or somehow get liquid in a place where it really shouldn't be, and you can do your best to mitigate that, but you know, you really -- one consideration is, well, what happens if liquid does get in there; what do I do? And we found, in one case where we had this weird effect where with some liquids we got some capacitive coupling of a signal and you could actually energize the coil inadvertently. This was done at the lab; this wasn't done out in the market. This was an example of what we do in the lab to make sure that we deal with these conditions.

So, again, what we did to address this is, we did encapsulation of certain key traces, which is where you would coat them to make them impervious to the liquid, but also we designed the circuit to be tolerant to liquid ingress.

So, again, these two circuits, the one on the bottom left is the original one where you see this controller that's essentially directly controlling the transistor that's labeled PFET that then controls the heater coil.

So in this scenario where we had this weird coupling effect, you could effectively have that line, even though you didn't want it to be held low, to be held low, and the transistor would be on. A design approach that fixes that is we essentially put a high-pass filter in line -- that's shown on the bottom right -- where what has to happen is, is that if that line is held high or low depending on what type of transistor you're using, it doesn't matter -- what has to happen is, is that you have to keep that line changing, so you have to be under active control doing something purposeful to the device.

It can't be that it's simply in an unknown state or a pin is pulled low. What would happen is if that were the case, this circuitry would then prevent that coil from staying on; it has a built-in cutoff time. So thought about a different way, it's essentially sort of like a double-fault protection, so in case you have a stuck-on coil.

I think the person from the FAA mentioned that earlier, there are ways to add additional layers of fault protection that would prevent those sort of conditions.

Next slide, please.

And then the final lesser-known consideration is we've actually had -- I'm happy to hear people talk about this -- overdischarge. And let me give you a little more clarity on that. Obviously, overdischarge, especially repeated overdischarging is a problem. And even if you have a battery protection IC, you know, that really shouldn't be your first line of defense because your battery will still self-discharge, and some of these battery protection ICs are kind of gross devices where, you know, that tolerance, that spec on the cutoff has a wide range.

And then to compound the situation, some microcontrollers, they have a brownout or a cutoff somewhere in the 2.5 to 2.8 V range, not all, but some. So what you could get is, you could get this scenario where you're not really sure who's in charge of making sure you're not overdischarging too deeply. And that's really not a state you want to be in; bad things could potentially happen. They could be low-frequency events, but there's really no reason to allow them if you do things properly. And you don't have that much battery capacity left anyway, maybe less than 10% of the usable energy.

So our approach, shown in this design here is, to say look at a cutoff voltage, for example, at 3 V. You go ahead and you cut off the circuitry. The processor would remain in charge, and it would put everything into essentially a low-power sleep state to conserve energy until the next time it was recharged, and that would allow it a long shelf life. I will say if a user had used it, set it aside, it's going to be fine.

And what's shown in the bottom left-hand side here are two circuits. This is just an example circuit used to take an analog reading. The one on the left has certain resistor values; it's perfectly functional.

But if you start it with a battery at 3 V and let it drain, it would just drain through this circuit, and it would take 162 hours roughly for this to fully drain, whereas small modifications to the design, by changing the resistor values, adding a capacitor, you know, that may be a 1-cent add, if that. It would let that product then last for 12,000 hours before being fully drained.

So you can see that it's hard to anticipate some of these issues, and they may not all be obvious, and a lot of times there are very simple fixes to these.

So if I can have the next slide.

One thing I want to do in this presentation is I know there are some current concerns about, well, could I make these changes and not impact aerosol formation? And the answer is absolutely yes. In a well-regulated device, you can say -- you can even go so far as to change the battery cell because that's pretty fundamental, isn't it? But a device that's power controlled or current controlled or at least controlled properly, you can improve the safety of the system without impacting the aerosol performance.

And that's what this graph at the bottom tries to show, which is what we did here is just ran a simple experiment where we took two cells. Let's say you had a cell without battery protection circuitry and the manufacturer wanted to add it. Well, you're going to have to use a slightly smaller cell to fit that circuit in there.

So here we have a 220 mAh cell and 330, and what you can see is from a vapor output production, which is just a generic measurement we have that correlates well to shot weight, you essentially get the same vapor output, the same aerosol output from the two different batteries.

So I think that goes to show that done right, it may be worthwhile to do these changes to improve safety, and you can do it without impacting the aerosol delivery.

Next slide, please.

And then one other thing I wanted to comment on is integrated cells versus replaceable. Currently, we only do integrated cells. Integrated cells can be tested. We can have the confidence of identifying the vendors, working with our manufacturers, and doing the testing.

And I think some of the other presenters mentioned there are challenges if you allow for replaceable batteries. You just don't know what the quality of the battery is, what the ratings are. And I think, again, some other users mentioned that some of these replaceable cells don't even have battery protection ICs.

So, anyway, that's -- I think that's just confirming the same point that a number of the other presenters made.

Next slide, please.

So just a quick recap. Follow the basic design principles. You know, even if you follow those principles, you can still have some low-frequency events, and having the ability to make subtle changes for the benefit of safety can be done in a way that does not impact the aerosol formation.

Next slide.

So in the 4 minutes or so I have left, I want to touch on the other aspect, which is the cell manufacturing, and I think someone else also mentioned it's obviously critical to have a great quality cell.

Next slide.

Most of these have been touched on. I think the things on this that maybe we haven't heard, from our perspective, from my perspective, personally, having been to at least a dozen cell manufacturers in Asia, is how do you start to qualify that vendor?

One of the things we look for, and I look for, is a clean and automated facility. As other people mentioned, contaminants lead to problems in cell manufacturing, and you want to look for an absolutely clean facility, if you can.

And then automated lines just offer more process stability and cell-to-cell consistency. So when you're testing a small lot and trying to extrapolate to what's going to happen to a million cycles, well, you can do that a lot more readily if you have a manufacturer with automated cell production.

Let's go to the next slide because that touches on the last few points anyway.

A good test that we found, and we would recommend to manufacturers, is the K-value test. Ask your cell manufacturers to do this test. And what it essentially is, is the cell manufacturer makes the cell, they take a voltage measurement, and they set it aside for 3 to 7 days, and then they measure the voltage again. And you want to look for a change in voltage to be within a certain range.

If that change is too high, that can be an indicator of problems; that can be like a microsite for the initiation of a micro-short, an indication of dust, burrs, metal impurity, or moisture in the process. It costs a little bit because, you know, they carry that inventory for another 3 to 7 days. But for us, it's not a perfect measure, but it's a good first-pass surrogate for identifying a quality manufacturer.

Next slide, please.

Really quickly. We also ask our battery manufacturers or cell manufacturers to test to certain standards. Some of these standards you can see mentioned here, and there's overlap in terms of the type of testing they do. And then you may choose, as a manufacturer, to do some additional testing. The ones highlighted in green are really the common standard tests to do; they go more towards safety. You may choose performance tests as well, and those are some of the un-highlighted ones. If you have good performance and good consistent performance, it goes to be a further indicator for the quality of the manufacturer.

Next slide, please.

And then I think someone mentioned this already, but you know, battery -- cell manufacturers will publish data of constant discharge conditions and standard conditions, but we do our own testing, and we ask our manufacturers to do testing using a more e-cig specific discharge profile.

And that looks like something like you mentioned with the power tool. It's basically on. We choose 5 seconds, that's a pretty aggressive e-cig user with a 5-second puff, and then off for 15. It's pretty aggressive, but it's more similar to what you would see.

And then let's do the next slide and then the next slide again.

And then in the 10 seconds or so I have left, there are some efforts going on in Europe on this very topic. There's a work group, Work Group Number 2, that is working on it.

And the final slide, please, next slide.

I don't expect you to be able to read it, but essentially what this says is this work is ongoing through 2018 through 2020, and they are covering some of the same topics we're discussing here in addition to ones in other work groups. And so I think anyone paying attention to this area should look into what's going on there and try to leverage that work.

Thank you very much.

(Applause.)

DR. YEAGER: Thank you, Mr. Alarcon.

And now we'll move to the Session 3 panel discussion for Failure Modes and Design Strategies. So if Dr. Forouzan, Mr. Shawcross, and Mr. Bellinger could join us.

So we'll start with a question from the audience, so please introduce yourself.

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

So I've got a question for John and Ramon. Do you see the need for real-time K-value testing while the device is in use or the ability for the device to be able to effectively calculate the load drop on the battery under known power conditions with the coil so that you could, in essence, screen out other bad cells, or if you're looking at a device that has the ability to accept a wide range of user-selected cells, to be able to screen out possibly cells that wouldn't be able to fit your power profile or that are degrading over time based on the long duty cycle nature of the e-cigarette? I mean, if it's sitting dormant on someone's desk or in a pocket for, you know, half a day, you should be able to tell if its leak-down voltage is excessive, you know. A poor K-value response essentially.

MR. ALARCON: I can --

MR. TYLER: Two questions in one, I apologize.

MR. ALARCON: Yeah, two questions. I mean, for us, just to reiterate, we don't do the replaceable cells currently, not to say we wouldn't. So I can say in our integrated devices we don't really see a need -- if you design it so that you have a sufficiently long self-discharge cycle or through your circuitry, it's probably not needed. But I think, to me, it makes sense, especially as you go up in that higher current capacity product to have some ability to do that. So I don't have any data that says you have to have it, but it seems to be like one of those commonsense things that would be reasonable to look into, and I would imagine, again, not having firsthand experience, but with some of these user replaceable cells, it may be more important in that sort of a usage scenario.

MR. TYLER: I mean, you know, effectively you would see, as capacity goes up, so does the surface area of the -- you know, the anode, the cathode, and the separator. Your defectivity is going to scale with that, so what's your D-zero, right?

MR. BELLINGER: We try to design for essentially zero self-discharge current when it's in a sleep state. It's an interesting idea. I think the problem is by the time -- you know, these are being used periodically throughout the day unless they're thrown in a desk drawer or they've got one at work and one at home.

Getting a measurable drop between, like even if it's one at home and they're not using it at work because they have a different one at work or whatever, getting a measurable voltage difference there will only screen out really seriously damaged cells. I mean, it's a fascinating idea, and I can go back in the lab and tweak some stuff and look at it because it isn't something I thought of, but just anecdotally I would say that's not going to catch anything except stuff that's probably also actively getting warm as you have it plugged in. But no, it's a fascinating idea and I'll look at it.

MR. TYLER: I got one last component, like, as a follow-on, and then I'll go sit down. All right, so you said zero current. I don't believe that -- obviously, you know, battery protection IC is going to burn 3 to 6 μA, you're going to have a micro that even in sleep mode is going to burn a micro-amp. What's zero?

MR. BELLINGER: We actually turn our micro -- we actually turn our -- other than our -- so zero is a couple of micro-amps, but we actually turn everything off and then hard power on so it is a true off-off-off-off-off. We have, like, an on analog switch watching battery voltage so you don't have self-discharge bleed from that resistive divider or things like that. So --

MR. TYLER: Low standby current, then?

MR. BELLINGER: Well, I mean, you're not really standing by anything because you just physically turn off rather than say, well, what can we sleep? But yeah, a couple of micro-amps at best.

MR. TYLER: Okay. And is that low enough? Do you mean on -- you know, what's that time constant look like for -- I mean, if you're only burning 2 μA, let's say, how long would you have to measure the device to see a differentiable result, do you know?

MR. ALARCON: I'll let you answer the second. I'll let you answer the second part of that. But if you think back to that slide, that example had a 224 mAh cell discharged to 3 V, and it was, what, 12,000 hours until it got to zero. So, you know, I don't know, to be quite frank, if that was through the battery protection, and I see you measured at a different point, but --

MR. TYLER: Correct.

MR. ALARCON: -- at a minimum, the rest of the circuitry, that's the quiescent current draw, and I think that's quite tolerable, and 12,000 hours is on the order of, you know, a year plus.

MR. TYLER: That's a lot.

MR. ALARCON: Yeah, that's a lot.

MR. BELLINGER: Sorry. Another important thing to consider with these, especially right now, is in a year the design is obsolete and people have moved on to the next shiny new thing. So, yeah, this isn't a remote telemetry device where you want to have it kept alive for the next 25 years because it's down inside a volcano. Yeah, I would agree a year is a perfectly fine standby time.

MR. TYLER: Thank you very much.

DR. YEAGER: So this first question, or second question, is for Dr. Forouzan. Can you explain how electrode slitting and burr control could be done better than using a dull razor blade? Are these items of manufacturing control well known across the industry?

DR. FOROUZAN: So that's a very good question actually because I think the answer to the second part of the question is already there, that it's not or else they wouldn't have been using a razor blade meant for cutting hair. So the industry has developed multiple different methods of dealing with burrs, dealing with particles, not specifically just related to incoming inspection of the raw material, but during the process of manufacturing.

Hardened steel: I've been to many manufacturers that invest over $100,000 just to machine one cylinder which has multiple blades, and it's made of a very specific material, hardened steel. It costs $100,000 to machine, and it is precision machining, but those are the ones that are tier one manufacturers. I don't believe that, unfortunately, many of the cells that are used in the end products, ENDS products, come from tier one manufacturers. So we are inevitably dealing with manufacturing sites that are not heavily invested in the technology.

But the other problem there is, is that there isn't a lot of conversation between manufacturers. Understandably so, you know. Some of them have invested billions of dollars over the years, over the last 20 years in developing manufacturing processes. Why would they want to share it with somebody who's just off the street and knocking off cells for real cheap?

So as an auditor, as an expert in the field, yes, I know that there are methodologies available, but unfortunately, it's not common.

DR. YEAGER: Do you have a question? You can stay there.

MR. KERCHNER: Okay. I'm fine.

DR. YEAGER: You sure? Okay.

MR. KERCHNER: Sure. I'm George Kerchner. I'm with PRBA - The Rechargeable Battery Association. We represent a lot of the tier one manufacturers you're referring to; they are product manufacturers. So the idea that we have a product here that has a heating coil next to a possible flammable liquid and you drop a cell in there that's not designed specifically for that product obviously gives our members a lot of -- a little bit nervous obviously.

So the integrated battery approach, which your company, Ramon, I think does, I think, is that an exception for -- to the rule for most of the e-cig manufacturers or what percentage of -- I guess my question is what percentage of the industry uses drop-in cells versus, say, integrated, for example?

MR. ALARCON: Sure, thank you. I don't know the exact percentage. I think that there are three really big manufacturers in the U.S., three large brands that primarily play in the cigalike or smaller form factory devices, and to my knowledge, we don't, and I don't think the other two large-by-volume play in that sort of space where we're really high energy capacity.

And I would hate to hazard a guess, but I guess what I could say is if you're interested, there's Nielsen data, at least for the portion of these three large manufacturers, that you could go reference and at least get a sense of scale. I think it's going to be more difficult to get real accurate numbers for the mods and large format devices because they may not report through some of the traditional sales data reporting schemes. But my sense is, it's a lot lower, but they are very popular nonetheless.

MR. KERCHNER: Right, okay.

MR. BELLINGER: Bonnie Herzog at Wells Fargo is the analyst that sort of follows this. If you want to get -- I mean, she's guessing, too, but her guesses are pretty good.

But our experience is that right now it's about half and half. But by volume, because the little devices, somebody might have a handful of them in their pocket because the battery life is fairly short, they're going to manufacture more, but in terms of puffs per device, half and half looks about like what we have seen.

MR. ALARCON: One other thing to your point. I know you mentioned flammable e-liquid. I think -- Paul, right? Paul was using that example as a hypothetical to see if it were, not necessarily that it is, and --

MR. BELLINGER: It is.

MR. ALARCON: -- I'm not aware of -- well.

MR. BELLINGER: It is.

MR. ALARCON: You have many different -- I guess my point is there's a range of formulation --

MR. BELLINGER: Okay.

MR. ALARCON: -- and in some cases it may be possible, but certainly there are things you can do with your liquid, so I wouldn't -- I'd just take that as a cautionary point. It does depend on the liquid you're using.

MR. KERCHNER: But to your company, blu cig, for example, you go out and you design -- you go to cell manufacturer facilities and you say here's our product, design a cell that will -- that we used in our -- that will be specifically designed for our product, for example. You're not using off-the-shelf cells; is that accurate?

MR. ALARCON: Both. Both, really. What we'll do is if we have a design that requires a custom cell, we will ask for a custom cell to be made and then put through the same -- the test processes and qualifications I showed on the slide --

MR. KERCHNER: Okay.

MR. ALARCON: -- whereas we may also have a scenario where a manufacturer may have an off-the-shelf offering, but then we would still require the same level of testing. So it really doesn't matter --

MR. KERCHNER: Okay.

MR. ALARCON: -- if they happen to have it or not. From our perspective, it goes through the same qualification process.

MR. KERCHNER: Okay. So one last question.

MR. ALARCON: Did I answer your question?

MR. KERCHNER: Yes. I'm sorry to hog the microphone, but as far as the standards go, so we've got UL 1642, 2054, the IEEE 62133. The work that's being done, you referenced that it's being done in Europe right now. Are there any e-cigarette standards anywhere that the companies are manufacturing to a specific for -- or for ENDS products at all?

MR. ALARCON: Yeah, I know of no -- I know a lot are under formulation. There are certain elements to ISO, there are certain -- I guess that was a very broad question. I mean, there are standards that are being manufactured to -- for example, a product has to comply for FCC Part 15B, right? And there are other things in Europe, their low voltage regulation.

MR. KERCHNER: Right, right.

MR. ALARCON: Low voltage directive, sorry. So there is design towards that in mind, but I'm not aware of anything that's finalized specific to e-cigs.

MR. KERCHNER: Okay.

MR. ALARCON: You can comment if you know anything else.

MR. BELLINGER: I was just going to say there are some in process; UL just posted one, and I think somebody referenced that. I mean, they're coming; they're not coming as fast as would help us out, but they're coming, we're assured.

And then just sort of on the counterpoint because, you know, Ramon's got sort of the cigarette-sized ones, and I've got sort of the other ones, the people that use my products really love your customers' products. Not that that will make you feel better, but -- because, you know, they really are looking for, sort of, high performance, long-lasting cells.

And it's also just part of where it is in the markup chain. When you're buying an integrated cell, you're buying it from the manufacturer, and then you've got to mark up to the device manufacturer, and then you've got to mark up to the distributor, you've got to mark up to the vape shop or the c-store to the consumer where it's -- you can actually use higher quality cells if you're replaceable just because, you know, it's a cell, the customer buys it with whatever markup there, so it's not -- you know, you can have an extra five cents because that doesn't turn into $2.00 retail, for whatever that's worth.

MR. KERCHNER: Thanks. I've got a presentation tomorrow, and I'm going to talk a little bit about the cell manufacturer's perspective on this whole thing, so I look forward to that, talking to you then. Thanks, appreciate it.

DR. YEAGER: The next is a general question or a series of them. Is e-liquid flammable? Are most explosions of e-cigarettes or the removable separate lithium-ion batteries? Wouldn't keeping a battery that is loose in a case prevent most battery venting and explosion?

MR. SHAWCROSS: So in terms of is the vaping liquid flammable, it can be, but certain conditions have to be met. So I believe most of their flashpoints are going to be above 150 C or so, but don't quote me on that. You have to satisfy conditions like your concentration, like I said, what temperature you're at. So in that sense, they're flammable; under normal use, no. But you have to -- when you're doing a failure modes analysis, you have to define when it could be and what the probability of running the risk of igniting them would be.

DR. YEAGER: Okay. And are most explosions of e-cigs or the removable separate lithium-ion battery?

MR. SHAWCROSS: So the question is if it starts with the battery or the e-cig?

DR. YEAGER: Yeah, it just says are most explosions of e-cigarettes or removable separate lithium-ion batteries?

MR. SHAWCROSS: From what I've seen, I think it's mostly in the battery, and if the question's tied to kind of a secondary condition from the vaping liquid, I haven't seen so much information on that, but that's just something that -- it's just it needs to be taken into account. But I think most of the data or most of the case studies I've seen have just talked about the battery failures.

DR. FOROUZAN: So unfortunately, you know, ultimately what fails is the cell, the battery, right, so the battery gets the bad rap. It's not necessarily the root cause of the failure. I think that the e-liquids are usually glycol-based and glycerin, glycerin-based.

UNIDENTIFIED SPEAKER: Glycerin-based.

DR. FOROUZAN: Yeah? Okay. So, you know, they are hydrocarbons; they are flammable. Certain criteria have to be met, but it's not terribly difficult to catch them on fire. In a closed container, the probability is very low, but it can.

There are fundamental design guidelines. You know, if there is a standard to be published, it really should come from the industry, right, in terms of the same thing with the IEEE 1725, the cellular phone industry sat down, and they kind of came out with that, and it pertained to that industry as a whole. So there's room for improvement, but one of the things that I need to stress again is that most of these standards that we're dealing with right now are really design verification standards. They are not meant to address PPM-level failures.

It is statistically impossible to predict part per million, part per billion level failures, okay? And, you know, the methodology that you proposed, the K-value, which I think it's just basically an open circuit voltage measurement, yeah, that's been done for about 20 years, and the tier one cell manufacturers have been doing that, and it's a very, very good indication of any abnormalities that are significantly influencing current paths of electron, for electrons that are unwanted, so if you have a chunk, a large route for an internal self-discharge mechanism. But a lot of the problems that we're seeing in the field don't really -- aren't really a result of gross defects. The razor blade that splits off and you have a splinter of it on the electrode can influence the delta V over time in the microvolt range.

So you and I would have to sit there for a couple of months monitoring the voltage, or it's just going to be hidden by the internal self-discharge mechanism of the lithium cell as a whole, so you won't be able to catch it. So that's one of the reasons I always, you know, think that self-regulation, self-awareness, penalties involved, you know, to kind of bring the industry back into a mode of self-regulation would be one of the better approaches.

DR. YEAGER: And the last part there was wouldn't keeping a battery that is loose in a case prevent most battery venting and explosion?

MR. ALARCON: Yeah, I think that, if I interpreted the first part, the earlier part of that question, I think it was really asked and maybe answered to some degree by Mr. McKenna from the U.S. Fire Administration, that he had some indication that at least roughly 50% of those were essentially the cell sitting loose in someone's pocket, right? So it's not in the e-cig itself. I may be misinterpreting the question, so I'm sorry if I am, but I thought that's kind of what I heard, and I think that second part of the question kind of goes to that basically do you protect the cell? And if you're having replaceable cells, you should prevent it from short-circuiting by a coin or a key in your pocket.

DR. YEAGER: Well, we appreciate your stretching trying to answer, but if the person in the audience feels that it didn't address their question, I would encourage you to write another card or come to the microphone for clarification.

The next question: How could temperature control and preheat settings affect battery health? These settings may cause current surges to quickly reach specific temperatures that might exceed the current rating of the battery.

MR. BELLINGER: All right. Well, this is asking about specific features in our products, so I guess this is on me. So temperature control we didn't get into here at all because it doesn't really impact battery safety. That's where we're reading the temperature of the heating coil and, you know, throwing power at it to heat up faster, get to operating temperature, and then back off to not generate carbonyls and things. You get a pretty good spike of current, but that's why we have, you know, active cell current limits.

So you can't -- you know, with that, that's still running within your wattage control loop within your, you know, power safety limits. So specific to my implementation, at least, you're still always running within whatever cell parameters are set up in EScribe or, you know, parammed (ph.) into the firmware. So, you know, as long as your cell is matching the settings you have set for the cell limits, preheat shouldn't really impact things.

MR. ALARCON: If I can --

DR. YEAGER: Yeah.

MR. ALARCON: If I can add to that. I would expect an open system or systems where especially somebody could change the coil, it could actually be beneficial. If you have a system that's uncontrolled and someone may hold the button down for 5 seconds, that continues to draw a current at whatever rate will be dictated by V=IR. So, you know, if you have temperature control, that coil's going to get hot, and the temperature control system would then back off the power and backing off the current; therefore, you're drawing less current, you're stressing the battery less. So especially in a system that has that amount of configurability, temperature control could have some maybe secondary improvement to battery safety; do you agree?

MR. BELLINGER: I agree. And also if you're talking just straight fire safety, I think the FAA presentation, one of the failure modes that they're likely seeing is if you have a device that isn't temperature controlled, you just hold down the button because it's in your luggage and it just keeps getting held down, that's going to keep getting hotter and hotter and hotter and hotter and hotter.

So eventually that will get hot enough to ignite your liquid, ignite your wicking, and sets other things on fire. So, you know, from -- if you're calling batteries the entire device rather than just the cell, then yeah, temperature control could help overall system safety.

DR. YEAGER: Okay, thank you.

The next question is for John Bellinger. In your presentation you mentioned that power tools aren't exploding. Are you aware that some manufacturers produce specific cells for the power tool industry because they know these will be used in high-drain applications? Some manufacturers also produce specific cells for low-drain applications without working directly with the cell manufacturer. How will ENDS manufacturers know if the cell you choose is designed for your application?

MR. BELLINGER: The manufacturers publish data sheets, including discharge curves and including target applications, pulse loading, things like that. So as an electrical engineer, if I'm spec'ing one in -- actually a technical mechanical engineer, but either way. But, you know, if I'm spec'ing a device in for a battery, you can tell, just like you know how any component is appropriate. The manufacturers publish the specifications for it, and you can say, okay, this is rated for 40 A peaks for 3 seconds, that's appropriate.

Yeah, the manufacturers aren't trying to hide what their cells are good for because anytime you have a cell that's specifically better than something else for some purpose, you can get more money from the people that make things for that purpose because, you know, they'll get better performance. So I mean, that's all in the cell manufacturer's datasheets, if you're working with, you know, cells from tier one manufacturers.

DR. YEAGER: Okay, thank you.

For Paul Shawcross. Temperature of the heating coil and wattage mode with 200 W can easily exceed 300 degrees C, and cars using lithium-ion batteries also reach high levels. At these temperatures, what is the likelihood for heat to damage cells or cars overheating and thermal runaway? What protects a car battery from overheating from, for example, running the engine and being in the sun and reaching high temperatures?

MR. SHAWCROSS: So I think on that one, with the battery temperatures and the coil temperatures, it's going to be also involved with your system design how easily that temperature or how the temperature is mitigated from reaching some critical points.

If it's the flammable -- I'm sorry. If it's the solvent or the vaping fluid in your e-cigarette, they'd have to take into account ways to -- if that's going to be the temperature for a heating coil at the surface of the coil, for example, find ways to mitigate that temperature from reaching the vape liquid. So you have to set some boundaries, some design parameters, and then assign some level of severity rank or probability of this occurring. In vehicles, it's -- I think a lot of this has the same applicability there as you would want to look at where the heat is concentrated, what design features of your system are there to keep it from getting to where it doesn't need to be, and if it does get there, what the effects are.

So you really have to, I guess, start from ground zero and build your way up and identify those worst-case scenarios. Even if they may have a very small probability of happening, you at least have to be aware of what they could be.

DR. YEAGER: Okay, thank you.

John Bellinger again. Does your physical board have a traceability aspect that would survive a catastrophic failure?

MR. BELLINGER: I guess that depends on how catastrophic the failure is. So our traceability is done in software, so the chip is more -- so I guess the question is are we printing something on each chip. If there was a fire, the chip is more likely to survive than printing on the board. So, I mean, the first thing we would do is try to harvest the chip and place it on another board and see if you can get it to boot up. But again, where you talk about how catastrophic the fires are, how much identifiability you can get, so kind of.

DR. YEAGER: Okay, thank you.

This is a general question: Many e-cigarette companies seem to be small companies. Is it feasible for small ENDS manufacturers to buy their own custom circuit boards and easily incorporate safety features without increasing the cost of devices significantly?

MR. BELLINGER: That one's for me?

DR. YEAGER: I think it's for the whole panel.

MR. BELLINGER: Well, I mean, that's kind of our market. It depends on whether they feel like our prices are significantly increased. But yeah, I mean, our bread and butter customers are making, you know, tens or at the most hundreds of thousands of devices a year versus, you know, the cigalike manufacturers are some tens of millions. But I mean, that's yes.

DR. FOROUZAN: So let me just add to that. Even if you go on eBay and do a search for lithium-ion battery circuitry, you will get some hits. There are companies, Asian companies, that provide little small circuits that technically look at voltage, current, and temperature properties of a battery that you want to assemble. So yes, I think the answer is that any knowledgeable manufacturer who knows that a lithium battery needs to have a protection circuit does have access to some sort of circuitry. Is it adequate or not? No, I don't know.

I mean, I think it has to be implemented and tested.

But one of the slides that I showed, that even some circuits that are designed to activate the PFETs within 11 ms and be responsive to any type of a potential fault, sometimes when you implement it into the device, it takes 250 ms to activate. So yeah, I think that anybody can design a cell with active circuitry.

DR. YEAGER: Thank you.

Please identify yourself.

MR. SAXENA: I'm Saurabh Saxena and --

DR. YEAGER: Speak into the microphone.

MR. SAXENA: I'm Saurabh Saxena. I'm a Ph.D. student here in the University of Maryland. We do a lot of work in the lithium-ion battery liability and safety analysis. So my question is, first question is how important is the supply chain management in the e-cigarette industry, and do you see it as a challenge currently for the e-cigarette manufacturer? Are there multiple players involved in the supply chain industry? Is it just a very simple connection between the battery manufacturer and the e-cigarette manufacturer?

MR. ALARCON: I guess I'm going to take that. For us, it is primarily between our cell supplier and our company. For example, we don't necessarily drill down into the electrolyte supplier or, you know, the raw material supplier. It's not to say we don't. Actually, it's a little bit of a false statement in that there are some regulations where we do drill down in a way. But what I want to communicate is the majority of the interaction is between us and that supplier, and the burden of meeting the requirements is placed on that supplier.

So for all the testing, all of that, if they need to then have a requirement for their sub-supplier, sub-tier supplier, that would be passed along, and we would expect that they would have to do that, and they're responsible for that. So I think that answers part of your question, and I think your other part was something as far as the extent of the supply chain, are there a lot of manufacturers? Is that correct?

MR. SAXENA: Yeah. My question is, like, do you see it as a challenge currently that there are so many players involved in that, like -- to e-cigarette, and does it affect any -- does it cause anything, affect the reliability of the overall battery?

MR. ALARCON: Again, I can speak for us. In the early years, it was a challenge. There were supply chain challenges; there were lot of manufacturers. And when I'm thinking early years, I'm thinking back 2009, '08 through 2010, something like that, maybe even 2011. I personally visited a lot of factories; there's a wide variance. Some you would just walk in and walk out because you know you couldn't work with them.

And I think where we've come -- they've come a long way now, and we've worked with our suppliers and identified a few key suppliers in this space, and there's really been no reason for us to go look, to reopen that search because we found some that met our criteria, and we have a good relationship with them; they have produced very good results. So I can say it was a challenge. Maybe if someone else has some other perspective on today if it's still a challenge, but my overall sense is that the overall sophistication of the market has improved, especially as -- I know some of the vendors, especially in China, they're overflow suppliers for some very well-known name brands. So if a very big name brand company, a tier one supplier, if you will, just doesn't have capacity for a particular type of cell, they may work with them.

They'll place additional requirements on them and their facility, and they'll be able to supply it to them. So I know that is going on, and I think that has improved the quality of the supply chain, but I'd actually like to hear, maybe, if anyone else has any thoughts on it.

DR. FOROUZAN: It's a difficult question to answer. One of the problems that we see when we perform audits, onsite audits, is that we find a lot of discrepancies between the actual numbers that are printed in specification sheets and a customer coming, a potentially large customer that can benefit that manufacturer financially significantly, asking for them to tweak numbers, right?

So a lot of the cell manufacturers are willing to entertain modification to their specification sheets, right? And it should be questionable if they come and suddenly say a top charge temperature of 60 degrees suddenly, in a day, yeah, 100 degrees is fine or 95 degrees is fine, because it takes a lot of time for them to verify those things. You've got to find a list that you're comfortable with, that you trust, and when they say they do something, they really do it. That is, I think, critical.

MR. SAXENA: Okay, thank you very much.

DR. YEAGER: Thank you.

So for John Bellinger. From the recorded statistical data you have collected since 2015 from devices in consumers' hands, have you analyzed data just prior to catastrophic failure?

MR. BELLINGER: No. I mean, I'm sure somebody on the internet will come back with a counterpoint, but as far as I know, we haven't had a catastrophic cell failure, but that's opening up the internet for somebody to say wait, wait, wait, I didn't tell you about this. So no. The other thing is we're analyzing data. If you had a catastrophic failure, it's unlikely to, then, somebody's going to connect and say, hey, I bet they really want this data, let me see if it still connects to the USB and, you know, dump the recording. So no, I don't have recorded imminent demise data.

DR. YEAGER: Okay, thank you.

So this question is a general one for the panel. What are the waste disposal practices in regards to malfunctioning devices and batteries? As many know, disposable -- disposal of even regular batteries can affect the landfill setting immensely. Are there any standard procedures your manufacturers and patrons use to dispose of devices and batteries appropriately?

DR. FOROUZAN: Let me take that, take a stab at that. It's an interesting question. It depends on what state you live in. It depends on which county you live in. There are some guidelines that are published. At the very least, you can send the cell for recycling, but in this case it's a catastrophic failure.

So when the guts of the cell is actually exposed, what do you do with that? Typically, you should follow the guidelines of the state, of the county that you live in. If it does require to go through -- just like a proper cell that's reached the end of life, if it does require to be turned over for recycling, that's the proper approach.

DR. YEAGER: Thank you.

John Bellinger. Does Evolv track how many different devices use different DNA chips and how many of each are manufactured? Is Evolv aware of the technology of the other temperature control chips and how similar or different they are to Evolv technology? For example, the YiHi chip.

MR. BELLINGER: That's two questions, right?

DR. YEAGER: That sounds like two to me.

MR. BELLINGER: Okay. Yeah, I mean just like wattage control, which we introduced. First, temperature control isn't unique to us. In fact, I would argue that it's part of generating a safe device. I don't dig into the nuances of how other people are doing it other than we're all sort of using the same technique, which is use a material that has a known temperature coefficient of resistance and look at changes in resistance to calculate changes in temperature.

But yeah, I mean, other than smoothness and whatnot, I have no reason to believe that other peoples' temperature control doesn't work. You know, it's an engineering system, so there are varying levels of work, but no, I don't have any reason to think that other people are just sort of pretending to do what, you know -- it doesn't really add that much complexity. And then I don't remember what the other half of the question was.

DR. YEAGER: It was technology, other temperature control chips, yeah. So how many different devices use different DNA chips?

MR. BELLINGER: Oh, good golly.

DR. YEAGER: And how many are manufactured?

MR. BELLINGER: Well, we make something along the lines of a million chips a year. How many different devices I would say at any given time, hundreds because, you know, we -- certainly I could go back and look up who's made stuff and give you my top 10, but there's -- there are makers of, like, high-end boutique mods who make 10 devices a month, and they buy those from a distributor. But no, there are hundreds of different devices using a dozen or so different DNA chips.

DR. YEAGER: Okay. And then I have a general question: Does the software indicate to a consumer when there is a safety issue or when the battery end-of-life conditions are reached? Could the software alert e-cig sustains mechanical damage or thermal moisture damage? So does the software indicate to a consumer when there is a safety issue or when the battery end-of-life conditions are reached?

MR. ALARCON: I guess I can give a little piece to that, and you might want to add on. The answer is yes, it's entirely possible. In certain systems that I know of, it would be a change to the software to enable that, and in some cases that may be a very valuable thing. And I think that gets into the discussion of, you know, technically it's a change to the code.

Maybe it doesn't impact the performance of the device as far as aerosol generation, and I think this question is anticipating that there's some safety, potential safety benefit to that. So I guess for me and our company, that goes to the discussion of when you have these opportunities to increase safety but they constitute a change, how do we collectively manage that? So that's sort of a question to answer the question, I suppose, is that --

DR. YEAGER: Right. Yeah, yeah.

MR. ALARCON: -- acceptable?

MR. BELLINGER: I mean, it's technically, like you say, very doable. You know, in the replaceable battery world, that's very hard because you say, okay, well, this -- the manufacturer shipped this, if they ship it with the cell at all, which often they don't; shift to the 2500 mAh cell, and now the device is reading 1500 mAh start to finish. Does that mean it's the same cell that's now damaged or somebody put in a low-capacity and high-drain cell instead of a medium-capacity and medium-drain cell?

So yeah, I could see in -- I could see the value, but implementationally, from our perspective, it would require the user to tell the device, anytime they change the cells, to what the characteristics are, to know what to look for, which should just be -- people aren't going to do it; they're going to set it to the top and say, yeah, good enough.

MR. ALARCON: If I could just add. I could see in an integrated device --

MR. BELLINGER: Yeah, absolutely.

MR. ALARCON: -- that would be very straightforward to implement, and that would be an interesting feature potentially to -- and I understand the rationale behind the question and --

MR. BELLINGER: Let me jump back in. But on the other hand if -- you know, the consumer may look at that as the printer ink, that you know, there's still that quarter of an inch of ink, you can see it and you know it's there, but it won't let you print. So the question is, you know, from a consumer acceptance standpoint, is shutting off when the cells reach half capacity or some other, you know, metric, are they going to see that as you're improving my safety, or are they going to see that as you're just trying to get another however many dollars out of me? You know, it might be one of these technologies that works, helps, and fails in the marketplace.

DR. YEAGER: And I see we're out of time, but we have two questions left, and I think we could probably fit these in.

So, John, are there situations that would cause the DNA chips to fail and turn back on either in the chip or devices because the battery voltage has gone too low?

MR. BELLINGER: Yeah. I mean, so we shut off if the battery voltage drops. You know, this is really better for one of our cell experts, but you know, the batteries have an internal resistance-based drop and a diffusion-based drop. So if you're hammering on the cell, it will drop in voltage but then it will rebound slowly, you know, while you leave it alone. And so yeah, you could have it go into hard turnoff and then come on, turn back on, and you know, it's going to turn off as soon as you get one more puff out of it, but you can sort of milk it down like that. I think that's the answer to the question.

DR. YEAGER: It's a question for you rather than me, so --

DR. FOROUZAN: Let me just jump in. This is a very typical problem that all industries have; it's not just e-cigarettes. Electric vehicles, cell phones, notebooks, tablet manufacturers, any manufacturer that deals with lithium, integrating a lithium energy source or rechargeable battery into a device. At what point do you stop the charge or the discharge proactively in order not to face a situation like that?

And typically, when you hit the discharge curve and you hit that knee, you have an option of terminating the discharge so you never have a shutdown -- an unwanted shutdown of your device. So it really depends on how smart that software is.

DR. YEAGER: I think that's a good comment that takes us to the last question. What protections, if any, can be designed into e-cigarettes to prevent consumers from risk associated with using their device not as it is intended to be used? For example, rewiring, mechanical mods, other things.

MR. SHAWCROSS: That's a tough one because there are so many things you can do. I mean, you would have to look at -- and just kind of thinking off my head, it's just basically kind of make it so you can't separate the heating coil from the battery, how that's done.

It doesn't take a lot of significant engineering for just disabling, just thinking about what the user would do to tweak the e-cigarette design and making it so they can't; I mean, that's really a challenge. But you have to, I guess, just be clever and find ways to not -- maybe not compartmentalize things so much.

MR. BELLINGER: I mean, there's an old engineering maxim that if you make it idiot-proof, somebody will invent a better idiot. So I mean, I feel like you probably have more gains making it so the device works safely even if they modify the atomizer or modify -- because, I mean, they're not really going to dig into the electronic circuitry; people aren't doing that. So if you can just make it so -- like with temperature control, with wattage control, with a whole bunch of limits and protections. You know, if you make it so -- even that it sort of goes this way, that way, that way, around, around, around, around, around, up and through, star coil isn't, you know, damaging the battery because the output in the battery aren't -- you know, you can separate those two as far as safety systems.

That's probably more gains than trying to, you know, put more and more layers of, you know, do not open, warranty will be void, blah-blah-blah stickers because that just means they'll cut one more sticker off.

DR. YEAGER: Mr. Alarcon, Dr. Forouzan. Go ahead, Mr. Alarcon. Oh, go ahead.

DR. FOROUZAN: So I concur. I mean, if there's a way to modify -- the same question, right?

DR. YEAGER: The same question.

DR. FOROUZAN: If there's a way to modify and fiddle around with it. So other industries that we've been involved with, they have tried encapsulating. If there's somebody savvy enough to go and modify the electronics, they tried encapsulation with epoxy. Non-user replaceable cells and cellular phones have been tried. Ciphering, in other words, maybe an electronic cipher/decipher has been implemented.

There are chips out there where you can actually do --

implement in a circuit where the device looks for that, and if the knockoff battery or if there's a modification that they want to make, if they don't see it, the device doesn't work. But they've knocked those chips off, at least the initial couple of revisions of them that were introduced about 10, 15 years ago into the market. So there's always an approach. I think cost has a lot to do with it, that's our experience.

If you introduce a device where the consumer will have to go and buy -- it's a $100 device and they've got to reinvest another 80, 100 dollars just to be able to swap out the cell, they will find a cheaper way of doing it. They will go to a third party, they will -- they don't know better; they don't care. So if the components as replacement parts are available, then you have a better chance of having the consumer swap them out appropriately.

DR. YEAGER: Mr. Alarcon.

MR. ALARCON: Sure, thank you. So one approach is certainly to throw money at it, right, and you could design a really tolerant system. Another approach is one that we take, which is we only sell integrated so you can't change the coil, you can't change the battery. But, you know, I know this workshop is focused on battery safety, but we need to look at the larger picture, is that this is an e-cig, an electronic vaporizer, there's an aerosol formation element, and I think, you know, we here are interested in battery safety, but there certainly -- what's happening to the aerosol?

And you have to ask yourself, you know, if you're testing a device-liquid combination and you're allowed to make changes to the coil, well, that would have an impact on aerosol formation, right? So, you know, I think at some point, and I'm sure this is part of the FDA's vision, is to bring all this feedback together and try to integrate it.

But I just want to throw out that if we have these systems, even if we have these protections in place from the battery side, you still aren't really sure what's happening to aerosol formation. And I think we would be a proponent of having systems where, you know, you can do the sort of changes that the -- one of the questioners asked, to make safety improvements and -- but to do those informed and in the context of the aerosol formation that you're expecting.

DR. YEAGER: Okay. Well, I'd like to thank Dr. Forouzan and Misters Bellinger, Shawcross, and Alarcon. Thank you very much.

(Applause.)

DR. YEAGER: And that concludes our workshop for the day. We will resume tomorrow morning at 8:30 a.m. Thank you very much.

(Whereupon, at 4:43 p.m., the meeting was continued, to resume the next day, Thursday, April 20, 2017, at 8:30 a.m.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

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

April 19, 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