CDRH TOWN HALL MEETING

DATE: May 5, 2011

PLACE: Sheraton Orlando Hotel Downtown
400 West Livingston Street
Orlando, Florida

TIME: 8:00 a.m. to 12:15 p.m.

REPORTED BY: SANDRA Y. KIDD, CSR, CP, CM
Notary Public
State of Florida at Large

P R O C E E D I N G S

The Town Hall Meeting on behalf of the FDA, on May 5, 2011, commencing at 8:00 a.m., at the Sheraton Orlando Hotel Downtown, 400 West Livingston Street, Orlando, Florida, reported by Sandra Y. Kidd, CSR, CP, CM, Notary Public, State of Florida at Large.

DR. JEFF SHUREN: Good morning. I and Steve Silverman, sitting right here, who is CDRH'S director of the office of compliance, am pleased to be here today and we're eager to hear from you your questions and comments regarding medical device regulation.

In 2010, we adopted four strategic priorities to fully implement a total life cycle approach to enhance communication, transparency, to strengthen our work force and workplace and to facilitate innovation and address unmet public health needs. We committed to achieve 114 actions by the end of 2010. In fact, we accomplished 104 of them, 91 percent, and then finished up on the others since

that time.

Over the past year, the Center has worked to make changes to reinforce our balance-public-health approach, a fostering medical device innovation,

while assuring safety and effectiveness. This approach is the cornerstone of our operations and it governs the decisions we make each and everyday.

Achieving this balance can be difficult and part of achieving this balance has been implementing a smarter approach to device regulation, using our unique vantage point to share much information as we can legally with industry, healthcare professionals, patients and other parties to solve existing safety problems and help facilitate the development of new technologies and safer, more effective next generation devices.

But we can't achieve this balance alone. We need to listen and we need to collaborate and that's what today is all about.

We crafted our 2011 strategic priorities, recognizing that we need to make progress and report results on the significant initiatives we've already taken; therefore, our priorities for this year, which you can find posted on our website, focus much of our efforts on completing for continuing the work

we started in 2010.

One of the major concerns we heard in our three town hall meetings last year was about how well our premarket review programs were operating and their

impact on medical device innovation and on patient safety.

In January of this year, we announced an action plan to strengthen our premarket review programs to provide greater predictability, consistency and transparency. We are now moving forward to implement that plan by taking 25 actions this year.

In February, we announced our innovation initiative to accelerate the development and assessment of breakthrough technologies while strengthening the U.S. infrastructure for all medical devices. One of our proposals was to establish an innovation pathway. We talked about this at our March 15th public meeting. And this pathway is available for pioneering technologies; however, if adequately resourced, this would become the new pathway for all or most technologies for which clinical trial needs to be conducted, particularly those subject to a PMA.

Today is the Center's second town hall meeting of 2011.

First, you'll hear from individuals and organizations. Several will talk about potential risks with surgical mesh and dental amalgams, two type of devices that we are actively reviewing

because of safety concerns.

Afterwards, we'll open the floor to anyone who wants to ask a question or make a comment.

Let me start by apologizing in advance. Sometimes you may get a response that is not as responsive as you would like it to be. If we are actively reviewing an issue, particularly if we might be developing a policy, our policy and that is for Washington typically is not to talk about or provide details.

Also, often times, we can't talk about when we might come out with an action, because there are a number of steps we need to go through that are outside of our control.

So, I may engage in Washington bureaucratic speak. So, I'll apologize in advance, but that's just long-standing policy and I need to stick by it.

The second is we don't generally discuss or answer questions about specific medical devices, particularly if they are under active review or appeal at the Agency, and again, that's also out of

fairness to those who may -- of the company. Even if the company raises it, we often don't do it because our responses tend to involve confidential information.

So, with that, again let me welcome and thank you for coming today.

MS. HEATHER HOWELL: So, we'll begin with our speakers.

Our first speaker today is Geary Havran with the Florida Medical Manufacturers Coalition.

MR. GEARY HAVRAN: Good morning. I'm Geary Havran. I'm the president of a medical device company in St. Petersburg, Florida and the current chair of the Florida Medical Manufacturers Consortium, which is our statewide trade association of medical devices here in Florida.

I want to begin by welcoming Dr. Shuren and his team to the great State of Florida. We're very pleased that you are here and I'd like to preface my remarks by saying that we in the industry certainly want a strong effective and efficient FDA. We recognize that we're partners in bringing the best care and technology to patients around the country and look forward to continuing to work with you.

Just a few comments briefly about the Florida

Medical Manufacturers Consortium. Florida, unknown to many people, is a great secret, but Florida is second only to California in the number of FDA-registered medical device manufacturing

facilities. That's a message that we try and get out.

We have over 470 companies here in Florida and hundreds more of suppliers to those companies. Our industry has a favorable balance of trade, which is becoming more and more unusual, and our industry pays average wages in excess of $55,000.

Also, somewhat unique to Florida is that our industry here is composed of a lot of small companies. 95 percent of our companies have 50 employees and fewer, and 85 percent of our companies have 25 employees and fewer.

And here to address one of our concerns and some of those driving factors originate with the FDA, and a lot of others are outside the scope of the FDA. Our biggest concern is that many of our companies are being driven to introduce products overseas, to move the manufacturing overseas and to lose our manufacturing base here in Florida and the U.S., and we want to do obviously everything we can to stop that trend or to reverse it.

And so, why is this happening?

Well, with respect to the FDA, we certainly appreciate the FDA's efforts to improve the premarket review in targeted areas; but, over the

past few years, there has been in the industry view just too much uncertainty in how the process is working.

The FMMC members are being concerned about the lack of predictability, transparency and sometimes question the reasonableness of the premarket review process, and as I think you know, there have been a lot of reports in the presence and elsewhere that some of the industry feel like some of the systems outside the U.S. are a little more predictable.

And just as an anecdote, I was talking with a consultant who has for years done applications and she said to me on the phone, she said, Geary, I used to think I could go to a client and say here's exactly what you need, here's exactly how long it's going to take, and she said lately, I'm of the opinion it is almost like I don't know what I'm doing anymore.

So, we hope to be able to work with the Agency and to get some clarity through that process. And while some, both within the FDA and outside the FDA,

are talking about the 510(k) process and particulars being broken, we will defend both the FDA and our industry in the fact we don't think it's a broken process, and while there may be some opportunities

for improvement, it is a case where we certainly don't want to throw out the baby with the bath water.

And I just want to make very clear that we're not asking that the bar be lowered in terms of the review of the technologies for new products; but, we want to make sure that the reasonable assurance of safety and effectiveness and clear guidance remains the key part of that program.

And I also want to make very clear that while there are probably a lot of folks getting wealthy right now doing studies, blaming the FDA for the problems or supporting the FDA and blaming those this industry for the problem, our position quite frankly is that anytime spent pointing the finger at one group or another is time wasted, which would much better be spent working together to improve the situation for all those concerned and most importantly for the patients who are the ultimate consumers of our products.

I just want to talk about a couple things and

specific items that we're not looking for an answer for, but just to mention and that is that someone managed to go all the way back to 1999 and find a what I think was called the Redaction Regulation

which talked about potentially getting redacted copies ready for FLI submitted with some of the industry documents so that the industry could in return get them back from the FDA in a much faster fashion and perhaps there is an opportunity for revenue stream for the Agency there to pay for that as well.

And then, we also know that we have a lot of suppliers and contract manufacturers here in Florida, and there was a public document issued a little over a year ago, I think, that talked about potentially removing the exception for contract manufacturers filing facility registrations, and I think the comments from industry indicated that industry has no problem with that and would support removing that exemption; but, unfortunately, the contact information in the Federal Register is now obsolete, and so, I'm trying to follow up on that. We're kind of hitting a road block trying to get to the proper person.

And so, I just -- I bring that up not as a

criticism, but there may be other public documents the say same way where, as contacts have changed, unfortunately, the original Federal Register Notice being the primary vehicle for binding the contact

kinds of leads people to a dead end and maybe others are smarter or more persistent than I am, but I tend to give up sooner.

So, with that, I just want to say that certainly I and my industry colleagues are certainly available to help in any way or to answer any questions in any way that the Agency deems appropriate.

And once again, certainly, I want to thank you for coming to Florida and we hope that today's meeting and your trip are both productive and pleasant.

So, thank you very much.

MS. HEATHER HOWELL: Our next speaker is Bernard Windham.

MR. BERNARD WINDHAM: I'm the president and research director for DAMS International, which is a patient support organization. I am a medical researcher and have a background in environmental externalities and health effects of toxic exposure, that kind of thing.

Like thousands of others who I'm aware of through my organization, after I became involved in it, when I got mercury poisoning, I gradually became disabled in the early 1990s and was diagnosed with

multiple sclerosis.

I had lots of, all kinds of problems, physical problems of all kinds, and lots of tests, and one of my tests found that I was mercury toxic, which surprised me because I was a mercury researcher for a state agency, though I didn't research dental amalgam. I researched emissions and that kind of thing.

I found the main source of my mercury was dental amalgam, and in researching the literature, I found that that was not unusual because it is the number one source of mercury in most people who have several amalgam fillings, which has been documented by hundreds of thousands of tests by medical labs and also by government agencies.

I had my amalgam fillings replaced. I didn't know how to go about doing that, but I started searching around to find people that knew how to do it and I had them replaced, and over the next three years, I had my amalgams and metal crowns that were over amalgam replaced and also did some

detoxification, which I also didn't know anything about much, but found out through my research and talking to people, and I basically recovered from all of my different symptoms. I got to where I was

so bad I couldn't hardly walk and couldn't drive and had to have my daughter drive me a lot.

And so, anyway, but after getting rid of my amalgam and doing the right things, I basically have recovered to where in my sixties I've been playing softball on city teams with a lot younger players and likewise basketball even again.

So, and I also was told I was going blind, and after doing this, my eyes got so good I don't wear glasses anymore.

And this is true of a lot of over 60,000 cases. We have over 60,000 cases of people we work with that have similar experience to me.

What I want to talk about a little more, though, is that there has never been a time in U.S. history when mercury was not known to be extremely toxic and when there was evidence that its use in amalgam might be safe.

I'm providing references of over a 880 pages of articles and dental journals from the 1800s, documenting the fact that the dental authorities

were aware that mercury was extremely toxic and that amalgam was unstable and its use caused high mercury exposure and patient harm. And I'm going to actually mention some excerpts from some of the

articles of that time.

Due to the high toxicities of mercury and the known documented fact that those that have amalgam fillings get significant mercury exposures and commonly experience adverse health effects, those dentists who used mercury in that time were called quacks after the German word for mercury.

By the late 1900s, there were thousands of peer reviewed studies documenting high mercury exposures from amalgam use and common significant adverse ill health effects. I used the Med Line National Issue of Health, National Library of Medicine for a lot of my sources for that kind of information, and there are thousands of studies there which I actually reference over 5,000 peer review studies on my website.

The following are excerpts from some of the articles in that 800 something pages I mentioned from the 1800s. They say from its inception, the better clients of dental practitioners wage war against its use. The manner in which it was

introduced called for the censor of all who have professional etiquette.

Dr. Harris of the Baltimore College of Dental Surgery stated it is one of the objectionable

materials for filling teeth that can be employed.

At the meetings of the dental societies, the subject was discussed and strong arguments made against its use. They reported that such substances were hurtful to the mouth in all parts and there were no caries that other sources couldn't be used for filling. The report was unanimously adopted by the societies.

In 1845, the Mississippi Valley Association of Dental Surgeons resolved that the use of amalgam was injurious and unprofessional and would not be continued use by its members. But the age of special interest and economic benefit came about in promoting amalgam fillings, and in spite of all of the record and the knowledge of the dental authorities, amalgam use has become fairly widespread, in fact, very widespread.

The Dental Registry of Dentistry in 1872 had the following case from mercury in a tooth filing: John T. Smith died of salivation caused from mercury in a tooth filling. Dr. Sprague attended the case.

Two other doctors consulted and agreed he was suffering from the effects of mercury. It was clear that mercury had caused his death. This is one of many cases cited in the journals of that time.

The reasons for the high known exposure to all with several amalgam fillings is due to mercury's unusual properties. It is a gas at room temperature and it's not stable at any other form. It continues to vaporize to a gas at any temperature over 10 degrees Fahrenheit, and as the temperature increases, the vapor pressure increases and it vaporizes faster.

In addition to that, if you put in amalgam with other metals you get a battery effect, and you can actually go down to Radio Shack and pick up a microamp meter and put one probe to the tooth to the filling and one to the hard pallet, and you can measure that it is pumping mercury and other metals into the body and accumulates, according to autopsy studies, to high levels throughout the oral cavity of people who have fillings. And from there, it moves on through capillaries and veins and nerves to all parts of the body and accumulates in organs to high levels that later in life causes a lot of problems.

As I said, our organization has documented, has worked with people who have recovered. We have over 60,000 cases of people who have recovered after getting rid of their amalgam fillings. And there

are a lot of other cases out there; but, our organization alone has documented 60,000 cases of recovery. And several of us in our organization had MS like me.

In addition, due to mercury's properties of and the high exposures of those with amalgam fillings, dental amalgam is documented by municipal sewer agencies and the EPA to be the largest source of memory in sewers and sewer sludge with very high levels in both.

The average person with several such fillings or crowns over amalgam is documented to excrete approximately 30 micrograms per day in sewers, a very high level, since mercury is the most toxic element people commonly come in contact with.

Medical labs found the average person with amalgam excretes almost ten times of mercury as those without amalgams, and you can find that on their websites on the web in a medical lab.

Amalgam is a significant source of mercury in water bodies to the environment, to fish.

So, in Florida, we have over -- most of our water bodies have warnings for mercury and are in fish. Well, dental amalgam is the largest source in sewers and major source in water bodies from the

sewer outfalls, and there is actually enough coming in to contaminate virtually all the fish in Florida to dangerous levels, and we do have that problem with mercury in fish in Florida.

This is true, also, in other states and some of the other countries that have actually banned amalgam. The environmental effects of the mercury going into the water bodies in fish is one of the reasons that they cite in why countries like, well, several countries in Europe have banned amalgam, and other countries, because of the harm to people, have put limits on use in women and children.

MS. HEATHER HOWELL: Thank you, Dr. Windham.

MR. BERNARD WINDHAM: Okay.

MS. HEATHER HOWELL: Our next speaker is Ashlea Ricci.

MS. ASHLEA RICCI: Thank you.

I would like to thank FDA for allowing us this opportunity to come in and speak today, and I will be speaking on behalf of my managers and colleagues at Conmed Linvatec.

I am Ashlea Ricci, a regulatory specialist at Conmed Linvatec in Largo, Florida, eight years of regulatory experience in medical device field.

I would like to take this opportunity to raise

some points of discussion for both FDA and industry at today's meeting, posing some questions but not necessarily for immediate answer.

The first point I would like to present is the recognition of consensus standards. Specifically, I'm referring to the third edition of IEC 60601-1, which introduced significant modifications to the family of medical electrical equipment safety standards, including the introduction of a risk management process, and we are interested in hearing how or when FDA does envision recognition of this IEC standard.

The second point I would like to raise is in reference to the unique device identifiers. Over the past couple of years, FDA has discussed this issue extensively up to the point of conducting a pilot study for UDIs, and we're very eager to learn what the FDA's position is concerning implementation of this.

The third point I would like to address today is the more popular topic of the 510(k) process, and

particularly, over the last two years, industry has seen a dramatic change of the apparent interpretation of guidance documents and consensus standards, and it would be interesting to hear

whether or not the FDA does share the same opinion, and additionally, to find out if there are any programs in place for cleaning up the outdated draft guidance documents so that industry has a clearer path for reviewing guidance documents and following those.

And we are also curious to find out the place within the 510(k) paradigm for special and abbreviated 510(k)s. There have been a lot of speculation that the special and abbreviated would no longer have a place in the FDA review and it is essentially a traditional review for all 510(k)s submitted. So, it will be interesting to hear the FDA's viewpoint on that as well.

Industry has also seen a trend towards side-by-side testing, subject to predicate devices in order to determine substantial equivalence. This has actually been seen in some of my recent experience with 510(k) submissions. It was actually a requirement to obtain predicate devices in order to test side by side and to perform those tests in

the same manner.

And it would be interesting to hear whether or not FDA sees this as a trend within the respected divisions of FDA and if FDA also takes into

consideration the additional costs that this imposes in an already difficult economic time.

In terms of the 510(k) process, itself, and the predictability, a recent article in the Washington Post discusses the quality of submissions as a delaying factor in submission approvals in an abstract from this article I would like to read shortly, and this involves Mr. Shuren.

The main problem the FDA has encountered in recent years, according to Shuren, is the declining quality of applications from device makers. He said that more than 50 percent of applications for conventional medical devices missed key information, leading to delays that should have been avoided. We are stepping up the plate to do our part to get this right, but if it is going to work, we need industry to do their part, Shuren told members of the house energy and commerce health subcommittee.

Seated with Shuren at the witness table was a trio of device industry entrepreneurs, who said the pace of non-predictability of FDA reviewers is

driving some companies into bankruptcy.

Despite this, the industry has also responded and pointing out as taken from the April edition of the Gray Sheet that during the review of premarket

applications, FDA has made formal observations that were minor in nature that may have been more efficiently handled in formal channels. FDA has asked for information beyond what is stated in the guidance documents or standards, and FDA has failed to inform industry of policy changes.

One experience I had was a statement made in an Osmond meeting that was later referenced in a deficiency for a 510(k) and it was referenced back specifically to the Osmond meeting and when that comment was stated.

So, there has been some inconsistency in the dissemination of FDA policy and formal pronouncements.

It is hoped that FDA recognizes the constantly changing FDA reviewer environment and lack of predictability when analyzing the completeness of industry submissions.

And I can speak for all of the other submissions that have gone and the ones I have worked on. Obviously, the precedent of prior

interaction with FDA reviewers is a big informer in what we do moving forward, and this has been inconsistent between reviewers, and what you learned from one 510(k) submission doesn't necessarily

translate into the next.

So, we look forward to the implementation of FDA activities in the upcoming year and hope that the working relationship between FDA and industry can continue to improve. Thank you.

MS. HEATHER HOWELL: Our next speaker is Charmaine Frederick.

MS. CHARMAINE FREDERICK: Good morning. I'm a registered nurse and concerned citizen, and I'm going to talk about mercury amalgams.

Over the years, I had many mercury amalgams placed in my mouth, 14 to be exact. It wasn't until I read Jim Hardy's book, Mercury Free, that I was well aware of issues regarding mercury. Issues such as --

Excuse me. I have Parkinson's disease, and it has affected my speech so you have to bear with me. Okay?

But as I read Dr. Hardy's book I was very angry with the dentists first of all who over the years put mercury in my teeth and didn't really tell me

what the risks were. And then I was kind of mad at the FDA, because I thought, you know, this debate has gone on since the 1800s. What are we doing here? You should have banned it a long time ago. I

don't understand why you haven't done this.

And thousands of studies have been done regarding this issue and I don't know why you haven't believed them. It doesn't make any sense to me. It defies comprehension to look at. You know. Trying to look at a normal range for a toxic substance doesn't make any sense to me.

The argument that you make is that if you have, that if you just take one substance of one chemical and you look at the emissions of it, it doesn't look at the cumulative effect of it in the human being. So, you know, it is just not mercury that is involved in my Parkinson's disease. It was all the other toxins I've been exposed to over my lifetime.

When you look at a toxic stew, that is really more than some of its parts that you haven't taken into consideration. You are looking at things in isolation. You do not look at the harm, Dr. Shuren.

It is very apparent to me that it is time that we let mercury go. When we know better, we do better, and it is the perfect opportunity to make a

ban against mercury amalgams.

MS. HEATHER HOWELL: Our next speaker is Julie Sadlier for the Society of Diagnostic Medical Sonography.

MS. JULIE SADLIER: Good morning. Thank you for allowing me to speak today.

Good morning. My name is Julie Sadlier. I'm a local sonographer representing Society of Diagnostic Medical Sonography based here in the Orlando area. I would like to thank you for the opportunity to provide comments on the Center of Devices and Radiologic Health Activities.

The SDMS represents more than 23,000 sonographers across the United States and in more than 40 countries. Sonographers are the dedicated professionals who create medical images using ultrasound technologies. Sonographers typically complete at least 18 to 24 months of education and training and then successfully complete a national certification examination to demonstrate their competency in diagnostic medical sonography.

Today, I would like to discuss the ongoing issue of entertainment or 3d/4d ultrasounds performed by untrained persons and the harm that may result from the lack of effective regulation of the

ultrasound equipment under the CDRH statutory and regulatory authority.

There is little question that sonography in the proper hands is safe and countless lives have been

saved by being able to look quickly inside a parent. However, sonography is also the most operator dependent imaging modality, requiring great knowledge of ultrasound physics and skill proficiency to obtain accurate medical sonograms. It is not just placing gel on the mother, applying a probe, and pushing a button to get a pretty 3d image or 4D image video.

Ultrasound equipment used for medical imaging is typically considered an FDA Class II or III medical device and requires a physician order for its legal use. Yet, its use by unqualified personnel continues to go virtually unchecked. Though ultrasound is non-ionizing medical imaging modality and certainly does not have the same risks associated with ionizing radiation, it is not without some risk, especially in the hands of an unqualified person. Because of the potential for mechanical and thermal bioeffects on human tissue exposed to ultrasound, the medical community agrees that ultrasound exposure should be kept as low as

reasonably achievable. This is also known as the acronym, ALARA. A proper understanding of how to use ultrasound in medical imaging is the best protection against inadvertent harm.

We continue to see an increase of entertainment ultrasound businesses without the following: Adequate physician oversight, qualified medical personnel performing the sonograms, and a lack of independent accreditation to ensure effective quality controls are in place so the equipment is operating properly.

We continue to hear reports of hour-long imaging keepsake sessions, and as I googled last night, you can have a baby shower for three hours and have cupcakes and punch provided as well. This is outrageous to me.

I'm here today specifically because last month one of my physicians asked me to file a complaint. He called me outraged that his patient had been to a 4D facility, actually the third one this month, because there is a mailing list and was told the umbilical cord was wrapped around her baby's neck. The mother was hysterical. We immediately rushed her into our office where we had to calm the patient and do our own ultrasound as well as provide

umbilical cord dopplers and a biophysical profile to reassure the mother's fetus well-being. The ironic thing was the cord was not wrapped around the fetus' neck; however, there was no amniotic fluid around

the fetus and we had to send the mother straight to the hospital.

This again points out the person operating these machines had no sort of medical background or physician within sight. At no time were we notified of any problem from this place as stated in the brochure.

I placed a call to the facility and spoke with the owner, who stated what was the problem? She told the patient this was really no big deal. I later found out she is a physician in Venezuela, a surgeon. She has no Florida license here.

I know that in the past the FDA has issued few warning letters, some press releases and has posted some consumer information on the FDA website about keepsake ultrasound, but it is not enough to simply tell Americans that the FDA-approved ultrasound imaging systems must be used at direction of a physician. As you just saw, I believed I was speaking with a physician; I didn't know she was a plastic surgeon.

Today, literally hundreds of ultrasound machines are currently available for purchase on eBay without any verification that the person purchasing is qualified to use the equipment.

Prices for these range from less than a thousand dollars to $70,000. If you have a credit card or cash, you can buy one today.

New technologies will only increase the regulatory challenges relating to ultrasound imaging equipment. For example, Mobisonte's MobiUS device that recently received the FDA 510(k) clearance is a mobile ultrasound imaging system that uses a smartphone and Internet cloud services. What steps is the FDA taking to ensure that these small portable devices do not end up the in hands of someone who does not know how to use them?

Being a sonographer and a mother, I understand a patient's desire for priceless pictures of their baby. I strongly recommend that physician approval as well as a study be performed or OB physicians are present should any problems arise.

I leave you with three questions:

Number 1. What has the FDA done recently to prevent the inappropriate use of ultra sound equipment?

Number 2. What is the FDA prepared to do in the future?

And number 3. How can the sonography community help the FDA in establishing these regulations?

Thank you.

MS. HEATHER HOWELL: Chris Scarano.

MR. CHRIS SCARANO: Good morning, Jeff. I brought you a gift this morning to thank you for allowing me to speak.

Jeff, do you know what George Washington our first president of the United States died of? George Washington was legally murdered in 1799 by the finest allopathic doctors at the time. He was given a fatal dose of mercury in hopes of curing his sore throat. You will not find this in our children's history books. It is not even mentioned on Wikipedia.

In 1799, they didn't know any better. It's been 212 years since George Washington was poisoned. You would think that our FDA has had enough time to protect us from mercury's toxicity.

Maybe our FDA needs to revisit the famous story of the cherry tree. You see the moral of that story was George Washington was an honorable child for admitting the truth. When will the FDA tell us the

truth?

The early 1900s saw the creation of the American Medical Association, a doctors' union created to stamp out homeopathy. At the time,

homeopaths were taking away too much business from the allopaths.

Why do I bring this up?

This disastrous union called the AMA, which works alongside the FDA, set into effect a system of profiting off of the sick. The AMA grew huge by making key alliances with business interests. The rise to power was mainly due to the money behind the drug and tobacco companies.

100 years ago, our government chose to put our health second to money and special interests.

150 is a number that's proudly stated on the FDA's website regarding mercury's long career in the dental profession. For over a hundred fifty years, amalgams have been placed into our mouths. In fact, a hundred fifty years ago, we had only 32 states and Lincoln was president.

Fact: A hundred fifty years ago, the idea of communism was invented.

Fact: A hundred fifty years ago, there was still slavery.

We have put a man on the moon and figured out how to split atoms; but, yet, you, Jeff, are still allowing this barbaric dental practice to exist.

The world already knows the truths about the

dangers of mercury. It is our First Amendment right to know the truth also. I will be so embarrassed to go to work knowing that I'm responsible for the slow poisoning of my own people, covering up the overwhelming evidence that exists and preying upon the poor and uneducated. I would also be embarrassed to come home knowing that's how I if he'd my family. Only a coward would choose money and politics over a human being's life.

Have you heard about the latest car stroller or car seat to be recalled? Our government is quick to act when one of these could be defective. An immediate recall is announced in the hope of preventing deaths.

Where was the immediate ban on amalgams?

There is enough mercury in one large filling to sufficiently contaminate a ten-square mile lake and restrict fishing.

I would also like to know why you allow dentists to place dissimilar metals into our mouths. This is another barbaric practice that creates a

battery effect. In my case, a gold filling is causing my amalgams to outgas even more.

The FDA is quick to urge the public the dangers while driving on certain medications. I would like

to know why, Jeff, you allow me to drive. I don't remember ever getting warned at a dentist office about the dangers of driving with mercury in my mouth.

Each time I step into my car, I run the risk of killing myself, my four-year-old daughter or somebody else.

For the second time in two years, I am having acute issues with my eyesight, vertigo and brain fog. My daughter, the love of my life, is placed in a dangerous situation each time I buckle her up.

The question that remains is can I sue you for my loss and suffering? This has affected the growth of my business for years. What about the permanent damage to my body? What about the expenses to remove my amalgams, put in new fillings, the cost of vitamin C IVs? Better yet, who is going to pay for the chelation I have to undergo?

While you are at home sleeping comfortably, I will be waking up every three hours for one to two years to give myself oral chelation. Extra expense

will be needed to radically change my diet. I will be at war with my body, endangering my life to rid of the mercury. Where is your responsibility in this?

The internet is freeing countries. Websites like Wiki Leaks are exposing corruption and new political parties are emerging to fill to rid of the beaurocracies like the FDA. I love America, but to think that our health is not a priority in your eyes makes me embarrassed to be an American.

This poisoning against our own people is a form of genocide and for sure is a crime against humanity that will one day be brought to a court of law.

I commend Kentucky for currently trying to kick the FDA out of their state. Just like Thomas Jefferson said no to the fellow government, we here today stand in unity to say no to our federal government. What is the point of federal regulation when you are biased and paid off? You have assumed an undelegated power to poison the people, the same people that pay your salaries.

Now, regarding your gifts, Jeff. I'm hoping that you might have a connection to get me approval to sell these devices to the public, these products to the public. I brought today a mercury mug, a

mercury straw and a mercury pacifier.

After reading your website, I feel totally confident that I can word it in a way to convince people that they are totally safe. First, we are

going to tell the public that they are silver instead of mercury. People are stupid anyway. They'll never question it. We will have manufactured these with the ingredients taken from your websites from a mixture of metals consisting of liquid mercury and a powered alloy composed of silver, tin and copper. They will only outgas minimally at standards that are acceptable to the FDA. We will ignore the worldwide evidence of the dangers in using them and will lobby the government heavily to ensure we're protected as a manufacturer.

Enjoy, Jeff. Just pay no attention to the skull and crossbones. Be careful when cleaning them and especially when drinking hot liquids in them. Oh, and do get back to me with the heavy metals hair test for your loved one's baby after sucking the pacifier, and don't tell me that the baby was eating sushi, Jeff.

MS. HEATHER HOWELL: Thank you, Mr. Scarano.

Our next speaker is Patrick Murphy with the International Laser Display Association.

MR. PATRICK MURPHY: Thank you for this opportunity. I have a slightly different topic. I am the executive director of the International Laser Display Association. We are the only trade

association for laser light show producers worldwide.

I want to talk mostly about laser pointers, but first some brief words about CDRH's variant system for laser light shows.

Our U.S. members' major concern is that the variant system is broken. Specifically, there is no real enforcement of the requirement for variances. Thousands of laser light shows are done every year without a variance. Often, these shows directly scan the audience with lasers, which is generally not allowed by CDRH.

Anyone can easily find YouTube videos of illegal shows like this. It seems as if no shows are stopped in advance and no one is fined or jailed afterwards.

Our members say that they feel like fools for filing variances, waiting for approval, and not performing certain effects, all while they lose business to companies that do these. They do shows anytime, anyplace with just about any effects,

including audience scanning.

What makes this worse is that the illegal companies are probably right. There have been only a handful of audience injuries from laser light

shows worldwide in the past three decades of laser light shows. This is after 110 million persons have been exposed to 11 billion pulses of laser light in their eyes. That's why there have been essentially no reported injuries from illegal shows in the U.S. or even overseas. They are of insignificant risk to the public.

Speaker number eleven today, Greg Makhov, will be presenting more ideas about this. I just wanted to emphasize that ILDA members' number one concern is fixing or even eliminating the requirement for variances for laser light show producers.

Our main topic today is these high-powered handheld laser pointers and more powerful lasers like this one-watt Wicked Laser that many people have heard about and seen on the internet and you can buy for a couple hundred dollars.

The main problem with lasers like this is surprisingly not eye safety. Since these one-watt lasers were commercially introduced last summer, there have been no reported injuries to the best of

my knowledge.

The main problem is the misuse of laser pointers by the general public against aircraft. About seven times every night in the United States,

pilots report seeing or being illuminated by laser light.

As a public service, we've been working to reduce these incidents. I should note we have no involvement in this. It is really nothing to what our members do everyday, but we do this as a public service and we want the public to have a positive view of lasers.

The aviation issue is a complex one with no single solution. Every party, from pilots to laser enthusiasts to regulators, has a part to play.

The CDRH can help by leading efforts for a voluntary or mandatory Aviation Safety Label on pointers and handheld lasers.

In fact, this one is one of the only brands that has one that says: Warning. Do not shine your laser at an aircraft. Shooting an aircraft is considered a felony in the U.S.

We would ask CDRH to again do a voluntary or mandatory standard to put this on lasers the same as they already have a label about this eye scan and

fire hazards. This alone won't solve the problem, but it is one important step. And there is very little cost for manufacturers, because they have to put the labels on anyway.

Finally, there is one concern regarding CDRH's new approach to regulating handheld lasers by incorrectly reinterpreting 21 CFR 1040.10. I appreciate that CDRH staff is being creative, and I support their general intention; however, their actual implementation of this is simply and completely wrong. It does not make sense legally and does not even make sense using plain English language.

The situation is that now CDRH is trying to regulate laser pointers and handheld lasers like this one by saying that this is a surveying, leveling and alignment product, or an SLA laser. The idea is, because of being a straight line, it can be used to make a straight line in surveying; however, this would mean that all lasers would be surveying, leveling and alignment products since they all put out a straight line.

Even a cursory inspection of the SLA uses listed in 21 CFR 1040.10(b)(39) shows that these do not apply either to pointers or handheld lasers. If

this interpretation were correct, then me thrusting out my arm and saying "look over there" means that I am somehow being involved now in surveying, leveling, alignment and angular measurement,

positioning parts or defining a straight line. I don't think anyone can legitimately argue that this is the case.

I've written to Daniel Hewett of CDRH, a great guy, with many more details about the SLA requirements and why they don't apply to laser pointers or handheld lasers. While there certainly should be regulation of these lasers, it should be done by appropriate statutory means and not in a 1984 sense of creating false meanings for clearly understandable English words.

In conclusion, ILDA has two main concerns. One is that variance system for our members' laser light shows, which is broken. The other is with laser pointers where we ask that, one, CDRH lead the effort for mandatory Aviation Safety Labels and, two, do not misapply existing regulatory authority for SLA lasers.

Thank you.

MS. HEATHER HOWELL: James Hardy, Consumers For Dental Choice.

MR. JAMES HARDY: I want to thank the FDA for hosting this town meeting and listening to all different points of view on different issues.

I'm here as a mercury-free dentist and I

learned about the mercury issue as a freshman in dental school in 1978. When I heard the fillings were 45 to 70 percent mercury, I raised my hand. I said, "What about the Minimata Bay disaster in Japan where there were a huge number of birth defects, stillborns and other things happening in Minimata Bay and it turned out it was mercury causing the problem, and what about the FDA taking tuna fish off the shelves when it is one part per million or more and we are putting in fillings that are chewed on for 20 or 30 years at 700,000 parts per million, how is that safe?"

My professor said "Well, it's all tied up." I said, "Well, if it's all tied up, why did they break down?"

They break down because the mercury comes out and it has been shown time and time again that mercury comes out of the fillings 24 hours a day, sometimes at a greater rate, sometimes at a lesser rate. Every 10 degrees rise in temperature doubles the amount of mercury vapor that comes off the

fillings.

Now, there is no need to use mercury fillings anymore. They were brought over here from Europe in 1833 before the Civil War. They are very old

technology. They are not as good as the new composites. I've been a dentist for nearly 30 years. I have never placed a mercury filling and I have not found a need to have a mercury filling in any restoration, that I couldn't use something else, that is safer, that doesn't contain a heavy metal. So, there is really no need to use mercury.

Now, there is a cradle to the grave problem with mercury fillings and that is when you first buy the mercury filling, you buy it in capsules. Those capsules can break, or after you shake them up and open them, that stuff can fall on the floor and it will contaminate the office. So, there is a real estate problem here.

Dental practices that have been in offices for awhile have most -- most of them anyway, probably, and if not all of them, have had a mercury spill somewhere so there is mercury inside the office. If someone came in during the sale of that piece of real estate and had a mercury vapor analyzer, like a Jerome mercury vapor analyzer, and analyzed the air

in that office they would say, "Well, this real estate really shouldn't be sold. It should be plowed under because of the contamination in the air."

There is another problem that the piece of mercury that the piece of mercury that is not put into the patient's tooth has to be treated as a hazardous waste from cradle to grave; in other words, from the dental office to the recycler, you have to have paper work that shows that it was disposed of properly.

After an amalgam is taken out of a patient's tooth, it also is a hazardous substance; but, somehow inside the tooth it is not. I don't quite understand that and any reasonable person should not be able to understand that.

Now, mercury fillings have caused other problems too, and I want to read you a quick story.

It was late August in 1989. The place was Michigan. Four people, two men and two women, who lived in the same home lay dead. Less than a month earlier, they were hospitalized after complaining of chest pain, diarrhea, nausea and shortness of breath. Their breathing became more labored and difficult.

Four days into their hospital stay, it was learned that one of the men had been collecting mercury fillings. He had been heating them up in the basement so he could extract the small amount of

silver from the fillings to sell.

Substantial respiratory support along with aggressive medical procedures to remove mercury from their bodies was initiated to no avail. All four died of mercury poisoning. Their house was extensively cleaned in the hopes of removing mercury; but, the cleaning failed and the contaminated house was declared unfit for habitation. It had to be torn down.

We can only hope that the mercury laden rubble was disposed of as hazardous waste.

This is the same filling that may be in your mouth right now.

When a substance can create problems from cradle to grave and there are plenty of good substitutes to replace it, it makes absolutely no sense to continue using it. So, I'm here to support ban on mercury used in dentistry. It is really the only, the only branch of medicine that uses something as dangerous as an implant inside the human body.

Thank you.

MS. HEATHER HOWELL: Our next speaker is Lance Giller, a medical device manufacturer.

MR. LANCE GILLER: Hello. We're a small family

business in Sebring, Florida. It is basically me, my father, my uncle, and my little brother works part time. And the manufacturer registration fees that we have to pay every year, this past year were just under one percent of our gross.

If Welch Allyn had to pay or Siemens or any of the large manufacturers had to pay one percent of their growth to the FDA to register, they would be up here hopping up and down screaming. It is an extreme burden for a shop as small as ours.

Last December, we basically sent what could have been Christmas bonuses for our family to the FDA. And then you have other things coming up that you need device identification, which is still somewhat of a mystery to us how it is going to be implemented, and we're a little concerned about how much it is going to cost us.

And sorry I don't have much more to comment, but we had a very simple concern. Thank you.

MS. HEATHER HOWELL: Our next speaker is Ms. Rebecca Lock.

MS. REBECCA LOCK: Hi. I want to thank you guys so much for listening to our concerns.

I'm here for my mom to speak about mercury toxicity in amalgam fillings, and my name is

Rebecca. I'm going briefly to tell her story and then just give some facts about mercury poisoning.

As a child, my mom was exposed to mercury in the form of the antiseptic mercurochrome after seriously cutting her knee. She was given a large dose and afterwards hospitalized and she was told by doctors or her parents were told she wasn't able to walk again.

She did however recover from that and she was able to walk. However, she did have fatigue and muscle pain and poor balance for the rest of her adolescence and childhood.

After getting a silver filling when she was a teenager, she experienced more problems and then, as an adult, she got another silver filling and then I came along and she was diagnosed with MS shortly afterwards.

As a child, I remember her not being able to walk, having do lay down a lot, not being able to see out of one eye. Very tragic things for a mother with young children.

A few years later, she watched a special on 60 Minutes on the possibility of the link between toxic exposure to mercury through dental fillings and neurological dysfunction. After having her

fillings removed, she was free from new symptoms of MS and she actually seemed to be getting better, and this has been consistent with thousands of other stories where similar situations have happened.

She unknowingly was exposed to mercury again a few years later when she got a flu shot, and they confirmed there was thimerosal in the flu shot. She had an MS attack and we wondered why. Sure enough, we looked back, and the flu shot she had had thimerosal. And usually, her attacks would happen very shortly after exposure, almost the same day sometimes.

She then again was exposed through some eardrops that were put in her ears and they again contained thimerosal. She didn't think to check them. And she now is pretty much wheelchair bound and she pretty much can't function normally. That's why she's not here today and she asked me to come and speak for her. She can't be the grandmother she wants to be to my kids and she, of course, hasn't been able to pursue many of her own dreams as well.

That's my mom's story. And I would like to thank you so much for listening to us.

I also would like to remind you about some facts about mercury poisoning and they are

documented by many studies.

Mercury, of course, as we all know, is a highly toxic and confirmed as a neurotoxin. The leader of the World Health Organization has stated that there is no safe level of mercury.

A silver amalgam filling contains about 50 percent mercury. Amalgam fillings have never been proven safe and they have never been -- I don't even believe they've been tested for safety.

Mercury in amalgam does leak into the body, and that's a scientific fact that has been shown in studies.

Autopsies show that people who do have fillings have higher concentrations of mercury in their organs and tissues than people who do not, and many times, I believe these are higher than safe standards.

Mercury toxicity does produce symptoms of nervous disorders, including tremors, blindness, speech and vision problems, balance disorders, mental dysfunction and retardation.

Mercury is used, as we all probably know, in multidose vial vaccines as a preservative for many medicines, cosmetics, cleaning chemicals and it is even now in things like light bulbs. Common sense

alone tells me this isn't a good combination.

Why are dentists and hygienists given such strict guidelines as Dr. Hardy probably mentioned when we have it in our mouths? After an amalgam filling, most of the time perhaps there is not traceable problems; however, what about the times when a body burden threshold is reached like the case of my mom and someone does become ill?

Most doctors, I believe, wouldn't even diagnose this properly, because like my mom, her symptoms mimic many chronic diseases that are becoming much more prevalent over the last hundred years, and I find that interesting.

With millions of people who have these fillings, isn't it skeptical to think that no one is affected when there is virtually no limits, no warnings and no precautions on amalgam fillings?

There have been thousands of people who have suffered ill effects after dental amalgams who have voiced their concerns, and thousands have been documented in medical literature.

Also, there is many health professionals who have warned against the use of mercury in fillings; but, they are ignored, silenced and the evidence is dismissed. I read that even dentists that even say

that they wanted to be mercury free or remove fillings actually get punished or get -- they hear it from the ADA for doing this.

And for the most part, America trusts her government and regulatory agencies. Because of this, Americans are blindly allowing this known neurotoxin to be embedded in their own mouths and in the mouths of their children.

I would like to respectfully appeal to you distinguished members of the FDA.

Please accept responsibility to warn and educate the American public from the dangers of mercury poisoning.

Please make policies that will empower dentists to have the responsibility and the opportunity to talk to their patients without being punished by the ADA.

Please do not let special interests, corruption and politics come before human suffering.

Please remember the money this is costing families, individuals and our weakened healthcare

system.

Please remember the thousands that are living an impaired life with a debilitating condition, and please remember my mom.

As we look back in history, we can see obvious mistakes made by generations before us, by institutions that shaped popular culture and policy, and I believe again in the future this will happen to our shame if we refuse to act on the issue of amalgam fillings.

I want to thank you so very much again, and God bless you.

MS. HEATHER HOWELL: Mr. Greg Makhov, Laser Lighting Systems, Incorporated.

MR. GREG MAKHOV: Good morning and thank you. Once again, I will be departing from the medical area, and certainly, we've been out numbered by the people concerned with the mercury toxicity issues by talking about laser displays.

I'm president of Lighting Systems Design, Incorporated, here in Orlando, and I serve as the chair of the laser safety committee for the International Laser Display Association that Patrick Murphy is the executive director of. I'm active in the laser safety community. I'm a frequent

presenter at the International Laser Safety Conference. I've also served on the G10 committee of the SAE dealing with aerospace hazards of lasers, the ANSI Z136.6 committee, and I also provide laser

safety training with Rockwell Laser Industries, one of the laser safety consultants, one of the largest ones in the U.S.

Specifically what I want to talk about is the variance process as it affects us in the laser display community.

The CDRH standard limits products considered as demonstration laser products to a maximum power of 5 milliwatts and a variance from the standard is required for products that exceed this level. Most laser display products for the past 30 plus years have exceeded this level by necessity and each product therefore requires a variance. Moreover, each user of the laser display products also required a variance as the CDRH considered a laser light show, that is not the product, but the show that's done with the product as a laser product, and therefore, subject to the standard.

Much has changed in the 30 years since then, including the advent of high-powered diode lasers and DPSS lasers, which have greatly decreased the

size, cost and complexity of a modern laser display. 5 watt DPSS lasers, 1 watt diode lasers, such as what Mr. Murphy was showing, are very common and amazingly cheap. Virtually anybody can buy a

Class IV laser system and immediately start using it for virtually any purpose they desire.

Let's be honest. Most people have never heard of the CDRH. They are lucky to have heard of FDA.

Online retailers now offer a variety of laser display products in excess of 5 milliwatts and most do not indicate there is any government regulation whatsoever. Right now, you can buy laser light show products on eBay in the multiwatt range and put them to immediate use. You won't even be informed that there is any regulations about how to use it safely.

However, if one obtains a variance, one also promises to not deliver a laser system to, quote, and this is from the variance form, any other party under an agreement of sale, lease or loan unless and until the recipient demonstrates they have a variance in effect at the time of delivery.

This would make sense if a variance could be obtained in a few days. Yet, being honest about this, the variance process takes months or even years for a variance to be granted. Even a

completely boiler plate application by a known provider can take over a year to process.

So, the customer can buy a laser display product online and no strings attached, or they can

buy it from a laser light show company with a variance and wait for their variance to be granted before taking delivery.

What do you think people will do? Of course, they'll buy it online and no strings attached.

With the change in the laser display products creating a much higher volume than in the past, it's become apparent to us that the number of users out there, people who want to do laser light shows, exceeds the realistic capability of CDRH both from a process and enforcement viewpoint. There simply aren't enough people to deal with this.

Also, it is unrealistic in the current financial situation to have any hope for budget increases that would provide the manpower to cope with this increased volume.

So, speaking for the laser display community, I recommend the following step and this is a bit radical so I'm not surprised that people may push back against this.

We need to remove the variance requirement for

laser light shows. The logic is simple. The laser light show, as a product, was a legal sleight of hand, in my opinion, that was implemented in the early days of CDRH, back then the BRH, because of

people like David and Fonti going around doing mirror ball scanning and audience scanning and basically scaring people. Yes, it is terrifying the first time you see a multiwatt laser going into a mirror ball.

But in the ensuing 30 years, the number of documented laser injuries, that's really what we're talking about when we're talking about regulation, injuries versus regulation, are statistically insignificant.

Patrick Murphy mentioned how many exposures there have been, and we can count on a couple hands how many injuries worldwide have been reported and documented. Outside the U.S. where there are essentially no regulations and, of course, there are a few exceptions to that, and horrible things like audience scanning are common and daily practice, we are not seeing an epidemic of eye injuries so the impetus for the regulation is now somewhat questionable.

We're not seeing injuries so why are we

regulating the practice?

The reality is that only those familiar with CDRH are following the rules. Any number of DJ outfits, nightclubs, mobile entertainers are doing

whatever they want and no one is there to stop them. Only large corporations with liabilities and professional laser safety personnel are really following the rules and maybe not even then. We can talk stories there.

I think we can and should keep the variance requirement for manufacturers, manufacturers have more knowledge, more responsibility, and that we should keep record keeping requirements for the sales and installation of lasers, who bought these, where did they go, but we need to rescind the onerous and useless variance requirement for the end user. It is not serving any purpose at this point other than as a scare tactic and it is more often an embarrassment for the professionals.

What we hope, in summary, is that CDRH would rescind the variance requirement for laser light shows, that light shows should be designed and operated in accordance with ANSI and IEC conditions, pretty much the same conditions we have in the variance. The manufacturers would still have the

variance requirements since they are above the 5 milliwatts. The manufacturers should document sales and installations of the equipment, and therefore, CDRH could focus more on rogue

manufacturers and the online sales of noncompliant products.

Thank you very much.

MS. HEATHER HOWELL: Next speaker H.L. Sam Queen, The Institute For Health Realities.

MR. H.L. SAM QUEEN: Thank you for this opportunity. I believe you will have copies of my speech here today. I'm the director of Institute For Health Realities out in Colorado Springs, and we developed the first objectively major health model.

I also was the author of the first medical reference book on chronic mercury toxicity. That came about from my own poisoning which was not from dental amalgam. It was working in the clinic laboratory back in the fifties and sixties. OSHA came by and removed that instrument. It doesn't happen anymore.

But as we listen here today and sit, understand that we're moving at 65,000 miles an hour, going around our big sun. We're really moving. You always wonder the big question is: Why doesn't our

atmosphere just blow up at that speed?

I'm not sure why we're talking about amalgam, except that amalgam is just part of a bigger story. Mercury is so incredibly toxic material. It's very

persistent. We can throw away a lot of chemicals into our depositories and they tend to degrade. Mercury has a hard time being able to do that and one reason is the fact that it vaporizes, it takes on a number of different reactions.

I'm also a member of the American chemical society.

MS. HEATHER HOWELL: Excuse me, Mr. Queen. Can you use the microphone, please?

MR. H.L. SAM QUEEN: I'm also a member of the American Chemical Society, and this is the international year of chemistry. And it is very interesting that we're trying very hard in the American Chemical Society to get rid of all further use of mercury. Everybody is.

The mercury project is really a phenomenal idea. We used to have a lot of mercury we used for the production of plastics. We don't do that anymore. We found a new way. But China, you know, they are still using it the old way, and one of the big problems we've got, we've got 500,000, excuse

me, we have 5,000 metric tons of mercury stored underground as a result of our Nuclear Weapons Plan when we used to use mercury for the enrichment of lithium.

Now, we had an HR 1584 tried to get passed to get something done to make sure nobody sold that. Well, we're not sure what's going to happen to that. We think that could be up for grabs to be sold. Would you like to have that happen?

Well, the big problem that's happening in the world today starts with mercury, itself. It is the most toxic material and it is an absolutely time bomb that we've got to do something about our own exposure, we've got to tighten up things, and we have to tighten up the whole world. Where we live right now is a very small planet, a very small place.

There has been an ongoing study of polar bears since 1920, and a report just out this year shows that, over the last 90 years, we have had an annual increase of 1.6 percent rise in the level of hair mercury in those polar bears.

Now, these are the canaries. There is two big sets of canaries that we look at. One is the polar bear and the other is the amphibians.

What's interesting about amphibians is the very fact that they have their eggs and through maternal transfer of mercury that's well established.

Well, what hasn't been established until this

year just reported in March of this year, the last of March, what's very clear is that we use subject the tadpoles that came from maternal exposures. When you expose them to very small levels of mercury from their diet, what happens is that they lose their ability to be able to think apparently, if you can imagine that, but they don't find their food well, they don't swim as rapidly as they did, and also they wind up having a mortality rate that's somewhat higher than -- actually 50 percent higher than you might expect in a creature so.

The idea is that it is not only just maternal exposure. We know from bodyburden.org, that was an interesting website at one time, where they studied how many people -- how many toxins our people are being exposed to everyday, and from those studies, it is very clear there is nobody in this room that is not exposed to a variety of toxins so it becomes a point of who is going to be exposed. Who is going to be exposed? Who is going to react to this? Everybody is exposed. So, it is a matter of

reaction.

I think we've come to a point as a growing population right now of people throughout the world that we can no longer afford to place mercury

directly into people's mouth.

When you think about it, the American Dental Association in their latest, if you pick up their latest journal, what you'll see is that they are bragging now about being green. And in being green, they are asking their followers now to use the mercury separators because it is somewhat law that they have to be able to handle that mercury once it comes out of somebody's mouth in a very careful way, and if you don't do that, we're getting in trouble. Environmentally, we're getting in trouble.

The effect of mercury in 1850 is different globally than it is today. We know that the scientists, environmental scientists, doing the bear study are showing us right now that, what, 95 percent of that mercury those bears are getting is coming from human activity. It is our activity.

We are in this thing together. This is not -- this is not just the FDA decisions. This is everybody's decision right now. We are in real big trouble.

Here's the thing that -- I'm also an investigating medical reporter. One of the things we have --

MS. HEATHER HOWELL: Thank you, Mr. Queen. I'm

sorry, we have to move to our next speaker.

MR. H.L. SAM QUEEN: Thank you.

MS. HEATHER HOWELL: John Kuseck, ConMed Linvatech.

Darlene D'Angelo?

(SPEAKER FOR MS. DARLENE D'ANGELO): Thank you. Darlene D'Angelo was unable to make it today. She was too ill to be able to be here with us so I was asked to read her statement.

Hello. I'm reading this testimony written by Darlene D'Angelo from North Palm Beach, Florida, who was an injured mercury poisoning consumer. I would like to be here in person, but due to my disabling health symptoms from mercury poisoning I am not able to endure two days of traveling and activities.

Since the onset of mercury poisoning, I battle everyday with severe chronic fatigue, malaise, chronic and sporadic pain. On bad days, I wake up with chronic and sporadic pain and feel completely drained. I cannot function and I need to stay in bed most of the day.

On better days, I wake up with chronic and sporadic pain and moderate fatigue, and I try to endure a few hours of functioning, but my energy level decreases rapidly and I need naps and

relaxation time everyday for a few hours.

I've been stricken with acute mercury poisoning. I had a silver filling drilled out and replaced with a white filling in August 2, 2010, nine months ago when I was 46 years old. Within a few weeks, I developed over 25 chronic and sporadic neurological and health symptoms, including extreme fatigue, malaise, extreme memory and concentration impairment, severe depression and anxiety, chronic and sporadic symptoms of leg and muscle pain, twitching, back and shoulder muscle pain, tingling in my hands and feet, numb hands, feet pain, ears ringing, ear pain, episodes of hearing loss, eye pain, blurry eyesight, chest pain, heart palpitations, fainting episodes, shortness of breath, hypoglycemia, abdominal pain, headaches, irritable bowel episodes, teeth and jaw pain, cold hands and feet, difficulty urinating, sweating episodes, insomnia and sleep disturbances, et cetera.

I went to many doctors and had multiple tests

done. I have been diagnosed with fibromyalgia syndrome, chronic fatigue syndrome, which is one of the main causes from mercury poisoning.

The unfortunate situation is that most doctors

are ignorant to the symptoms related to mercury poisoning and most dentists don't inform their patients of the potential dangers of fillings being -- mercury fillings being filled or removing mercury fillings in their teeth, despite thousands of scientific studies proving that they are a hazard to human life and the environment.

I had to do my own research to find out what happened to me. I learned that mercury poisoning is difficult to test and diagnose and that most doctors don't consider the possibility that chronic or acute exposure to mercury from amalgam fillings can be at the root of over a hundred symptoms.

Mercury is known to kill cells and can cause serious diseases of neurological system, mental disorders, immune diseases and cancer. At this time, Sweden, Denmark and Norway have banned mercury fillings and many other countries require health warnings.

A schedule to phase out mercury require controls on dental waste.

California, Maine and New Hampshire require dentists to warn about mercury dangers.

My question to the FDA panel is: When will the FDA require all dentists to warn patients about

mercury poisoning dangers and the proper methodology and protocols with special techniques and equipment which would reduce 90 percent of mercury exposure, according to a study published by the Sweden government, and inform the doctors and the public about mercury poisoning from silver fillings, which is the second most toxic non-radioactive element in the face of this earth as they did for lead?

Thank you.

MS. HEATHER HOWELL: Jocelyn Jennings.

MS. JOCELYN JENNINGS: Good morning. My name is Jocelyn Jennings. I'm a regulatory professional and I work at BioMerieux, Inc. It is an in vitro medical device company.

So, thank you for having this town hall meeting. I had never been to one before. I'm finding it extremely interesting and I'm glad that I was able to participate.

So, I wanted to bring just a few concerns that I have as a regulatory professional working for an in vitro diagnostic company. One is what the FDA

has talked about before about being transparent, predictable and consistent in their reviews.

From a regulatory professional working at a device company, it is very hard when you really

can't go from one 510(k) to another 510(k) and use your experience from one to the other, especially when you are working within the same division, which is the division of microbiology and OIVD.

We would also respectfully state that a lot of the advice that we get is not necessarily scientific in its origin and we also are concerned that the special 510(k) and abbreviated 510(k) do not seem to have a place today with the FDA reviewers. We have been discouraged from submitting special 510(k)s especially.

The other concern is the long interactive review periods that we have once our 510(k) has been submitted, and while I will say on a positive note that the interactions with the reviewers is very timely, we can do it via e-mail which in the too distant past was unthinkable. That is very helpful. Sometimes it can be over burdensome. We, for example, have had one instructions for use changed about four times by the same reviewer, some of it the same wording that's been reworded, and that puts

an extra burden on us. We've had to ask for at least two 60-day extensions and we're running up to maybe having to ask for a third one.

So, we would just like to state that while we

like the interactive review and we like being able to interact with the reviewers via e-mail and telephone, that it would be helpful to have it if it is IFU, or whatever, reviewed one time, everything reviewed, instead of multiple times.

The other issue I wanted to bring forth is requiring unnecessary 510(k)s. We have a product that's a blood culture product. It will be a new instrument and we have a bottle that is regulated by Cebert that goes with that instrument and we're now told that we have to do two 510(k)s, and I can't get anyone either in Cebert or CDRH to explain to me why especially because for Cebert's point of view they -- the regulation of that instrument is not under their purview. So, what would the review from Cebert really gain us?

And a question that I had was because I work specifically with microbiology and blood culture instruments was whether or not the FDA still considered the 1991 blood culture guidance document relevant, and if so, were there any plans to update

it and make it final, because it is still draft and again it is from 1991.

And on a positive note, I would like to say that the pre-IDE process we had found has been very

instrumental in assisting us in conducting our preclinical and clinical studies to meet the FDA's expectations and get our products cleared.

Thank you.

MS. HEATHER HOWELL: Ms. Freya Koss.

MS. FREYA KOSS: Good morning. Thank you for allowing us to be here, Dr. Shuren. I am one of millions of Americans who have suffered grave health consequences as a result of mercury poisoning from my dental fillings. My name is Freya Koss. I am a director of the Pennsylvania Coalition For Mercury Free Dentistry, and I'm here to express my deep concern about FDA's continued suppression of the scientific evidence supporting the serious health effects of mercury dental fillings.

In 1998, I was suddenly struck with double vision, drooping eyelids and loss of equilibrium and many other neurological effects. I would like to show you, if you haven't seen this yet. This is what I looked like seven days after I had an amalgam filling placed. That was in 1998.

Four years later, after amalgam removal and a treatment of detoxification, that's what I look like.

As you can see, I look like I was hit by a Mack

truck. I looked like that for four years.

Based on my symptoms, five neurologists diagnosed me with either lupus, multiple sclerosis, which you've heard from several other people today, or myasthenia gravis. In the end, I had myasthenia gravis from mercury fillings.

Not one of these doctors considered that my symptoms were or could have been from dental fillings. That's a real problem in medicine today. They don't look at mercury as a possible cause for any autoimmune disease or neurological problem.

According to them, there was no known etiology cause of any of these diseases and no hope that I would get better. In fact, a neurologist at University of Pennsylvania Hospital told me that I better get used to being sick because I was going to be sick for the rest of my life.

I rejected those diagnoses, and if I hadn't done my own homework, I wouldn't be here today to tell you the story.

At the time I was unaware that silver-colored

fillings were actually 50 percent mercury, a known neuro toxin. If I had been advised by my dentist that a silver filling was mercury, I never would have allowed that filling to be placed in my teeth

and I certainly wouldn't have allowed mercury fillings to be placed in my children's teeth, but I did.

The warnings listed in the material safety data sheet for dental amalgam only seen by the dentists, never the patient, are frightening. For example, mercury is a pulmonary sensitizer, a neurotoxin, and amalgams are contraindicated for patients with kidney insufficiency, in children under six, and expectant women.

Parents and expectant women are not told that there is mercury in a silver filling. They sit in that chair and they get those mercury fillings, and they never see those warnings on the material safety data sheet that the dentist sees.

I ask you, Dr. Shuren, how is it that FDA continues to officially endorse this toxic product as safe and effective with no risks?

Would you condone that filling for your children?

The very scientists hand picked by FDA in 2006

and 2010 to evaluate the risks of amalgam have told FDA that mercury doesn't belong in the teeth of children or pregnant women. The same scientists recommended labelling amalgam as mercury, not

silver. Yet, FDA remains static, taking no steps to educate parents or protect children.

In March 2011, the U.S. State Department endorsed a phase out of mercury fillings, asking all governments of the world to protect children and fetuses from mercury. The Scandinavian countries banned amalgam in 2009.

Canada issued mercury amalgam warnings for children and pregnant women in 1996. Considering the removal of mercury from pet and childhood vaccines, contact lens solution, Mercurochrome, thermometers, thermostats, car switches, and blood pressure machines.

When will FDA remove mercury from amalgam dental fillings? If you continue to dally, Dr. Shuren, the children of America will remain guinea pigs in having their health sacrificed to protect the faction of dentistry that clings to this pre Civil War primitive product. My hope is that you will hear us.

MS. HEATHER HOWELL: Thank you. We need to

move on.

MS. FREYA KOSS: Can I just finish this sentence?

MS. HEATHER HOWELL: Yes.

MS. FREYA KOSS: Thank you.

My hope is that you will hear us loud and clear, that you will acknowledge the science, and that you will do what's necessary to protect our future generations by banning the use of mercury in dentistry.

Thank you.

MS. HEATHER HOWELL: Our next speaker is Mr. Frank Levy.

MR. FRANK LEVY: Good morning. Thank you for the opportunity to speak, Dr. Shuren, and your staff, as well.

I'm Dr. Frank Levy. I've had the opportunity to work over the past several years with some of the leading physicians in medical grade CO2 usage.

There is growing concern in the medical field as to the FDA's standpoint on medical grade CO2 and the use in medical procedures. The European community has already addressed medical CO2 and freely allow its medical use.

Although medical CO2 has been used for over

50 years, the FDA still hasn't defined it, how it is regulated. It is uncertain as to whether it is considered a drug or a displacement gas.

It is our understanding the FDA has not

addressed the issue merely because they feel the physicians are using it without the regulations safely and for over 50 years so really have made no effort to clarify it.

This has impeded the progress of medical developments regarding the use of medical CO2. Many physicians will not use the medical CO2 until such time that the FDA concludes it is an approved medical gas.

Currently, medical CO2 is being used for insufflation, laparoscopies, tissue separation, venous procedures, angiography procedures and many more medical procedures.

Medical CO2 gas does not change the molecular structure of cells in the body and is merely a displacement gas. It is actually a natural by-product of the human body. An angiography procedure is much safer and much less expensive than contrast media. It is the contrast agent of preference for use in renal patients and patients with diabetes. Renal patients can have adverse

reactions to contrast agents, resulting in weeks of hospitalization and sometimes years of or lifetime of dialysis.

With the use of CO2 in imaging tumors to the

pancreas, liver and other critical organs can be detected and treated months, if not years, in advance of contrast agents, making it a more treatable condition than today when you find out what type of tumors in the liver and pancreas can do when finally found, you know, as a life-threatening problem.

There is no allergy risk to patients exposed to CO2 in the medical procedures, where it cannot be said for many other agents used in medicine.

If the FDA were to allowed physicians to use medical CO2, there would be significant saving in money and lives.

My question is: How can we work as physicians with the FDA to regulate CO2 as a displacement gas and allowing more physicians to use this?

It is safer. It would save money for the doctors, insurance company and patients, billions of dollars. You could visualize liver, pancreatic and renal artery tumors much earlier and, of course, save lives by doing that. More doctors would use

it, of course, because they would feel more comfortable not using an off-label gas, which they have been using for 50 years as very safe, and we would eliminate the complication long hospital stays

and dialysis as well as have better imaging.

So, I appeal to the FDA to see how we can work together and doctors and see how we can make this a more viable procedure or procedures used for procedures so that all these advantages can be reacted and seen.

So, thank you so much for your help.

MS. HEATHER HOWELL: Dr. Kirk Youngman.

DR. KIRK YOUNGMAN: All right. I had a little technical difficulty here and couldn't print. I didn't bring this up here because I'm high tech.

So, my name is Kirk Youngman. I'm a dentist. I also graduated from Washington University of Saint Louis. I was in a class behind Dr. Hardy here. I wasn't bright or brave enough to ask a question about mercury. I just listened to the lectures and got through everything as best I could.

But as time would have it, I actually spent time in the public health service after dental school in the Indian health service and after that in migrant farm care, all following my accepting a

national service corps scholarship. So, I understand the confines of working in that environment also.

I became interested and cognizant of the fact

that mercury in amalgam fillings is a neurotoxin and not just an innocuous ingredient in 1992. I started private practice in 1991.

I'm here to address what I consider the recent lack of regard of mercury as represented by amalgam as a toxic device. I don't know how it's possible that I can add more given all that's been said, and I'm sure many of you may agree with that, but I'll go on since I did drive two hours to come here.

I do want to emphasize that I feel it is an important distinction to speak of mercury and its toxic properties, which are not ameliorated or eliminated when mixed with metal and implanted into teeth calling it amalgam as I have been told as a dental student and dentist, and so, I'm not talking about what I consider a made-up word for mercury filling called amalgam, and I'm not addressing or discussing anything to related amalgam's promulgated innocence of negative consequences as regards local or systemic disease.

That amalgams release mercury is why I'm an

interested party addressing the significance of its properties as far as it's recognized as a neurotoxin. It is my experience that addressing of amalgam as amalgam's meant to obfuscate it having

any causative role in adverse reactions in the body, ignoring the truth that it is a filling emitting mercury, which is the causative agent that is under scrutiny and the true criminal of this subject at hand. Again, amalgams are the source of this known and regulated neurotoxin, and I feel it is important to make this distinction. Again, there are those in my profession who make less of amalgam fillings, deflecting the guilt by ignoring or avoiding the fact that they do emit mercury as is evidenced by the fact that even the dissemination of information to dentists as regards to this one simple point, the emitting of vapor. Until 1984, it wasn't even mentioned by the ADA when they conceded that mercury vapor indeed does come off.

The more I saw data or looked for data that validated this new information, right, that mercury was a neurotoxin actually emitted from mercury fillings, the more that I became interested.

So, I know you, as the FDA, are aware of the science and that other speakers have spoken to you

at length regarding that science, more people today have also, and it is my opinion that the science has to be being ignored, misrepresented, abdicated devaluation by people not credible to give

scientific importance to it or otherwise resisted, and for that reason, I'm not going to lay down papers and quote what you already know as it is in our own publications other than to substantiate, you know, what I'm going to be saying.

So, what I want to know and will address is that given all the agreed upon scientific truths regarding mercury's properties, its level of neurotoxicity, the fact that it volatizes at room temperature, its instability and increasing volatility with increasing temperature and agitation as occurs in the mouth, the fact that it is absorbed readily into human tissues and demonstratively creates adverse biological effects on living organisms, and most importantly man that we're talking about, although I have a huge affinity for polar bears, how is it possible that it is being justified to being put into virtually any and every person in the world's teeth by a dental organization with a specious reasoning that its combination with other metals as a dental filling material renders it

safe because in the fact, and I'm sorry, when in fact the justifications for its use is due to its low expense and the fact that it's been used for well over a hundred years, ignoring voluminous

scientific data for that entire time?

I have no idea what that has to do with scientific data or evidence-based research. Not only that, but I've said facts are further obscured by using the word, amalgam, in negating its causation of disease when, in fact, the truth is we're all talking about the emitting and absorption of mercury from a mercury-contaminated filling and the resultant pathophysiology as well as symptomatology observed and identified in any medical publication on toxicity.

This obfuscation of the facts and position that is taken by amalgam protagonists is offensive, ingenuous, unscientific, harmful, misdirective, purposely altering the importance of a vitally important issue and where it limits the public to desire dental and medical care, I feel it's criminal and even inhumane.

I would like to make an analogy to point out the misuse and obfuscation of facts and terms that I am talking about, and that to say amalgam is safe is

not unlike a statement of generality that food is safe to eat, water to drink, air to breathe, clothes to wear or houses to live in; but, if the food, water, air, clothes or houses are contaminated with

a known neurotoxin that one is being exposed and being contaminated with and in as occurs with mercury implanted in amalgam, and then to say these things are safe is now not a true statement.

To call them safe when they are contaminated with a known neurotoxin and encouraging the public to feel safe using these contaminated items mentioned would be ignorant at best and again criminal at worst.

The fact in this instance at hand that the known neurotoxin is an integral and permanent part of amalgam should not justify mercury not being named and recognized as the villain in this mixture, nor justified giving it an innocuous name such as amalgam to deflect and ignore such villainy.

We're talking about mercury and its causes, known and unimpeachable, and why it should be protected, should not be protected because it is called an amalgam filling with no known disease causation, and that its implantation in teeth be discontinued in and as a dental restorative

material.

So, since I can't really duplicate and understand the information as a dentist of 27 years, I feel like I sort of need you need to explain to me

as a 12-year-old kid, not biased with my professional education, how when you are attacking mercury's existence -- when I say you are attacking mercury's existence, I mean the FDA or trying to limit in these venues -- when you are attacking mercury's existence in air, water, food and every other article we come in contact with, with firm regulations and regulatory bodies, how it is you allow the implantation of mercury laden fillings in the citizens of the United States either implying or stating outright it is safe in the face of the following. And then I want to quote a few things.

The Food and Drug Administration, FDA, Modernizing Act of 1997 called for the FDA to review and assess the risks for all food and drugs containing mercury. The toxicity of mercury and its components have been recognized since antiquity and are recognized and acknowledged in industry.

And then, again, it's been mentioned MS, Alzheimer's, all these things, but when I'm looking at mercury, no different than when lead is talked

about, which talked about its symptomatology with mercury, tremors, neuromuscular weakness, polyneuropathy, slurred speech, memory loss, emotional lability, shyness, fatigue, headaches,

insomnia. It's a long list.

And I want to juxtapose that with lead because when lead is talked about, here it is less toxic, and yet, it is treated fairly and it's censored due to its known cause of toxicity evidenced by -- I have a following list which is not dissimilar to mercury, because lead being irreversible neurological damage, as well as renal disease, cardiovascular effects and reproductive toxicity, and blood levels once considered safe are now considered hazardous with now known threshold and it being a wholly preventable disease, all of which I feel applies to mercury equally.

Again, symptoms of lead, as you know, fatigue, irritability, lethargy, abdominal pain, muscle pain, headache, you know, very similar list.

MS. HEATHER HOWELL: Thank you, Mr. Kirkman.

DR. KIRK YOUNGMAN: Okay. Thank you.

MS. HEATHER HOWELL: Carol Stapleton.

MS. CAROL STAPLETON: Thank you. Thank you for coming and hearing our heart-felt expressions of

chagrin. I'm sure this isn't your first rodeo and you've heard a lot of heart rendering testimony about the adverse effects of mercury toxicity.

Correct me if I'm wrong, but I believe that the

role of the FDA is to be our overseer, to be our protectorate, to look at the market, look at what's going to affect us, what we're going to consume, what we're going to have flashed in our eyes, what we're going to be exposed to and ascertain whether that that is safe, and the job of the FDA is to protect us from harm.

Research on mercury amalgam is not a new thing. Obviously, it's had a hundred fifty years and many, many documentations of why it should not be used. Doctors Vimmie, Doctors Haley, Doctors Hardy, there have been so many doctors and so much documentation. Dr. Kennedy has excellent footage of mercury vapor. There is lots of evidence of how it gets into the system, stays in the system, is pernicious, affects many different aspects of us, that it is not stable, combined with other metals. It is only stable in glass, and then even so, it is just -- it is just deadly.

It also conducts electricity quite well as do we. We're roughly 65 percent water. We're like

walking water bags of lightning rods. We're like bags of water with legs ready to conduct all these things coming off our laptops, our Bluetooths, our technology that's bouncing all over the place.

Those things are conducted in our mouth with a kissing cousin to battery acid, which is our saliva. We're got this electrical storm going on in our mouth just inches away from our brainstem so there is no wonder why there is so many neurological effects of MS and why it is difficult to name what the problem is, because we're all distinct individual our bodies are all just a little bit different. We metabolize things in a different way and we're affected by things in a different way.

So, although it may be dismissive to think of these people with the MS and all these dreadful symptoms as perhaps being hypochondriacs or it being difficult to pin down as what it is, I think the part of what the real question is for me and the slippery slope and the giant elephant that we're not talking about in the room is the fact that once the FDA and other responsible bodies recognize the deleterious effect of this and so many people that there will be litigious, you know, someone is going to have to reach in their pocket and start saying

that it is not right and there has to be some kind of retribution or redress for the injuries that have been caused by this very toxic substance.

And I'm wondering why the FDA, although I'm

grateful you are here to listen to us, why is the FDA holding these silly and redundant meetings about things that have already been substantiated. That envelope has been closed with a hammer. We know. We don't need another hundred years of research to know that this is not working for us. And I know this is a slippery slope and implore you, as do these other kind individuals that have been so deeply affected, to do the right thing. The Turkish have an expression, "No matter how far you've gone down the wrong road, turn around, turn around." And I am I implore you protect interests that you have been so endowed with and assume the mantle of protection and let that supercede all the bed fellows, the ADA, the insurance companies that want to use something cheap and no one wants to take the responsibility.

Please, please, Dr. Shuren, take the responsibility to say no and start banning the use of mercury amalgam fillings.

Thank you.

MS. HEATHER HOWELL: Ms. Carol Roberts with the Wellness Works.

DR. CAROL ROBERTS: Thank you to the FDA for listening to us. I'm a practicing physician who

does look for underlying causes of chronic illness which are not taught in medical school.

Mercury was introduced to the dental profession in the 1800s by a pair of German brothers, nonprofessionals, above the initial objections of the dental association at the time. The low cost of the material and ease of insertion won over the public and the pejorative origin of our term, quack, became widely accepted.

Since then, the dental profession, itself, has been most negatively affected by chronic slow mercury accumulation. The extremely high suicide rate among dentists and their early average age at mortality may well be due to the toxic effects of mercury. In the rest of us, mercury vapor is released from amalgams with chewing, brushing, cleaning and drilling. A hair analysis can easily detect extremely elevated levels of mercury after a dental cleaning.

The tragedy at Minimata Bay in Japan brought to the fore the extreme toxicity of acute mercury

poisoning when hundreds of people died from exposure due to a factory that was dumping industrial waste containing methyl mercury into the bay. Still, the more subtle manifestations of chronic exposure have

yet to be acknowledged.

The inability of most people to efficiently eliminate this highly toxic material leads the body to do the next best thing, to store it outside the bloodstream.

We simply did not evolve in a world where mercury exposure is a common problem until the advent of amalgam fillings. Now, most of us carry lethal amounts of it around in our heads.

It has been shown that a pregnant sheep who receives an amalgam filling in her tooth begins to pass that mercury onto her unborn lamb within a day. In functional medicine, the axiom is the fetus is the toxic sync.

We now know that the cord blood of newborns contains upwards of 250 toxic chemicals. Most of these have never been tested for safety and certainly the combination of multiple chemicals in a newborn is impossible to evaluate.

Mercury is the most toxic element that is not also radioactive. It does its mischief by replacing

normal minerals and enzymes all over the body, thereby inactivating them and by destroying components of cell membranes and this is especially damaging to the central nervous system.

A few of the multiple dare one say mercurial disorders which can be associated with mercury toxicity are the following: Allergies, asthma, autoimmune diseases, ALS, ankylosing spondylitis, myasthenia gravis, Parkinson's disease, Alzheimer's disease, anxiety, panic attacks, hypoglycemia, low thyroid function, depression, ADD, learning disabilities, multiple chemical sensitivities, chronic fatigue, fibromyalgia, gastritis, arthritis, bipolar disorder, sleep disorders, colitis, Crohn's disease, anorexia, nervosa, bulimia and yeast overgrowth.

Naming, labeling also called making a diagnosis, is not a substitute for understanding underlying causes.

In my own functional medicine practice, I've been testing patients for metal toxicity for 17 years. The ubiquity of heavy metals, especially lead and mercury, is astonishing. These two toxins have synergistic negative effects on the body; in other words, they amplify each other's toxicity.

It is easily possible to monitor the amount of metals removed with treatment. Removal of the metals is usually followed by dramatic improvements in pain, fatigue, depression and many other

symptoms, although not always and not in every patient. But prevention is always preferable to treatment.

Germany, Denmark, Sweden and Norway have all banned the use of amalgam fillings.

If we are interested in keeping the costs of healthcare down, the FDA can institute a simple public health mandate right away which will have profound cost savings implications in the future for ourselves, our children and many generations hence.

Please ban the use of mercury amalgam fillings today. Thank you very much.

MS. HEATHER HOWELL: Dr. Clair Stagg.

DR. CLAIR STAGG: Hello, everyone. You know, when our patients come to us as dentists, they always say, "I hate dentists. I really don't want to be here today."

And I don't envy your job, because I feel for you. However, I would like to share my journey. My journey is a different than most of you. I'm a practicing dentist with an emphasis on mercury

removal.

I trained in France. And we were trained a little differently than Americans. We had a lot more of a natural way of learning a lot of

homeopathy, a lot of alternative medicines that I grew up that I thought were very natural.

We were told when we were, you know, in those days, we had amalgams, we had the mercury, and we actually had to pour the mercury in and use the drop cloths and see the little beads of the mercury fall down on the floor, and they always said like don't touch that, that's not good for you, and it will eat the gold on your rings so we don't wear your rings; and yet, we still place it in patients' mouths.

So, what happened is I came to America and I married an American. And a young man from church we found out was deathly ill and had been through a lot of different ways of trying to heal himself and found out that he was mercury toxic, and it wasn't because of his mercury fillings; it was actually because he worked in the sign industry on the ballast and the fluorescent lighting caused him to be sick.

So, that was very interesting. I thought, well, heck, you know, if he's gotten sick with

mercury with ballast and we're putting it in patients' mouths, what does that mean that we're doing to our patients? And I stopped using mercury, because I didn't want it in my mouth. But then the

thing is that what do you with it when it is already inside the mouth?

So, there was a whole journey for me to learn how to take it out safely, safely for the patients, safely for myself and for my staff, and that's when I went to the IUMT. The IUMT taught us there are certain protocols we can use that will be more careful and more safe to be able to remove the mercury.

At my first meeting, I heard of a doctor called Stephanie Cave, and Stephanie Cave talked about the children that she was finding back -- she was bringing back to life literally which had been lost to autism, and that was a whole other exposure now, thimerosal in vaccines.

I had a girlfriend, a friend I met in Granada. She was in medical school in Granada when I was working there in back in the early eighties, and Julie was a staunch advocate: "The American Academy of Pediatrics would never hurt our children. Nothing is wrong with the vaccines."

I debated with her for several hours. I said, "You know what, Jules. That's your choice. That's your decision, but I think you should really look into it."

The reason I called her up to tell her about Stephanie Cave was that when we were building our "green building", because we have one, a unique one, her kid kept rocking all the time at the table. I said, "This isn't right. Something is wrong with this child." And sure enough, the child was autistic.

Julie had an incompatible blood and was given RhoGAM when she was pregnant and then within four weeks of her delivery had amalgam fillings. Needless to say, Danny was a severely autistic child. Interestingly enough, Julie is now a staunch advocate of autism child's and had has a foundation in Jacksonville called Heal. Julie has written a book and it is amazing to think that in less than eight years this woman has done a hundred eighty degrees in saving children's lives. People come from all over the country to see her.

The FDA was founded, I mean, sorry, not the FDA. The ADA was founded in the 1830s because there was a problem with the masses not being able to have

dentistry in an affordable manner. A lot of people have already said the facts. German fellows devised amalgams 50 percent mercury, 35 percent silver; the rest is copper, tin or zinc. What happened is not

everybody could afford gold or not everybody could afford what was there at the time so amalgam was founded.

And another doctor, another person I thought spoke very well, I'm thinking that if the ADA actually does admit -- the reason why ADA was founded because the association at the time did not agree with the use of mercury fillings. So, the American Dental Association was founded then.

So, think of the logistic and legal nightmare that is going to happen if the ADA, that all us doctors are under the envelope of, have to admit that what they've been using or doing or advocating for the last eighty-two centuries is toxic material. It just blows your mind. That's where I think you have a big, big, big problem to handle.

I know I should actually finish talking. But one of the things that and my last little topic is that when we were pregnant, it was 11 years before I was able to get pregnant and we had a wonderful birthing coach who was not really financially able,

not that I was either at the time, but she said, "Could we have a party at your house to go ahead and celebrate all the other parents who had children."

I said, "Sure."

And there were about five or six of us. There were about total 20 parents, 20 sets of parents with children. And one of them the biggest, biggest memories I'll always have of that party is, yes, we have lots of happy families, but there was one that will break your heart, and it was a parent that had to hold their child because the child couldn't hold their head up because they lost it after the last set of vaccines and the child was as limp as a noodle.

And I know, I know some of you are probably parents and I'm sure you have fillings in your mouth and children, try and do something. If anything today you take away with it, try to see if you can change it so you can make sure that the children don't become noodles, also.

Thank you.

MS. HEATHER HOWELL: Mr. Paul Funk, Florida Health Freedom Coalition.

MR. PAUL FUNK: My name is Paul Funk. I'm from New Port Richey, Florida. The good news is that I'm

the second to the last speaker. The bad news is I'm here to talk about mercury.

Okay. I got into this business to save myself. When I was about 40 years old, I had a bunch of

fillings put in my mouth. My lower mouth only had one filling on each side. They went from the back to the front. I figured those teeth are going to last forever; they are never going to get used again.

So, I was doing fine. About 55, 60 years old, I started having neurological issues and health issues, and I thought to myself this must be what getting old is like.

So, then, one day, I met this gal and she says, "Well, you know, there is -- I had this problem called mercury toxicity." I never heard of it. I said, "Now, where do you get that?" And she showed me this picture of herself. She looked like she was dead. The only thing missing was the pine box.

So, she starts talking about Hal Huggins and it's in your head so I called them up, got the book, started reading about it, and I then opened my mouth in front of the mirror and I looked. There is a lot of that gray silvery stuff in there.

So, I worked on getting in it out of my mouth

and then I worked on getting it out of my bed and I spent quite a bit of time and money on that trip. And I'm now 77 years old and I feel a lot better than I did when I was 60 years old.

So, let's take high school science. There is something called the Periodic Table. There are 90 plus elements in the Periodic Table. One of them is radioactive uranium. According to the Journal of Toxicology, that's the most toxic element on planet earth.

According to the Journal of Toxicology, mercury is the second most toxic element on planet earth. So, you could say that mercury is the most toxic non-radioactive element known to man on the plant earth. Okay. So, there are probably other things more toxic than the elements.

So, what are the physical characteristics of mercury? We've had this up here a few minutes ago, but anyway, if you take water and heat it up a little bit, it turns into something we call steam and that's a gas. You take water and you cool it down a little. It turns into something solid. We call it ice. Liquid can turn into a gas or it can turn into something sold.

If you take mercury, while water is turning

into solid at 32 degrees Fahrenheit, mercury is starting to move from a liquid to a gas at 10 degrees Fahrenheit. So we all know from our high school science for every increase of 10 degrees

centigrade in temperature, the pressure to vaporize doubles.

So, there it is, high school chemistry. Don't you love it.

So, what happens when you heat up mercury? This is a story of a lady who heated up her mercury. She was having facial pains and she had a treatment called diathermy, and what they do is microwave things like sonic frequencies to do deep heating treatment and try and alleviate pain and so that's going to heat up.

She had four normal size mercury fillings in her mouth. And how much mercury is in a mercury filling? About the same amount that's in a mercury thermometer. If you drop a mercury thermometer in school and break it, you close the school and you bring in some specialists to clean it up.

Well, she has four mercury thermometers in her mouth. This is what happened to her.

At age 34, in 1984, Barbara had been extremely active and athletic all her life, playing a lot of

sports and tennis. She had four mercury amalgam fillings at the time. And at a doctor appointment, the office was running a special on electrowave diathermy treatment for pain or discomfort. She

told them she had some discomfort in the oral area so it was agreed to do a diathermy for that area, and she was not told there might be a problem.

After a period of time, her mouth started to feel very warm. She decided to summon a nurse. By the time the device was taken off, the area felt like there was a blow torch applied to it.

The sensation did not stop when the device was removed. She had severe facial pain, constant taste of metal in her mouth area and developed chronic fatigue and many other adverse symptoms in the period following the event.

The metals from the amalgams had melted or separated and were extremely evidenced in her saliva. She described it as the metals were bubbling up in her saliva.

She had many continuing symptoms as before, including her hands and arms felt red hot much of the time. She had many visits to doctors and dentists, but nothing was accomplished to diminish her health problems.

The metals bubbling up in her saliva then began affecting her throat, stomach areas, many adverse effects over these areas over a significant period of time as well as constant major pain in the oral

area.

She consulted other doctors, including the Mayo Clinic, about the pain and other issues and was told that the trigeminal nerve damage and her problems were due to the fact the diathermy should not have been used in the oral area for a person with amalgams and had separated the metals in her amalgam fillings, causing her major mercury and other toxic metal poisoning.

The doctor at the Mayo Clinic who stated this opinion was Dr. Malpovich. She had provided the Mayo Clinic with a 22-page history of symptoms, and doctor and dental appointments, history, etc. The constant pain and other symptoms required much treatment during the entire period, and she would advise and consulted the FDA about her problem.

She saw Dr. Michael Syskan (ph) with the FDA, who was the person who wrote the FDA user effects manual on such devices regarding warnings and contraindications for the devices or treatments. Dr. Syskan agreed that the problem was caused by

improperly using diathermy in an area with mercury fillings, and because of her consultation with Dr. Syskan, he agreed that devices such as diathermy should not be used in the oral area with amalgam

fillings and included that as a contraindication in the FDA manual on diathermy treatments.

So, something good came out of this very bad experience.

After six months of the poisoning event, she went to her dentist at her regular cleaning appointment. During the cleaning, her symptoms and pain all got worse. She became paralyzed and lost the ability to walk.

After more consultations with doctors, she did some research and decided to have her amalgam fillings which had suffered major damaged replaced. She also had to have oral surgery several times since there were lots of metal in the gums and oral area, mercury tattoos and such.

After more research on what to do about the significant mercury and toxic metal poisoning, she's had to undergo metal detoxification, found a doctor with a good record using herbal detoxification and began detoxifying.

Most of her problems other than the trigeminal

nerve damage pain got better after the amalgam replacement and surgery and detoxification.

So, this is a person who did get better, not returned to her prior status. So, that's a good

thing.

Now, what happens today, what loosens up mercury in your mouth?

Well, you take electromagnetic force, you get a hair dryer and you are drying your hair. There is a motor there. It generates electromagnetic force. Now, you have a mercury filling here. It stimulates the mercury.

MS. HEATHER HOWELL: Thank you, Mr. Funk. We need to move on.

Our final speaker is Stuart Scheckner.

DR. STUART SCHECKNER: Good morning. My name is Dr. Stuart Scheckner. I'm a dentist. I'm living proof that mercury exposure from any source is a critical health hazard. I'm a dentist with documented occupational mercury poisoning.

From 1978, I sat over a large spill of mercury hid in the deep shag carpeting in my dental office. Six years later, I was completely disabled to practice my profession. I lost my dental practice, my income, my marriage and almost my life to this

horrible insidious poison. I went through years of torture with not one local physician having a clue. My neurologist did not even know that dentists used mercury.

I contacted the American Dental Association for help. In response, Dr. Langan of the Council on Dental Therapeutics sent me a letter stating that I could not possibly have mercury poisoning.

I had to fly across the country from Florida to the State of Washington to a doctor specializing in mercury toxicity. After a week of testing, the doctor's report stated that I was a classic case of mercury poisoning. I was referred to one of the leading world mercury toxicologists, Dr. Louis Chang, who validated my condition of mercury poisoning.

The American Dental Association stated to me in writing that I could not possibly have mercury poisoning in direct contradiction to a leading world toxicologist. The ADA uses the same criteria on the millions of people who have suffered from mercury poisoning from their mercury silver dental fillings.

The ADA was wrong about me and also wrong about the millions of people who have had their health destroyed by this insidious poison in their dental

fillings.

It is okay to place these mercury fillings in a person's mouth; but, once outside the mouth, it's deemed to be an environmental hazard by the

Environmental Protection Agency. This is indeed a contradiction.

In my reading about mercury, there was a connection with multiple sclerosis. I met Vivian Bennett who told me her amazing story. She had MS for years and her condition had been deteriorating. Her priest was over her home and saying last rites for her. She had a premonition that she needed to have her mercury fillings removed.

Within a few weeks after her mercury fillings were removed, she was completely free of MS symptoms, never to have a recurrence.

In collaboration with Dr. Michael McCann, a pediatric immunologist, we published a document in the Journal of Clinical Pharmacy. Essentially, we state that mercury, even in small amounts, can act as a trigger in autoimmune diseases such as multiple sclerosis and Grave's disease in genetically susceptible individuals.

Due to great variation in susceptibility, every individual reacts differently to mercury exposure.

This may range from no symptoms at all to slight symptoms such as irritability and insomnia to major illnesses such as MS, Parkinson's disease and Alzheimer's. The science is very clear mercury is

primary neurotoxic and secondarily immunotoxic.

Mercury does leak out of mercury silver fillings. It does become deposited in tissues throughout the body. Maternal mercury does become deposited in the fetus where the developing brain is at high risk.

While other countries such as Sweden, Denmark and Norway have prohibited the use of mercury in dentistry, the United States lags behind.

It is very clear that the continued use of mercury in dentistry is a health hazard to both dental personnel and dental patients.

To coin a phrase from Professor Alfred Stock, head German chemist in 1926, the introduction of mercury fillings was a nasty sin against humanity.

It is time for this archaic extremely poisonous material to be prohibited from further use in dentistry.

In conclusion, about 50 years ago cigarette manufacturers were advertising in the Journal of American Medical Association and leading magazines.

The headlines read "More doctors smoke Camels than any other cigarette."

In 50 years from now, will the use of mercury in dentistry, the most toxic nonradioactive element

known to man, be remembered the same way?

Thank you.

MS. HEATHER HOWELL: Thank you.

Okay. At this time, we'll take a break and we will meet back together at 10:30 and we'll have a Q and A session at that time.

(Recess off the record from 10:15 a.m. until 10:30 a.m.)

DR. SHUREN: We'll go ahead and get started. This is part two. The first part, you had heard from people who had signed up to speak.

We now open up the microphones for anyone who wants to make a comment or has a question. What I ask is if you do come up to the microphone, there is one up here, to introduce yourself. If you are with an organization or business or whatever, please state your affiliation. If you are making a comment, I would ask that you please keep it very short, just a minute or two.

So, with that, you can just come up to the microphone. I'll take folks in order.

MS. KATLYN TISSUE: Hello. Katlyn Tissue, Genicon, medical manufacturer in Winter Park, Florida.

My question is regarding the class

registrations I, II and III. What is your opinion and, if you may, is it a majority opinion on dividing Class II into IIa and IIb?

Thank you.

DR. JEFF SHUREN: So, we had undertaken a fairly comprehensive assessment of our what's called our 510(k) program. For folks who may not be very familiar with it, it is available for, and I'm over simplifying, a more moderate risk or lower risk devices that may have another device on the market very similar to it, and under that pathway, you are actually comparing yourself to the device that's already on the market, and if you meet the standard of substantial equivalence, you will get cleared and you can be sold in the U.S.

A lot of concerns have been raised about the operation of that program and aspects of the program. We applied for high risk devices that's called premarket approval, or PMA program. We undertook a fairly comprehensive assessment of the 510(k) program, very detailed, but also aspects of

our PMA program and issued two reports in August of 2010.

I will tell you that the concerns range from the FDA stifling innovation due to concerns about

insufficient predictability and consisting in transparency and on the flip side not providing sufficient protection for patients. We heard that from other groups; we're not providing sufficient information to make well-informed treatment and diagnostic decisions. And hence, we undertook those assessments.

One of the recommendations that came out of those reports was to split up our Class II devices. Those are more moderate risk, into a and b.

So, the proposal on the table was to put under IIb those devices for which we were asking for either clinical information, manufacturing information or we conducted a preclearance inspection.

Nothing in that proposal was about adding new requirements to devices, but rather as a heuristic to make it easier for manufacturers to maybe anticipate if there were additional data requirements or additional expectations for those kinds of technologies.

That was a proposal. We heard comment on it from the public. We received a number of concerns about making that split and we have deferred making a decision until the Institute of Medicine, which is

conducting an independent assessment of the 510(k) program, has an opportunity to weigh in, if they so choose, and subsequently, we'll make a final decision.

So, you can anticipate sometime probably in 2011 we'll be giving a determination.

MS. KATLYN TISSUE: Thank you.

DR. JEFF SHUREN: You're welcome.

MS. JOLIE DAVIS: Thank you for coming today. My name is Jolie Davis. I've been a dental hygienist for 20 years full time, and I just wanted to make a comment.

When I was in dental hygiene school, they never explained to us what mercury was. It was always referred to as a silver filling and they explained to us that we were take tin oxide and polish the crap out of it until it was real shiny. That's what people wanted. That's when it looked good.

Out of dental hygiene school, I worked for a practice for about eight years, and during that time that I was there, we had carpeting on the floor. We

did, I'm going to say, 95 percent of our fillings we did were the mercury fillings. There were several times that I would witness that the dental assistants would drop mercury on the floor. I'd ask

them if there was any issue with it. They said, "It is not a problem. It doesn't have any kind of smell. You know. Don't worry about it."

While I worked for that practice, I ate very well, very healthy, took vitamins, exercised regularly, went for regular checkups, but I was on antibiotics a minimum of four times every year. Patients would always come in. People would come in from time to time with colds, sore throats, you know, different things like that, and you get that generally. But I was always having to fight something off. I was always feeling not quite right.

In the mid nineties, I was lucky enough to read a book called Mercury Free by Dr. James Hardy, and it explained to me in laymen's terms what exactly mercury can do.

When the 60 Minutes subjects came up and patients would come in during the practice and ask about that, at my first practice, I was told by the dentist that it was basically a ploy by dentists to

make money, that it was a scam, that they wanted to take the silver fillings out just to be able to put the composite fillings in, they weren't as strong, there was nothing that showed that they were

worthwhile and it was just for aesthetics and to make money.

When I spoke with Dr. Hardy, after reading the book, he had explained to me that the worst thing we can do as dental hygienists is polishing the amalgams, because not only are we creating that vapor and it is coming up and it's toxic for myself, but also toxic for the patient, for them.

Since that time, everything for me has stayed the same, exercise, diet, the whole nine yards; but, I can tell you that during that time that I have worked for a mercury-free office, meaning that we have several different things that we do in the office safely to remove amalgam fillings, we do not place any amalgam fillings. We have special ionizers and different things set up in our air-conditioning units and things set up in the rooms to make it healthier for our patients and for ourselves.

We still get patients that come in that have strep throat and the end of different things coming

in, but in the last close to 11 years I've been on antibiotics one time. And I can't -- I can't see anything else in relation to the fact that I am not having that constant exposure to the mercury.

Thank you.

DR. JEFF SHUREN: Let me take a minute on dental amalgam. I don't know if anyone has heard about dental amalgams, but let me take a minute.

So I actually came to the Center For Devices of Radiological Health as acting director in September 2009. I became permanent director just a little over a year ago.

We've heard the concerns raised by a number of people obviously with going dental amalgams and we take those concerns seriously. It is why we had announced that we are revisiting our policy and why we reconvened our advisory panel in December of 2010.

What I can tell you is --

And now, remember I apologized in the very beginning and said I may go into Washington beaurocrat speech.

So, if we are taking an action, we will likely have to go through rule making to do so, which by law is a fairly cumbersome process. There is a lot

of hoops and hurdles we have to go through. You can anticipate if we're taking an action and you haven't heard much to date, it is because there is a lot of steps we would have to go through in order to do so.

Should we be making any changes, it is my hope and we would then explore can we at least communicate the intentions earlier than we might otherwise do by going through the entire rule making process, and that's where we are on dental amalgams with the FDA. We are seriously and actively looking at them.

MR. JORGE RIVERA: Good morning. My name is Jorge Rivera and I am an owner of a small manufacturing company that is located here in Florida. The name of the company is called Care Systems. It is intended to clean and disinfect blood pressure cuffs for patients. Especially now, we have a couple of sites in Orlando dialysis clinics, which are using the device to clean and disinfect the blood pressure cuff between each patient.

The biggest problem that I'm having, we took product to market last year. The FDA registration and listing fees were 200 percent of our revenues last year alone, you know, beyond patents,

trademarks, and everything else, the cost of gasoline and going from clinic to clinic.

Myself and a partner of mine, that's the company. We have great prospects of growing the

company. But we are hoping that the FDA could somehow reduce or eliminate the registration listing fees for small businesses like ours.

I used to work for G.E. Healthcare for several years. I was a product manager for blood pressure cuffs there, and it seems a little bit disadvantage when they are paying the exactly same amount of money that I'm paying for marketing my device in the U.S.

Typically, as you probably know, it takes a good five years for getting product acceptance, for people to set up product in the marketplace, and being small is not easy, it is not an easy task.

So, I'm hoping that the FDA could do something about that, hopefully, for FY-12 coming up. You know. I already paid the FY 10 and 11 this past year. So, I'm hoping that you guys can help my company grow.

We're here located in Orlando. We think we can grow the business enough to hire people. In this economy, I think that would be a great thing and

welcome for the folks here in Florida.

I'm working with Congresswoman Sandy Adams, Mark Rubio. I've been sending letters like that as well. And the folks in your office are wonderful.

I think that's a positive note. They helped me tremendously in the first couple years when we were developing the product, answering questions.

So, you guys are doing a great job on that end.

I'm hoping that in terms of the registration on this thing we can get a little bit of help to go forward.

Thank you.

DR. JEFF SHUREN: Well, I appreciate the concerns. Let me talk to user fees for a moment and you can stand. You can sit. I can drone on sometimes.

So, the Agency receives, or I should say the Center For Devices receives funding from Congress and it receives funding from the medical device industry. That's indirect funding and it's related to certain applications that they submit or to registering with Agency. That was created by law starting in 2002 as a means for supplementing resources for the Center and other parts of the Agency to try to assure we have enough people to

monitor products, make sure they are safe and also to conduct timely reviews of products coming on the market, so that, if there are important technologies, they are not held up and patients have

access to them.

The user fees actually make up a fairly small amount of our program, about 20 percent of the activities otherwise covered by funding, very different from the drug setting where most of the funding for those programs in prescription drugs are actually paid for from user fees from industry. But it is set up so that no individual company is in line where those fees actually influence decisions that are made.

The amount of the fees in the structure is actually discussed between the representatives of industry, the Agency and Congress, and the fees that are set is an agreement from all those parties. Ultimately, legislation is passed as to what those fees would be. So, they are actually in there by law.

And the registration fee is by the number of facilities you have. So, actually, G.E. pays a lot more than you do. It is by the number of facilities. Actually, the registration fee for one

facility is about $2,000. That's what it is as opposed to what the real costs are for all the work that's done, which is enormously higher.

And in fact, we had made that arrangement for

the $2,000 fee by facilities with the groups representing the small companies like yourselves that this was the equitable way for doing it because the amounts, in fact, were small compared to all the other costs that are involved in medical device development, other requirements that have to be met. This is actually fairly tiny and it is spread out based upon the number of facilities so the big manufacturers actually pay a lot and the smaller folks pay less.

I appreciate the fact that in your circumstances your particular company may be in a place where given the money you have that money is spent on a variety of different activities, many of them outside of FDA's control. The fundings available to you may put you in a somewhat different stream.

MR. JORGE RIVERA: I appreciate it. I don't mind paying the first year, but any help.

DR. SHUREN: I want folks to know that fee is actually $2,000, which if you know what fees are in

a variety of different things that businesses pay for, it is relatively small.

MR. BRUCE ROSENBERG: Bruce Rosenberg, National Meshoma Foundation. We've met before.

And similar to today's topic about amalgam breakdown and subsequent injury or poisoning to the host patient, it is kind of on line with the synthetic surgical mesh issues of bladder slings and hernia mesh they use in individuals that the CDRH is aware of degradation issues with some of those synthetic materials and subsequent injuries such as erosion and migration issues, degradation of materials that we are not fully aware of what the potential harms could be.

Is the CDRH planning on publishing any of their data and more enhanced warnings to the public in terms of informed consent or enforcing the manufacturers to increase their warnings to patients regarding the potential degradation issues or subsequent injuries?

I have a question about the study or methodology to use Medicare claims database to evaluate device safety, evaluation of urogynecological surgical mesh. Is there any findings from that study that you have published

yet.

DR. JEFF SHUREN: Nothing to report yet on that study. The reports we do get about adverse events that may be related to surgical mesh, we actually

are posting on our website. They are all out there.

In terms of what we're doing, I'm back to the Washington bureaucratic speech, and as we've talked about before, we are -- this is one of the products that actually we are doing a fairly full look at. And one of the issues comes down to the kind of mesh and for what it is being used, because the experiences and the data that we've got is different for the different kinds of meshes and their uses, and we are sifting through that.

MR. BRUCE ROSENBERG: In terms of that, this particular study, this methodology using a claims database, which is an actually excellent way to get objective data as opposed to the log site, which is more subjective anecdotal data that insurance companies have excellent objective data for the billing and CPT codes, will you be looking at any of that?

DR. JEFF SHUREN: Yes. We have looked at other sources. Here's one of the challenges about claims handling and CPT coding. It actually doesn't get

granular enough often times for the specific product. And that's one of the reasons why a unique device identifier, which was a question that was brought up from our second speaker, could be

exceptionally helpful.

So, one of the problems, unlike with a drug where there is a unique code for that drug so you can actually link up what the patient got, the specific drug they got and the strength, with what their experience may be, you don't have that in the device world.

So, claims data is only helpful for certain kinds of devices where you can get that granula. Most of the times, the data, if it has anything in there, it will tell you that they had, for example, this kind of a device, not who made it, which version, which can make a big difference in terms of what the risks are for the technology.

The unique device identifier, this would be a numerical code that would tell you who is the manufacturer, what's the product and even specifics, maybe even down to what lot and expiration date it is so you can identify if there was a problem. Maybe it is not every single one of that version of the device, but a certain kind. We'd be able to

track it.

Once that's out there, there is an opportunity then to use that and this will be up to the insurers if they will use that in their claims data that

would be more helpful in terms of making that data more useful, even could be into electronic health records.

The status for UDI is we are planning to issue a regulation this year to -- proposed to set up what that will look like and we have been conducting several pilots. There is more than one that's out. I think over four now. Looking at how to operationalize this, because you need the code, how you develop it, you've got to put it on the product and then how do you link it up to other information, and that's what we've been finding.

MS. CAROL CHANDLER: I'm Carol Chandler and I have a company that markets medical infrared imaging devices. We're a type I device. And we're a small industry. And one time a couple years ago, somebody came in my office and said, "There is somebody here from the FDA to see you."

So, I got to realize the real new reality about what it is to be a 510(k) holder.

And consequently, in my industry, I'm probably

the most in compliant of anyone, which is a good thing. I'm glad it is over, but I'm glad it happened.

However, what has happened is that in the

industry I can see where all of the others, the ones that are my competitors, are not in compliance, and one of the things I'd like you to address for me is the FDA approval. They made me, of course, take that off of my website. It is a type I device. I don't know if that is related only to the type device I have. I know this, that all the drug companies, of course, say they are FDA approved. In our industry, we are a little bit concerned about the FDA approval terminology.

And also, I'm at a disadvantage because of my competitors. Some of them are not even registered, and so, they are selling the infrared devices to doctors for medical use and they don't even bother to do the 510(k) so now they are not even, you know, they don't even have to comply.

So, what I'd like to know is there some way that we can police ourselves, or is there some way that I could --

If I talk to my competitors about it, they don't, you know, they don't take me seriously. But

I don't want to be a whistle blower either. I don't want to file a complaint on everybody, because that's not good for our industry.

So, I'm just wondering if there is some kind of

a way that I can help my own industry be more compliant and then also if you'll explain the approval thing.

DR. JEFF SHUREN: In terms being more compliant -- and I appreciate the fact of your talking to other companies out there, and as you said, they are not listening. It is helpful to us, though, to know who those folks are. And the person sitting to my left just happens to be in charge of then following up with those folks.

Do you want to speak to that? And then we'll come back on the approval.

MR. STEVEN SILVERMAN: So, I'll make a couple of observations.

The situation that you describe is something that we struggle with day to day at the Agency. The reality of the resources that we deal with is that there are manufacturers who we will go and inspect.

And sometimes we find problems with the manufacturers, which are quickly resolved.

Sometimes we end up having an ongoing

relationship with the manufacturer where it takes a little bit longer to get the concerns that we identify taken care of.

And then there can be a range of similarly

situated manufacturers who we don't inspect, or there may be cases where there are manufacturers that we are simply not aware of because they haven't complied with the registration process. We may not even know that they are operating in the marketplace.

So, we struggle with the fact that we don't have the inspectional resources to cover the entire landscape of industries who are manufacturers who are not complying with requirements they ought to be complying with.

When information comes to us, from you or from other sources, then we look at it, and the fact of the matter is that we try do so in a risk-based way, and it is not the case every time we get a complaint that somebody is inappropriately marketing a product or somebody has failed to meet a regulatory requirement that we immediately follow up, because for each complaint that we receive there are ten others that we have to weigh against it, because we try to make the best decision that we can that

reflects the relative risk of the problems that are being reported to us.

Now, that's not a really satisfying answer on its own to us or to you.

So, one of the things we try to also do is to find strategies that complement the more traditional inspection and citation approach that we rely on. So, we do a lot of outreach from within the Center, including, when you and I were talking in the break, we have a division of small manufacturing information, which is an excellent resource not just to answer questions that are brought to the Center on a case-by-case basis, but also to make available information that can be put into hands of individuals like yourself and then shared around.

So, it is not you saying this is what your responsibility is. It is you saying, look, this is communication from the FDA about what all us manufacturers are responsible for.

In addition, we do a lot of outreach that involves going to locations like this one and talking to the public and to manufacturers and getting on the phone and having conversations with manufacturing groups.

So, to your point about how can you bring

together people in a less antagonistic forum to make them understand what their responsibilities are, one thought that comes to mind is maybe the conversation is how do you pull those people together and is

there someone within our office who we can put on the line, on the telephone line, for example, who can provide an overview of the regulatory landscape that's going to be kind of consistent with your own experience, and that's a conversation we are very open to having.

I'll make a quick point about the approval issue. We refer to products that go through the 510(k) process as cleared, not approved. We have a premarket approval process which is separate and in many cases lengthier and more involved an analysis than the 510(k) clearance process.

So, for products like your own that are subject of cleared 510(k)s, we don't permit firms to characterize those products as FDA approved.

DR. JEFF SHUREN: That's also a manifestation of the law. So, for drugs, what a drug, a standard for getting on the market generally what they have to show and what they have to do is much the same if you are a brand name drug, and generics also have their same way of coming to market.

Devices are a entirely different kind of framework to get into the market. That's why the terminology for what some of them approved, some of them cleared, and many devices don't get reviewed by

FDA as a matter of law before they go on the market. They can't say either FDA approved or cleared.

MS. CHRISTINE JENKINS: Good morning my name is Christine Jenkins. I am vice president of Laser Network in Miami. We do laser light shows. We also build laser light show projectors.

Laser Net started in 1968, making it now the eldest company in the world doing laser light shows that I'm aware of, and I'm here to -- I also sit as a member of the board of directors for the International Laser Display Association. You heard from Patrick, the executive director, and Greg Makhov, our safety officer, about variances being dropped on the user side, not the manufacturer's side. We manufacture and we use so we do both.

And I am asking you to consider that proposal in dropping the user side. The cost of compliance, as you know, for any industry can be large, especially a small industry. And the cost of compliance for our company, doing major productions as well as installing the local nightclub, puts us

at against other smaller, you know, guys who buy off of eBay, "Oh, I can sell a laser or we can beat Laser Net. We can do this. We can do the other thing."

We lose business. We're trying to function within the realms of the law, we do always, but it becomes more and more difficult these days when pictures are in the newspapers of lasers scanning the audience and we are saying, "Oh, we can't do that. It's illegal."

"Well, here it is in the newspaper." "Well, I'm sorry. It is still illegal."

We're getting laughed at. We're getting losing business. But economics aside, you don't have the manpower to deal with it anymore.

I've got variance applications in your hands for clients since 2008, I don't even have an exception letter for yet. 2008. I mean you guys must be seriously overwhelmed or there is a big room somewhere with my applications. So, it's not necessary. You talk about, like, that gentleman spoke about risks, you know, what's really important.

Okay. You've got this many applications, but the risks are way down here. We already know laser

lights are everywhere. They are in every club in every country. There is almost no issues of reported incidences in the past decades.

So, maybe we should take the pressure off of

you and let it go. That's my comment.

DR. STEVEN SILVERMAN: So I'll just take a minute and respond. To be explicitly clear, I am not aware of any room at FDA that is holding your variances. If I come across that room, I will let you know. It is not like a Harry Potter book with a secret chamber with your variances.

So, I'm the head of the office of compliance, and I'm not -- I don't have primary responsibility for oversight in this particular compliance area, but I'm not going to simply summarize that or make that point and then go ahead and sit down.

I think that your points are well taken. You are right. We, as an agency, we try to make risk-based decisions about where we're going to dedicate resources. I thought that the points that were made by all of the representatives in your industry were interesting and your points are well taken.

My plan simply is to bring that information back to the folks within CDRH who have

responsibility for this program.

I know that you are already talking to these folks, and obviously, Jeff is the ultimate decision maker on behalf of the Center so he's heard this

message as well.

I think the dialogue has to continue and I will absolutely communicate to the individuals with responsibility in this area what was communicated to us today.

From my own perspective, again, your points are very well taken and I do think that in a resource-constrained time, we have to make smart decisions about what is high risk and what is not and to be willing to make decisions to stop doing things that are not high risk.

But, again, for me, personally, I don't have the expertise to make the assessment in this particular context, because it is just not an area where I have experience, so I'll bring this information back to the folks who do.

MS. FREYA KOSS: My name is Freya Koss, Pennsylvania Coalition for Mercury-Free Dentistry.

I would like to address a question or two to Dr. Shuren. You mentioned that you are revisiting your ruling on dental amalgam since the petition for

reconsideration was filed.

My concern is this. We are privy to your original draft for the classification which included many of the neurological problems. That draft went

to the Office of Management and Business, and they changed it, and they removed most of those warnings.

I called the FDA to find out how that could possibly happen. You had the science. You were aware of the dangers. You wrote the rule accordingly and OMB changed it.

How can we be guaranteed that won't happen again? They seem to have leverage and you have no options once they do that.

They are supposed to look at the economics, I think.

Maybe you can explain more to me how they are able to change a ruling that protects the American public.

DR. JEFF SHUREN: In terms of OMB, I can't comment on the specific rule, but I can say for OMB was created by Congress, I believe, and they are given oversight authority for some aspects on rule making so they do -- they are part of a clearance process in many cases for regulations going up and out the door, and they may elect to review

particular rule makings from the Agency, as may some other parts of the federal government before we go out.

MS. FREYA KOSS: But what aspects are they

looking at? What are they mandated to look at?

And if you are the agency to protect the public and you are looking at the health issues, how is it that an agency that is supposed to look at the economics make those changes?

DR. JEFF SHUREN: Well, they do look at policy issues as well, but OMB is not a part of the FDA and it is not something that we created, but they are a part of or can be part of the review process for a variety of different rule makings and other policy actions by various different federal agencies.

MS. FREYA KOSS: So, do we need to get in touch with them directly and discussed what happened so it doesn't happen again?

DR. JEFF SHUREN: So, I can't tell you who to speak to or not to speak to. We are still in a democracy, but --

Let me leave it at that.

MS. FREYA KOSS: I was advised not to go there. What does that mean?

DR. JEFF SHUREN: What?

MS. FREYA KOSS: That means we'll never get -- we'll never have an appropriate classification for dental amalgam if they have anything to do with it.

DR. JEFF SHUREN: Well, I can't speak for OMB

and I can't control OMB and I don't know if we go forward with the rule making what OMB will say, but I do know we will control what the FDA's position is and we will -- if there is actions to take, we'll take what we believe are the appropriate actions.

MS. FREYA KOSS: Do you have to present the science to them that your rule making is based on?

DR. JEFF SHUREN: So the answer is when a rule goes up to whomever will review it, the rule itself will discuss the basis for the decision being made, and as part of the administrative record, it will include all the data that supports that decision.

MS. FREYA KOSS: But they have the last word. That's what it sounds like to me.

DR. JEFF SHUREN: What I can say is that decision making on rule making, what ultimately comes out is a -- and I am putting it diplomatically -- a complicated process.

MS. FREYA KOSS: I know. I hear that. And we're at jeopardy because of it.

I have one more question about -- I know you

don't want to hear from me anymore.

DR. JEFF SHUREN: I actually have to say, Freya, I'm actually seeing you more than some people in my family so I feel like I should be sending a

holiday card.

MS. FREYA KOSS: That's sad. That's too bad.

DR. JEFF SHUREN: I know. They won't let me out of the office. So, what can I say?

MS. FREYA KOSS: The other question was about classification. I know that the attorneys, who we work with, believe that amalgam should be classified as a Class III because it is an implant that's put in the body for more than 30 days. Why is it classified as a Class II?

DR. JEFF SHUREN: First of all, you can be a Class II and be implanted in the body for more than 30 days. That's not how our classification system works. But there are standards for determining what the classification would be and we have to follow what those rules and regulations are.

MS. FREYA KOSS: But this product is 50 percent toxic mercury. It is in the body for more than 30 days. It could be in for a lifetime. Why wouldn't that be considered a Class III?

DR. SHUREN: So all I can say we're back to

what the Agency will ultimately do, and what I can say is, and I know you hate my saying this and I hate not being able to be more clear with folks, but we are actively reviewing it and we will be making a

decision and then announcing that to the public.

MS. FREYA KOSS: I hope you do the right thing. Thank you.

DR. JEFF SHUREN: You are welcome.

MS. MARIA BOLTON JUVERA: Hi there. My name is Maria Bolton Juvera. I live in Oviedo. I live close to hear. I'm here on behalf of the local group of the Sierra Club.

For those of you who may not know, Sierra Club is the oldest grass roots environmental organization. It is from 1892.

So, I'm going to speak on behalf of Sierra a little bit and then as a civilian, an individual.

My first question as an individual is: Do you have any amalgam fillings in your mouth?

DR. JEFF SHUREN: Actually, I have no fillings in my mouth.

MS. MARIA BOLTON JUVERA: Have you ever?

DR. JEFF SHUREN: No, I mean I have no -- never.

MS. MARIA BOLTON JUVERA: The gentleman next to

you, do you happen to have any? Honestly.

DR. STEVEN SILVERMAN: Well, I mean, I certainly wouldn't lie if I did. I know I have some composite fillings. You are more than welcome. I

mean there are a number of dentists in the room. If somebody wants to -- I am confident that these --

MS. MARIA BOLTON JUVERA: Are they mercury, though?

DR. SILVERMAN: I am not a dentist. I don't know what composite in my mouth contains or doesn't contain. I am confident that in the past I have had fillings implanted that probably included mercury. I grew up in the sixties and seventies so I --

MS. MARIA BOLTON JUVERA: Right, before they knew.

DR. SILVERMAN: But my point is simply that I would have gone through kind of standard dental care and the likelihood, if I had cavities, they were being filled with a mercury composite, then probably yes.

MS. MARIA BOLTON JUVERA: I would like to see a study done of who is with the FDA and how many have the more expensive ones that are typically not covered by the insurance or if they have the mercury ones and maybe some kind of data showing who is

being affected and how that's affecting the pay, how that's affecting the --

Forgive me. I don't do a lot of town meetings. This is, like, one of my second times talking on a

mic.

I'm just curious. Obviously, since you are saying one thing, I'm wondering whether or not you have mercury in your mouth so that's interesting. I would love to see a study done on government employees and how they are doing if they do have mercury.

But anyway, back to Sierra as an environmentalist, I'm not paid to be here. I'm 29 years old. I'm a freelance artist and I care passionately about the environment and the animals since we are all connected.

I have something here and this isn't going to be anything new for any of you.

But anyway, mercury pollution is widespread in U.S. rivers, lakes, bays with dangerous amounts of mercury commonly found in freshwater and saltwater fish. Over 50 percent of Florida's rivers and lakes have warnings regarding eating the fish and most bays. Over 33 percent of all U.S. lakes have fish consumption warnings, 15 percent of all U.S. river

miles, 90 percent of Atlantic coastal miles, and 100 percent of all Gulf coastal miles. Most Gulf cost saltwater predator fish species have high levels of mercury.

Anyway, as an environmentalist and someone that's concerned about the environment with how the dentists and other people in the profession were saying how they are disposing of the mercury and if it is getting contaminated and into the environment, that's why I'm here talking, well, what about the fish, what about the animals, what about it getting into the watershed.

Us living in Florida at sea level, we deeply affect the aquifer here and the watershed so that definitely should be a concern as far as how are we disposing of the mercury, how about we stop using it, putting it in our mouths.

I was also curious. The person that presented the gift from the one guy, the mercury gifts, I was wondering hopefully they are not going to be just tossed in the trash, because now that you have the high mercury content, that needs to be disposed of properly like everybody was saying; otherwise, that's, in turn, contributing to the problem.

So, as an environmentalist, that's my concern.

And I'm actually a vegetarian now. So, fortunately, I don't have that mercury problem with the fish, because I've given up eating fish fortunately, and I consider myself very lucky that -- I had no idea

about any of this, but I consider myself very lucky that I had the silver, "silver", silver fillings as a kid, and fortunately I lost those teeth, kind of like you, so I don't have that problem.

But my heart goes out to everybody that spoke on the mic today. I was about to start crying. I'm, like, I have got to hold myself together here. But for anybody that has had these fillings over the last 50 years and now to be suffering with all these problems, and when you entrust yourself in the government, and the FDA is here to take care of you and either they are too proud and they can't back track for 200 years and say, you know, we made a mistake. Like someone said, it is from the 1800s. How can we rely lie on that kind of data now?

You need to step off the high horse, realize that there was a mistake. There needs to be some kind of retribution or at least an apology. I haven't even heard an apology today to anybody that's been suffering from a condition to say we're sorry that you have MS or cancer or you are dying or

you are losing your hair.

The government needs to step up. And you guys, I realize you are taking the heat. You are one of the first tiers. There is other people. And it is

going to be a long process, but there needs to be some kind of action done.

I can't imagine that all these people just have eaten too much fish or swordfish or have done something else. There is too much data. There is too much science at this point, and I would love to hear an apology and some kind of action being taken this year. It is 2011. It is not the 1800s.

George Washington is probably turning around in his grave right now thinking can someone save the American people.

We're a fairly new country, but that doesn't mean that we have to be too proud to not apologize to our own people.

So thank you for being here. I'm sorry that you are taking all the heat.

And I'm an emotional person. I am half Italian and I am half Irish so it is very hard for me not to get emotional.

Thank you for being here. Thank all of you for speaking. And I'm really sorry for anybody that's

been affected here healthwise by the government, by the United States of America. We're supposed to be taking care of our people and you need to be less proud and just realize what's been done and make

change for a better health care.

And it is interesting. One last thing. I find it very, very interesting, forgive me, that the pharmaceutical industry is one of the top five businesses in this country. I hope, and this is the cynical side of me, I hope that this isn't the case, but for everybody having the mercury in their mouth and getting sick and then having to get on a drug and then you are hooked on that drug, it is a cycle, the cycle needs to end. Holistic medicine, finding out what's wrong from the get go versus getting on a pill that's -- that the sides effects are going blind or losing a leg or, worse case, death, let's not do that. Let's be more green and more eco and holistic and let's take care of our people. Thank you so much for being here and thanks for listening to all of us.

MS. CINDY TAO: Good morning, Dr. Shuren. I'm Cindy Tao. I'm from a pharmaceutical company in Princeton, New Jersey.

My question today is regarding human factor

testing. And human factor testing is an evolving area and obviously FDA has heightened the requirement for this testing. And in 2010, last year, CDRH endorsed the HE 75. That's the

international guidance on this. And even with that guidance and also the old 2000 FDA guidance on human factor testing is quite generic for a specific device to follow.

So, we thought it could be a good idea to have a set of guidance for the required human factor testing for a specific group of devices. And I'm asking if CDRH has thought about working on set of guidance of required human factor testing and successful criterias for a specific group of device.

Do you have any plan on that?

DR. JEFF SHUREN: For specific devices, we are looking at providing greater clarity for certain technologies, and actually, last year we started asking for on a case-by-case basis and that might become for all infusion pumps. Those are the boxes that control rate and flow of fluids. That could be medication. It could be just to make sure someone is hydrated. It could be for nutrition.

Just so folks know, human factors is actually the engineering science regarding the interface of

people with machines. And so, if you think about it, if you don't take into account the people who use the technology and the setting in which it is used, you may design what you think is a well

functioning technology, but in fact and practice, you may run into errors that are made due to flaws in the design of the device, and that matters a lot more for some devices than it does for others.

And human factors testing is actually about taking what you develop and let people use it and see what happens.

And in infusion pumps we found things like the button to turn on and off the machine was right next to the button to turn on and off the flow so you turn the machine on, you set it for how much of the medication you want to give. You think you hit the button to turn on the flow and you actually turned off the machine. Example of human factors, which is why we're looking to change our practices regarding that technology.

So, to answer your question, we are looking at certain devices where it may make sense to provide some greater clarity or to expect to receive studies on human factors, but we're approaching that case by case, because as you've laid out circumstances may

be different for different technologies.

That may not translate into specific guidance on that technology initially, but it might down the road.

More generally, we would look to provide greater clarity on human factors testing.

MS. CINDY TAO: Because the HE 75 does include hundreds, maybe thousands of device in Class I and Class II. And CDRH does have a lot of specific guidance in past ten years, I should say, on specific groups of devices like you mentioned infusion pump, for example, and others like glucose monitor. And we just wonder if you can have that kind of guidance on human factor testing, what specific set of testing is required by agencies.

So, that way, you know, so can follow and so there is no misunderstanding and it will safe review time as well.

DR. JEFF SHUREN: Thank you.

MS. JOCELYN JENNINGS: Hello. So I wanted to ask a couple of questions, and so, one that I had submitted earlier because I was hoping that Alberto Guitierres would be here from OIVD so it has to do with that dreaded 1991 blood culture guidance document and so my question is, one, whether or not

there are plans to update it and, two, does the FDA consider it still relevant?

DR. JEFF SHUREN: So there aren't plans to update it right now, and probably the best thing to

do for those kinds of technologies is to, I mean, you know them, you just look under the pro code in our database, and then, for any of the recent 510(k) clearances, we'll lay out what our expectations were for that device, and that actually can be fairly informative as to what we may be seeking on another device coming in the door.

This is one of those cases where we have the capacity to put out a certain number of guidances or update a certain number of guidances each year, and while we love to do that for the many guidances that are out there and develop more, we do not have the capacity to put out what we would really like to see and that one is lower on the cue than many others out there.

One of the other challenges and one of the reasons we put out the basis for our decisions is so that people can actually see why did we approve or clear a device, what did we rely on, what did we ask for.

That's so doctors and patients have a better

understanding. It is also for manufacturers to have a better understanding of what our expectations are if they're making a similar kind of technology.

If we were positioned to do it, we'd love to

put out more guidances and we'd love to update on a much more frequent basis those guidances that are out there.

MS. JOCELYN JENNINGS: And I also had a question about the 510(k)s about the specials and the abbreviated. So, are those two particular types of 510(k)s still applicable and is there a change in the FDA's thinking about those two particular types of 510(k)s?

DR. JEFF SHUREN: So they are still available as pathways generally, but they may not be available for certain technologies. And sometimes as we gain more experience, it may have been not appropriate in the past to allow a special 510(k) and abbreviated 510(k), and with more experience over time with both industry and the Agency with the technology, it then may be appropriate to allow for those more streamlined pathways to market, and in other cases with more experience, it may not be appropriate to continue to accept those kinds of applications.

An example is with some of the radiation

therapy devices like accelerators for which you could submit a 510(k) before. We had announced last year that we are now looking generally in most cases for a traditional 510(k) because of the some of the

problems that we had seen that was not able to readily detect if we just have a special 510(k).

MS. JOCELYN JENNINGS: Okay.

DR. JEFF SHUREN: We approached that more on a technology-by-technology-basis.

MS. JOCELYN JENNINGS: Because we have previously submitted special 510(k)s for our blood culture bottles and we were told recently that we should submit a traditional rather than a special even though it met the criteria for a special, and we were not really given a scientific or regulatory reason as to why we could not submit that special 510(k) so that's why we were asking and we have a concern that at some point those two options may go away.

DR. JEFF SHUREN: Not as a general matter. For your specific device, again, I said we wouldn't talk about specifics here, but I would follow up with Alberto or Don Saint Pierre separately on that question, and sometimes it changes because if there is a change in the device that you were bringing

forward, and I don't know the specifics, it may be that in this case, if you made changes, a special would not be appropriate in that circumstance.

MS. JOCELYN JENNINGS: And then I was wondering

if you could point me to who I can talk to to get help with this dilemma I have with our device that is under the regulatory review of CDRH and we are following as a migration guidance document for our bottles to show that they are equivalent on our new instrument versus our old and we are being told because one of those bottles is under the review of Cebert that we have two submit two 510(k)s even though the instrument isn't regulated by Cebert, and we can't seem to get someone to give us a straight answer, and we don't understand why within the FDA CDRH cannot talk to Cebert about that one particular -- the data for that one particular bottle rather than us having to spend the time and money to do two 510(k)s and also spend another $5,000 on user fees.

DR. JEFF SHUREN: We normally, again, not knowing on the specifics, we -- when there are cases where two centers are involved, we try to do that under one application.

Usually, if we're coming back to say you need a

separate one, it is because the second technology you are dealing with was changed enough that that other center would actually ask for a different application, but -- and not knowing the specifics, I

would say -- if you can either e-mail me and I'll connect back with Alberto or over to Alberto.

MS. JOCELYN JENNINGS: Okay.

And then my last question is, I know within the activities that you are doing last year and this year, one of the big things again is predictability, consistency and transparency, and so, I just wanted to know if you could give some more feedback about how that will truly be implemented.

DR. JEFF SHUREN: So if you take a look, I'll give a little bit of an overview, but we've laid out exactly what we plan to do and, in that plan of action we posted in January. So, there are two pieces that actually summarizes all the public comments, and it discusses each of the recommendations and what we were planning to do regarding and we made, by the way, 55 recommendations in August 2010 that will go through all of those, and then we follow that up at the same time we went out with and here is specifically what we're going to do in 2011 and with the time frames

for when we would do them, and that's all up there.

And as we take actions, we then post what we've done on our website. So, there is a lot of transparency about the specific actions we're

taking.

By categories, we are providing some greater clarification regarding the 510(k) process in some aspects pertaining on clinical trials, particularly as regards PMAs and a number of those guidances we made commitments about getting out the drafts this year.

Secondly, as an internal mechanism on oversight for decision making, particularly if there is a decision to change the expectations for what kind of data needs to be submitted, those decisions which before were made down in the review branches will now be brought to a new center science council for consideration so that we assure that our senior managers and our experienced scientists have an opportunity to weigh in on that, and we had committed to set up that center science council with a charter by the end of March. We met that deadline. The council is already set up. It is now meeting. I sit on that counsel as do the office director. Steve sits on that council. And we also

bring in a number of experienced people depending upon the topic. That's another big aspect of what we're doing.

There will be additional training opportunities

for staff for the very first time. The center will have mandatory training for the reviewers on core competencies and they will have to get certified as new reviewers.

And we have now been going across different disciplines with the reviewers, with medical officers, public health specialists. All of those core competencies are being developed and the certification program has been piloted and we are moving.

MS. JOCELYN JENNINGS: So, for the core competencies and the certification, is there a look to do it for current reviewers as well or just new?

DR. JEFF SHUREN: Mandatory on new and then we're looking at opportunities for what we may expect of people who have already been there.

MS. JOCELYN JENNINGS: Okay. Thank you.

DR. JEFF SHUREN: You're welcome.

UNIDENTIFIED MALE SPEAKER: Thank you. I had a rather general question for you on the amalgam issue basically. Do you know within the ten years or so

if there has been applications come your way for a classification of some replacement material, particularly one with the gallium involved in it? Has that been submitted to your office?

DR. JEFF SHUREN: With gallium, I don't know offhand.

UNIDENTIFIED MALE SPEAKER: Has there been other, beyond the gallium, has there been other materials that have been proposed? Is that something that you are free to say anything about.

DR. JEFF SHUREN: In terms of what may be submitted to us, then I can't talk about that.

UNIDENTIFIED MALE SPEAKER: Right. But okay. Let me ask you another question. I'll get you off of that.

DR. JEFF SHUREN: I actually can't because that information is considered by law confidential and we're obligated not to discuss it.

UNIDENTIFIED MALE SPEAKER: That's fine.

Speaking of economics here --

DR. JEFF SHUREN: Now, if you do want to go talk to certain people to change those requirements, we would probably then have an eight-hour town hall meeting.

UNIDENTIFIED MALE SPEAKER: Yeah, that's right.

We could do that.

Talking about economics for just a second, it could be that it is fair for you to answer this question or not. But relative to the funding for

the FDA, you mention we got some from Congress and some has come from the medical device industry.

Would it be fair to say that there would be significant contribution from an amalgamator type operation that would help to fund that end of your department?

Would there be some organization, some business within that medical device that is participating in the funding of your department?

DR. JEFF SHUREN: Yeah, any of the manufacturers are required to register with us. It's telling us who they are. They list, they tell us what they make. There is a fee with registration.

Then, if they are submitting a application for a new device or certain changes to an existing device, many of those applications have fee amount tied to it and that applies to all manufacturers.

UNIDENTIFIED MALE SPEAKER: Does the FDA keep track on an annual basis, do you think it would be available to me if I ask what the contributions

might be, variations from different companies and from Congress? Is that data available readily so?

DR. JEFF SHUREN: The data in terms of our budget is publicly available from what we get from

Congress. We also report on what our user fee collections are globally and we put that out in an annual report.

Specific for individual manufacturers, that information doesn't go out publicly.

UNIDENTIFIED MALE SPEAKER: Thank you very much.

MS. JULIE SADLIER: I thank you for being here. I'm going to remove my fillings as soon as I get out of here next week. I've learned today.

But I just wanted to ask -- I was here about the ultrasound. Does the FDA have any regulations on the 3d/4d separate centers that are just there for entertainment purposes?

And if they do -- we were told at one of our other meetings you guys just have a lot on your plate and we're kind of at the very bottom of the totem pole -- do you have something in place to reinforce it?

And if you don't because of funding or we're kind of last on your list, would you be willing to

work with volunteers, say, from chapters of the SDMS in every state to help you?

I've done the research and found out these physicians aren't legitimate. Anything we can do to

help in any response to the regulations and what you foresee?

DR. STEVEN SILVERMAN: So, I'll respond to your comments, not about the fillings, but about the sonograph issues.

I suspect that comments that you were referencing previously probably came from me, because I had an interesting conversation with a representative, I believe, of your society at a prior town hall meeting.

And just to clarify, the message was not, was not that you are at the bottom of the totem pole. The message I think is kind of consistent with what I said earlier in that there are many different demands on the Agency, and because we don't have resources to take all the actions we would like to take, we have to make decisions on a risk basis so I encouraged the gentleman with whom I spoke, and I will give you the same encouragement, to the extent that you are able to give us analytical evidence that demonstrates potential risk to individuals

associated with these procedures, that's extremely helpful.

I will also tell you that that while on the one hand, for policy reasons, we don't talk about

specifically what we're planning in terms of compliance actions or which firms or providers we intend to take action against, this is an issue that we are aware of and we're looking at actively.

To your question about other opportunities to collaborate, I think the answer is absolutely yes. I mean, kind of speaking generally, again, when it comes down to resource questions, because we have constraints, we can't take as wide a scope of action as we'd like so we need to look for alternative strategies, and finding opportunities to get the message out through constituents is a great example of that, and so, you can contact me. You can contact others in my organization. I can put you in touch with folks within the office of compliance who have the lead in this area.

One thing we've been trying to do more so recently is to think about how do we communicate to the public? And I think that this is a really good example, a situation in which that kind of strategy may be most applicable.

So, I mean, if you've got a manufacturer that is putting into a marketplace a device that doesn't have proper clearance or it is made in a way that is manifestly unsafe, then it is relatively -- it is

more straightforward for us as an agency to go to a manufacturer and say you are out of business, you are enjoined from doing this until you clean up your act.

The situation becomes more complicated where the product is widely distributed and it is used in some situations totally legally and used in some situations in ways that may be unsafe or illegal and where consumers are primary drivers of those market places and may not have all the relevant information.

So, one of the things that we've been thinking about as an agency is where there are opportunities for us to get messages out to consumers, in this case pregnant women, how can we within the Agency work with outside groups as well to tell women. This is just in the case of boutiques sonography, this is just a bad idea, and even if there is not kind of manifest evidence of risk to women and their fetuses, excessive exposure to sonographic energy is a bad idea and ought to be

avoided.

Those are messages that we absolutely stand behind, and to the extent that we can find ways that don't require a significant resource in terms

traditional enforcement strategies, if we can get that information out, I think it is a real win/win.

MS. JULIE SADLIER: Just one final thought. When I asked the patient after we did all that information, and we won't go into healthcare and politics, but most of our patients are now Medicaid. We've had to take that on because of the economy. It amazes me that people can't pay for insurance, but they can pay for boutique ultrasounds. And then they have to come back to us and we do this arrangement of tests and put them out because we have to cover our butt basically from this being done.

Our practice, the first thing we did is put out a memo so every single patient when they come in gets a little folder and we have a memo: This is how we stand. This is what we believe. Stay with us. We understand you want a cute picture. You know. We get it, but here's what we believe.

The patient when I asked why did you go there, we are your doctors, we do ultrasounds here, and she

said, "I didn't know better. I didn't know. She said she was a doctor. I had no idea. I thought she would have called you."

So, I think that's be part of the problem.

Somehow -- I don't know how we can educate, but just from going on the websites, I think I've seen they are illegally using SDMS and AIUM, and I've gotten those off. It is just interesting. I'm just one person and just spent a couple minutes, and I thought we can join together. I know we'd be certainly glad to do that.

So, thank you for your time.

DR. STEVEN SILVERMAN: Absolutely. Thank you.

UNIDENTIFIED MALE SPEAKER: Hello. I was supposed to be on the speakers list and something happened. My story is only about three minutes long. Is that okay?

DR. JEFF SHUREN: Sure.

UNIDENTIFIED MALE SPEAKER: This is about I've suffered from schizophrenia for many years. I have kind of a panic/anxiety disorder so I'm going to try to do this on my own; if not, we have a plan B in place.

I remember in elementary school, I was considered above average. I won the school spelling

bee. I corrected the teacher once. Then, my amalgams were put in around 5th grade.

My dad died in 1980 when I was 10 and I thought of overdosing on sleeping pills in our barn.

Despite my dad's death, everywhere I went, everyone commented on what a nice young man I was, and things were still pretty good for me up to age 14. Then the nightmare began.

At age 15, I started hearing voices and hallucinating. I started punching holes in the walls and ripping doors off the hinges. The voices and hallucinations were so bad that once, when my sister made me mad, I picked up a machete and I started walking towards the living room where she was. In my confusion, I was going to kill her and I also thought my mom would approve of her death. I put my mom and my grandmother, two sickly widows, through torment over the next few years.

One day, when I was mowing a friend's yard, I had a compulsion to put my hand on the steaming hot carburetor. I did so and my hand swelled up until it looked like a baseball glove.

High school was hard for me. I started having panic attacks and anxiety. My grades went to straight Fs. The kids I went to elementary school

with asked me if I had taken too many stupid pills, and I quit high school soon after that.

When I was 18, I moved away from my family who really needed me to be the man of the house. I was

not there for my grandmother when she passed away during this time.

In 1999, I had my first suicide attempt. I went to a psychiatric hospital and there I learned about the mental health system and people who were going through the same thing I was.

The next year, my mom passed away. I was not there for her death either. I was in a mental health facility when she died. Over the years, I would have 30 or 40 admissions to these facilities, probably costing the taxpayers at least a million dollars.

My sister soon disowned me because I wasn't there for my mom and I haven't seen her since. My whole family was gone now. If I hadn't had the other people in the mental health system, I never would have made it.

I hadn't always done so well on my jobs so I went to disability. I developed a problem with shoplifting during this time. I was having compulsions to steal things, sometimes of very

little value, even only a dollar. This was part of the reason I wound up in jail for a short time.

Over the next few years, I had incredible memory loss and could barely remember my family

anymore.

In 1994, I felt some temporary relief and I went off of disability for the next five years and worked full time. I was still hearing and seeing things, but I managed to push through. I was attending a great church during this time and I really felt like a member of society. I managed to get some college credit and felt on top of the world.

But around '97, the illness started kicking in again. I was at work when I saw a talking severed head right next to me. That was when I first truly acknowledged my illness. I would be walking and would have compulsions to go back and rearrange leaves on the sidewalk. I was seeing demons laughing at me.

I soon lost work, school and church. I started having to go into the hospitals again, pounding on cement walls begging for it to stop.

By 1999, I went back into the mental health system and lived at a residential facility. I went

back on disability. I started having massive homicidal thoughts. For awhile, I would get sent to isolation rooms or be tied to the bed because of the homicidal thoughts. I would see talking severed

heads all around me all talking. It got so bad around this time that I knew I would be institutionalized to a state facility probably for the rest of my live.

It was around 2000, I remembered hearing about this CBS television 60 Minutes special on dental mercury, which mentioned that psychiatric patients had become well after removal of their amalgam fillings and I decided to have mine removed. My symptoms went down by a third that week. It was enough to keep me out of the state hospital, but I still had symptoms and it would still be seven more years before I would be completely detox'd from the mercury.

One of my worst points was I told a friend I wanted to stab somebody at random because I wanted to go to jail. Soon, though, I discovered chelation therapy and it helped in part to clear my head and the homicidal thoughts, but the mercury must still have been embedded in me.

In 2002, the voices and hallucinations were

still so bad that I had my third and most severe suicide attempt. I took a massive overdose of prescription medicine and almost died.

The next five years would still be difficult.

For awhile, I would pace eight or more hours straight from my kitchen to the bedroom and back again. My compulsive disorder got so bad -- just one more page here -- that if I didn't wash my hands a certain number of times, I would throw away anything that I touched. I wound up throwing away almost everything I owned.

At one point, I was hearing voices coming out of an unplugged radio saying my name. I would hear the telephone ringing over and over all day long.

This is the part that's hard to admit, but mercury can -- mercury intensifies thoughts so it can increase the sex drive. I had to deal with many sexually deviant thoughts over the years. I have done some things sexually that I would not have normally done.

Finally, in 2007, after doing ionic foot baths, I feel totally detox'd had from the mercury. I have some permanent damage from the amalgams, but removing the mercury has taken intensity of my illness to where I'm not a danger to myself or

anybody else, and I want to thank God for getting me through this.

I've seen incredible suffering from this illness in the last 22 years. Three people at a

mental health social center I go to have lost to their illness and committed homicide, and one of our friends who used to come to my social center was killed by another client.

I know when people watch the news and hear things like that, it makes them mad. But I feel anger mixed with sadness because they could be going through the same thing that I did. And I truly believe that over 50 percent of people in jail or prison could be mercury related.

Life is looking up for me now. I've been visiting my old church and I'm doing better. I found a job program that is going to help me get back to work. I've gotten all my memory back and I should be working part time soon.

In closing, I think we should remember the example of Louis Pasteur who said you have to wash your hands before surgery and was mocked for many years.

Thank you.

MS. MERRY LEE BAIN: Hi. My name is Merry Lee

Bain, and I'm a medical device regulatory consultant. I just have a couple of general questions for you.

Recently, there has been some talk about kind

of revamping or reviving the interactive review process. Could you maybe speak a little bit more on that and see maybe what you are thinking what the targets might be, how that may be practically implemented?

DR. JEFF SHUREN: So we did commit as part of our strategic priorities for this year to reassess interactive review and then consider about making changes to that program so that is under way.

Much of the issues with interactive review have been the following. It can be beneficial, but in some cases, depending upon how it is handled by the Agency or by the company, it has led to sometimes longer review times, even though that's not what the ultimate intent was.

Interactive review, for folks, is the ability for the FDA reviewer and for the company to try to address issues through a more informal back and forth. In our review, we are assessed, in part, by the amount of time it takes us to complete our review. We attempt to be more timely. We have

performance goals.

In the interactive review, that continues to be a back and forth on the time the FDA spends on a review, and so, part of what we try to work out is

if we're asking a question of the company, if the company takes off for a long period of time and we're waiting, it looks as if we're taking a long time on the review when, in fact, we wait for the company to get back to us, and that's been one of the challenges we try to work out.

So how can we stay and try to have timely review, but by the same token, see if we can address unresolved questions more informally than through a formal communication by the Agency, which then stops the clock and it goes over to industry, and that's just background for the folks.

We'd like to have interactive review work. So, not only are we doing our assessment as part of our discussions on reauthorization of the User Fee Act, which is ongoing now with both industry and other stakeholders, this is a topic of discussion.

MS. MERRY BAIN: Do you foresee having a target, like, do you expect certain time lines or certain number of communications? I know it is all kind of --

DR. JEFF SHUREN: Yeah, and the reason I don't know is because it is part of the dialogue that's going on now and that's not wrapped up.

MS. MERRY BAIN: And then my other question

was --

DR. JEFF SHUREN: But when we do, we'll talk about all of that publicly.

MS. MERRY BAIN: Interactively?

DR. JEFF SHUREN: Interactively, yes.

And any things that, by the way, come out under user fee, we put out for the public to comment on. We're going to have a public meeting on that and get a comment on that before it goes final.

MS. MERRY BAIN: My other question was about building expertise within the FDA staff. I know new technologies, combinations, the different things they are seeing now at CDRH, how do you give people incentive to come work for the FDA that have that expertise?

I mean I know a lot of your reviewers are fresh out of college and don't have the real experience that sometimes may be needed, and I'm just curious about how maybe you can build some of that in.

DR. JEFF SHUREN: Two things. First, I must say that we have actually an amazing group of

experts at the Agency. In some cases, they are major people in that field, either in that discipline of science or in the technology. But it is also unrealistic to expect that we're going to

have in house all the experts who are going to understand particularly new technologies, because in those cases, it may be a very small handful of people who have any kind of experience with it.

So, I've got two issues: One about how do we assure we're recruiting the best and the brightest to be at the Agency.

One, we need the dollars to make sure we can have the cadre of people.

Two is one of the challenges in recruiting or retaining good people is -- one is the pay within the government does not like what they can make in the private sector, and that's been an issue. The second is the workload that they have on their backs when they come into the Center. The workload is very high and it leads to the higher turnover we see in our center for devices, because we have a high workload, but not necessarily all the people to get that work done.

The third is -- and this is no criticism to people here, but when I was younger, public service

was viewed very differently. I don't know how many people go back even to the times of JFK, and I was a JFK baby. I will now date myself. But people talked about public service in a different way. I

will say the tone of discussion both in Washington and for the public on blaming everything on the government beaurocrats, these horrible people, who, by the way, are friends and neighbors of people, they may be in your community.

I was a practicing physician. I was on faculty for many years. I felt that it was important to engage in public service, but I will tell you the number of people who then to try to get into government look at it and say why? We tried to recruit some people and they say I don't want to put up with that crap, I don't want to go and be told I'm part of the problem if I'm actually trying to be part of the solution. And that actually is a difficulties incentive on our recruiting. We have a number of people that won't do it because they don't want to be put under that microscope.

I will tell you the people who are at the Center are amazingly dedicated, who say regardless, this is important work, we need to be here.

The second piece is, as I mentioned, not

realistic to have all the experts in house, one of the other actions we are taking this year is for setting up networks of external experts, people we can go to to ask scientific questions, not

regulatory decisions about approve or not approve, but better understand the science who we can tap into as needed. But to make that work, I at least need a sufficient cadre of experts in house, because I'm a neurologist. You are not going to send a dermatologist or biomedical engineer to have a conversation on neurology, and vice versa, I'm not going to send a neurologist to have a conversation on orthopedics.

So, even if you tap into outside experts, you need to have the internal cadre who at least can have that conversation. We need to do both pieces.

MS. MERRY BAIN: Do those outside experts that you might bring in, are they paid, are they reimbursed for their time, or how does that work?

DR. SHUREN: Yes. So, right now, we do have outside experts who go through who are what are called special government employees. There is a very intensive screening. And those people are the pool we tend to choose from, from our advisory panels and their expenses are reimbursed when they

come in.

For the networks we're looking at are not for paying people. It is for people who are willing to spend a little bit of time to at least talk to us

and try to answer some questions if they are experts in a field.

MS. MERRY BAIN: Kind of be a sounding board and that kind of thing?

DR. JEFF SHUREN: Yeah, well, not on policy --

MS. MERRY BAIN: No. On science.

DR. JEFF SHUREN: -- but on science, because there are a lot of very smart people that understand the science that we need a way of being able to reach out to them to answer questions that we can do within the legal framework and the constraints that we operate under, but so we can leverage that expertise in our decision making.

MS. MERRY BAIN: Okay. Thank you.

DR. JEFF SHUREN: You are welcome.

UNIDENTIFIED MALE SPEAKER: Good morning.

DR. JEFF SHUREN: Is it still morning?

UNIDENTIFIED MALE SPEAKER: It's close. It's close. I appreciate your time today, Doctor, and Mr. Silverman.

I'm a Ronald Reagan baby so I'm not only dating

myself, but painting myself a color. I also appreciate your comment that this is a democracy; but, I would also like to remind you that as a tax paying American, it is also a republic so we

appreciate that you are going out and learning that you can, but that you also make the right decisions as you see them as opposed to maybe the popular ones.

I appreciate everyone on the amalgam perspective. That was new to me, and I appreciate all the information I've gotten today.

I am from a medical device company so I do have a medical device question. A young lady was up earlier talking about side-by-side testing and how it is becoming important. We appreciate getting consensus standards passed is a long process and we also appreciate the FDA has been quick to move in areas where safety can be increased or assured by side-by-side testing as the technology tends to move faster than maybe some of beaurocracy can, but side-by-side testing is a very difficult because as a company it is both pricey as well as potentially unethical for me to get a hold of competitors products to do side-by-side testing.

So, is there anything in the future that the

Agency is looking at to maybe make some of that data more available through more process-base means, so that, as we need side-by-side testing and need to compare devices that we might need to access that

information through the Center as opposed to attempting to retrieve it on our own?

DR. JEFF SHUREN: So, in terms of information, you can use one I mentioned in terms of the bases for our decisions where a number of them are already up that we've authored and we are moving towards having everything, all the decisions, authored by us and up there on the website so that information is available.

In terms of actually going to the science, the underlying science, there are certain prohibitions on using what someone else submitted. You can use it, though, in the case if you have a device under the PMA, something called the six-year rule, and six years out, there is an opportunity that you may be able to leverage the data that was submitted for another PMA in support of your own.

In other cases, it is getting a right of reference from the other company to rely on it.

We'd like to --

We are -- by the way to get back to the earlier

point which I think addresses some of these issues, is standards development. We are actively engaged in development of standards about, I'd say, 25 percent, I think it comes out to that, of the

folks in our center have some engagement with standards development, and I'd like to see more of it; but, that again becomes a resource constraint.

The other is the standards development process is so lengthy for getting consensus standards. So, someone had mentioned IEC. There is I SOS and others. It can take years for those standards to get developed. I actually think that's the dialogue that should be engaged in by industry and healthcare professionals and patients and the standards development groups and regulators about is there any way to speed that process up, so that, we can make modifications and develop new standards and then adopt, adopt them, and we adopt, you know, hundreds of different standards.

UNIDENTIFIED MALE SPEAKER: Thank you.

DR. JEFF SHUREN: You are welcome.

MR. DAVID LINK: My name is David Link, and I worked at FDA from 1970 to 1980. I managed the regulatory effort for medical devices from 1971 to 1980 and was appointed first director of the Bureau

of Medical Devices and Diagnostic Products when it was created in 1974.

So, in essence, I am one of Dr. Shuren's predecessors.

From 1976 to 1980, when I left, we managed the development and issuance of many of the regulations that are in place today and are used by CDRH.

From 1980 to 1991, I worked at medical device companies and then became a consultant to the industry in 1991. Over the course of my working with companies and being consultant --

This is a question that has to do with the 510(k) process, nothing to do with amalgam. I'm sure most of you will appreciate one of my observations then was that many of the problems with the 510(k) review process had to do with reviewers asking questions which had little relevance to the examination and review of the submission itself. They were questions which were wouldn't it be nice to know, and I'll give you an example.

I worked for one company that had a device, a mechanical device had a spring in it, and a reviewer asked who makes that spring, who is the manufacturer of that spring, which I thought was clearly not relevant.

And my question to you, Dr. Shuren, is whether there was a practice in ODE for supervisors of reviewers to review the questions they want to ask to make sure they are, in fact, relevant and

necessary to receive the answer so to continue with the review process.

DR. JEFF SHUREN: Well --

MR. DAVID LINK: Thank you.

DR. JEFF SHUREN: You are welcome. Don't thank me yet. I haven't said anything.

MR. DAVID LINK: Well.

DR. JEFF SHUREN: So, in terms of questions being asked by reviewers, there are a lot of different questions that are asked. I know a concern has been raised as to whether or not reviewers ask the nice to know. But don't necessarily need to know, and whether or not is there appropriate supervision over them.

We have taken some look at the extent to which we may be asking questions that maybe they are informative, but do we need ask them. So far in our review, to the extent that's occurring, we're not finding that as a significant driver in our engagement or our review times to date, and we continue to look at it.

But there is an issue about adequate manager oversight in our process generally, and one of the challenges we have is that in our review offices, you mentioned ODE, the Office of Device Evaluation,

the ratio of staff to the front line manager, our branch chief, is on average about 1 to 14, which if you know good management practices is too large, particularly if you are dealing with a lot of complex issues and a lot of different applications going through.

In our other office, our office in vitro diagnostics, the average is about 1 to 27, which is huge.

And this is one of the challenges we face with the resource constraints we have is assuring we also have an adequate cadre of managers over that process and it is a subject of discussion in the user fee reauthorization that's ongoing right now.

MR. DAVID LINK: Well, I would only finish by asking or suggesting that managers of reviewers consider that one of their major jobs, to review their subordinate reviewers, and that reviewers be trained to confine their questions to things to subjects that are, in fact, relevant for reviewing the application.

DR. JEFF SHUREN: And I appreciate that. I will tell you that while we had this conversation, dozens of applications came in the Center for review. We received thousands every single year.

MR. DAVID LINK: I know. I was there when we were receiving thousands per year also.

UNIDENTIFIED MALE SPEAKER: I just have a quick comment about one of the remarks made by one of the recent commenters. The person who was talking about his experience with his mental health issues and schizophrenia and violent thoughts and actions and this kind of thing, commented that perhaps 50 percent of the people in the criminal and mental health systems might be related to mercury toxicity, and I will tell you that since I'm a researcher on that type of thing that I am aware that there is such documentation that documents that.

I will actually leave you a reference to a review paper that documents that at least 50 percent of criminal behavior and from studies in prison systems in California and other states and so forth and also likewise in the mental health systems document that at least 50 percent, by testing the patients and doing things to them to treat those problems, find that about 50 percent of the

criminality and juvenile delinquency and a lot of the mental health issues of people in mental health hospitals and so forth are, in fact, related to toxic metal, not just mercury, but toxic metal,

lead, manganese, mercury and so forth, and there is peer review studies documenting that kind of thing, and there are also things that can help those people a lot, and there are clinics like Pfeiffer Clinic, for example, that treats those kind of people and it has a huge, I mean, a really successful rate of curing, in essence, those people of their violent prone actions and so forth, and also, the prison studies show that too. There are a lot of studies that show that a lot of the criminality and violent prone actions and so forth are related to toxic metal, and if you do the right things, you can control that through very simple means.

I'll leave you with the reference.

DR. JEFF SHUREN: All right. Thank you.

UNIDENTIFIED MALE SPEAKER: Remember the Mad Hatter in Alice in Wonderland? The Mad Hatter. It was mercury.

DR. JEFF SHUREN: The felt hat industry. People were using mercury in the making of felt hats and hence the -- yes. Actually, a lot, as you know,

a lot of characters in Lewis Carroll were from different kinds of poison, which maybe is the note to end on since I know our time is up. And some people are now grinning, it looks like, like the

Cheshire cat.

So, let me thank everyone for coming. We really do appreciate the comments and the input, and we will take all of this to heart, that one girl that had so many questions was Jocelyn Jennings.

(Proceedings concluded at 12:15 p.m.)

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CERTIFICATE OF REPORTER

I, SANDRA Y. KIDD, Certified Shorthand Reporter and Notary Public, declare that I was authorized to and did stenographically report the foregoing Town Hall Meeting held on May 5, 2011, and that the transcript is a true record of the proceedings held therein.

I further declare that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

Dated: 06/16/2011.

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SANDRA Y. KIDD, CSR, CP, CM

NOTARY PUBLIC IN AND FOR THE STATE OF FLORIDA AT LARGE