THE FOOD AND DRUG ADMINISTRATION'S

OPIOID POLICY STEERING COMMITTEE:

Prescribing Intervention - Exploring a Strategy

for Implementation

Part 15 Public Hearing

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Food and Drug Administration (FDA)

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A P P E A R A N C E S - Continued

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STEVEN STANOS

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C O N T E N T S

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P R O C E E D I N G S

MS. TOIGO: Okay. We're going to get started. Since I have five minutes and I think I've got six minutes of comments, so I don't want to start out behind. So we're going to start a minute early. So welcome, everybody, to today's public hearing entitled Opioid Policy Steering Committee: Prescribing Intervention - Exploring a Strategy or Implementation.

The purpose of today's hearing is to obtain broad public input about how FDA might under its REMS authority improve the safe use of opioid analgesics by curbing overprescribing to decrease the occurrence of new addictions and limit misuse and abuse of opioid analgesics.

My name is Terry Toigo. I'm the Associate Director for Drug Safety Operations in the Center for Drug Evaluation and Research, and I also serve as vice chair for the Opioid Policy Steering Committee. And today I will serve as the presiding officer for this hearing. Before we begin, we need a few administrative announcements.

So first, please silent your cell phones or other mobile devices as they may interfere with the audio in the room. We ask all attendees to sign in at the registration tables outside the meeting room. Restrooms, if you haven't found them already, are down the hall behind the coffee stand to your right and they're on your left.

We're planning one 15 minute break in the morning and afternoon sessions. The lunch break is from 12:12 to 12:42 and that's 30 minutes for lunch. Unless we're running really far ahead, then we might get a little more. There's sandwiches, salad, and beverages for purchasing in the lobby. If you'd like to order lunch in advance, I think there are forms at the registration table or else just go right to the kiosk and you can order in advance and it'll be ready for you.

So now I'd like to ask the FDA staff to introduce themselves, who they are, and where they're from, what organization they're representing.

MS. SHERMAN: I'm Rachel Sherman, Principal Deputy Commissioner.

MR. MARKS: Peter Marks, Director of Center of Biologics Evaluation and Research. I'm a hematologist/oncologist by training.

DR. WOODCOCK: I'm Janet Woodcock. I'm the Director of the Center for Drugs and I'm a rheumatologist by training.

MR. DAL PAN: Gerald Dal Pan. I'm the Director of the office of Surveillance and Epidemiology Center for Drugs and I'm a neurologist and epidemiologist by training.

MS. FIELDS: I'm Ellen Fields. I'm the Deputy Director of the Division of Anesthesia, Analgesia, and Addiction Products. I'm a pediatrician by training.

MS. BRANDELL: I'm Abby Brandell. I'm a lawyer in the office of the chief counsel.

MS. TOIGO: And there is a spot for the commissioner, but he's at a hearing this morning. So hopefully he'll be here later this afternoon when the hearing is over. So now I'd also like to

identify the SA Press Contact on Michael Federman (ph). If you're here, Michael's in the back raising his hand. So members of the media, if you're here today, please sign in, and if you have any questions or you're interested in speaking with FDA about the public meeting, you can contact Michael.

However, just to remind people, in keeping with the purpose of this meeting, it's for FDA to listen to comments from the presenters. The panel members and other FDA employees are not going to be available to make statements about the hearing.

On our agenda today, as you've seen, we have 34 speakers scheduled for presentation during time slots. In order to keep the agenda to time as closely as possible, I'm going to outline a few ground rules. First, the meeting is informal. The rules of evidence do not apply. Only FDA panel members will be allowed to question a presenter. No participant may interrupt the presentation of another participant. And today's meeting is a listening meeting. So the FDA panel

is not here to address any questions.

The public meeting is subject to FDA's policy and procedures for electronic media coverage of FDA public administrative proceedings. Representatives of the electronic media may be permitted subject to certain limitations to videotape, film, or otherwise record FDA's public administrative proceedings, including presentation of the speakers here today.

This meeting will be transcribed and we expect that the transcript will be available publically in about 30 days. In the meeting notice we identified three topics for which the FDA is interested in getting feedback today: REMS approaches, particularly the use of prescriber documentation to reduce misuse, abuse, and addiction associated with opioid analgesics. Second, non-REMS approaches that the Agency may consider within its statutory authority to reduce the misuse, abuse, and addiction associated with opioid analgesics. And finally, any additional measures intended to improve the safety of

patients' storage and handling of these medications.

FDA will use the information it obtains today during this public meeting, as well as comments that are submitted to the public docket to help inform our policy development in this area.

Each individual speaker has been given an 11 minute time slot on the agenda. Speakers have been asked to take no more than eight minutes so that we leave time for FDA panel members to ask clarifying questions. If the speaker ends early or if questions from the panel do not take the full allotted time period, then we intend to move to the next speaker. This means that speakers may find themselves being called to give their presentation before the time, their allotted time on the agenda. So stick around.

For those of you who did not register to make presentation, but would like to present your comments at the meeting, you may be able to speak during one of the two open public comment periods, the first of which is scheduled to begin at 11:57

a.m., and the second at 4:04. But again, we may run a little early. Those interested in presenting during the open public comment period at the conclusion of the, of the presentations this morning should sign up at the registration table outside the meeting room by 10 a.m. for one of the two minute time slots available.

So there's two minutes in the morning, two minutes in the afternoon on, for multiple presenters. But you need to sign up and we may need to cut off the speakers or the number of speakers that we're able to accommodate.

The meeting is not your last chance to comment. The docket will be open until March 16th and we strongly encourage anyone who is interested to submit comments to the docket by that date. Please see the Federal Register notice, which is available as a handout at the registration table if you would like additional details on how to submit comments to the public docket.

So before we hear from our first speaker, I'd like to provide a few additional instructions for

the presenters who will be speaking today. So we, again, we request that you, you stick with your allotted time period, which is eight minutes, so that we're able to keep on schedule. When you speak, you'll come to the podium and you'll see that there's a small light up on the top of the podium. It will be green when you start. It will go to yellow when you have one minute left, and when a presentation is ended, it will turn red.

The microphone will not shut off, but I may interrupt you if you keep going. I'll try and be good about it, but you need to, we need to kind of have everybody respect the time, the time periods.

So then, so as speakers come, you can still provide additional comments, but the place you do that is in the docket. So we need, we're going to do this very orderly, but we're not going to cut you off. So I think on, that's enough with the administrative details and we'll get started with our first speaker which is Ms. Amanda Proctor from the Cauda Equina Foundation. Okay, Amanda, the floor is yours.

MS. PROCTOR: Thank you for having me. This presentation is Do No Harm presented by Cauda Equina Foundation. Our mission is to improve the quality of life and care for individuals with cauda equina syndrome. I'm representing almost 2,000 constituents with cauda equina syndrome living in chronic or chronic intractable pain. Today's objectives directly respond to question six and seven, safe handling and prevention of accidental overdose, misuse.

At our foundation we have a motto when we talk about the opioid crisis and that is we cannot solve one epidemic by creating another: suffering and suicide. So our goals for today are decreasing -- our goals for our presentation are to decrease daily dosing for pain patients when appropriate, decreasing accidental overdose opioid-related deaths, and potential for addiction from opioid therapy.

So one way that we talked about is actually dual dosing. It's called step opioid therapy. And this is where you would give a chronic pain

patient or an acute pain patient a lower dose for days where their pain is less, but Tylenol and Advil will not be sufficient, and a higher dose for days when they have more pain. And this is to increase functionality without increasing suffering. We're going to skip that slide. So hold on. Wait a minute.

So your solution to decreasing the opioid endemic is to give two opioids to a patient? Yes, but let me explain. So this is directly related to handling. We recommend if this were to be in place, and even if it wasn't to be in place, we are recommending smart pill bottles in conjunction with RFID, RFDI pills, which is radiofrequency identification pills, which was recently approved by the FDA for use.

So according to a study done on cancer medications and HIV medications, smart bottles with redundant reminders have 100% adherence to those that did not have redundant reminders.

So what does the smart bottle feature look like? This is not currently something on the

market, but we feel it's a good recommendation. These smart pill bottles would only dispense the right dose at the right time. If given the step opioid therapy with the lower dose and the higher dose, the pill bottles must talk to each other, meaning, they cannot take both at the same time, nor take them so close together that it's unsafe to do so.

They would have redundant medication reminders that would track usage habits for the patient and going into a patient portal that the physician and the pharmacist could both look at to have better control over their patient's pain. It would also be tamper resistant, meaning they couldn't just dump out the entire pill bottle, which is rare in chronic pain and intractable pain patients.

They would also be alerted to take their medications and it would interface with a patient portal for the patient use where they would input their pain, their mood, their functionality so that physicians have a better idea of how their

patient feels when they're taking their medication and what types of pain they're having.

So why the radiofrequency identification pill in conjunction with this? Well, just because you take a pill out of a bottle doesn't mean you took it. Now we have to account for sometimes people drop a pill. Now I have done this. I cannot get on my hands and knees to look for a pill. So two things.

One, with the smart pill bottle the physician would have the ability if the patient calls and says, hey, I dropped my pill and I really need it, he could then put in a requisition to the pharmacy and the pharmacy could release the pill remotely. But that would also be documented so they could look for trends in this usage.

So the other thing is if the pill was taken out of the bottle and over a time period several pills are taken out of the bottle but they're not ingested, well, now we can have a conversation with our patient of, hey, we noticed that you're missing a lot of your pills, but they're being

taken out of the bottle, can we talk about this, and have a real conversation.

So together with smart bottles and RFID pills, we feel that it is a good step for decreasing misuse, abuse, and even accidental overdose. How many people here have forgotten if they've taken a medication before? You know, this, and I have done that where it's like did I take it or not? Well, I'm still hurting, but I can't remember if I just took it or not. So in my case I don't, but there are other patients that may not do that. They may go ahead and take it again.

So what are the goals of this therapy? So the smart -- the step opioid therapy, the goal of that is to decrease the daily average dosing by allowing the patient to take less when they hurt less and more when they hurt more, overall decreasing the daily dose, decreasing dependency. It gives the doctor more control over dose changes, allows monitoring of usage, prevents accidental overdose, increases medication adherence, and it would provide data that we could

use for research.

We do not feel that this approach work, work for every type of pain patient out there. For instance, some intractable pain patients need around-the-clock therapy. This is not for them. We have to give the physicians the ability to use their clinical judgment based off their patient's assessment.

So the title of this presentation is Do No Harm. Where we're at today, we have seen a huge increase in patient suicides. So while at the foundation we say we cannot prevent one epidemic by causing another, this is what we're talking about. These are 24 individuals that have committed suicide since last year due to being refused pain care altogether, being force-weaned to subtherapeutic levels, or being turned away and not offered alternative therapies.

So that's what we mean when we say do no harm. Prevent accidental overdose, but treat your patient with the respect and dignity that they deserve. Pain hurts and pain can kill.

So with cauda equina syndrome, these are common comorbidities. Each one in red causes its own type of pain, one of which requires chronic pain management. Most cauda equina syndrome patients have all of these. So we call those pain storms.

So, and with that I'm going to go ahead and close and take any questions you may have.

MS. TOIGO: Thank you, Ms. Proctor. Questions from the panel? Okay. No clarifying questions. Thank you very much for your presentation.

MS. PROCTOR: Thank you for having me.

MS. TOIGO: Our next presenter is Dr. Richard Lawhern.

MR. LAWHERN: Good morning. I'm Richard Lawhern, sometimes called Red. I am cofounder of the Alliance for the Treatment of Intractable Pain. We're an organization of about 200 medical professionals knowledgeable with chronic pain patients and caregivers, healthcare providers, and others. We get a daily reach of about 80,000 viewings from social media. We're here to

represent the concerns and interests of three million chronic pain patients who are under regular treatment with opioid analgesics.

Next level. I have to do this, I guess. Yes? Very good. Organizing a late minute session, I wanted you to have the takeaway points up front and these are going to be a little surprising to some in the audience.

First of all, FDA is chasing the wrong opioid crisis. Second, the REMS in its present form will harm hundreds of thousands of patients to no good outcome, and help almost none. And I'll expand on these points in the presentation.

Second we implore the FDA, and by the way, the DEA, to stand down from further regulation. Take a breath before you do even more harm than the CDC guidelines already have. We focus on the recall and revision of the CDC opioid guidelines, which right now have a wide level of criticism among medical professionals on the grounds that I'm stating here. Those guidelines are dangerously incomplete, they are dangerous to public health,

and they should be withdrawn and rewritten on a priority basis.

Now here is a chart which in a strange way speaks to the very thing I've just remarked upon. Pill counting and supply restriction are not working and the statistics of the CDC itself demonstrate that. The number of prescriptions peaked in 2011 and began to fall.

Since the mandated reformulation of OxyContin, prescriptions of that prescription opioid have dropped by two-thirds, but opioid prescriptions being at a low, overdose depths due to all sources have continued to ramp up. That should be an immediate indicator that what you're doing isn't working, and I'll speak to that in some greater detail as we go.

Now I mentioned that I think you're chasing the wrong opioid crisis. We now know from the CDC statistics that opioid deaths are dominated by street drugs, particularly these four. Prescription drugs are a distant fifth in this mortality rate.

We have heard the message parroted over and over that 75% or more of addicts start with prescription drugs, and by the way, and alcohol, but most of these drugs are diverted. They're not prescribed by a doctor to a patient who overdoses on them.

Massachusetts did a review and tracked their overdose deaths for a year back to their PMP. They found that fewer than 8% of those who died had a current opioid prescription. Likewise, the typical new addict and the typical pain patient are different people. The demographics don't work.

The typical addict, or if you will, a person with addiction - I don't want to be disrespectful to any of them - is an adolescent or early 20s male with a chronic history of unemployment, family trauma, and perhaps mental health issues. That population is medical underserved. They come from depressed areas of the US, but the typical pain patient is a woman in her 40s or older who has a history of accident trauma, failed surgery,

fibromyalgia, and other diseases that produce chronic pain as a symptom, and older women whose lives are stable enough to see a doctor for a prescription are very rarely addicts. You can't make the trail of bread crumbs between these two demographics. It doesn't exist. Now there are eight questions in the FDA REMS. I will speak briefly to each as we go.

First, should the FDA specify a drug amount threshold for additional risk benefit review? If you'll pardon my venturing slightly in the vernacular, our answer to this is not only no, but hell no. And there's for good reason. Because the CDC guidelines have already specified such a special and that specification has resulted in doctors leaving the practice and in hundreds of suicides. It is literally of that magnitude or larger.

Patients are regularly being deserted, discharged, or coerced into tapering down to subtherapeutic levels of opioids. That's got to get fixed. The guideline have also created a very

hostile regulatory environment. Hospitals are actual refusing to treat palliative care patients with opioids in a few cases.

There is no one-size-fits-all patient or treatment plan. Each patient must be treated as an individual and we have seen ample evidence that those limitations and rigid pill counting directly harm patients by forcing them into subtherapeutic levels of therapy. Likewise, we should add that the state regulations which mandate for increased visits and shorter visit times for people coming back for prescription are also helping very few and harming great numbers.

Prescription being denied at pharmacies is endemic and it's being denied on an abundance of care because these people are afraid of being persecuted out of business by the DEA, and I do mean the term persecuted. Extralegal measures are being used to condemn without a trial people who are being forced out of practice for no good cause.

Likewise, the second point in REMS. If you

want to ensure compliance, you're going to have to put portals in every doctor's office and in every pharmacy in the country. And the problem we have here is the pain patients themselves are a small minority of all people with addiction. You're going after 100% of a cohort of three million people in order to help solve a problem among maybe eight to ten percent of them. Whatever happened to first do no harm? That certainly isn't a good example.

We should also remark that very few doctors who are in normal practice are casual about prescribing. You've been successful in getting their attention and very few patients quickly become addicted.

There's something not in my presentation I want to add here. There's a study that I recommend to each of the members on this commission. It was published in this month's British Medical Journal. It examines over 560,000 post-surgical patients prescribed opioids and it finds after following them for an average of two-

and-a-half years, that 0.6% of them are reported with a diagnosis of an opioid misuse disorder, 0.6. That means that 99.4% of all patients treated in the short term for largely acute pain do not become addicted. That's a direct contradiction to the CDC nonsense and it is that. It's nonsense.

MS. TOIGO: Dr. Lawhern, I don't want to interrupt, but your, your time is up.

DR. LAWHERN: Oh, I beg your pardon.

MS. TOIGO: You want to wrap up --

DR. LAWHERN: I will --

MS. TOIGO: Thank you.

DR. LAWHERN: Let's go back to the bottom line and the rest of this you can catch on the update, if you will. The FDA is now chasing the wrong crisis. Overregulation is going to make the real crisis worse by driving patients into the street. It's already happening. You will drive more patients into disability and death if you do not realize the regulation is not the answer.

The guidelines must be suspended and the VA

must be directed to remove and rewrite their practice standard which mandates the elimination of opioids from practice. That is not optional. It is a moral and ethical imperative. I'm open for questions. I beg your pardon for running over.

MS. TOIGO: Thank you, Dr. Lawhern. Any clarifying questions? Dr. Woodcock?

DR. WOODCOCK: Yeah. Leaving aside chronic pain patients, though, what is your -- and you say in your text that you feel that diversion from home isn't much of a problem.

DR. LAWHERN: I'm sorry. I need to correct that if that was the impression I generated. It is a problem. It's a major problem and there are ways to deal with it. Diversion from home, however, we do not know and surveys cannot tell us whether we're dealing with diversion from relatives to other relatives, which is voluntary, or by theft. So we can't answer that question.

We don’t know that answer, but we do know that diversion's happening and there are ways to deal

with it. We just heard one presentation that can be a part of that. Another is, candidly, that you can build a pill safe that screws into the wall inside a medicine closet and do it for less than $200 a copy. Making (inaudible) and biometrically opened and you got a very serious, let's say, quite a barrier to theft and despite the rule.

DR. WOODCOCK: What percentage of the -- the exposure of that population is extremely high. You present that in your graph. All right. Just the number of prescriptions. How much of that you believe is chronic pain and how much of it is simple postsurgical, post-accident, ER type? My impression is there a large amount of prescribing of that type, which doesn't relate to what you're talking about here.

DR. LAWHERN: Yes and no. Obviously the treatment of acute pain for a few days is a major component of that peak, but the numbers are still dropping and we're seeing truly draconian measures being applied where you send the person home without an opioid prescription who's just had a

hip replacement and asked them to come back five days later, and that is not an unrepresentative case. I've heard that from multiple patients.

So we got to get smart about what we tell people concerning acute pain, as well as chronic pain.

MS. TOIGO: Thank you.

DR. WOODCOCK: Thank you.

DR. LAWHERN: I beg your pardon for taking longer.

MS. TOIGO: Thank you, Dr. Lawhern. Our next speaker is Ms. Kristen Ogden from Families for Intractable Pain Relief.

MS. OGDEN: Good morning. My name is Kristen Ogden. I'm really pleased to be here and I appreciate the opportunity. I'm the cofounder of a very small advocacy group called Families for Intractable Pain Relief. So I'll start off by saying right up front I'm not a medical professional or a scientist. I am, however, a family member of an individual who has suffered from pain throughout his entire life and we just

celebrated our 45th wedding anniversary three days ago. I have assisted him. I've been his caregiver and advocate for over 20 years and more recently over the last five years I have been more involved in advocacy on a broader level.

Our group is comprised entirely of intractable pain patients and their family members. Family members are fully engaged in the care and issues that their patient's family members are experiencing today and I'm here to talk to you about some of those issues and to suggest ways that we might make life better for those people.

Our goals are to raise awareness of intractable pain and the challenges faced by those who suffer from it, and to advocate for continued and better access to standard and nonstandard pain therapies to treat intractable pain.

Well, what is intractable pain? There are numerous definitions I'm sure, but I want to make clear I do not in any way minimize the impact of the pain experienced by any person, and our motto, our goal, one of our guiding principles, you might

say, is at the bottom of every slide here that "free from pain to the extent achievable is the most fundamental of all human rights." However, intractable pain that I'm talking about is a level of pain that is very severe.

It's constant. It's not curable by any other means. It causes adverse biological effects on the body's various systems, leads to a bed-bound or house-bound state, and early death if not adequately treated. And I would agree with Ms. Proctor, people do die from under-treated pain.

What are the characteristics of intractable pain? I'll just point out a couple that I think are very significant for you. That it is, in fact, constant 24/7. I have had the opportunity to become acquainted with many intractable pain patients whose illness fits the definition I just read to you. Their pain is content.

It can be effectively helped. Oftentimes it requires high doses of opioids to do that, but it can be addressed, it can be managed to enable these individuals to have a better life. But

without adequate treatment it is constant, excruciating, 24/7 pain.

So I would ask when you have a moment to just stop and think what, about what's the worst pain you can imagine having or have had perhaps in your life, and think about what your life would be like if it was like that all the time, every minute, of every day, every week, every month, for years or decades.

This message has been lost somehow. Most people don't believe this is real, but I'm here to tell you it is real. My husband isn't one of these people.

Other important points. The pain is so bad that it causes physical and mental incapacitation because you can't do anything but think about how you're going to get through the next few minutes. The underling cause, incurable, not removable.

In order to treat intractable pain clearly it is our belief that a person must have already tried all the available avenues of what you would call standard of care, but what you find is that

these particular patients are not helped by standard of care. So extraordinary methods and means are required in order to give them a decent quality of life.

And my message to you is that that can happen. It can be done. Generally unique personalized medication regimens are going to be required and trained as a last resort higher dose of opioids and other nonstandard medications or therapies. We never want to come across or be understood to suggest that opioids should ever be the first line treatment for pain. We don't agree with that at all, but higher dose opioids are necessary and a last resort for many patients when all else has failed. And that's what we're talking about.

If pain is not adequately treated with centralization results, we have found that the World Health Organization's three step analgesic ladder provides a good model to describe how one might go through the process of standard care and ultimately go to nonstandard care.

Throughout the '80s – step 3 – if steps 1 and

2 have failed, you move on with basically the addition of an opioid. When the ladder was first created there was no upper end defined on the dose that could be given. I think in today's environment where we have the CDC guidelines with the 90 mg threshold we have other guidelines out there in the states and different, put out by different agencies, perhaps the 90 mg. should serve as our threshold above which we could say standard of care has failed. Extraordinary measures were necessary.

Profile of failed patients. One important point here that I haven't spoke to necessarily. Patients become nonfunctional and family members will be at their appointments with them saying my family member needs help. We have tried all these other things. Nothing is working and my family member needs help.

The underlying cause of intractable pain as I've described, it can be thought of as being twofold or two-pronged. The initial injury or disease must have been severe enough to cause

activation of microglial cells in the spinal cord and the brain. This causes neuroinflammation of the central nervous system, the spinal cord and the brain, and this is what generates the constancy of pain, the 24/7 that it never stops.

Only the most severe, serious diseases or conditions are severe enough to cause it and we've given some examples there. The great majority of people with pain at this level or magnitude suffer from one of these illnesses that I've shown.

Why treat it? Because it's the right thing to do and because with appropriate medical management that is often with high dose opioids, patients' qualify of life can be improved. Their blood pressure will fall. They will be able to get up and be more active and as they're going about a somewhat improved life, they are stabilized to the extent that physicians who know what they're doing and know how to treat these people can search for the true causes and try different treatments to try to bring down that pain and ultimately perhaps reduce the need for the opioid.

I'm going to thumb through our eight slides here that address the specifics very quickly and I would ask you to come back and take a serious look at them. I started with my introductory slides to give you a context in terms of where we're coming from. We agree with many of Mr. Lawhern's points. We feel that we're after the wrong target here.

Very rarely do abusers or addicts come out of the population of people that I'm talking about, but they are being harmed. They are being harmed. They're losing access to the only medication that gives them any quality of life and enables them to be productively treated for their underlying illness.

We have a few myths and misconceptions and I'm going to say them real fast here. Intractable pain patients like my husband who does take a very high dose of opioids are not addicts. They do not fit the definition of substance abuse disorder in any way. They demonstrate no, none of those behaviors. They are not likely to overdose or die. They do not get high. I invite you to take

a look at these. Absolutely they are not drug abusers or drug traffickers.

What can the FDA do? Let me say I am wrapping up here. We do think there's specific steps that someone can take, consider taking. Hold focus groups around the country and invite intractable pain patients at this level. I know you've talked to a lot of chronic pain patients, but I'm not sure you've heard from very many intractable pain patients.

Yes, it's difficult for them to travel in many cases, but their family members will be right there with them and will help them get to a meeting. If you'll announce one, I can guarantee that. They all are very frustrated because they do not feel they're being heard.

Helps us change the public narrative by acknowledging that people like my husband exist. He takes a very, very high dose, but he has been on the same stable dose for seven years. If not treated, it does escalate. Establish the regulation that needs to protect these patients,

identify them somehow, and please, look into establishing a training and licensing program to enable community-based doctors to treat these patients. As we baby boomers get older there's probably going to be more of them, perhaps, not necessarily fewer. We hope the science advances to where the causes of this kind of pain can be more readily treated.

Please take time to listen. Stop causing harm through inaction or lack of knowledge and denial of care. Thank you. I'm sorry I went over. Are there any questions?

MS. TOIGO: Any questions from the panel? Thank you, Ms. Ogden, and congratulations on your 45th anniversary.

MS. OGDEN: Thank you. I'm looking forward to the next 10 or 15 or 20 at least.

MS. TOIGO: Our, our next speaker is Mr. Lex Feldman.

MR. FELDMAN: Hello. My name is Lex Feldman. I am a pain patient for, I'd say the better part of nine years. I had a, a similar patent device

that was a good balance between patient care and abuse, which would be a biometric scan box that would only allow them to get the dose that they're allowed to have per day. So they wouldn't be handed 90, 150 pills at one time that they often share or misuse or take too many.

I personally am given three 15 mg. oxycodone a day. My first one's gone before I even get out of bed. I have a lower back fusion, a neck fusion. I'm 38 years old and too young for a double knee replacement. I've had advanced carpal tunnel surgery on both hands. I broke my hip when I was 15. I have permanently damaged growth plate in my right elbow that hasn't straightened up since I was eight years old.

I have chronic pain every day. I don’t have good days. The backlash of this has been that pain patients like myself lay in bed most of their life. I have one good week a month. I believe that, like I said, my device would be a healthy balance between the two. I think controlling what somebody is able to take or over-monitoring isn't

really necessary. I think it should be kept relatively simple.

I have a seven-year-old daughter that often comes into me and says we can't hang out with dad because your back hurts. It does. Again, I don’t have good days. I had a speech written here, but Dr. Lawhern came pretty much covered that entire thing. So I really didn't have much to add to that other than the fact that the over-regulating is unnecessary.

And as far as doses go, I was on at one point -- and this doctor's license was taken and he might have even been arrested. I'm not sure. I was on what some of you are going to guess, but I was on a 100 mg. time-release and 15 mg. oxycodone a day. In that time I built two houses. I worked every day 16 hours a day. Since then I've been shut down and I've been obviously on a drastically lower dose. I've been in bed for almost five months.

I won't make it through this meeting. I'll probably have to leave early and get home 'cause I

have a four hour drive. The distinction between addiction and chemical dependency is often significant and, and that's just not true. I'm chemically dependent. If I don't take them, I get withdrawal symptoms. It doesn't mean I'm an addict or that I'm out doing illegal behavior to obtain it.

Again, I think that the, the prescribing should be done on a patient-to-patient, you know, evaluation. They often say that they want to come up with some sort of pain measuring device. I am trying to get something patented as far as that goes too and I think that will help significantly as well.

You know, they think too scientific and they want to, you know, try and stick something in your neural pathways, but in translation that pretty much comes up with a person's pain. So however, the device that I have and I think that would cut down significantly on unnecessary people being on pain medicine.

We do think differently when we're in pain.

We move differently. We, you just, if you have knee surgery or have ever had knee pain you can related to the change that you do in your regular activity. The P, I think he said PMP, if this device was put in, it could be given a DIN number. So that would be nationwide. So you'd be able to track it from patient to patient just like they do a cell phone, cell phone products. I think that would simplify that a little bit.

Let's see. What else do we tell them? I think that's all I can really add. I've been trying to get the funding for this device. I've gotten a little bit of support from guys in health insurance. I contacted a lot of organizations that are supposed to give grants for that. I've never even been responded to in an e-mail or a phone call or got all their responses.

I think we want to wrap this up and not take too much more time. Like I said, I think Dr. Lawhern really nailed that pretty passionately. So I thank everybody for allowing me to come here and say what I had to say. Like I said, I had a

pretty long speech written out, but that would take excess of 10 or 15 minutes.

So I think we're all here for the same reason, really. Thank you.

MS. TOIGO: Thank you, Mr. Feldman. Questions for Mr. Feldman? Okay. Thank you. Our next speaker is Mr. Donald Kosiak.

DR. KOSIAK: Well, good morning. My name is Dr. Donald Kosiak. I'd like to thank the steering committee for the opportunity to provide some input. As background for my presence today, I'm a practicing board certified emergency medicine physician. I've served as a medical officer with the US Army. I've served in multiple tours of duty in support of operations in Iraq and Enduring Freedom, and I continue to serve the US Army National Guard, currently the state surgeon for the state of South Dakota.

Needless to say, I've seen firsthand the devastation and challenges of this crisis and the opportunities to make a difference in the lives of providers, patients, and their families. In fact,

by the time I finish giving my remarks, unfortunately another person will likely needlessly died from opioid overdose or suicide associated with its use. In addition to my clinical work, I'm the chief medical officer for Leidos where I provide medical subject matter expertise and prospective and support strategic planning and the deployment of technology in medicine.

I'll begin by agreeing the FDA's REMS authority is appropriate and can decrease the appearance of new addictions among acute and chronic pain patients. Moreover, this authority is consistent with the recommendations offered in the National Academy's report chartered by the FDA.

In particular, we are in total agreement with the academy's recommendation 5-4 to conduct and sponsor research to improve the collection, sharing, and use of either administered by drug monitoring programs for surveillance and intervention.

So on behalf of myself and my 32,000 Leidos colleagues, I recommend the FDA reconsider how you interpret pre- and post-market surveillance and intervention. Specifically REMS' authorized activities to moderate and monitor opioid prescriptions at two stages and the dissemination of these drugs, first when the healthcare provider issues a prescription, and second, when the patient or patient's caregiver fills the prescription.

Furthermore, in accordance with support of the National Academy's recommendation 5-5, we can curb that such activities should inform educational direction to providers and patients. Simply we want to follow the famous medical adage here today, first do no harm.

Now I will address prescribing documentation implementations for Question 1, 2, and 3, specifically focusing on the acute pain situation. We agree a properly designed decision supported platform can be highly beneficial both for real time assessment of benefit and risk for the

individual patient, and perhaps over time be linked to a community benefit risk analysis.

A nationwide system effortlessly accessible by prescribers in all states would address current challenges of finding an accurate history of prescription use by the individual patient. While we have made progress to date, many states still have separate registries, and still many more are not integrated within a clinical workflow.

So unfortunately the overall usage and checks across providers in distance states are limited. Accurate past usage combined with real time clinical decisions could dramatically improve the current state. However, I caution here that the system would be, not overrule a provider's decision, but rather supplement the provider's reasoning with the evolving risk assessment findings across the larger population.

Therefore, we recommend FDA's REMS implementation for opioid drugs be informed with a hybrid analysis of both traditional and nontraditional data sets about the patient, the

provider, and the larger community within which medical treatment is administered.

Put simply, the data is everywhere. We need to bring it together. We believe such an advocation would operate efficiently and consistent with the provider, provider's workflow if it can quickly and accurately check for past opioid usage and it includes an automated, evidence-based algorithm featuring sedative attributes known to effect individuals at high risk for addiction, while the final set of these attributes should be determined by the FDA and very likely tailored to the prescriber's speciality, patient diagnosis, and attributes of the community at risk.

I'll mention a handful of examples included in the opioid risk tool for narcotic abuse, which was validated over a decade ago for use in primary care. These attributes include things such as a history of risky behavior, illicit drug use, substance abuse, both personal or in their family history, history of psychological or mental trauma

or abuse, and a history of personal conduct problems, depressive symptoms, or psychological distress.

If after real time automated calculation of these recommended thresholds for opioid abuse is not met, then perhaps the clinical decision support tool might ask the prescriber to consider nonpharmacological therapy such as physical therapy, acupuncture, or the use of non-opioid medication or genetic targeting for accurate usage of opioid medication.

The last docket question addressed today will be question five, which goes to the education, public health communication campaigns to ensure health professionals, patients in the larger community know the safe storage and disposal of analgesics, as well as the risk of misuse, abuse, and addictive behavior. Through Leidos's long-held efforts supporting community practices, military medicine, and veterans' health, we are well aware of the biases towards and against some treatment modalities.

Our experience on the ground with patients and families, as well as findings from our academic colleagues provides evidence and benefit of efficacy of alternative therapies. These same studies also show increased risk to individuals and society resulting when payment for these alternative therapies is not available.

Therefore and consistent with the academy's recommendation 5-3, we would recommend the FDA collaborate with other federal health agencies to facilitate additional studies and policy changes that reimburse for evidence-based, cost-effective, comprehensive pain management and nonopioid therapies.

We also support the idea of the FDA should leverage their LIMS authority to require opioid drug sponsors to provide medication guides, consumer medication information in patient package inserts with information on safe storage and disposal of opioids, but such information needs to be complemented with an accessible and accepted mechanism to dispose of such drugs.

While today I do not provide comment on these details of potential mechanisms, our prior experience and analysis of behavioral pattern indicate that it must be anonymous. If the public perception of the disposal mechanism has a hint of big brother either corporate or government, then the unused drugs will stay in the medicine cabinets, grandmother's kitchen drawer, and likely find their way into our schools and on the streets.

In summary, Leidos concurs that the expanded consideration of data sources along with a hybrid analysis that informs benefit and risk considerations, along with past medication usage, embedded in the clinical work for the provider could impact the current state; however, they must have consideration not to undermine the authority of the health professional.

The FDA should support education and public communication campaigns trailered to providers, patients, and the community of caregivers. Additionally, we wholeheartedly recommend expanded

focus on alternative therapies that can help curb the need and use of opioid medication.

Again, and on behalf of myself, my Leidos colleagues, our clients and customers and the community of neighbors we support with charitable contributions, I thank you for allowing us time today to provide comment and input on your docket questions. I hope to, this information provides some help to the FDA as you further consider your response to the public health crisis. I look forward to answering any questions generated from my comments today. Thank you.

MS. TOIGO: Thank you, Dr. Kosiak. Questions from the panel? Okay. Thank you very much. Our next presenter is Mr. Joel White from Health IT Now.

MR. WHITE: Thank you for the opportunity to present today regarding approaches to utilizing electronic systems in conjunction with REMS to improve the safety of opioid analgesics. My name is Joel White. I'm an Executive Director of the Health IT Now coalition. I appreciate the

opportunity to present.

Since our inception a decade ago, Health IT Now has focused on the adoption of new health IT systems of data to address healthcare's pressing challenges. We share the committee's belief that opioid abuse is a pressing national problem and a massive challenge that requires a consummate public policy response.

And so this, we believe this multifaceted problem can only be effectively addressed by all sectors of the healthcare system and this is why you explored and launched a multi-stakeholder advocacy coalition to bring tech solutions to bear on the opioid problem.

In many cases we believe doctors and pharmacists lack good information to make informed clinical decisions at the point of care. It is for this reason we explored, we have focused our attention on the problems with the current electronic systems that use prescription information in prescribing and dispensing.

Our approach in this area is two-pronged. The

first is to facilitate and improve the current state PMP audits, and secondly is to institute a national facilitator model that would create real time information flows within a clinician's workflow to better inform, inform clinical decision making. We believe that that could be achieved through a REMS program.

But first I want to say a little about who Health IT Now is. We came together 11 years ago. We are a nonprofit coalition, multi-stakeholder groups, patients, healthcare providers, employers, insurers, and others who believe that we can solve a lot of healthcare's pressing challenges through an application of Health IT and data.

And we, our core priorities include expanding and facilitating interoperability, leveraging technology-enabled care like telehealth, creating regulatory frameworks that reduce burdens on providers and developers, and yes, using technology and data to solve the opioid problem. Our recently launched opioid safety alliance focuses on agenda to bring health IT to bear on

this crisis.

I think we have all seen the devastating numbers that represent the impact of the opioid crisis. Four-point-three million Americans abuse prescription opioids each, each month, partly as a result of hospitalizations. And ER visits are up significantly, 64 and 100% respectively over the past decade.

This drives up the cost of care 78 billion dollars. There's a CDC number and it's on the low end. Recently the White House put out numbers from the National Economic Council that pegged the cost of the opioid crisis at 540 billion annually, but whatever the economic cost, I think first and foremost we should recognize that 64,000 Americans died from this problem and that we've seen the first drop in life expectancy since the AIDS epidemic in 1993.

These are significant challenges, but I think too often we forget that these numbers represent individuals, our families, and our communities, and therefore, we believe it is time to bring the

full weight of technology, innovation, and data to bear against this problem, but to do so we need to understand how current information flows in the system and how prescribers and pharmacists use that information to decide when and to whom prescription opioids are, are given.

So the current process -- this is -- excuse me. The current system of PMPs began largely several decades ago as a tool for law enforcement and they have worked well in many instances. They are statewide electronic data systems that collect, analyze, and make available prescription data on controlled substances dispensed by nonhospital pharmacies and practitioners. Forty-nine states and the District of Columbia currently employ a PMP process and that information includes type of drug dispensed, quantity of drug dispensed, number of days, etc.

This graphic summarizes the current process in steps that a physician or pharmacist must take to check the PDMP. A prescriber or pharmacist must basically exit their system, go to a dedicated

website, and login, navigate to search, enter patient identifiers to generate a patient specific report. That report is then viewed for problems, analyzed for potential red flags, and then the provider must logout and perhaps login to a different system. In this area, for example, you might check the Virginia PDMP and Maryland PDMP.

This research indicates that this process is not all used and takes significant time when it is used. So on average, 14% of doctors check PDMPs. That number is 20% where, in states where it's mandated. The amount of time it takes is between two and six minutes. That is significant for a clinician and patient encounter. And it's costly. It takes time at the pharmacy level and it takes time in the physician office.

But I do want to note that the National Association of Boards of Pharmacies is working on a model to link and better share data across PDMPs and they're making progress. Companies are also working to put this information within the workflow of clinicians and they're making process.

And I also want to note that Congress is looking at providing additional funds to make the PDMPs work better and that's important, but we also believe that this process could be, could be improved because there's three primary problems.

First, the information is not in real time. It is not in front of the prescriber or dispenser when they are treating the patient, is not in the workflow, in other words, and it's not generally interoperable across states or within clinicians' clinical operating systems.

And so in most cases this information is retrospective. It relies on batch uploaded files from pharmacies on a daily, perhaps weekly, or even a monthly basis. It requires -- it's done in a different interval reporting times and if the data contains administrative errors, it's often delayed in getting implemented and integrated into that PDMP website.

We would note that it's very important to have real time information in order to make real time medical decisions about a patient who's in front

of the pharmacist or prescriber.

Because states have implemented their current system at different times and in different ways, many are not able to talk to each other and they're unable to talk to the information systems that clinicians currently use. And so this map, as you can see, points out how those are integrated to the different types of clinical systems that pharmacists and prescribers use.

Only two states, Iowa and South Carolina, have systems that are integrated with health IT. Almost half of the states have no access to PDMPs by an integration with the system. That's a significant and real problem. Progress is being made there as well, but more needs to be done.

Finally, I think we should recognize that a lot of the work has been done to break down barriers across states. Interoperability among states, however, is only a piece of the puzzle and the clinical integration into the EHR systems. So we do think educating providers is a good first stop, but it doesn't solve the information

problem. We do think that FDA should authorize a national nationwide prescription history system to provide clinicians real time information in the workflow regardless of the system used or the geography in which the person is.

With that I'd love to take any questions at this time.

MS. TOIGO: Thank you, Mr. White. Questions from the panel? Ms. Sherman?

MS. SHERMAN: Do you have any data that suggests that - I believe it's Iowa and South Carolina - have taken steps to integrate into the workflow? Do you have any steps, any data --

MR. WHITE: Yeah. I think, I think where it's integrated into the workflow there's been some bumps, but in general it's putting that information in front of the prescriber, for example, to see this pop-up-type deal. We can get back to you on the effectiveness, any effectiveness studies. Brandeis University has a lot of data on how the PDMPs are doing --

MS. SHERMAN: It would be great to put that

into the docket.

MR. WHITE: Yeah, absolutely.

MS. TOIGO: I have one question. So you're a coalition?

MR. WHITE: Mm-hm.

MS. TOIGO: The health professional organizations?

MR. WHITE: Yes.

MS. TOIGO: Are they -- are there others that are not included in that are part of this coalition?

MR. WHITE: Yeah. Our members comprise 65 different organizations and they are some prescribers, a lot of pharmacies, some long term care facilities, etc. Our opioid safety alliance is a subset working group of Health IT Now and that organization is comprised of 17 distinct members that incudes things like health systems, like (inaudible) for example, pharmacies like Walgreens, NACES (inaudible), NCPDP, and McKesson.

MS. TOIGO: So the pharmacy (inaudible) medical?

MR. WHITE: On the prescriber side? No --

MS. TOIGO: Not (inaudible).

MR. WHITE: Well, I should take that back. So we have Centerstone, which is a regional community-based provider that includes physicians.

MS. TOIGO: Thank you very much. Any other questions? Okay. Our next presenter is Mr. Stephen Mullenix from the NCPDP.

MR. MULLENIX: Good morning. My name is Steve Mullenix. I'm a Senior Vice President of public policy and industry relations at the National Council for Prescription Drug Programs. I'm also a pharmacist by training with lengthy professional experience, Hispanic community hospital, health system pharmacy administration, and addiction treatment, just to name a few.

I want to first thank the members of the committee for their concern regarding the increasing epidemic of opioid misuse and abuse in this country and their commitment to finding ways to assure the safer use of these important medications.

Secondly, I want to thank you for allowing me to be with you today to share NCPDP's perspective regarding a model designed to do just that and to allow existing safe PDMPs to realize their full potential.

A little bit about NCPDP, the organization. NCPDP is a not-for-profit, ANSI-accredited standards development organization located in Scottsdale, Arizona. Its stated vision and purpose are to lead the industry in creating healthcare standards for the common good and to standardize the exchange of healthcare information to improve outcomes.

Membership is comprised of representatives from all sectors of the healthcare industry. We have a specialized process that we use in decision making. Decisions are made using a consensus-building approach with an obligation to be nonbiased. So for the over the 40 years of NCPDP's existence, they've been using this very defined process in serving as a problem-solving forum for the healthcare industry.

Results include things like various published solutions, industry guidance, and maybe most significantly, has been the development of several interoperable electronic communication standards used in healthcare, many of which have been named in various federal legislation and/or regulation.

Two of the most prominent examples are first a telecommunication standard. Telecom is a real time, bidirectional communication standard that connects the community pharmacy with the payer and other entities. Virtually every community pharmacy in this country has been utilizing this standard for more than three decades and today the activity represents literally billions of transactions either sent or received.

Script is the second example authored by NCPDP and is the communication standard on which all outpatient electronic prescribing is based. This standard is also real time and bidirectional, and it connects the prescriber to the pharmacy. The advantages of utilizing electronic prescribing are many and serve as a basis for why many sates

either have or are strongly considering mandating its use for all prescriptions.

A little bit about NCPDP and its commitment to this whole opioid issue in particular. As I mentioned earlier, NCPDP has long considered itself as a problem solving forum. And in the case of PMPs, several of our members came to us over five years ago and asked if we could examine the issue in more detail. Our response was a whole strategic action group meeting near here in Baltimore where 40 to 45 subject matter experts attended a full day session where the issue was level set for all attendees.

The question was asked as to if NCPDP could be hopeful in moving toward an industry solution, and if so, how. The result was the development of a prescription drug monitoring task group and the creation of a white paper that outlined the perceived problems of the existing state of PDMPs and proposed solutions. That task group remains in existence today along with now four additional task groups related in various ways to this

effort.

As mentioned, the prescription drug monitoring task group's first charge was to create a white paper first released in March of 2013. That document is now in its third edition and its entitled "NCPDP's recommendations for an integrated, interoperable solution to ensure safety use of controlled substances." The document is available on the NCPDP website at ncpdp.org.

But in brief, the document outlines many of the challenges expressed by Mr. White in his testimony today. Things like lack of timely data, inconsistent input of data, difficulty in managing patients beyond the state boundaries, challenges in information retrieval, and the time commitments necessary and associated with mandatory review, etc.

A little bit about the solution. The solution is described as employing the use of a national facilitator that connects to both the dispensing pharmacy via telecom and the prescriber via

script. The national facilitator also utilizes a DUR type alert system so when either the prescriber electronically prescribes, or the pharmacy dispenses, in this case an opioid, a real time alert is generated only when a potential risk is identified. In these situations the prescriber and pharmacist are prompted to request a medication history if they have not already done so.

Preliminary research suggests that these alerts would be triggered approximately 7% of the time. This then allows prescribers and pharmacists to focus on those patients at greatest risk while illuminating the inefficiencies currently associated with things like 100% mandated PDMP review.

The model also provides the opportunity for individual state PDMP administrators to do all the things they do today to assure the health and safety of its citizens within their respective states, only now they would do so utilizing a complete, timely, and accurate information. These

advantages combine the presumed improved efficiency in data transfer and management appear to be welcome enhancements to most, if not all, existing state programs.

In short, the solution utilizes existing infrastructure and its prescribers and pharmacists to a national facilitator via two real-time, bidirectional, HIPAA compliant standards as a means of providing those entrusted with the care of patients with complete, timely, and accurate information on which to base their clinical decisions.

And while the opioid endemic is admittedly an extremely complex issue, NCPDP believes strongly that utilizing this approach will go far in helping to reverse this deadly trend while at the the same time maintaining important medication access for those with legitimate need.

In addition, while the emphasis of our discussion today is squarely directed toward opioids, NCPDP members are keenly aware that this model can accommodate any and all prescription

drugs deemed necessary in order to further assure safe use.

Lastly, it is important to point out that as a standard of a development organization, NCPDP has no authority or financial incentive to see this model implemented. Rather, as in the case of NCPDP standards in general, the model is voluntary. Therefore, the actual implementation would require action by the private sector and/or government legislation or regulation.

Fortunately, we have indications from within our membership suggesting substantial, bisector interest in making this, this model a reality and a shared vision that it is right thing to do for patients and caregivers alike.

I want to thank you again for allowing me to address the committee today and for allowing NCPDP to provide our comments. I'll be happy to answer any questions. Thank you.

MS. TOIGO: Thank you, Mr. Mullenix. Any questions? Dr. Woodcock?

DR. WOODCOCK: So risk factors that you have

would be patient safety network step of this. Are these intended to be other usage data such as you have from the PDMP or other, other information?

MR. MULLENIX: I'm, I'm not sure I understand the question.

DR. WOODCOCK: All right. Do you identify that 7% as you estimate of the prescriptions, 7% of the patients would be determined to be at risk based on what?

MR. MULLENIX: Based on a study that was performed by -- and actually that, that study result is available on our website, our foundation website. But it was a study that was initiated by (inaudible). So it is, it is available and it is, it was an assessment of, if I recall specifically, the 12 month rolling history of controlled substance users in the community and ambulatory setting. And there was, it was the result of their assessment using their criteria.

DR. WOODCOCK: Okay. So it said -- so what -- the factors that would be put in place are history of usage?

MR. MULLENIX: Yes, correct.

MS. TOIGO: Other questions from the panel? Okay. Thank you, Mr. Mullenix. Our last speaker for this session is Ms. Kelly Wygal from McKesson.

MS. WYGAL: Good morning. My name is Kelly Wygal. I'm Vice President of McKesson Speciality Health. I want to thank the opioid policy steering committee for their commitment to improving the safe use of opioid analgesics.

Last May Commissioner Gottlieb shared the following with agency staff. "Unquestionably our greatest immediate challenge is the problem of opioid abuse. This is a public health crisis of staggering human and economic proportion. The epidemic of opioid addiction is not a problem that FDA can solve alone, but we have a key role to play in reducing the rate of new abuse and in giving healthcare providers the tools to reduce exposure to opioids to only clearly appropriate patients so we can help reduce the case, new cases of addiction."

McKesson agrees that the opioid epidemic is a

multifaceted problem that cannot be solved by one stakeholder. Rather, the solution must be comprehensive and to include, among others, the doctors who write the prescriptions, the pharmacists who fill them, the distributors who deliver the pharmacist's orders, the manufacturers who make and promote the products, the payers who make reimbursement decisions, and the regulators who license the above activities and determine supply.

McKesson has proposed several recommendations to combat the opioid abuse epidemic presented in our March 2017 policy paper and otherwise. But today I will focus our comments on the committee's questions three and four.

Policymakers and other stakeholders have proposed a wide range of policies aimed at curbing abuse and misuse of opioids. Specifically, there has been much attention on giving both prescribers and pharmacists access to patient prescription data, the prescription drug monitoring programs, or PDMPs, so they can assess whether a patient is

at risk.

We support these efforts and we're pleased that the Comprehensive Addiction and Recovery Act, known as CARA, included funding to support state PDMPs. We also know the National Association of Boards of Pharmacy, or NABP, is working towards connections and data sharing efforts between state based PDMPs known as PMP InterConnect to address the problems of accessing patient prescription history across state lines.

Finally, we know that members of Congress have proposed to provide additional funding and to strengthen these monitoring programs, including proposals to facilitate a national database of patient prescription history. As Joel White noted in his testimony, there are limits to current PDMPs including, one, latency of data, two, information that is not within workload processes making it difficult to readily access, and three, the need for solutions that are real time and interoperable.

We strongly support a system like PMP

InterConnect that can break down barriers that currently inhibit interoperable exchange on health data. But it must be implemented on a state-by-state basis and integrated with every provider system such as ES, EHRs, and pharmacy dispensing systems.

We believe more can be done. Technology, industry standards, and connectivity exist today that can harness information near term to help prescribers and pharmacists make the best clinical decisions for their patients.

Another important area of legislative focus is electronic prescribing or e-prescribing which allows prescriptions to be transmitted to pharmacies securely, minimizing the risk of alternative or alteration or diversion and allowing authentication of prescribers before dispensing controlled substances. Federal law permits e-prescribing of controlled substances, or EPCS, in all 50 states, yet only eight states have enacted legislation to require e-prescribing.

A nationwide e-prescribing requirement for

opioids could be a promising solution to facilitate the prescriber's side time, real-time, data-driven solution leveraging the NCPDP script standard. The NCPDP model outlined by Steve Mullenix referred to on this slide as a prescription safety alert system is a solution aimed at establishing alerts to improve clinical treatment decisions by providing better information at the points of care of prescribing and dispensing.

Under the current system, the burden is on prescribers and pharmacists to leave their workstations and check the PMP website. Unsurprisingly, research indicates that prescribers and pharmacists do not always and often infrequently consult the PDMP. As Steve indicated, legally delivering alerts in real time through the very same system that pharmacists use for dispensing and prescribers use to write prescriptions would save considerable time, and most importantly, would increase the likelihood that these healthcare professionals consult their

PDMPs.

The NCPDP model will send an alert to prescribers and pharmacists when patient safety issues are identified. For example, in instances where a patient's prescription history suggests they may be at risk for abuse, the system would notify the pharmacists who could then take additional steps before dispensing, including consulting the State's PDMP, talking with the prescriber, and counseling the patient.

The system would complement PDMPs in two significant ways. 1) By providing real-time alerts to prescribers and pharmacists within their current processes that are based on patient prescription history data that is not limited by boundaries, and promoting more targeted use of PDMP information since prescribers and pharmacists would know when to consult the PDMP rather than having to check it for all patients.

It is possible to implement such an interoperable safety alert system in the near term by leveraging existing workflow. The system would

further facilitate the shared responsibility of prescribers and pharmacists by providing greater visibility.

Pharmacists serve as a critical line of defense for patient safety. Such a prescription safety alert system will further inform clinical decisions, enhance use of PDMPs, facilitate greater coordination of a prescribing clinician, and support patient counseling regarding safe use of their opioid analgesic medication.

It is possible to implement such an intraoperative system in the near term by using existing nationwide infrastructure and communication standards. In order to manage the risks associated with use of drugs or drug classes, the FDA has existing authority to require drug manufacturers to create risk evaluation and mitigation strategies, or REMS.

Given the potential safety risks associated with opioids, the FDA mandated a class-wide REMS for ultimate release and long-acting opioid analgesics now includes the immediate release

opioid formulations as well.

We urge the FDA to employ its existing REMS' authority to ensure full participation by all pharmacies and prescribers in the model solution as described by NCPDP. This can be achieved by the FDA modifying the existing REMS or by creating a new REMS whereby (inaudible) sponsors must comply and provide their opioid products to those who certify and participate in the national prescription safety alert system.

For example, the FDA could require pharmacists to be specially certified to dispense covered products by simply demonstrating they're connected to the safety alert system and by agreeing to make prescription data available to the system.

Thank you for allowing me to share McKesson's perspective regarding real world solutions to address the opioid abuse epidemic. We believe the NCPDP model solution presented today offers a unique, practical, near-term approach to improve prescribing and dispensing practices. We look forward to working with the agency and others to

ensure that all stakeholders who have been impacted by opioid abuse, especially patients and their loved ones, (inaudible) this promising solution. Thank you.

MS. TOIGO: Thank you, Ms. Wygal. Questions from the panel? I have a question. Can you, can you add anything to what Mr. Mullenix said about the risk assessment and, and, and in the, thinking about the patients we heard from this minorities, the model you're proposing, how do you address the concerns that they gave about access to medications?

MS. WYGAL: Yeah. So thank you for the question. A couple of ways to think about that. Number one is this model is focused on informing clinical judgment. So we believe a decision around access and appropriate use for patient resides between the patient, prescriber, and also the dispensing pharmacist who plays a role in that. So we believe that by providing greater information and visibility to the patient's prescription history, it's real time, you know,

across state borders, across payment payer system, and so on, would give the healthcare professionals greater information to make those decisions.

So in this time it's an alert. It's simply pushing that information to the prescriber or the pharmacist where they can again go in and pull data if they wish from a PDMP or other resources, but it does not impede or stop a patient from receiving their medications, especially those that are in need and have chronic pain and so on.

So they can still certainly receive their medication. It's more of a check for when we see some type of aberrant behavior or something going on that causes us to stop and take the time to double check within the PDMP to better understand what's going on with that patient. Given if you do it 100% of the time, it just simply isn't going to happen.

MS. TOIGO: Thank you. Any other questions? Okay. So that -- thank you, Ms. Wygal. That concludes the first session and we've got, made up a few minutes. So we'll take a break and we'll

come back at 10:10 by my, by my clock instead of 10:18. And so anybody who wants to sign up for any of the slots that are available for the open public hearing, now's your time to do it because we need to plan for the two open public hearing sessions and adjust time accordingly. Thank you and we'll see you at 10:10.

(SESSION BREAK)

MS. TOIGO: Okay. This is the last announcement. If anyone wants to sign up for the open public hearing, go to the registration desk and we'll get started with our session, second session. And the first speaker is Mr. Stanley Campbell from EagleForce Associates.

MR. CAMPBELL: Ms. Toigo. (Inaudible) and the rest of the panel, thank you for having us. My name is Stanley Campbell. I'm the CEO and CTO of EagleForce Associates. My testimony today is informed by retired Dr. Capt. MacLeab (ph) from the United States Navy. She is a chief gynocologist and answer doc. (Inaudible) Lt. Jones, Don Morgan (ph) was the (inaudible) for

NATO, and Dr. Senti (ph) Mackly (ph) who was our chief pharmacy officer.

We would ask that the medical society will call for lifesaving drugs that will provide for those people who actually need them in doses and quantities and frequencies as needed. And the (inaudible) the right person at the right time for the right reason.

We'd also like you to imagine a society where layers of regulations do not impede the flow of information, impact quality of life, or hinder productivity (inaudible) legitimate basis (inaudible) heard from this morning, including their representatives and keep them from suffering from undue pain and (inaudible).

We'd also like you to imagine a society where a secure platform could intercept (inaudible) prescriptions, prevent too many pills from entering too many households, that allow the right number to get to the right people at the right time.

Then lastly, we'd ask you to imagine an

objective, interoperable real-time solution that is here and that is real. The technologies that we will talk about today are actually based on those, the premises of the NCPDP dot zero transaction.

They transit and transmit at every point of sale in the pharmacy in the United States and the four territories today. They've been employed on the baselines for the analytics, is, is based on very proven analytics as developed through other means and methods and employ nationally and other government assistance.

These systems as they are based are not new analytics or predictive analytics. We have to consider when Mr. Mullenix talked about the NCPDP standards, as we look at first name and last name, date of birth, PC, and then group plan, the document, the MPI, the doctor provider ID, the medication ID, all those are mandatory fields. This information already exists, is already transmitted, and it is already moved across the enterprise of the national systems.

The issues that we hear are we're trying to solve a nonlinear problem with linear structured data. I'll say that again. We're trying to solve a nonlinear problem with linear structured data only. First name fits in the category well. Last name, David Hurt (ph). PCM, PCM for those, the pharmacy controlling, but which is not in every field because if you're self-insured, that doesn't exist.

But then, however, (inaudible) already transmits across every state because a bank identification number is the same structurally as that (inaudible) control currency. So there's no new rules (inaudible).

Now let's look at quantitatively what happens when you use the implication of the REM. If we took (inaudible) as an example where the doctor has to be certified, the pharmacist has to be certified, and the patient has to be certified, the cost of a REM in that, in that particular sense realistically is about $15 per transaction and all have to go through a single, single REM

adjudicator. So you increase the cost for every same prescription while increasing the time and money.

Now let's look at the issue if you are now doing that. We already heard the statistics associated with the increase in time for the provider, which also doubles over to increasing time to the pharmacist. If that now goes to a REM, that six to seven minutes goes to ten minutes. Ten minutes times the volume of prescription drugs, to include benzoids and, and stimulants, and relaxers, that still does not close the gap between one doctor seeing that information from another doctor.

We've seen this movie before. What you see here is, is a transactional authority that we did with NATO. The 20 nations (inaudible) when, when the only individual independent electronic medical records. We employed the interoperability and information sharing system at NATO in 2014 based on what they call NATA standardization (inaudible) 2714.

So the rules of the road for sharing healthcare data including voice and video already exists and is already an abject of the United States Government who (inaudible) military already certified to secret load comments and already deployed a national war fighter and international war fighter systems.

These are not systems that are independent to the US. They've migrated into it. They've been deployed in every node in Europe. Consider those nodes as a state and consider the fact that they've already been deployed to these United States, and as well to the Pacific. And they've done that, we've done that within the confines of secure and unsecured transactions.

The blue line represents unclassified network. Any one of my devices could actually have an encryption code put on it to be able to migrate, transmit information to any individual, and then move to also include sensors. So we should not be doing a simple system.

Now let's look at the NCPDP standards. As

they move today, this is what you see. In a neural computing system where featured records are assigned, this is how it would look. But we can, we have the ability the solve multiple problems. We can look at PAP or 340(b), a low income subsidy, or for any of those things, including the analysis. And I'll, I'll enter a (inaudible) question that was asked to Mr. Mullenix (inaudible) differently.

Where the rules, the rules of the road for where a PMP structure should go is at the states. You have to have a system that actually in through, informs the state that the person's (inaudible) even if they're in jurisdiction (inaudible) across state lines. This exists and this is existing in every day.

We actually touch every point-of-sale pharmacy and we have all 220,000 medications. We look at the script and look at the call that was referenced. You see the doctor's information, the prescriber's information, the medication, and the pharmacy.

This already exists and it already exists for all 220,000 medications to include the Class 2 and Class 5 opiates. And with that being said, thank you for your time and your attention. The real time nature of this is 20 millisecond turn. It's scaled to 1,200 simultaneousness transaction, and it exists every place in the United States. Thank you.

MS. TOIGO: Thank you, Mr. Campbell. Questions from the panel?

MR. CAMPBELL: With that being said, we thank you and we also remind the board that by the time we're done today, 75 people will be dead and probably 12 veterans will have lost their lives to suicide.

MS. TOIGO: Thank you, Mr. Campbell. Our next speaker is Ms. Alexis LeDantec-Boswell from invisABILITY.

MS. LEDANTEC-BOSWELL: My name is Theresa Alexis LeDantec-Boswell. I'm cofounder of invisABILITY, a nonprofit 501(c)(3) whose mission is to advocate, education, and knowledge share on

behalf of chronic pain patients afflicted with pain and disabilities.

I'm also the program director for the Butterfly Protocol, a closely modulated opioid step-down protocol for chronic disease patients. First I'd like to thank the FDA for a distinguished record as a sentinel over our food and drug health, which is why we question the development of arbitrary prescription guidelines by any other agency when this is a prerogative that clearly falls under the purview of the FDA.

Who am I to question the FDA? I just came from a barn in the middle of kidding newborn goats. Well, I'm a caregiver to a chronic disease patient afflicted with Chiari 1 malformation who has logged over 241,000 hours of intractable, chronic pain. That diagnosis took ten years to acquire.

In December of 2014 she succumbed to serotonin toxicity induced by a polypharmacy regimen of Duragesic, methadone for pain, and diazepam. She stopped breathing three times and no practitioner

recognized serotonin toxicity, not even one practitioner questioned adverse directing her actions. The ER doctor labeled her as a prescription drug abuser. False.

Serotonin toxicity has nothing to do the aberrant drug-addictive behavior. One year after a grueling posterior fossa craniotomy with a full C1 laminectomy, her prescription opioid regimen has created more challenges than her baseline pain. So she approached the lead on her team to support her through an opioid cessation plan.

He abandoned her, dismissing her intentions to achieve opioid independence. No practitioners, pain clinics, treatment centers, or pain management programs in Ohio would treat her, not one. And if Cleveland Clinic is here, you are among those who refused treatment. Why?

Her daily MME exceeded 50 MME daily dose directed by the CDC guidelines which is actually what is being implemented, not 90 MME. Luckily a courageous practitioner and a pharmacist with 37 years experience stepped up to guide her through

four continuous step-downs off of opioid prescription medications.

The entire process took over one year. She was only able to achieve opioid independence by engineering her own prescription opioid stepdown protocol because there are no mainstream guidelines to this effect. Others are not so lucky. Since the publications of the CDC guidelines a vast number of patients have been abandoned and thrust into forced opioid cessation.

Today you've invited us here to discuss further reductions and limitations on prescription opioid administration. Who are we? We are 116 million US American citizens. We are ordinary citizens who have placed their faith in the FDA as the only stewards appointed to be sentinels over the food/drug safety of America, the only sentinels that we the people have agreed to have as sentinels over our prescription health.

Do you know what an average patient goes through on the journey that I've described above? Do you know how many doors we must knock upon, how

many procedures we must try, how many medications we invest our money in hoping to find some semblance of relief? One hundred percent of all prescription opioid patients who adhere strictly to a sustained prescription opioid regimen will succumb 100% to iatrogenic opioid dependence or IOD.

IOD is not equal to ODD. It is not equal to addiction to opioids. Less than two to three percent of prescription opioid patients are afflicted with the pre-existing chronic disease of addiction which precedes stage 1 exposure to any potentiate of the disease of addiction. Meanwhile, opioid withdrawal symptoms provoked by a forced cessation can induce heart failure.

And here we are discussing measures that will further induce practitioners to consider forced tapers in chronic disease patients. The inevitable result of additional restrictions on prescribing will further cripple healthcare infrastructures. Patients who find themselves without chronic disease treatment will resort to

alternative modalities of pain relief, and that includes self-medication and suicide. And this is a quote, a direct quote. That was a direct quote from a practitioner.

What is the role of the FDA in this modern day challenge? First and foremost the FDA must reposition itself as stewards over the prescription health of we the people. When will the FDA publically recognize the temple state of iatrogenic opioid dependence? When will the FDA require labeling on all prescription bottles of opioids as to this very well consequence of exposure to prescription opioids?

Why is iatrogenic opioid dependence not part of the dialogue taking place here today? It affects 100% of prescription opioid patients. Less than 2% become afflicted with the chronic disease of addiction.

Smart interventions executed at stage one is within the, within the purview of the FDA and that includes mandatory labeling for IOD, public awareness campaigns about IOD, CME credits for

practitioners as to the challenges of both iatrogenic opioid dependence and iatrogenic withdrawal syndrome, including, pardon me, among those interventions, the FDA (inaudible) hydrochloride, which is currently under FDA review and is a viable treatment option to address the very real pain of iatrogenic opioid withdrawal syndrome. How can the FDA be effective stewards? That is what --

MS. TOIGO: I know you've got a lot of slides left, so that --

MS. LEDANTEC-BOSWELL: I'm going to cut it right here. How can the FDA be effective stewards? That is what each and every one of you as you as American citizens are here to tell the FDA today because you are the boss of the FDA. Thank you very much for your attention.

MS. TOIGO: Thank you for your comments. Any comments from the panel, questions? Okay. Thank you, Ms. LeDantec-Boswell. Our next speaker is Mr., Mr. Fred Brown.

MR. BROWN: I would like to thank the opioid

Opioid Steering Committee for giving me a few moments to share my thoughts. I'm Fred Brown from Orlando. I'm a member of the Alliance for the Treatment of Intractable Pain, or ATIP, which represents the interest of over 88,000 interested parties as Richard had mentioned.

Would someone please explain to you along with members of the audience who are patients, if I have diabetes, heart disease, or one of many other illnesses, why is there no problem for me being treated by a physician and if necessary obtaining medications? I would live with illness or disease of legitimate, chronic, intractable pain. Why am I looked at by many physicians and pharmacists as someone who is seeking strong opioid medications with, quote "funded," close quote, and thinking I'm an addict?

A copy of the x-rays of the back of (inaudible) that each of you have, the committee, is what has caused me to be the person I am today, which started 20 plus years ago. Before the issues began to occur, I enjoyed work and loved

working. I'm the father of four daughters and have a beautiful wife who is being incredibly, incredibly supportive of me. Life was pretty good. Then my body began to deteriorate.

I've had four cervical and two thoracic surgeries using both anterior and posterior approaches and fusion of the spine. I have been fused from cervical 2 all the way to the thoracic 1, while four of these operations in straightforward language failed. My postoperative pain is far higher than what it was preoperative. It was necessary to have these procedures performed because I was advised by two neurosurgeons if not I would go into paralysis.

During the past nine years I've had four bilateral knee surgeries. Out of the four, three were successful and a full knee replacement has left me with an increase of pain from 21 months postop. Some alternative treatments have been tried to help reduce inflammation and reduce the increased pain.

Am I unusual? Perhaps, but any one of the

problems that I have listed could happen to you, and you, and you, and anyone in the audience. I'm a long-term, chronic pain patient who has tried to live my life to the best of my ability. I was referred to a very highly qualified, board certified, fellowship-trained pain management physician. He has been able to keep me stable with opioids, with other medications, procedures of injections and some other modalities.

I have learned to do the best that I can each day. One day may be better; the next day, not so great. Sixteen years ago I could no longer work and went on disability. With my pain treatment I continue to be in psychotherapy. I have been able to live my life within limitations.

Why opioids and no other type of pain medications? Others have been tried. Believe me, they have been tried. But opioids are effective and continue to work. Yes, like any medicine they can and do have side effects. Remember the benefit versus the risk discussion? The pain patient receives a significant benefit from these

legal, legitimate prescription medications.

I am most certainly above 100 MME dose. What happens if you and other agencies decide not to let me have what is required and necessary? My life is no longer stable. I will not and I will be, not be able to function and have a quality of life such as coming up from Orlando on two airplane trips.

Long term chronic pain patients only receive the benefit of reduction of symptoms from the severe pain we live with each day. In turn this gives the patient the ability to have a quality of life. Every patient who lives in chronic pain must take control of his or her own life. Do you believe that I among the thousands of other legitimate pain patients should not, should not have the right to seek relief if the medications are there to help us?

We are American citizens who are part of society in which we live. Is it not, is it not inhumane for me and thousands of other patients to suffer without the medications that can best help

us?

Most patients live in pain due to no fault of their own. Their lives have been devastated, entirely turned upside down by illness or an accident. What is going to happen to the legitimate pain patient? Federal and state agencies say no, no when these agencies tell your doctor you're no longer able to write for these prescriptions as necessary? Who is going to take the responsibility? Who is going to take the responsibility when the suicide rate increases, the street drugs increase?

Please take into consideration what my comments have been, along with the other speakers today and the many, many letters which you have received to make the right and non, nonpolitical decision and honest decisions necessary for legitimate, chronic pain patients. Thank you.

MS. TOIGO: Thank you, Mr. Brown. Any questions for him? Thank you, Mr. Brown.

MR. BROWN: Thank you.

MS. TOIGO: Our next speaker is Ms. Barbara

Carter for the National Association of State Controlled Substances.

MS. CARTER: And good morning, committee members. I am Barbara Carter. I'm actually the Director of the Minnesota Prescription Monitoring Program, but today I'm here as, but today I'm here as President of the National Association of State Controlled Substances authorities. So I appreciate the opportunity to share with the committee the work that our organization, states, and other stakeholders are executing in partnership to address the opioid crisis.

We commend the FDA and its opioid policy steering committee for holding a hearing to receive stakeholder input on how the FDA might under its authority improve the safe use of opioids by curbing overprescribing to decrease the occurrence of new addictions and limit misuse and abuse of opioids.

NASCSA is a 501(c)(3) nonprofit organization whose members regulate controlled substance prescriptions in all states, commonwealths, and

districts. The majority of our members oversee and operate prescription drug monitoring training programs, PDMPs. We strive on a daily basis to guide the public from the socially and economically devastating consequences of prescription drug misuse, abuse, and diversion.

We know firsthand how critical state PDMPs are to the protection of public health and safety. PDMP members working in conjunction with fellow PDMP officials around the country have created a national network of state PDMPs. Through this national network, state officials collaboratively identify and address problems of common concern and strengthen their PDMPs, responses to needs of local health, as well as safety professionals.

Some of our colleagues may be less familiar with this national network than with other state PDMP efforts. The reason is simple. State PDMP officials are doers and not promoters. They focus their time and attention on enhancing their programs in overcoming the obstacles so they can affect even more operational improvements.

In 2016 NASCSA and their national network of state PDMPs while streaking the marked consistency with the development of a comprehensive model of PDMP act that captures the collective knowledge and experience of state PDMP officials. The model offers congressional and state policymakers the guidance that can only be gleaned from the in-depth, detailed experience of this national network.

Today I would like to address the committee's request for input regarding the consideration of requiring sponsors to create a system that utilizes a nationwide prescription history database to facilitate safe use of opioids. Although PDMPs are separately managed and maintained by each state or jurisdiction, the national network facilitates more uniformity among the states.

Forty-nine states, the District of Columbia, and St. Louis County in Missouri use the same standard for reporting prescription data to the PDMP, requiring the use for American Society for

Automation and Pharmacy, ASAP standards.

Additionally, they collect the same core prescription information from all dispensers within their states. In 2017, 45 PDMPs collect, collected prescription data every 24 hours, some more frequently, and there were three states that were collecting every 72 hours. PDMPs that participate in a national network remain able to react to local and regional needs within their jurisdiction to support resource allocation, evaluate effectiveness of legislation, support unique health and safety concerns, and support policy decision processes.

They also provide an unbiased and timely patient specific information, uncovered substances to prescribers and pharmacists to assist them in making informed treatment and dispensing decisions, and they provide patient specific prescribing data and dispensing information on all those covered substances to regulatory, law enforcement agencies, medical examiners and coroners, and child protection agencies to assist

them in investigating public health and safety.

Currently about 90% of the PDMPs have legislation in place that allows them to send alerts to prescribers and/or pharmacists. I'd also like to point out that 44 states or 44 PDMPs actively are sharing data, accounting for more than 89 million transactions in 2017. These PDMPs are utilizing the PMP Interconnect solution provided by the National Association of Boards of Pharmacy at no cost to the PDMPs.

Additional PDMPs are in the process of executing interoperability memorandums. Currently Minnesota is connected to 37 of those 44 states. So we are actively sharing data across borders. More than 500 healthcare facilities and 2,500 pharmacies in roughly 32 states provide access to PDMPs via their clinical workflow. In 2017 there were more than 280 million transactions via these integrations.

New integrations are occurring monthly, and in addition, eight states, Arizona, Indiana, Kansas, Massachusetts, Michigan, Ohio, Pennsylvania, and

Virginia provide or are in the process of providing integrated PDMP data for every prescriber and pharmacist in their states. PMPs are currently evolving to provide clinical decision support, patient support, patient engagement, and care team coordination.

If indeed integration of access to PDMP data within the electronic clinical workflow is the ultimate desire, then the creation of a parallel system or even an alternate system would become a duplication of efforts and costs. Furthermore, we recommend that the FDA focus on marshalling funding for integration solutions with the expectation that such solutions would plug into existing PDMP systems and not into a new system.

The National Association of State Controlled Substances goes on record as opposing any initiative or program that duplicates or replaces individual state prescription drug monitoring programs. NASCSA continues to support state-based PDMPs, their efforts to share data across borders, integrating access into clinical workflows, and

that they remain the responsible owners of the data from the entities licensed by their state to dispense controlled substances.

Thank you for the opportunity to provide this information on the current status of PDMPs and the position of the NASCSA membership. We are committed to continuing our work to ensure healthcare providers can access reliable PDMP data quickly in order for patients to receive appropriate, informed treatment options. I'd be happy to answer any questions.

MS. TOIGO: Thank you, Ms. Carter. Questions from the panel? I have a question I think and I might have missed it. If, if the eight states you're referring to, are they, were the PDMPs within the workflow? I'm trying to -- I'm listening to the presentations this morning about what's in workflow and not in workflow.

MS. CARTE: Yes, there are eight states that have funding to provide that statewide.

MS. TOIGO: So they have funding to provide or it's already in operation?

MS. CARTER: Actually they are 32 states where there is some form of integration already occurring. Those eight states are committed to, to rolling that out statewide. Minnesota, for example, we have integration efforts with two hospitals across the borders, three hospitals across the borders, and currently two in Minnesota that are working on integration.

MS. TOIGO: Thank you.

MS. CARTER: You're welcome.

MS. TOIGO: Our next speaker is Ms. Danna Droz from the National Association of Board of Pharmacy. I'm sorry. I, my mistake. Our next speaker is Mr. Brad Bauer from Appriss Health.

MR. BAUER: Good morning. My name is Brad Bauer and I'm Senior Vice President with Appriss Health. On behalf of Appriss Health, I want to thank the committee members for the opportunity to appear today to discuss those alternatives and/or additions to prescriber intervention as detailed within §2, items number 3 and 4, within Docket No. FDA-2017-N6502.

We commend the FDA for its renewed interest and prioritization policies designed to help to fight the opioid crisis facing our nation. Additionally, we appreciate the work the Opioid Policy Steering Committee is doing to receive industry comments and how the FDA might improve the safe use of opioid analgesics by curbing, curbing over prescribing to decrease the occurrence of new addictions and limit misuse and abuse of opioid analgesics.

For context, Appriss Health maintains and provides the most, nation's most comprehensive platform for opioid identification prevention and management of substance use disorder with a focus on opioid use disorder. We provide state government agencies with the most advanced repository of controlled substance dispensing data and deliver a real time clinical decision, support, critical insights and interventions to physicians, pharmacists, and care teams to access, assess and manage clinical risks in order to positively impact patient safety and population

health outcomes.

Today Appriss Health provides a platform of software for 42 and 52 established prescription drug monitoring drug programs, also referred to as PDMPs, throughout the United States and US Territories. The national network of PDMPs continues to evolve and innovate in the face of our nation's opioid crisis. While each state faces unique challenges brought on by the opioid crisis, tremendous progress has been made with a few critical areas, each of which has been identified by government and research organizations as important to ensure effective PDMPs.

I want to take a few moments just to highlight a few of these. Interstate data sharing. Today the vast majority of states are sharing millions of PDMPs transactions per month across state borders for a highly effective and mature hub. The ability for states to share PDMP data in a secure manner provides users with a more complete view of a patient's controlled substance

prescription history and enables more accurate assessment in identification of a patient's risk.

In collaboration with the National Association Boards of Pharmacy, NAPB, and Appriss Health built and maintains PMP InterConnect. In 2012, three states participated. Today, 45 states are part of the PMP InterConnect. In 2017, PMP InterConnect facilitated over 180 million transactions between multiple states. Moreover, InterConnect is provided at no cost to states. Policy issues, not technical issues are preventing the remaining states from sharing PDP data.

The PMP InterConnect hub is (inaudible) and secure and can easily support connections to every PMP at no cost. Some policy and regulatory refinement, all states can be sharing data through the national PMP InterConnect hub.

Second is integration of data within workflow. I want to spend a few moments here of the most impactful developments we've seen in the PDMP industry, the states integrating within workflow for prescribers and pharmacists. State PMPs have

made tremendous strides in this front. For the past two years state PDMPs and Appriss Health have collaborated to bring common methodologies to integrate PDMP data and analytics within the prescriber's health record, in a pharmacy dispensation system.

Within the two year period state PDMPs have gone from a very few PDMP integrations to integrating over 288 new patient reports within workflow in 2017. Today, 34 states have approved integration of these data and analytics within clinical workflows. Another 12 states are planning to engage on PDMP integrations in 2018.

Integration represents a major step forward in promoting the efficient use of PDMPs. States recognize positive impact of making PDMP data available within workflow that may continue to make tremendous progress in workflow. PDMP integrations combined with interstate data sharing helps to enable practitioners to identify potential misuse and abuse of opioid analgesics.

This next section I think is of critical

importance as we see the industry and the PDMPs continue to evolve. While interstate data sharing and integration of PDMP data within workflow both are considered industry best practices and have progressed tremendously, there's also been the recognition that to maximize the impact on the opioid crisis, PDMPs much do much more than provide medication history tools. Simply sharing and integrating raw data is not enough.

Big data analytics, additional insights, and more (inaudible) practitioners identifying risk and clinical tools and resources must aid practitioners in intervening to address that risk additionally. So substances play a much larger role in the crisis. The adequate assessment of risk requires information beyond patient prescription history.

PMPs are already moving this direction. They have transformed their basic PDMP systems into substance abuse disorder platforms that deploy the capabilities necessary to impact the epidemic.

Just a few examples. Inclusion of additional

data. PDMPs are increasingly mandating in addition that data sources be included in the database, such as history of nonfatal overdose, drug court information, and toxicology data.

Next, patient risk force. Making them much more intuitive. Patient risk force are designed to predict the likelihood of adverse events based on established thresholds and risk algorithms. Numeric scores can help practitioners engage with their patients in a much more meaningful way not previously possible.

Treatment referrals. We're building to refer patients for treatment within the PDMP and ensure patients do not need to leave a physician's office without a treatment appointment and clear instructions. Also referred to as a warm handoff among states. Guaranteeing coordination. Facilitating the effective communications and care coordination among practitioners and pharmacists as they come (inaudible) healthcare. Messaging among practitioners, assuring of care plans and pain contracts, and the trading of alerts can all

ensure that practitioners are universally aware of patient's substance use disorder risk and can act in a coordinated fashion to address the risk. This is happening today.

In this background of mine I would like to address the committee's request for input regarding consideration of requiring sponsors to create a system that utilizes a nationwide prescription history database to facilitate safe use of opioid analgesics, understanding the overarching goal of helping healthcare providers identify potential misuse and abuse and facilitate safe use of opioid analgesics.

Appriss Health supports state PDMPs in their effort to innovate and evolve based on a state's specific challenges and objectives. Creation of a nationwide prescription database to facilitate the safe use of opioid analgesics represents a duplicative process compared to the basic state PDMP models in a process that lags behind the innovation currently happening among the nation's PMPs today.

Given the complexities of the opioid crisis combined with the existing safety in PMP legislation, statutes and policies, we do not see any immediate or long term benefit from FDA support of a nationwide prescription history database. We encourage the FDA to adopt policy that would support the current state PMP infrastructure with additional funding sources to further the innovation that's currently occurring within PDMPs.

With that, thank you very much for the opportunity. Any questions?

MS. TOIGO: Thank you, Mr. Bauer. Questions from the panel? Rachel Sherman.

DR. SHERMAN: I do. I have one question. So your patient responses. What are your patient risk scores?

MR. BAUER: That a patient risk score --

MS. SHERMAN: In a system?

MR. BAUER: Right, they're, they're embedded in the system which are embedded into workflow for electronic health records and pharmacy

dispensation systems. And there are a series of numeric scores 000 to 999 that represent defined algorithms among states that identify perhaps high risk patients or additional data that's available on controlled substance prescriptions. That can be anywhere from a series of visits to prescribers within a certain timeframe. There can be distance traveled to obtain prescriptions. That could be multiple pharmacy seeing, that could be overlapping drug therapies, etc.

DR. SHERMAN: Does each state have its own risk algorithm and do they each validate their algorithms?

MR. BAUER: Each, each state has their own thresholds that they develop. Not necessarily their own risk scores. The risk score is more of a universal risk score that we employ. But each state does have their own threshold that can be used in alerting prescribers and pharmacies of potential risks such as seeing multiple, multiple prescribers in certain timeframes or could be joint interaction information to (inaudible) the

provider.

DR. SHERMAN: So it is -- maybe I missed it. Is it been described this morning that there would be a push alert that the practitioner could do what they think best (inaudible)?

MR. BAUER: It, yeah, today it operates depending on the protocol used to access whether it's a web portal, they must enter through the right portal. If it's an integration through a pharmacy dispensation system on the EHR, that information is automatic and be available to that clinician directly within the workflow.

MS. TOIGO: I have one other question. On, in a couple places you remain intimate policy issues on technical solutions for preventing things, preventing states implementing certain things. Is that policy issues at a state level or policy issues at the federal level, or can you clarify that?

MR. BAUER: Sure. I sure can. So for those states for example that are not sharing data, it could either be a policy statute or a legislative

issue. Ford is a classic example. They have Senate Bill 8 and House Bill 21 pending which will give them the authority to share data with other states. There are a handful of other states that have similar issues where they need the authority to be able to share and integrate data into workflow.

MS. TOIGO: Thank you very much. Our next speaker then is Ms. Danna Droz. I'm sorry about that mixup there.

MS. DROZ: My name is Danna Droz and I represent the National Associate of Boards of Pharmacy, also known as NABP. I went to thank the FDA and this panel for the opportunity to present this public hearing. NABP (inaudible) for your interest in seeking stakeholder input to explore strategies that address opioid policies at the federal level.

By way of background, prior to coming to work for NABP I worked in several state governments. While in Kentucky and Ohio, I created and operated their PMP for a number of years. So I know what

it takes to create a PMP and how to keep it running, as well as the issues. I'll never say that PMPs are perfect, but we, and we are very open to enhancements and innovation.

NABP is a 501(c)(3) nonprofit association that seeks to protect public health, license state boards of pharmacy and other agencies with programs that benefit consumers of pharmacy services. Since our mission is to support regulators that protect public health, we were approached in 2010 by several of our members who recognize the need for PMPs to share prescription data across state lines.

NABP agreed and worked with state PMP directors across the country to create a system that meets the needs of the states regardless of whether that state PMP is located on the Board of Pharmacy or some other state agency. The InterConnect was created and is maintained using only NABP-funded resources.

PMP InterConnect is a public-private partnership in 20 NABP in the states. We provide

all of the funding to operate, maintain, and enhance the system. The only cost to a state is whatever that state's vender charges to create and maintain the state side of the connection. Each state retains ownership and complete control over its own data. By signing one memorandum of understanding with NABP a state gains access to every other state in our national network.

Our goal is and has always been to have 50 states that are able to share prescription data with 50 states. We started in 2011 with three states. Today we have 45 PMPs that are onboard. Forty-four are states. One is St. Louis County which now has expanded to encompass more than 70% of Missouri's population and over 89% of Missouri's providers. We actually, this changed last week. We actually had 44 that are live. St. Louis County is expected to go live with sharing in February.

Now in the interest of time, don’t pay any attention to the words on this. I should have done something different. Here's what I want you

to get out of this slide.

Number one, prescribers and pharmacists log in into their own state PDMP to utilize the benefits of PMP InterConnect. PMP InterConnect relays encrypted messages from one PDMP to another PDMP. And because the messages are encrypted, NABP holds no protected health information or personally identifiable information.

Last year we relayed 89 million interstate requests and that does not include the direct to the PMP in state requests for information. Last month over 15 million requests and 30 million responses flowed through our system and the volume is increasing every month. We have much more detailed information on our new website, PMPInterConnect.com.

In summary, every state has a functional PDMP whether it is run by the state or by cities and counties. They all collect the same coordinated elements (inaudible) and they all disseminate prescription information to prescribers, pharmacists, law enforcement, and others.

Moreover, most of them have created an alert system to notify providers when their patient meets a threshold of concern. Many also notify, notify law enforcement when they have concerns about criminal activity.

We have created a national network for PDMPs to share prescription data across state lines. It's provided at no cost to the taxpayers, a true public-private partnership for public health. In addition, as you heard from Mr. Bauer, we've collaborated with Appriss Health to provide PMP information to prescribers and pharmacists with one click from within their electronic patient records.

Numerous studies and surveys have confirmed that if it's easy, the providers will use it. Let's leverage the systems that are already built and already functioning to expand the availability of the PMP data to all prescribers and pharmacists. This is Superbowl weekend. We're on the five yard line and it's first and goal. We're almost there. Let's, let's use these systems to

get where everyone wants to go much more quickly and less expensively than building a new system. I'll entertain questions.

MS. TOIGO: Thank you, Ms. Droz. Questions from the panel? Dr. Sherman?

DR. SHERMAN: Thank you for your comments. So I just want to ask a basic question based on the last three presentations. Well, actually two questions. One, if, so these state burdens are not supported by state dollars?

MS. DROZ: Our program is not supported by state dollars. The state PDMPs are supported by state, different state funding, as well as federal grant funding.

DR. SHERMAN: And your support is?

MS. DROZ: Our support is from our own revenue service. We provide services and products to the pharmacy community, pharmacy boards. The most, the example that you can understand easiest is the board exam that all pharmacists have to take to get a license. We, we administer that and there are fees for taking it. So that is one of our

revenue streams.

DR. SHERMAN: So this service --

MS. DROZ: This InterConnect service, we use our own funds to build it, maintain it, and enhance it.

DR. SHERMAN: And if I wrote a prescription in the state of Maryland, would I know or how would I know what state's I was actually able to view?

MS. DROZ: If you go directly to the Maryland PMP and you're putting in your request for a patient, there will be on that screen a list of the states that Maryland communicates with and you can choose any of those. If you are within your EHR and it's integrated with one point access, that is already built in and I think there are multiple mechanisms where you can automatically, maybe either on a board, you might want to check two other states. If, and then you have access to other states maybe through patient vacation or is a snowbird or something like that. So it varies if you're within workflow.

MS. TOIGO: So if I -- and Dr. Sherman's

example, there's not -- I have to choose which states? There's not a way where it searches in all, in the data from all the states?

MS. DROZ: That's a great question and it often comes up. Yes, it could be done, but what happens is that you've got lots of James Smiths with the same date of birth and the patient identity issues. Kentucky actually for a period of time had an option all border states and they had to take it off because they got so many complaints about false positives.

So, so, so commonsense and judicious use of selecting states is the preferred method. When we get a national identifier, if that ever happens, then it's a whole different ballgame. Then it's more like credit cards or insurance companies because you've got a number. Right now there, there is nothing.

DR. SHERMAN: So in that same example, about how long have you surveyed does it take physicians to do the clearing? Do you have data on that?

MS. DROZ: If you go directly to the PDMP, go

to their website, login, two, three, I've heard six minutes. It, it depends on a lot of factors. The report is returned in seconds. So if you're, if it's integrated with one click access, the report is ready there, but the time you open your laptop to that patient record.

MS. TOIGO: One last question. So when you, since you're NABP, you probably get complaints. So what's the biggest complaint with your pharmacists about the system?

MS. DROZ: About our system or about using the, using InterConnect?

MS. TOIGO: Yeah.

MS. DROZ: That every state's not on, not part of our system.

MS. TOIGO: Mr. Michael Warner from Cerner is our next presenter.

MR. WARNER: Thank you, FDA and committee for allowing Cerner to provide public comment on this very important topic, and thank you to the previous presenters as well. These are great opportunities to learn.

For those of you who don't know who Cerner is, Cerner is a provider of health information technology around the world. We're one of the largest suppliers of HIT to hospitals, physician practices, integrated delivery networks, pharmacies. We span the entire care continuum in various venues and specialities dealing with data, needless to say. And we have a long history of figuring out, innovating, and driving the movement of health data.

So we've been in this from the beginning and we continue to push the standards with Medaphors like common well, and care quality, exchanging prescription data through ECPS, and electronic prescribing of union clinical information. We span this and we're extremely passionate about interoperability.

Okay. Let's get to the meat and potatoes. PDMP data and EHR workflow. So I'm the workflow guy. So everybody has talked about getting this data into workflows. So how can this actually help getting the data in an easy, seamless fashion

in front of a physician, not only helps them prevent abuse and over prescribe, but the hidden benefit too is also reducing the physician's risk on that over-prescribing, which means that the physician has availability and a level of confidence on the data that they're seeing. They may be more open to prescribing that opiate when the medical necessity is there.

So they don't have to be afraid of not knowing what the patient's on. They can have a level of confidence in actually the data that they're getting so that they actually can prescribe the medication safely. So I don't want that to go unseen because the awareness in giving that data and the fear of the unknown can be a barrier, which is what we intend to solve for with workflow integration of PDMP data.

Now Cerner's been leading the way with this. Our first client went live with PDMP data inside the physician workflow, maybe the EHR, roughly over two years ago. We've encountered barriers. The first and most notable barrier, that if we

discuss this it's EHR adoption overall. If a provider practice or a hospital doesn't have an EHR, they're not going to have easy access to this data now. Statistics will tell you that EHR adoption has drastically gained, but that is worthwhile calling out.

So today we do have the PMPI. We do have Medaphor; however, there is no national federated clarity. We can't say there's a national federated clarity until all 50 states are onboard. And by federated ability, that means we don't necessarily need a centralized database. As long as we have access to those individual databases we can go get the data that's needed, we can aggregate that data, and then provide it back to the physician.

So a centralized database is not necessarily needed and we have lots of Medaphors within the HIT world, and specifically, Medaphor interoperability to show that federated query is working and gaining adoption. But we can't say -- until we have a 50 state plus District of

Columbia, we can't say we, we have it across.

Economic challenges. So our, our clients, our health networks, our hospital, our physician practices, they're, they're cash-strapped. They had to go back these investments. They've gotten some subsidies in certain states, but any additional cost is burdensome. So that has been a big barrier to adoption.

Obviously the adoption's been greatest in the states that have funded this. Brad mentioned a handful of states that are subsidizing workflow integration and other community data. That's where adoption is the biggest and I'll show you some statistics at the end of the presentation.

Disparity, again, not every state is supportive of this from a policy perspective or they're not on the technology to actually enable this integration. There's no standard today. Cerner asks that we have a standard. If that standard is being asked, Cerner will go develop on that app. So we just need a standard that is consistent across every state that does allow for

the movement of this data.

Cerner has clients in every single state. In fact, we have some very large clients that span multiple states and today the answer, we actually have to say, well, what states do you want to implement this in. And there's several large clients that, that are in kind of those gray dot states and can't get access to this data and can operate in other states. Consistency is what we're asking for.

Another barrier is privacy. We live in a state that does not have a state level PDMP due to privacy concerns. If implemented properly, these privacy concerns can be addressed. We're addressing those and general interoperability. We support this for the purpose of patient treatment. So again, this should be a part of the medical record and there should be information that the provider can consume to make well-informed and conscious decisions.

So Cerner's recommendation. A national approach. We want to have an answer in every, for

every client that Cerner has in the United States across all 50 states. We do like the federated query approach versus a centralized database. We do realize some things may be easier with a centralized database, but a federated query approach solves the job and allows the ownership of the data to remain with the individual states.

Patient privacy, again, we're addressing patient privacy concerns, which is general interoperability. We have several different Medaphors that are working today, search scripts medication industry crosses state boundaries. Common well and car quality, document exchange interoperability crosses state lines as well. So there are Medaphors for solving that.

The economic burden. The more time Cerner has to go develop something new state by state by state, the price goes up and it costs time, energy, and money to support, maintain, and develop answers to the same question in different ways. So we want a single answer that we can use to help solve that economic burden.

So when we do get this data into the clinical user's workflow, specifically a physician-based workflow, here's a sampling of what can happen. Okay? So we have sampling inside of 12 of our connected clients that expand into care, ED, urgent care, 154,000 reports viewed. Okay?

So that may not seem like huge numbers as compared to what PMPI is actually moving data, but again, this is a very limited subset. So there's 100 and almost 55,000 reports we can say that the physician viewed that. Okay? That's when they're actually opening up. We dare say that I don't think any of the websites are getting those kind of numbers in that that data's being viewed.

So this is a win. This can happen in every single state if you solve some of those barriers that I mentioned during the previous slides. Thank you again for your time and consideration. Questions?

MS. TOIGO: Thank you, Mr. Warner. Questions from the panel? Dr. Sherman.

DR. SHERMAN: You mentioned an important

barrier was EHR adoption. Could you say a few words about e-prescribing option? Are they still linked or if one took off, would that help offset data?

MR. WARNER: So EHR adoption has, has gained tremendous, tremendous growth. Obviously (inaudible); however, it's not 100%. We see venues of care like long term postacute care where it's lower. Your traditional hospitals are probably in the upper 90s. Physician practices, small and the providers still, still struggling with adoption.

Electronic controlled substances prescribing is, is still gaining momentum. Even across our Cerner base we don’t have full adoption of those capabilities. However, just standard e-prescribing has tremendous adoption. They're typically included in the EHR packages and we actually see some electronic prescribing adoption outside of the EHRs with some singular type solutions.

MS. TOIGO: Thank you, Mr. Warner. Our next

speaker is Mr. Jerry Cox from IdenTrust Services.

MR. COX: Hi, everybody. My name's Jerry Cox. I'm with IdenTrust. IdenTrust is part of HID Global and we've been involved with EPCS primarily for quite a few years on the prescribing side, as well as on the pharmacy side.

The testimony that I'm going to provide today focuses on really three different information technologies. We've heard from, we've heard about EPCS a little bit. I think, I think (inaudible). We've heard about state PDMPs and linkage with state PDMPs through InterConnect. Great stuff going on there. We've also heard from an HR application provider, one of the leading providers in the company about bringing that data into the EHR so that it can be provided to the doctor in a manner in which they can make better clinical decisions.

So some pretty cool stuff, but how do we link it all up? I'm going to talk about these individually and then kind of summarize at the end with recommendations on linkage.

So first of all, EPCS alone greatly helps with the opioid crisis. It's been mandated in many states now. We've got New York, Maine, Connecticut, Alabama, Virginia, North Carolina where it's been mandated by law. We're shortly, it's already (inaudible) become a mandate shortly. There's legislation in the works in other states to mandate it and this is because it does help with the opioid crisis in many ways.

It helps prevent prescription pad theft, ordinary fraud. People come in, they receive a prescription for their opioids and they come in, my dog ate my prescription. All right. So that kind of stuff. EPCS greatly helps with that type of fraud. It also helps ensure the providers are held accountable.

A lot of times, most of the time I would say the providers are trying to do the right thing like careful observations, but there are providers that will succumb and either overprescribe or fraudulently, fraudulently prescribe, and we need to make providers accountable for having

prescribed these medications.

And certainly prescription information is part of the health record. EPCS in a nutshell provides an electronic foundation that can help all of the other aspects of what we've been hearing about today.

So state PDMPs are sometimes called PMPs. What they generally do is limit the number of abilities or the period for which opioids can be prescribed, which is probably a good thing. Probably help people from getting, keep people from getting addicted in the first place.

Generally they require a provider to check against the state PMP database to make sure that we don't have somebody that's out there shopping or we don't have chronic abusers. All right. So they need to check the database and, and see what's been going on with this patient before they prescribe the opioids. But as we've already heard, there are issues with this approach.

The, the provider in the middle of a patient setting has to stop what they're doing. All

right. So they're in the middle of an electronic healthcare record application - we've just heard from one - and they have to stop, get out of that application, physically log into another database system and check, right, if the precheck hasn't been done.

This isn't a scientific study, but I asked my daughter who's an RN. She's a pediatric ER nurse. She's a charge nurse at a local hospital around here. And I asked her does this happen. It doesn't, right. How many -- I don't need a show of hands, but how many of you have ever been with your doctor and seen them log in to a PMP database to check before they prescribe that opioid?

Okay. Some far two acute care patients, a few pain patients have. But very rarely does that ever happen. So I asked her why and the answer was really simple and kind of surprising. They don't remember the password. So, you know, as much as we want to spend money, they spend trillions, right, on, on this InterConnect and trying to, trying to do all these technical

things, but if we don't make the data easily available to the providers, it's not going to help them with the data that they need in real time when they're seeing patients.

So health IT applications. To me these are the -- this is the magic of where things could really come together because this is the application that the doctor, the provider's using on a day-to-day basis. They're sitting there using this application as they see the patient, right, and this is where they're typically prescribing (inaudible) drugs from.

If they're using that application for EPCS, at the point of that prescription, like if the data could come up automatically from a PMP database or a PMP InterConnect, having heard from three different venders that already offer PMP InterConnect, venders or entities, right, two were nonprofits. We had one vender.

But if within the EHR that data could come up automatically, the provider would have the information they need to know whether that patient

or somebody's out there getting drugs or whether they're an acute pain patient that really needs those drugs. And so enable the providers through the EHRs and having that data there and available.

There are some issues. APIs, we've, we've heard about this from Cerner a little bit. APIs are challenging, right? We don't have consistent APIs into the PMPs. Some can (inaudible). They don't even exist. Right? So the only way to get at the data (inaudible).

We also don't have consistent data structures. So we've heard today from NCPDP, right, and they have a format that's being used consistently for prescription drugs to the tune of billions of transactions, right? So pretty much most of the prescriptions that are handled electronically today already use that format. Why not leverage these, these formats and these standards that have already been developed by nonprofit orgs to tie things together so that the EHRs can gain access to the data PMPs? All these bits and pieces already exist today.

So how do we tie all this together and leverage it? First of all, drive the adoption of EPCS. It's proven. It's already being done by many states. More states are doing it. Why not drive this, right? Could happen. Drive the state PMPs. Do standards or PMI for data structures. There's lots of good examples about how this has already happened. Washington State, I'm sure Cerner and our press can use lots of other good, good examples.

And then drive the InterConnect, right? So phase one, EHR applicators venders need to automate queries into the PMP database at the time of EPCS (inaudible). Really simple. And all of the pieces exist today to make that happen. It just needs to be driven at a federal level.

Phase two, which is a little bit different, is taking data at the time it's prescribed and from the EHR driving it into the PMP systems. Okay. So instead of coming from the pharmacies where the data, there's latency, it may not be a good time, drive data in terms of what has been prescribed

into the PMPs. So the provider has the information not only about what they received, but what they've been prescribing. And then you can start to see patients that are hopping doctors or doctor hopping even before the prescription's been fulfilled.

I appreciate the opportunity to provide testimony. I can answer any questions.

MS. TOIGO: Thank you, Mr. Cox. Any questions?

DR. WOODCOCK: I have a question. What do you think is the actual greatest barrier to having this kind of knowledge available for prescribers and probably (inaudible)?

MR. COX: I think it's cost. It's a money issue. We've talked a little bit about it, but I think it's cost. So the InterConnect already exists. OMC in 2014 gave out 100 grants to drive InterConnect, interoperable grants, and that, it worked. All right. So, but beyond the point of that grant and when the science experiment ended, they were dropped. Right. So it needs to be made

part of meaningful use or some other incentive where it drives people to actually adopt EPCS and adopt that interoperability. Make the checks.

DR. WOODCOCK: Has this case been articulated clearly to policymakers?

MR. COX: I'm trying to do so today.

DR. WOODCOCK: Thank you.

MS. TOIGO: Dr. Sherman.

DR. SHERMAN: If, if this were to come, I'm sure we're going to have to leave the workflow with the EHR, would they still have to leave their workflow to electronically prescribe (inaudible)?

MR. COX: No. So, so that was a key point that I failed to mention, is that the EHRs today because of the state laws have already mandated EPCS, most of the EHRs today already support it in the EHR and the pharmacy applications already receiving it also already supports EPCS. So there is nothing in the way of a federal mandate technically.

DR. SHERMAN: But do, they have to leave their workflow to comply with the (inaudible)?

MR. COX: No, they don't. Right in the workflow they can electronically prescribe controlled drugs today and it's in all 50 states.

MS. TOIGO: So have you looked at the, what's gone on in New York?

MR. COX: I have.

MS. TOIGO: And can you comment at all?

MR. COX: So, so the interesting thing with New York --

MS. TOIGO: Because they're the only one that I have any (inaudible) comment?

MR. COX: Yeah, so what's really interesting with New York is once they put EPCS into place, all the sudden a lot of the fog that they were dealing with in New York, stealing prescription pads, drug, drug rings, all of that type of thing, went away. And what started happening is all the people started going to New Jersey and Connecticut, states surrounding New York.

So now what we're seeing, if you look at (inaudible). Right, those states that are adopting EPCS (inaudible) transactions. But what

you see now is that all of the states around New York are lighting up with legislation because everybody (inaudible). So, so obviously it's working. It's pretty interesting.

MS. TOIGO: So the PDMP model doesn't pick up or that's how they're finding all of the people going to the surrounding states?

MR. COX: What you see are the surrounding states adopting laws to mandate EPCS because the people from New York, all the drugs rings that were in New York are nothing new. It has nothing to do with the PMPs or with that interaction. It's EPCS alone. Thank you.

MS. TOIGO: Okay. Thank you very much, Mr. Cox. Our last presenter is Dr. Robert Heary from the American Association of Neurological Surgeons and the Congress of Neurological Surgeons.

DR. HEARY: Hi. My name is Robert Heary and I'd like to thank the FDA for holding this public hearing. I'm representing a number of groups of organized neurosurgery and I think I'm a pretty typical person for, for my field.

I've been a physician for the past 32 years and during that time in 2001 we had the joint commission telling us that pain was a good vital sign and that it was required of us to speak to patients about their pain each and every time we evaluated a patient.

Now coming almost full circle, we're hearing in FDA public hearings about the possibility of overuse of opioid medications. And it really places many clinicians such as myself and others in the neurosurgery field into a sort of double edged sword because which are we supposed to do? Are we supposed to take pain as a vital sign, which the joint commission have subsequently gone back on that position over the past number of years? However, to some degree we need to be careful to treat pain adequately while at the same time we need to avoid opioid overuse.

And I'd like to give you a few points from our group. So a typical prescription and a number of the different thoughts about the high volume of opioid prescriptions that likely contribute to the

opioid crisis by making the drugs widely available to the public, just various scenarios where people can get, currently can get pain medicine prescriptions with no questions being asked.

It's at this crucial point in the healthcare system where massive amounts of opioid medications enter the public space. It's also at this crucial point in the healthcare system where targeted, careful regulation would likely be the most helpful.

Mandatory safety programs currently used by drug companies to optimize the safe use of other types of medication. Part of the FDA's requirement, I quote, "should not unduly burden patients, healthcare professionals, or the healthcare system" end quote.

Our proposal requires cooperation between prescribers, pharmacies, and the FDA. The prescriber can complete a short standardized form that would accompany all opioid prescriptions. The form represents the medical documentation needed to justify the opioid prescription. This

form is sent along with the opioid prescription to the pharmacy. This mechanism does not unduly burden patients, healthcare professionals, or the healthcare system.

I do recognize we heard in some previous talks there are issues in, for clinicians with respect to things like remembering user ID numbers. I probably have in my own practice approximately 50 combinations of user ID and password combinations and they change every three months for each of them. So it is really a bit of a burden.

The form specifically specifies a patient diagnosis appropriate for the opioid therapy; specifies the indication for opioid therapy in the patient such as acute pain, chronic pain requiring maintenance opioid medication; acute postoperative pain; pain exacerbation requiring opioid dose escalation; and/or palliative care; or cancer pain. This certifies that the patient has failed an appropriate nonoperative therapy prior to the initiation of opioid therapy.

At the pharmacy the data from the form would

be entered into a federal database. I've heard a number of the talks here about PDMPs and I myself work on doing some papers that were evaluating these. A national PDMP would be ideal if it worked well and if, as previous speakers have mentioned, that there, the data were able to be secure, privacy issues being respected, or interlink state PDMPs some form of way across talk between the different states and then the medication is dispensed to the patient.

The advantages are the form would require only a small amount of the prescriber's time. The form would require more deliberate and responsible opioid prescribing. The PDMP cross check is performed by the pharmacy at the point of drug dispensing where access to the federal database is readily available.

Access to PDMP databases is not always available at all points of patient care, such as emergency rooms, walk-in clinics, satellite offices, etc. The form instantly classifies a patient to the appropriate opioid prescribing

scheme limiting denials of needed therapy, new acute pain diagnoses, and dose escalations schemes would be subject to the five to seven day limit. Chronic maintenance opioids, postop pain meds, and palliative opioid therapy would be subject to the 30 day limit consistent with the current state and proposed federal laws.

A single federal PDMP or interlinked state PDPMs would prevent patients from pill shopping across states lines.

The leadership of organized neurosurgery believes that reasonable mechanisms can be created to both curb inappropriate opioid prescribing practices while preserving access to opioids to those patients who would likely benefit from them. We greatly appreciate the opportunity to work with the FDA to optimize opioid prescribing in an effort to curb the opioid crisis in America today while aggressively treating pain.

I'd like to thank you for the opportunity of participating in this survey.

MS. TOIGO: Thank you, Dr. Heary. Questions

from the panel?

DR. WOODCOCK: Yeah, this is I think a bold proposal and I congratulate the neurosurgery community because it's trying to really grapple with this issue. We, we understand and we've heard from pain patients this morning. We fully understand we need to deal with pain, both chronic, acute pain, and chronic pain syndromes, while at the same time curbing inappropriate prescribing. And we do not, you know, it is very difficult to define that in a given patient's case. It has to be a clinical judgment, right?

So are you, so this -- are you assuming this would be integrated into the workflow through some, through the electronic health record in prescribing mechanisms or even prescribed by others?

DR. HEARY: I'm going to anticipate that it would be integrated into workflow; however, I will tell you we've just recently done a survey that's not yet published and a survey of our membership that shows it adds approximately three minutes of

time. And although that doesn't seem like much, if you're seeing a full day of patients, it, it can have an impact to some degree on the workflow and potentially can be a hindrance to workflow to some extent.

DR. WOODCOCK: And I have one other question. So the part about the certification or, or a testation of other methods have been tried and failed, for, say, postsurgical patients, and so we, would you be relying on historical data that, that opioids are an appropriate intervention of that type of surgery, what have you?

DR. HEARY: Yeah, that, that's something that a number of people in our group have also had clarity because some of the -- failing non-opioid is not necessarily appropriate for major, big spinal fusions. It would not be necessary and it would not actually be required or appropriate.

The other thing is some of the lesser medications include things like nonsteroidal anti-inflammatory drugs which are specifically contraindicated in the immediate postop period for

future patients because you want -- in the second phase of fusion is the inflammatory phase. You want inflammation then and to have to go through a nonsteroidal anti-inflammatory would be counterproductive to what you're trying to achieve.

DR. WOODCOCK: Thank you.

MS. TIOGO: Any questions? Thank you very much, Dr. Heary. And so thank you to all of the speakers on the morning panel for their thoughtful presentations. So now we move to the open, for the morning open public hearing session. And we have five speakers and, so they're each going to get three minutes. We'll do the same thing. We'll use the podium. We'll use the same lighting system and you'll, at two minutes your light, the light will go on and I'll let you know that you have another minute, and at the end we'll ask you to, to wrap up.

So our first, just the five people I have are Marissa Schaefer, Lauren Stump, Jack Henningfield, Amy LaHood, and Margaret Wilson. So we'll go in

that order. Hopefully I've gotten all the names right. So Marissa, if you could come up and be our first speaker?

MS. SCHAEFER: Thank you. Thank you. I'm pleased today to provide input on behalf of the pharmaceutical care management association, or PCMA, a national association representing America's prescription benefit managers or PDMs, which administer prescription drug plans for over 266 million Americans.

I will address only some of the questions posed by the FDA today. Other questions will be addressed in PCMA's written comments.

On specific threshold drug amounts above which prescribers will be required to provide documentation of medical necessity, PCMA believes threshold amounts should generally be in concert with the CDC guidelines released in 2016. We support a limit of 7 days and 50 to 90 MMEs for short term, nonchronic, non-oncological pain. We also support evidence-based exceptions to such prescribing guidelines based on variable patient

characteristics.

We would support regular updates of such standards in accordance with appropriate new evidence. An addition REMS approach, specifically those related to PDMPs and whether the FDA should consider requiring sponsors to create a system that utilizes a nationwide prescription history database, PCMA believes a system that could better integrate separate state PDMP data would be helpful in addressing the opioid crisis.

The goal of such a system should be interoperability across all states, operating with as close to real time data as possible, and made accessible to individuals across the supply chain respecting the need for individual patient confidentiality.

We would encourage the examination of suitability of the existing data platforms and possible needed changes before an entirely new one is proposed. We do believe that sponsor could play a role in supporting such a system.

On whether the FDA should require sponsors to

take additional measures to ensure that healthcare providers, patients, and caregivers are educated on safe storage and disposal, and the risk of misuse, abuse, and addiction, PCMA believes sponsors should be required to take such measures.

For example, the warnings of opioids should be made to be just as extensive of those accompanying buprenorphine. Additional warnings should be made in consumer-friendly language and should not allow promotional messages.

Thank you for this opportunity to speak on behalf of PCMA.

MS. TIOGO: Thank you, Marissa. Our next speaker is Lauren Stump.

MS. STUMP: Good morning. I'm Lauren Stump from the American Veterinary Medical Association. The America Veterinary Medical Association represents over 91,000 individual veterinarians engaged in private practice and other veterinary professions. We appreciate the Steering Committee's work to identify potential solutions to the opioid epidemic and the opportunity to

comment. We will be submitting written comments as well.

Veterinarians are greatly concerned that the United States is on the midst of an opioid crisis and want to be a partner in an effective strategy to combat this growing problem. The issues presented by the opioid crisis pose unique challenges for our profession, and our patients, their owners, and our prescribing practices.

Veterinarians prescribe or dispense opioids with very limited uses and do so relatively infrequently. Additionally, pharmacokinetic, and pharmacodynamic differences in species make our dosing practices unique. Regardless, it is critical for certain animals to receive these medications and veterinarians agree that precaution should be taken to avoided unattended consequences.

Concerns about diversion are top of the line for the veterinarian professional even though our patients do not face the same risk for addiction. Veterinarians take thoughtful steps and meticulous

record keeping in control of opioids. They also apply their medical expertise and training to patient care every day, including the multimodal use of pharmaceuticals and other interventions to effectively manage pain.

If the agency pursues a strategy with (inaudible) to specify threshold drug (inaudible) for opioid analgesic prescriptions above which prescribers will be required to provide additional documentation of medical necessity or other strategies regarding opioid prescribing behavior, we would ask that you first consult with the veterinarian community to determine the appropriate level of participation considering our unique scenario.

Further, veterinarians can legally use FDA-approved human drugs under the extra-label drug use provisions in the Animal Medicinal Drug Use Clarification Act. In crafting any regulations the agency most fully preserve veterinary access to these essential drugs.

Purposed solutions to managing the epidemic

must support the ability of veterinarians to appropriately care for patients and it is critically important that veterinarians continue to be able to access, prescribe, and dispense these drugs so that patient care is not compromised.

The AVMA and its member veterinarians look forward to being part of the constructive solution to the opioid crisis that grips US communities. Thank you.

MS. TIOGO: Thank you, Ms. Stump. Dr. Henningfield?

MR. HENNINGFIELD: Good morning. Thank you for the opportunity. This has been a rich hearing already. I'm a Johns Hopkins professor of behavior biology and (inaudible) I consult unsafe opioid medicines and alternatives for treating pain.

We face two problems in opioid prescribing. People who get prescriptions who should not have gotten them, while many people with pain are not appropriately treated. Those hurt most are low

income and ethic minorities and that's the focus of my comments.

The main driver of the opioid endemic is not prescribing and is not low income and ethic minorities. It is the exposure of cheap heroin and fentanyl logs and counterfeit pills that are often counted as prescription opioids in some general surveys.

So my focus is on concerns that some policies are worsening the already serious healthcare disparities that we face for low income persons and minority persons inarticulate. For example, their problems are already (inaudible). Now many will struggle with multiple copays per month due to increases in five and seven day prescribing limitations.

This is a conundrum. It's a conundrum that has to be wrestled with, but it's reality. I'm also concerned the FDA's success in incentivizing a market transformation for the most deadly and addictable analgesics to new safer analgesics is being undermined by the reluctance of third party

payers, including the Veterans Administration, to reimburse for them.

Ironically their argument is they have the most patients who are prescribed do not abuse opioids or convert them. This is a conundrum, but it has to be addressed. If you don't pay for the medicines, you won't get them developed.

Here are a few suggestions. 1) Do not make doctors overly fearful of treating pain. Low income and minority persons will bear the brunt of (inaudible) reducing prescribing (inaudible) report of 2011 reported this. It's gotten worse since then and it's worse now.

2) Encourage third party payers, including the VA, to pay doctors who spend more time with patients and provide more support and oversight. We all know that's needed, but what's happened is we're asking doctors to do more while we're paying them less. That won't work.

The other thing, and I've said this in several hearings, FDA cannot solve America's problem with opioids by itself. It's much bigger than

prescription opioids. And recognizing that all that we're talking about today will be of limited impact in helping those who are already using illicit drugs.

We must demand a healthcare system and budget described to achieve Surgeon General Koop's role of making addiction treatment as accessible as addicting drugs as the often said forgone the people.

Finally I have a simple test. For every recommendation and policy you consider, ask if it will help or hurt low income and minority persons who are already least likely to have their pain appropriately treated. This is an important test of your policy.

Thank you for doing what you're doing and for the opportunity today.

MS. TIOGO: Thank you, Dr. Henningfield. Ms. LaHood?

DR. LAHOOD: Thank you for this opportunity. My name's Amy LaHood and I'm a family doctor from Indianapolis. I started my medical career in

1996, the same year OxyContin was approved. I learned early on from well-intentioned colleagues there was no ceiling dose for opioids and was indoctrinated with indiscriminate (inaudible) as well as directives to optimize age cap scores.

I've had a front row seat to the opioid epidemic. The collective harm from the iatrogenic crisis is mind-numbing. The death toll is staggering, and although the death rate from illicit opioids has now eclipsed that of prescription opioids, it remains in 80% of persons using illicit opioids began their addiction with prescription opioids.

The death are just the tip of the iceberg. The economic cost is astounding and the harm to communities is incalculable. Tragically there is no evidence that widespread opioid use has reduced pain or eased suffering. The crisis has reached a tipping point in many communities. Twenty-four states have adopted bizarre and desperate strategies of passing laws limiting and regulating health providers that prescribe opioids.

The primary responsibility of regulating and protecting the public as it pertains to prescription drugs lies squarely with the FDA. Many physicians like myself have naively made the incorrect assumption that FDA approved drugs were clinically proven at some level to be both safe and effective. Neither of these holds true for long-acting opioids.

The OxyContin FDA label cites a single clinical study of 133 patients that lasted a total of 14 days. The primary outcome was analgesia. Today it's universally accepted that measuring analgesia in isolation is not an acceptable proxy to measure opioid effect. Measurement of social, emotional, vocational, as well as physical function over an extended period of time is essential to evaluate drugs with abuse potential.

As a consumer and clinician, this is absolutely unbelievable. On behalf of all Americans, I believe it's imperative the FDA immediately address the following issues.

Update opioid labels and REMS education to

inform providers. There's no evidence of a benefit when opioids are used long term. Opioids pose a dose-dependent risk of harm and opioids greater than 90 MED should be avoided when treating non-nonterminal chronic pain. Update REMS to include best practices in case studies for diagnosing opioid abuse disorder and weaning opioid-dependent patients.

Update REMS so providers understand there's no benefit of long-acting opioids versus short-acting opioid. Update REMS so providers learn about hyperalgesia. And lastly, change the misleading terminology of abuse determent to tamper deterrent. Thank you.

MS. TIOGO: Thank you, Dr. LaHood. Our last speaker is Margaret Wilson.

MS. WILSON: Thank you for this opportunity to speak. I am advocating today for patients in pain. In all the conversations today, policies and procedures were focused on predominantly. So far only five advocacy speakers for pain and four patients in pain, and 11 for management

procedures. However, all the prescriptions, policies, and procedures are for people, our patients, patients in pain, whether acute or chronic. These people should be the primary focus. They should be the number one stakeholder because is it their lives that are predominately affected.

I have family members and friends in chronic pain. Their pain, their suffering effects not just them, but our families as well. They have all tried multiple treatments for pain and found opiates are very important to manage their symptoms and increase their function. I have watched them suffer in pain and now I watch them suffer in fear.

They fear losing their medications that make life bearable and losing the function that has been hard-won. They fear speaking out, being labeled as addicts. They also have been model patients with no dose increases, taking the minimum that allows them to function. Yet now they suffer from peer prosecution, as well as

pain. Their humanity is impinged as they're treated not even as second class citizens, but as less than, as addicts, people who cannot control themselves and are more interested in self-harm than anything else.

This is devastating to patients suffering from real illnesses trying their best to function and be productive family members, as well as productive citizens. You've heard the many ways the pain harms patients, even kills. Studies support this. Studies also support that patients in pain rarely become addicts, yet these patients are being treated as addicts and abandoned by doctors due to overly-restrictive policies impinging on the doctor-patient relationships and patient care.

I urge you to remember the people, the patients suffering in pain. I implore you to ensure their protection, their quality of life, and their care as you make regulations concerning opiates. People in pain deserve pain management, true pain management as prescribed by their

doctors who know them and their pain best.

Thank you for your time and your compassion towards patients in pain.

MS. TIOGO: Thank you, Ms. Wilson. So that ends our morning session and we're running just about on time. And, so actually we're running a little bit early. So I think we're still going to go, we'll go 'til 12:42, which lunch is scheduled to end at, just so that people coming for the afternoon, we don't want to start, it starting before they arrive in time.

And then it gives people more time for lunch and to get through the, get your food and, and be back in time. So we'll see everybody at 12:22 and thank you for your attendance at the morning session.

(SESSION BREAK)

MS. TOIGO: Okay. Welcome back, everyone. We're ready to start the afternoon session and our first speaker is Dr. Diana Zuckerman from the National Center for Health Research. Up here, Diana.

And just a reminder for people who haven't,

weren't here this morning and are speakers this afternoon, we're using the color system. You'll get eight minutes to talk. At seven minutes yellow will come on. At eight minutes, red. The microphone won't turn off, but I will encourage you to move along. And I, I think that's it.

We're asking everybody to try and be respectful of the time as everybody was this morning. So we appreciate that cooperation. Okay, Dr. Zuckerman.

DR. ZUCKERMAN: Thanks very much for the opportunity to speak today. I'm going to address two of the questions, number five, which was on REMS, and number eight, which is disposal.

So you, of course, all know that REMS is really aimed at educational efforts for providers and the question really is how effective are they and how do you measure how effective they are. So the main measure has been physicians' knowledge and that's obviously important, but how does that actually affect prescribing and other behavior?

And dare we think about looking at the outcome

in terms of what is happening with patients in terms of misuse or deaths. Oops. I didn't mean to do that. Okay.

So these are some data that FDA has presented in the past, so not new to you, but I just wanted to emphasize just a few of the questions that didn't get as much learning as one would have wished.

So for the key risk message number one, which was assessing patients for treatment, the good news is that 68% of those who took the training did learn the message, but that also means that almost a third did not and that was a relatively good response.

For number two, which had to do with initiating, modifying, and discontinuing therapy, this is a real problem clearly with only 17% of them learning that message and 83% not learning it, and that's a key place where problems can occur.

For number five, which was general drug information, again, we have basically two thirds

learning the message and a third not learning it. Two thirds is good, but it's not great and this is only the people who are actually participating.

And then the last question that I'm going to be looking at, number six, which is product-specific information about specific products where just over a third did learn the message and almost two-thirds did not. So clearly there are some issues here where learning isn't always taking place even for those minority of physicians who are participating.

So FDA's prescriber survey also found that since the implementation of the REMS for opioids, 48% say that, no, that it did not change their prescribing habits. Well, what doctors say doesn't necessarily mean what they do, but that's still not a particularly good sign that about half are saying it didn't affect them.

Again, 49% do say that they use the patient counseling document, but that means half don't. And the FDA's own survey found that the majority, the vast majority of physicians don't even know

about the REMS training.

So I want to use this quote from Comm. Gottlieb, which we think is an excellent quote. We don't want to improperly convey a perception that a product that's resistant to manipulation and abuse is somehow also less prone to fuel an addiction because that's simply not true.

And this gets to one of the key educational issues, what does abuse deterrent mean and what do doctors think it means and what do patients and family members think it means.

So we think that information about abuse deterrents and its meaning should be included in the REMS because we know that too often it's misinterpreted to mean it's not as addictive and that the studies show that 46% of physicians misunderstand the meaning of abuse deterrent.

So let's talk about how we can have more accurate labels. They're not happening now. When we -- these are two photographs you can see that in one case these are injection resistant and crush resistant. Why not label them as injection

resistant and crush resistant instead of labeling them as abuse deterrent. Let's call them what they are and make it really clear what they are and also clear what they're not.

Another issue is whether sponsors should be doing the REMS training. Are they providing the best training? Is there another way to provide training? Clearly the better the training is, the fewer prescriptions there will be that creates a conflict of interest.

Alternative pain management therapies also will reduce prescriptions, so does that also create a conflict of interest? And as many of you know, the 2017 Boston Medical Center study found that the FDA blueprint for prescriber education failed to provide prescribers with adequate information.

Now I'll just quickly talk about disposal issues and the question should FDA require sponsors to create a mechanism by which patients could return unused pills, and if so, to whom?

Clear data has shown that unused opioids can

become misused opioids. The JAMA surgery review had six studies showing that between two-thirds and 92% of patients reported that they had unused opioids.

I can tell you I just had surgery a week ago and I've got a whole bottle of unused opioids in my house now. I am happy to say that they prescribed fewer than the last time I had surgery, but still they're there. I never used it. I never opened the bottle and I still have them.

Forty-two to seventy-one percent of opioids obtained by surgical patients went unused, but I fall into that category, and many patients, most patients stopped or used no opioids doing, due to either adequate pain control without them or because of adverse effects.

So you can see from these data that there's a lot of issues with unused opioids. What's going to happen to them? And there are low cost interventions that can work. Not necessarily work real well, but, for example, in a 2018 -- oh, I think that's probably 2017 study, doctors gave

surgery patients an educational brochure WashU and, and it did increase disposal. Now it increased it from 11% to 22%, but that's still an improvement.

CVS now has disposal kiosks. They say that early results are promising. Unfortunately, we have no real data to show how promising. Walmart has a, a packet. Looks good to me. But again, we don't have data showing how good they are, how effective it is. And myoldmeds.com has a nice guide for safe disposal. Again, we have no data. Oops. Sorry.

So we think that sponsors should implement an effective ad campaign and they should show -- I think it's good for them to show they're fighting the epidemic and they can use FDA resources that already exist. And so we would heartily recommend that.

And basically just to finish up, we think that there are possible solutions. Some are better than others, but we need really good data on disposal and we need better data on the REMS

training. Thank you.

MS. TOIGO: Thank you, Dr. Zuckerman. Any questions for Dr. Zuckerman? I, I, I have one. You, you referenced the FDA disposal (inaudible) flush list. Are they good tools or are there -- do you have comments on those?

DR. ZUCKERMAN: Well, I have to say I don't have data to show how good they are. But we do think that you start with what you have and get a better sense of what they are. You know, I know that every person I know that has, whether it's opioids or any other drugs that are unused, people really don't know what to do with them.

It seems kind of overwhelming. You know, do I have, you know, I could mix it with kitty litter, but I don't have a kitty. You know, that kind of thing. So, you know, we have to find easier ways, these kiosks and other things, but, you know, should it be on the flush list? I think that's another question. So I think that for many, for those of us who care about the policies, we want better data.

I think for your average patient, they just want to know what should they do and almost any information that's legitimate would be better than how a lot of them feel right now, which is they're afraid to flush it, they don't think they should throw it away, and it just sits in their medicine cabinets where somebody else can get to it.

MS. TOIGO: Do I dare ask what you're going to do with the ones you have?

DR. ZUCKERMAN: I'm going to go in and talk to the --

MS. TOIGO: Never mind. It's not --

DR. ZUCKERMAN: I'm going to talk to the panel afterwards and ask your advice. Thank you.

MS. TOIGO: Thank you, Dr. Zuckerman. Our next speaker, our next speaker is Mr. Eunan Maguire from Adapt Pharma.

MR. MAGUIRE: Okay. Good afternoon, and thank you for the opportunity to address the meeting. The focus of this presentation is on expanding the proposed prescriber intervention to include offering a naloxone prescription when higher risk

opioid prescriptions are written.

So my name's Eunan Maguire and I work at Adapt Pharma. Our sole focus is on Narcan or naloxone nasal spray. It's an emergency treatment for opioid overdose. I also want to note that we filed a citizens' petition on this topic in 2016, which I understand remains under review at FDA.

Okay, so let me start by emphasizing that prescription opioids remain a major contributor to opioid overdose deaths. Many people who use illicit opioids first misused prescription opioids. So they're an important potential point of intervention.

FDA proposes to require a prescriber intervention above a threshold amount of opioids as a safe use condition under the opioid REMS. We feel the proposed intervention of noting a medical need for such a prescription does not go far enough in mitigating risk.

We strongly urge FDA to expand the scope of that intervention to require clinicians to offer naloxone alongside such high risk opioid

prescriptions. We also suggest opioid labels be updated with these recommendations.

Okay. So we made this recommendation for a few reasons. First of all, we made it because we know that prescription opioids, certain opioid prescriptions are associated with high risk opioid overdose. Secondly, prescribing naloxone when these elevated risks are present is recommended is a risk mitigation strategy by many organizations, including CDC in its guideline for opioid prescribing for chronic pain.

And finally, we recommend this step because pilot studies have demonstrated the beneficial effects of such an intervention both on opioid prescribing as witnessed in the VA and on opioid related harms as demonstrated in the Coffin study.

So these are just some of the organizations that are supportive and recommend naloxone co-prescribing include federal agencies, medical associations and societies, and advocacy groups. These are just a sample of those organizations who are supportive. FDA, for example, in the draft

provision for prescriber education blueprint recommends naloxone prescribing with high risk opioid prescriptions.

So I'm here today because this widespread support has not translated into a meaningful rate of prescribing relative to the high level of high risk opioid prescriptions. While this chart shows that the blue line, which represents naloxone prescriptions, is growing, it also highlights in the gray bars that at the end of 2017 there were just eight naloxone prescriptions for every 1,000 high dose opioid prescriptions.

So the takeaway is that organic adoption is not meeting the public health goal of rapidly expanding naloxone access. The coverage gap is significant and research suggests the slow adoption is attributable to stigma and low awareness.

So we know that encouragement and recommendations alone lead to slow adoption. We're also fortunate to also know what will work. Two states, Virginia and Vermont, in mid 2017

implement a requirement for clinicians to prescribe naloxone alongside high risk opioid prescriptions. The criteria largely mirrored CDC recommendations, but in each case at a higher opioid daily dose threshold. And what happened was stunning.

Within a few months clinicians greatly expanded access, and as this chart shows, the rate of naloxone prescriptions compared to high dose opioid prescriptions in Vermont and Virginia is now like 15 times greater than the national average. So the message here is if you want to rapidly expand naloxone access to those receiving higher risk opioid prescriptions, a requirement rather than request seems highly effective.

In the absence of a universal approach, multiple state legislatures are exploring naloxone co-prescribing, as are payer systems and closed health systems. However, this is leading to an inconsistent set of different legislation, regulations, and rules. And it seems odd that your, your location or your provider would be the

determinant of whether you were offered naloxone prescription with a higher risk opioid prescription.

We believe FDA is the appropriate agency to set the conditions of use of prescription opioids. We strongly support efforts to reduce opioid consumption, but when the benefits of higher opioid doses outweigh the known risks, we urge FDA to require offering naloxone as a risk mitigation step.

We have seen from examples in Virginia and Vermont their requirement would very rapidly meet the public health code of expanded access to naloxone. Such an intervention would not be unduly burdensome as naloxone is now FDA approved in forms appropriate for community use, is readily available in pharmacies, and is covered by insurance at affordable co-pays.

In this final slide we list our specific recommendations, which are consistent with the CDC Opioid Guideline. The FDA is in our view the sole agency with the authority to implement this

sensible step nationwide. We know that time is of the essence in trying to slow the growth and ultimately reverse what is an avoidable human tragedy.

Thank you for your consideration.

MS. TOIGO: Thank you, Dr. Maguire. Any questions from the panel? Okay. Thank you, Dr. Maguire. Our next speaker is Ms. Emily Walden from FED UP!

MS. WALDEN: Good afternoon. I would like to thank the committee for allowing me to participate in this process far from my home in Louisville, Kentucky. It is my sincere wish that you hear my words, that you recognize my voice and demeanor the struggle that is this opioid epidemic. It has cost hundreds of thousands of American families the lives of their loved ones.

I'm Emily Walden, a mother who lost my 21-year-old son, TJ, to the drug Opana in 2012. TJ was an army veteran who loved his country, but was ultimately betrayed by the very mechanisms that were supposed to help him, doctors, pharmacists,

clinicians, and the very government he swore an oath to defend with his life as necessary.

Please know that any anger and frustration directed at this or any other agency pales in comparison to the guilt and pain that I and many, many other loved ones of these victims feel on a daily basis. What could we have done differently?

Surely some government agency has overseen the approval of these drugs and placed the needs of the citizens first and foremost. Surely we have morals and values as a country above any self-interest. I have asked myself these questions over and over again, but the question that I ask every day is how many have to die.

I have reviewed and researched the questions the committee has presented to the public and my concern with the questions is that, as we've heard today, these have already been implemented in many states and many will follow.

I believe the FDA needs to focus on items that can have an immediate impact and correct mistakes that have been made in the past that have led to

this epidemic. The FDA needs to immediately delay any new approvals for opioids. When a new opioid is approved, the pharmaceutical company markets their drug aggressively and prescribing increases. By delaying approvals for a period of time the FDA will be sending the right message of concern for public health.

According to your own mission statement, the FDA is responsible for protecting public health by ensuring the safety of drugs. The FDA should take a hard, common sense look at enriched enrollment. I don't think you could enter an eighth grade science fair using that logic.

Compare the Opana trials from 2003 to the 2006 trial using enriched enrollment and it is very clear there is no way to determine safety. This must be reviewed and changes made to ensure drugs that are approved are safe.

It has been proven in court of law that many pharmaceutical companies deliberately misled doctors, parents, and patients on the addictive nature of these drugs. REMS is nothing more than

a piece of paper to them and completely disregarded when it comes to their marketing.

How is it possible that Purdue Pharma lied to doctors, killing thousands, yet was trusted by the FDA with the approval of OxyContin for children as long as they didn't market to pediatricians? The FDA took their word for it? They suddenly became ethical?

These companies cannot be trusted to educate doctors or have any influence in this process. They are only concerned with the almighty dollar and they have proven that. The FDA should have policies in place that can stop this type of unethical behavior with consequences applied to the bad actor and there are plenty of bad actors that are responsible for this epidemic.

Another aggressive and unethical marketing scam is abuse deterrent formulas. These companies want us to believe that this epidemic exists because of abuse. This is not true. The discussion and efforts towards abuse deterrent formulas is a big form of distraction from the

real problem.

I am asking that the FDA not allow this to be labeled as such, giving false hopes of safety and yet another way to mislead doctors. We cannot continue to bury our heads in misinformation and ignore bad decisions that has created this monster.

The FDA needs to look at the reality of this and act quickly. Stop the use of enriched enrollment, place restrictions on how opioids are marketed, apply proper labeling, and delay your approvals. Please put public safety first. Removing the highest dosages of opioids from the market would also be a great step in the right direction. This is a matter of life and death and it needs to be treated that way.

My son was trained in the military. He learned to scan the area around him for weapons, bombs, armed insurgents, and vehicle IEDs. He could insert a tube in your chest to inflate your collapsed lung and he would pull you out of a burning vehicle without a second thought to his

own safety. It's what soldiers do.

But for all his training, toughness, and mental resiliency he was destroyed by a government he trusted. The very government he was sworn to defend failed to protect me and my son from something they knew was more dangerous than a terrorist attack. My son never stood a chance as he walked into the perfect storm of overprescribed drugs and a broken system that refused to apply necessary precautions.

I am very, very thankful we now have an FDA Commissioner that is concerned and taking action. This is what I've been praying for. We will never get beyond this without the FDA taking an aggressive leadership role to ensure the safety of all of our citizens.

Please address the items that will have the most impact in the shortest amount of time and correct past mistakes. I truly want to stop asking how many have to die.

MS. TOIGO: Thank you for your comments, Ms. Walden. Are there any questions from the panel?

Thank you. Our next speaker is Dr. Patrice Harris from the American Medical Association.

MS. HARRIS: Good afternoon, and thank you for this opportunity to present before you today. I am Dr. Patrice Harris, a psychiatrist from Atlanta and AMA Trustee.

Ending this epidemic absolutely requires physician leadership and all of us working together to reduce opioid related morbidity and mortality and increase access to treatment for substance use disorders and pain management.

The AMA strongly supports the FDA's call for immediate actions to help those with opioid use disorder get medication assisted treatment or MAT. The AMA also commended the recommendations of the President's Opioid Commission, particularly in recognition of the need to eliminate barriers to assessing the full spectrum of multidisciplinary pain treatment options.

In 2014 the AMA create, created an opioid task force which I chair. That task force is compromised of 26 national specialty societies,

state medical societies, the American Osteopathic Association, and the American Dental Association, and the task force allows us to amplify our collective voices and action.

There is a significant alignment, as you can see, with our recommendations between FDA policies and our task force recommendations, including encouraging physicians to use state PDMPs, enhance our education, co-prescribe naloxone, and eliminate stigma. These recommendations guide AMA advocacy and play a role in helping enact naloxone access laws in all 50 states, as well as federal legislation to allow partial fills.

The professions' collective efforts are producing results; although, clearly we have much more work to do. This slide shows a significant increase in queries to state PDMPs from 60 million in 2014 to almost 140 million in 2016, and a decrease in opioid prescriptions from 259 million in 2012 to 215 million or so in 2016.

Other metrics are also improving such as the rapid increase in physicians trained to prescribe

buprenorphine, but we still have a long way to go to close the treatment gap, and I have to say that the lack of access to treatment cannot be overstated. There are nearly 20 states where only 1 in 10 patients can access MAT and that is unacceptable.

As the FDA considers new policies to address this epidemic, it is important to avoid creating new administrative burdens. Statements in the meeting notice about using electronic prescribing integrated into a prescriber's workflow to meet new REMS requirements overstate and overestimate the current capabilities of today's electronic systems.

We are not there yet regarding the point of care health technology and we know that there are many factors that influence EHR usability, and ensuring these factors work in harmony is a challenge. You've heard that earlier today. It is also important to consider that the creation, complication, and then dissemination of computer readable prescribing guidelines and then

integrating them into EHRs and the physicians' workflow can take years and be costly.

Previous upgrades to federal requirements for EHR systems have raised and caused serious concerns about sudden price increases by vendors for upgrades, new features, and add-ons.

Frankly, we do not agree that the assumption that e-prescribing in its current state, I might add, could be used by physicians to document medical necessity. Increased data entry burden would take more time away from patient care and increase physician dissatisfaction with IT tools.

I want to be clear that physicians like electronic prescribing. I do it every day and it really has helped. I always worried about my DEA number floating around on a paper prescription. So electronic prescribing is a good thing, but the combination of PINs and passwords, and you've heard that earlier today, is a burden.

Just a quick story. As a psychiatrist I prescribe a lot of Schedule 2 drugs. I'm in my EHR. I have to then go to the PMP to check that.

Then I have to go back to the EHR, start the prescription. Then go to another system, put in a password, log in, sign in. Then get a text message with a security code, and then write the prescription. And if I'm lucky when I go on to my next patient, I'm not timed out of my EMR. But unfortunately, even if I'm prescribing another Schedule 2 right after that, I have to start that process all over again. Clearly that is not an efficient use of my time and it takes time away from our patients.

The DEA requirements for two-factor authentication are onerous and too limiting and the AMA has urged the DEA to revise these regulations and the President's Opioid Commission agrees.

Quickly turning to the questions raised in the federal register. In terms of what threshold opioid analgesic amount should be and how they should be determined, it is critical that the goal of the new policy is to improve the number of patients whose pain is well controlled and who

experience functional improvement without high doses of opioids for lengthy periods of time.

In other words, our focus cannot be limited to just reducing the supply of opioids. We must also improve care for patients with pain, which means we have to make sure there's access to non-opioid, non-pharmacologic options for pain. Just so it can be stated, the AMA agrees with the CDC that physicians should consider the circumstances and unique needs of each patient when prescribing.

In terms of how to inform physicians of new requirements, first an observation. Increasing documentation requirements has never been an effective means to improve quality of care. Guidance on pain management should be developed by the specialties who manage different conditions and disseminated through medical journals, medical education, GME, and CME. And this slide illustrates a couple of examples of the development and dissemination of clinical guidelines.

And again, clinical guidelines have been

developed by medical specialties for managing back pain and opioid prescribing. More than 300 resources from medical associations and other trusted sources are available on the AMA opioid microsite.

I was pleased to participate in the FDA public hearing on opioids last May and here we learned of many effective education programs that are having good results, good patient outcomes, and we should build upon these innovative programs.

In terms of creating a national PDMP, I will say that others have said there is no need to reinvent the wheel when 43 and I heard 43 states' PDMPs already share information.

Lastly, certainly the AMA supports public health education regarding safe opioid storage and disposal, and that is again one of our recommendations. And I will close there and be happy to take any questions.

MS. TOIGO: Thank you, Dr. Harris. Questions from the panel? Dr. Sherman.

DR. SHERMAN: Thank you for your comments.

How would you suggest we stimulate development of more guidelines? Who, whose responsibility might that be?

DR. HARRIS: I believe that is the specialties that are, as you saw from my slide and actually you heard from my neurosurgery colleagues doing that as we speak. And actually that is not only occurring at the specialty level. That is also occurring at the individual practice level.

I, I'm on the board of trustees as I noted and there is a plastic surgeon on the board who just looked at his own practice, did a survey, and based on what his patients were actually using post-rhinoplasty, he then began to change his own opioid prescribing.

So this work is going on in the macro-level with specialties and the micro-level with practices. And we believe that that's where the work should continue and the guidelines should come from the specialties.

MS. TOIGO: Thank you, Dr. Harris. Our, our next speaker is Dr. Soumi Saha.

DR. SAHA: Good afternoon, and thank you to the FDA for the opportunity to provide comments before the Opioid Policy Steering Committee. My name is Soumi Saha. I'm the Director of Pharmacy Regulatory Affairs with the Academy of Managed Care Pharmacy.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Our over 8,000 members provide medication therapy services for the 270 million Americans covered by a prescription drug plan.

So AMCP commends the FDA for establishing the Steering Committee and for seeking public input to help identify key areas of focus that the FDA can address. AMCP did recently provide detailed comments to the FDA on areas of focus for the Steering Committee, but for the purposes of today's discussion I'll focus on the following three areas. One, REMS. Two, labeling, packaging, storage, and disposal. And third,

additional focus areas where AMCP feels that the FDA can be actively involved in combating the opioid epidemic.

So before I begin answering the questions posed by the FDA specific to today's hearing, I wanted to share a guiding principle that AMCP believes is critical in helping to address the opioid epidemic. And that is focusing on evidence-based strategies before implementing any regulatory or policy changes.

AMCP encourages the FDA to use evidence in furthering policy and regulatory changes that can help manufacturers, help plans and patient advocacy groups combat the abuse of opioids.

In regards to manufacturers, we encourage the FDA to work closely with biopharmaceutical manufacturers during the drug development phase to ensure the FDA's expectations for robust clinical data, including data on public health effects and incorporate it into clinical trial design and post-marketing surveillance.

We also caution the FDA to carefully consider

the unintended consequences of designating any novel opioids as a breakthrough therapy designation or other accelerated approval pathway. Products with such a designation often come to market with limited clinical trial data to truly understand their public health effects and long term impact on addiction or behavioral health.

In regards to health plans, FDA should work closely with managed care organizations to understand current evidence-based benefit designs and best practices for addressing the opioid epidemic, including cost effective methods to increase patient access to medication-assisted therapy.

And in regards to patient advocacy groups, we encourage the FDA to engage with patient advocacy groups via the patient focused drug development framework to better understand the clinical outcomes that patients suffering from both acute and chronic pain are experiencing.

So in regards to REMS programs, it is crucial that REMS are integrated into physician and

pharmacists workflow and allow for meaningful data extraction. Because pharmacists play an important role in the administration of REMS programs, their expertise should be consulted on the design and assessment of the programs.

Consideration should be given to the development of a categorization system similar to drug recalls so pharmacists and other healthcare practitioners clearly understand what actions must be taken for what type of REMS. For example, in the drug recall system it's very clear what is required for a Class I recall versus a Class II recall.

Finally, managed care organizations should be allowed to have comprehensive information on prescription drug records and REMS protocol information to conduct research on effectiveness of health outcomes on opioid-related REMS.

So in regards to labeling, packaging, storage, and disposal, AMCP encourages the FDA to consider updates to the label and packaging of opioids to minimize the risk of abuse and diversion and to

better convey the potential harms associated with opioid therapy. For example, we encourage the FDA to consider short course unit dose packaging similar to the current packaging used for a five day course of Zithromycin or several migraine medications. We encourage the use of these packaging for opioids to limit maximum dosage. For example, to a seven day supply or a dose based upon morphine equivalent doses.

Another benefit of this type of packaging is that black box warnings could be affixed on each unit dose that would be clearly visible to a patient as traditional package inserts are often not included with the dispensed prescription.

A short course unit dose package would also allow the FDA to include information pertaining to the proper storage and disposal of opioids, information on how to identify and seek help for addiction treatment, as well as other pertinent warnings and relevant information regarding the safe use of medications.

AMCP also encourages the FDA to consider

updates to the label for opioids to distinguish between appropriate dose and duration for acute versus long term use of these medications. The FDA should also consider adding minimum effective dose while considering the impact of patient size, weight, metabolic factors, and other variables on dosing.

Finally, the FDA should ensure that labels are dynamic and updated regularly as real world evidence becomes available. So AMCP also encourages the FDA to work collaboratively with the CDC to develop a robust education strategy for prescribers on the CDC guideline for prescribing opioids for chronic pain.

In addition, AMCP encourages the FDA to work collaboratively with managed care organizations who are in a unique position to provide appropriate provider education and quality incentives to healthcare professionals, to ensure compliance with evidenced-based guidelines, and facilitate the use of medications used in the treatment of substance abuse disorders.

We also encourage the FDA to develop training on how to safely store and dispose of opioid medications to minimize the risk of theft, accidental digestion by children, or abuse by family members and friends. These resources and materials should be aligned with the Agency for Healthcare Research and Quality, Health Literacy Universal Precautions.

In regards to additional focus areas, AMCP believes that the key is collaboration and that is collaboration with Congress and other federal agencies to address the opioid epidemic. One, we encourage FDA to work with Congress to align confidentiality of drug and alcohol treatment and prevention records with HIPAA to allow access to information essential for providing comprehensive patient care.

This access would allow healthcare providers and managed care organizations to appropriately care for patients and avoid prescribing, administering, dispensing, or otherwise providing opioids to an individual being treated for

addiction.

Pharmacist's access to such records at the point of sale would also provide an additional opportunity for review, counseling, and intervention.

FDA should also work with states to provide access to prescription drug monitoring programs for managed care organizations. While AMCP has no position on the national database, we do support your interoperability of PDMPs that are integrated into EHRs and dispensing systems. The interoperability issue would also address workflow issues that can act as a barrier to the current use of PMPs.

We also believe that FDA can work with DEA to promote widespread adoption of electronic prescribing of controlled substances, which is grossly underutilized. We also believe that they can work with the office of the national coordinator to enable access to prescribing guidelines within prescriber workflows, and finally also work with SAMHSA to expand the

definition of qualified practitioner under the Controlled Substances Act to include nurse practitioners, physician assistants, and pharmacists.

So in conclusion, AMCP suggests that the Opioid Policy Steering Committee consider the following issues: One, incorporate evidenced based policy and regulatory changes for manufacturers, managed care organizations, and patient advocacy groups. Two, consider updates to packaging and labeling to meet the needs of patients. Three, develop and distribute educational resources for providers and patients. And four, collaborate with other federal and state agencies and Congress to address gaps in current policies.

Again, thank you for the opportunity to be here today and I'm happy to answer any questions that you may have.

MS. TOIGO: Thank you, Dr. Saha. Any questions? Dr. Marks.

MR. MARKS: Can you tell us a, a little bit

more about what you would envision for pharmacists' access to medical records to permit review at the point of sale? We're talking and we've heard earlier today about concerns about changing the patterns of workflow, also about patient confidentiality. This does seem to have potential issues there. Could you just tell us a little more about that?

MS. SAHA: Sure. So currently under Part 2 CFR, records for substance abuse and treatment are protected very differently than they are under HIPAA. And there's a misalignment with those regulations versus what we see in HIPAA. And what we'd like to see happen is for Part 2 CFR to be aligned with HIPAA so that a healthcare provider does have access to those substance abuse records.

The point of sale we recognize might be a, a stretch, but we do think it's important when a dispensing pharmacist sees a prescription for an opioid come through to better understand if that patient does have a history of substance abuse or is currently in treatment for substance abuse

prior to dispensing that drug product so that they can potentially intervene, counsel the patient as necessary, and make recommendations.

MR. MARKS: Is that something that currently happens at all by pharmacists calling providers?

MS. SAHA: They may call the provider, but the provider may also not provide that information depending upon how that patient is being cared for and what laws and regulations prevail.

MR. MARKS: Okay. Thanks very much.

MS. SAHA: Thank you.

DR. WOODCOCK: I have sort of a clarifying question. On your slide on policy and regulatory changes you talked about breakthrough designation as an accelerated approval pathway. That's actually not the case.

MS. SAHA: Mm-hm.

DR. WOODCOCK: So you, are you saying we shouldn't use accelerated approval per se as an approval pathway for opioids?

MS. SAHA: Yeah, and what we're hearing from a lot of managed care organizations is that, you

know, as the breakthrough therapy designation accelerated pathways are being utilized more in the past few years. There have been several situation where drugs are coming to market and approved by the FDA when phase 3 clinical trial data is not publically available and not published on clinicaltrials.gov or drugs are coming to market with only phase 2 trial data available.

So in those situations there are concerns that perhaps the data available is not as robust as it may have been if it were not approved under such a pathway. So they're concerned about the type of data that's available and the robustness of the data and the timing of when that data is available.

DR. WOODCOCK: All right. Well, those are fair concerns, but they've always, that's what we did with HIV drugs, for example. That's always been the case with accelerated approval. So I just feel that you're conflating two different things, accelerated, breakthrough designation and simply designation.

MS. SAHA: Okay. Appreciate that.

MS. TOIGO: Okay. Thank you, Dr. Saha. Our next speaker is Dr. Stephen Stanos from the American Academy of Pain Medicine.

MR. STANOS: Thank you, Steering Committee, and AAPM's happy that we were allowed to present today. I'm going to kind of go through a couple of things in a short amount of time.

I'm the President of the American Academy of Pain Medicine. I'm a board certified pain medicine specialist and a, a physical medicine rehabilitation specialist. I practice in Seattle, Washington. I run a pain system services for a, a large hospital system.

So we're going to in this short time kind of cover about six or seven of the different questions around prescriber documentation, REMS approaches, as well as additional considerations primarily around improving education and public education campaigns.

I think this has been discussed a lot and mentioned by a couple of providers today, or

speakers, about do no harm. I think given the crisis that we're in with regards to the opioid epidemic, also the crisis of not having the ability to treat chronic pain for our patients, and so we can do some good and this is an opportunity for all of us to get better strategies.

I think what's important is that we can't make opioid management synonymous with pain management. Many of our patients, even patients that spoke today are maybe on opioids, but also are on other medications or on other treatments or lack access to those other treatments and we can't forget that.

So in our own state of Washington as a clinician I see patients. Every patient has a different story and understanding that is going to be critical. Focusing just on morphine equivalent we're going to miss some of those real intricacies of patient care that's probably even more important, depression, anxiety, previous psychologic trauma, and other issues around their

care and assessment.

In our own state we've had multiple clinics that have closed. One clinic closed where 8,000 patients were looking for care. It, it created a crisis within our own state and we learned from that. Many of those patients we took over. Some of those patients we reviewed. Some of those patients were doing well and/or fine on the medication that they were on. Other patients need better behavioral health. So we really need to be thinking about that when we're discussing adding other tasks for physicians to do with the hopes of curbing the epidemic.

There's other policies in our state with prescribing opioids for first time scripts that have been beneficial. So we need to understand that other states are already doing things that I think are helping to improve the quality of care and safety for our patients.

At the same time our patients are constantly seeing, especially with the number of hundreds of different lawsuits against pharmaceutical

companies, the messaging about pain management being a rather negative one and we have to be cognizant of that.

So there are different opinions and I think there are different stakeholders, but we can all, I think, work towards a common goal.

With that, there are truths and I think there's mistruths. There's evidence-based medicine. There's bias and I think there's a lot of things that we're talking about today, we need to kind of focus on that left side versus the right side. But there are issues with our patients being stigmatized whether they have a substance abuse problem or they have chronic pain, and we need to be cognizant of that as we develop better programs and better policies.

I just want to just briefly touch upon the Mason Report which I think reflects well on a lot of what was talked today. The second bullet in the report talks about influencing prescribing practices and a lot of that is around taking this time to really improve education about pain

management. Not just opioid overdose, but pain management, behavioral health issues, those things that are really affecting our chronic pain patients in society.

So our physicians are stressed with their electronic medical records and we are initiating pathways for our whole primary care clinic and our system. All of the providers have different backgrounds with regards to the EHR. That in itself is, is trouble for them, and then adding on additional burdens may make it harder for them to prescribe or treat patients with chronic pain.

Also I think it's important to remember in the middle here we show that unfortunately in 2016 the number of deaths related to heroin, or to illicit fentanyl, outpaced heroin and then opioid prescriptions. And as that, unfortunately, continues to rise, we can't forget this issue around treating chronic pain management appropriately.

Our providers are aware of the CDC Guidelines. They're aware of different guidelines within their

state and I think we're seeing an improvement in the management of patients. But again, it's important to remember every patient has a story, every patient needs to be individually assessed.

Dr. Harris showed the slide from the CDC about that clinical decision making needs to be made from the, with the physician and the patient and understanding all those intricacies, and again just concentrating on more of an equivalent may blindside our providers and may not provide the best care for their patients.

This is just a, a breakdown of our own system where were have 35 primary care clinics at Swedish in Seattle and we've developed different pathways for our pain, primary care providers to better treat patients, when to screen patients, when to do (inaudible), when to do opioid risk tool, when to do urine drug monitoring.

So a lot of these systems around the country are doing these things. And so to add more may make our providers who are already somewhat resistant to some of these pathways even more

resistant to treat our patients.

So I just want to go through three different areas. With regards to prescriber documentation, AAPM does not support at this time a REMS threshold drug amount for opioid analgesic prescriptions above which prescribers would be required to provide additional documentations of medical necessity.

Unfortunately, the complexity and variability of physical and psychological characteristics of individual patients makes it impossible and clinically inappropriate to dictate specific dual thresholds and need for further documentation of medical necessity.

For those patients requiring chronic opioid therapy, there remains consistently no evidence to support a threshold level that properly predicts misuse, abuse, or addiction. We do appreciate the high, higher doses are associated with greater misuse and overdose, but no dose is relatively safe. So documentation and justification should be necessary for any dose and it should be

included in the medical record consistent with standards of medical care.

These standards are included in most state laws and outlined by the Federation of State Medical Boards. Other strategies including the CDC and state guidelines recommendate, recommend pill limitations for acute pain prescribing and careful justification including documents documenting improved pain and function, and justifying doses greater than 90 morphine equivalents. So we do have strategies in line.

More documentation for a subject of higher dose patients would not necessarily equate to better care. All doses need to be treated the same. Greater attention should be on proper education of providers and documentation in the medical record explaining the relationship of the risk of that opioid therapy as part of the treatment plan versus the potential benefits for that individual patient.

Also use of arbitrary dose thresholds may contribute to stigmatization of stable patients

requiring these relatively higher doses that benefit from therapy without adverse effects and could lead to the unintended consequences of an approved, of inappropriate screening by governing bodies and pair groups which we're starting to see.

Additionally focusing too narrow on the MED itself may lead to a false sense of security like was mentioned, and again, it ignores those important patient characteristics, depression and anxiety, other traumatic events in their life or other issues that are going to be important with regards to the risk for problems or safety concerns.

In my own hospital our primary care network has about 35 primary care clinics. The average dose of prescriptions is less than 50 morphine equivalents in 90% of the doses. So we like to recommend to all of our providers to treat every dose the same and document the medical necessity in all your notes.

Because of these reasons, again, AAPM does not

support a REMS threshold dose, any need for opioid prescriptions, and requiring that additional documentation of medical necessity.

So I'm going to skip through because the, I think a lot has been mentioned on REMS in the databases for opioid prescribing and -- I'm sorry, for PDMPs, and just make some comments on the third part.

AAPM supports developing public education campaigns targeted around pain management, addiction, and medication safety, and we support the recent updated REMS blueprint submitted in May of 2017, and we're awaiting the final approval for that.

We support the need to improve physician and provider education, not just around opioid management, but even greater need to understand the complexities of assessing and treating pain, acute pain, and cancer pain.

So we want to improve the patient's ability to better be informed about the decisions with their physicians, and all that's going to be important

with greater public education.

One last thing. I know I'm over my time here. REMS education we feel should be mandatory for methadone because of the intricacies and dangers associated with it. And the opioid REMS education should be mandatory for all prescribers, but not linked to DEA registration. And we feel that the state level regulations of providers' qualification is a better avenue to explore.

So with that, I'm sorry for going over, but I want to thank you and AAPM looks forward to collaborating with the FDA, but remembering our goals of advocating for a safe and comprehensive care for our patients and really helping to stem the tide of the opioid epidemic.

MS. TOIGO: Thank you, Dr. Stanos. Questions? Dr. Woodcock.

DR. WOODCOCK: Could you say something about unit abuse packaging?

MR. STANOS: I -- we didn't cover that in our recommendations and we're, we're -- I did want to mention that AAPM has an opioid advisory committee

and we are going to be putting together our formal recommendations. And we are a member of the Opioid Task Force with the AMA and also support what they're saying.

DR. WOODCOCK: Thank you.

MR. STANOS: I'm sorry I didn't comment on those.

MS. TOIGO: Okay. Thank you for your comments, Dr. Stanos. And our next speaker is Dr. Norman Kahn from the Conjoint Committee on Continuing Education.

DR. KAHN: Thank you very much. I'm Norman Kahn. I represent the Conjoint Committee on Continuing Education. This is a national coalition of 27 organizations in medicine, nursing, pharmacy, dentistry, physician assistants, and nurse practitioners.

We've been working since 2011. I got involved early when the FDA was developing the blueprint and have had the privilege of providing the health professional educational role. There's an enforcement role. Obviously, there are groups

like DEA and ONDCP and others that are involved in enforcement. There's a public health role. We've, we've heard about naloxone. We've heard about medication-assisted treatment. We're in -- our role is to provide education to the health professionals in this particular epidemic.

So we've been around now for six years in doing this and we'll be continuing to do this. We work in an interesting collaborative relationship with the FDA and the REMS program companies. Of necessity there are firewalls between these three groups, but nonetheless we have very good communication. But as I said, we have the opportunity to participate in the development of the original blueprint, the FDA's blueprint, and are now the folks that are facilitating the education of health professionals and clinicians in opioid REMS.

We have four work groups that we, that we use. The first one, data collection, we're working very closely with the FDA. Doris Elk (ph) is our main contact at FDA. Outcomes assessment and

evaluation, also working with the FDA. Promotion and marketing, we've been working with, working with the REMS program companies on that. And then educational content I'm going to talk about and methods here in just a moment.

So we've had some successful strategies. There is some very high quality education for health professionals out there. Some things I think you would find interesting. One of them is if you provide this online it's much easier to get to. Now this, these REMS blueprint compliant modules are two to three hours.

So that's, that's a bit of a barrier even there, but if you provide them online they're much easier for people to get to, but so there are a lot more people who takes these programs online, but they don't all finish them. Whereas if you provide them live, an example I'll use is at the annual meeting of the American College of Physicians. There's a course that's offered there and the people who take these programs live pretty much all finish them, but it's a lot harder for

clinicians to get to live programming.

All of our educational programs incorporate the blueprint and to some extent they're tailored to need, but that's the, the, the concept that I'm going to share with you toward the end of my remarks on adaptive learning, which is the direction that we're headed.

So let's talk a little bit about quantity. This data comes from a combination of the Accreditation Council for Continuing Medical Education. So physicians, but also physician assistants are counted there. The American Academy of Physician Assistants has additional data. The American Osteopathic Association, which accredits its own programs for osteopathic physicians. The American Academy of Family Physicians, which accredits its own programs for family physicians.

So we're well over 800 activities now and this slide is already out of date. We're -- I did a program last week at the Alliance for Continuing Education in the Health Professions and added it

all up and there's, there's now 350,000 clinicians. That's physicians, physician assistants, pharmacists, osteopathic physicians.

The one group that we're struggling to get data on are nurses. There are 3.8 million nurses in the United States. They're not all practicing nursing and they're in situations where it's sometimes difficult to figure out who has gotten which education. But it leads to one of the areas that we're very pleased with the direction that the FDA has gone in previously, which is to allow members of practice teams to be counted in opioid REMS education because chronic pain management is not something that's done only by physicians. It's done by teams of practitioners.

There are a number of challenges. One is there are a lot of people who rarely prescribe and therefore don't recognize the education as a priority. In some cases the prescriber is the export, expert and don't sense a need to take the education. A lot of lack of awareness. People, some people just say this is not my problem.

Enforcement is going to solve this problem.

And indeed, and I'll just pause here for a moment, we have seen in the last few years that there are now a decrease in the number of opioid prescriptions. There are now a decrease in the number of deaths from prescription opioids.

You all know what I'm going to say next, which is that the number of deaths from heroin and fentanyl-laced heroin have just escalated, which is something that's a very big challenge for all of us.

Mandatory CE is an interesting issue. It's very tempting. We're an evidenced-based group of educators. It's very tempting to say, you know, we've educated about half the number of clinicians that we would like to. And if you know Rogers Diffusion of Innovation Curve - I should have a slide on that - we've gotten about up to the middle. We've gotten about, the innovators, the early adopters, and the early majority. And now we're struggling to get into the late majority and it would be easy to just say, oh, well, you know,

we took, we've got all the people who self-identified a need and voluntarily took the education, let's just make it mandatory for the rest.

There is no evidence in the published literature that mandatory education increases knowledge or changes behavior in practice. Those studies have simply not been done. So if there's something you would like to do as an FDA, it's probably not your business. But to fund the research on mandatory education, that would be very helpful.

If the goal is to count the number of people who complete the education, then of course we should make it mandatory. If on the other hand the goal is to have people learn and change their behavior in practice, that doesn't happen with mandatory education. That happens with voluntary education. So how are we going to get these people to, to do it?

So I sort of just did this slide just to let you know that there's a lot of mandatory education

out there because governmental agencies, particularly at the state level, feel that they need to do something to protect their public and the only thing they can really do is pass a law or regulation that says you must have certain number of hours of this and that, and there are no evident studies in the literature that show that that works and it's extremely frustrating because it provides a burden.

So what are we going to do? What we are going to do is we're going to move to a new model called adaptive learning. It's actually not a new model. It's been around in elementary education for a long time. But we're going to bring it into health professional education.

Adaptive learning doesn't start with education after which you test people on what they learned. It starts with a test and you're tested on a blueprint, and all the questions in this test will, will relate and come from the FDA blueprint. And some of them will come from state laws that mandate to help the clinicians meet their state

requirements.

So we're going to develop this. What happens when you take an adaptive learning test is you get an immediate needs assessment, your gap analysis identified. Then you get to answer the questions a second time, and if you don't get them right, you get rationales for the reason. You get the education at that point. You also get links to the, to the evidence.

So we feel that this is going to be a very attractive model particularly because we've already got a commitment from the American Board of Medical Specialties that they'll count this for maintenance of certification, whatever the new level of maintenance and certification looks like.

We discussed this with the Center for Medicare and Medicaid Services who think it would be a very good model and would count for an improvement activity under the MITS program. So now we're beginning to align with programming that will be very attractive to clinicians.

So this is the direction that we're going to

go and I'll end by thanking the Food and Drug Administration. FDA is aware of this direction we're going in. You were very supportive of us last summer when we testified. We've been talking with folks this morning about the fact that you committed to helping us count people that we actually do this kind of a model and we'll let you know how well it works.

MS. TOIGO: Thank you, Dr. Kahn. Questions from the panel? Dr. Sherman.

DR. SHERMAN: Approximately how long do, does this typically take someone to work their way through that, or does that depend on how large the gaps are?

MR. KAHN: So two answers for you. The first is the, the program we have right now, which is REMS compliant, is a two to three hour program. You take it first and then you, you take your post test. By the way, what's interesting is we don't do a pre-test because what happened was we discovered from the Boston University folks that when they did a pre-test they had a 41% attrition

before they ever got to their first module. When they eliminated the pre-test they had an 18% attrition. So we don't do pre-tests any more, but we do post-test.

If we do adaptive learning, however, you start with a test. And so now it's not timed. Now it's the amount of time it takes you and if you're like me and I was a rural family physician, I didn't prescribe very much, I may not get the questions right very much. It may take me a little longer. If you're like Dr. Stanos, someone who's a real pain expert, it may not take them that much time at all. But it'll be, it will be tailored in that way because you get your own self-assessment, your own needs assessment.

DR. WOODCOCK: Could I just state this addresses one of the primary objections we've had from clinicians, which is they're all starting at different levels.

DR. KAHN: Right.

DR. WOODCOCK: Yeah.

DR. KAHN: This is one of the reasons it's

good to collaborate with the FDA when you're doing things.

MS. TOIGO: Thank you, Dr. Kahn.

DR. KAHN: Thank you.

MS. TOIGO: Our last speaker for this session is Ms. Sharon Wrona from the American Society for Pain Management Nursing.

MS. WRONA: Good afternoon. I'm Sharon Wrona. I'm a pediatric nurse practitioner as well as a psychic, psychiatric mental health specialist specializing in pediatrics. I'm also the President of the American Society for Pain Management Nursing and I want to thank you for allowing me to share our story of nurses as prescribers and educators.

In lieu of time I'm not going to go over the last 50 years of pain management history; however, we do need to recognize there are pieces and parts to this history that have been helpful, as well as pieces and parts that maybe have led us to the problem we are in the US today.

All healthcare providers need to own this

problem, as well as dentists, licensing and accrediting bodies, governmental agencies, healthcare institutions, insurance companies, and many more. And we as nurses want to be part of the solution.

We need to find a balance. We have millions of people in the US who are suffering from pain every day that are impacting their quality of life. We need to continue to treat our patients with dignity and compassion. We as nurses are experts in helping to find this balance as well.

As many people have talked about, we have less opioids being prescribed in lower doses, but we still have that mental health component that puts our patients at higher risk that we need to make sure we're addressing when we're prescribing those opioids to our patients.

Nurses have helped with addressing the opioid issue and will continue to do so. ASPMN is well ahead of this opioid epidemic by writing position papers, working with the Joint Commission on ensuring we're treating pain appropriately by

doing it in a safe manner.

We have been testifying before states, the FDA, and Congress on what nurses in practice, nurses who are performing research, and nurses who are educators have helped and will continue to help with writing policy, with establishing standards of practice for safe and effective pain management for those who are in pain, as well as working in interdisciplinary work groups on pain management that is effective.

We cannot use an arbitrary dose or arbitrary number of opioids to treat pain even in the acute setting. This cookie cutter type of fashion will lead us to unrelieved pain and overdoses of other substances. Does anyone in this room truly want your family member to experience this type of pain management that might not be effective for their pain?

We have to have rules in place and guidelines. Several states have implemented things and it's made it very problematic for us as prescribers to prescribe an appropriate amount of doses and days

of pain medications for our patients even with acute pain.

These rules can lead to unintentional consequences, require more healthcare costs for prior authorizations, unnecessary ED visits because patients are not going home with pain medications or the appropriate amount, or patients just simply turning to the streets to the dealers who will give them anything they ask for, for money or bartering.

And do you know that opioids on the street are more expensive than other medications such as benzodiazepines and the fatal fentanyl and heroin that our patients are dying from? We have got to stop and we've got to make a change.

Most people in pain management probably know about these guidelines for treating acute pain. But do people outside of the acute pain world actually know these guidelines and other guidelines for treatment of acute pain are in existence? We need to make sure they're aware of these.

Do clinicians ask the right questions? Do they ask about anyone if they have mental health when they're prescribing pain medications in the acute setting? No one takes an opioid to become an addict. No prescriber prescribes an opioid because they want their patients to become addicted. However, if we don't ask the right questions in any setting we could be putting our patients up for a potential misuse and overdose. It is very important that we ask those questions.

Some states are, were fully supporting educating prescribers in the best clinical practice guidelines, but we need to make sure they're correct. Some states are mandating requirements for pain management. Some states are requiring mandatory education for addiction only. What about pain management? What does that really look like? How do we talk to our patients about benefits of risk? How do we find those patients that have risk and get them set up with safety nets to protect them from becoming addicted to our opioids?

Nurses are well prepared to educate and we're happy to help. The risk with leftover opioids is only a source for potential future misuse, is what many people think. However, there are 32 calls a day occurring to US Poison Control Centers related to unintentional opioid ingestion and 60% of these are in kids less than five years of age. We have to get the message out that you have to lock up your meds.

So how many of you in this room have medications including opioids unsecured in your home? If so, you may be an unintentional drug dealer. The cost of a lockbox is at least $15 per lockbox and many of our families struggle paying $15 for a lockbox versus putting food on the table for their family. We have to require lockboxes be free of charge for all opioid prescriptions. And then we need to monitor how patients are using them and if it's effective.

Additional ways that we can help. ASPMN has over 1,200 members and we collaborate daily and we are happy to help collect data, we're happy to see

what guidelines are effective and what guidelines need to be tweaked. Let us help with that.

We've talked a lot about mobility for electronic prescribing and we support that. We have to change insurance coverage. Insurances are denying non-opioid medications as well as other therapies that can be very vital and reduce the need of opioids in many of our patients.

We need to mandate the use of our PDMs. We have to have more awareness of proper drug disposal. People don't know they need to get rid of their meds. And then if we make the restrictions for prescribing so harsh, our families won't get rid of them because they'll be afraid they will not be able to get medications when they truly need them.

The use of unit dose packs could be helpful; however, in some of the data that we found maybe our patients only need three doses or maybe a patient that had wisdom teeth only need three doses versus seven days. So we don't want to overprescribe and leave those opioids out there.

So let's really ask our patients and families the question, how much do they need.

We need to own the problem and we need to be part of the solution. Prescribers need to know how to assess their patients who might be at risk, and education is the key for our patients and families under benefits and risk for securing.

ASPMN has lots of educational materials for providers and we're happy to share those. We are happy as nurses as well because we spend lots of time with our patients and we're happy to give you feedback on how things are working.

Thank you for your time.

MS. TOIGO: Thank you, Ms. Wrona. Questions from the panel? Okay. No questions. So that's the, the end of our first afternoon panel and we're running on time, so we'll take a 15 minute break and we'll be back at 2:20.

(SESSION BREAK.)

MS. TIOGO: Okay. Our first speaker for this afternoon, it's late afternoon session is Mr. Kevin Nicholson from the National Association of

Chain Drug Stores.

MR. NICHOLSON: Thank you. Good afternoon. I'm Kevin Nicholson, Vice President of Public Policy and Regulatory Affairs for the National Association of Chain Drug Stores. First of all, I want to thank the Opioid Policy Steering Committee for the opportunity to address you today to talk about how the FDA can use its current REMS authority to help address the opioid abuse problem.

As a matter of background, NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies. Chains operate over 40,000 pharmacies and NACDS has nearly 100 chain member companies who include regional chains with a minimum of four stores and national companies.

Chains employ nearly three million individuals, including 152,000 pharmacists. They fill over three million prescriptions yearly and help patients use medicines correctly and safely while offering innovative services that include patient healthcare and report-ability.

Last year NACDS announced four new public policy solutions to help address the opioid epidemic. First we are pursuing legislative and regulatory limits to prevent the over-prescribing of pill substances, specifically a seven day limit for addition prescriptions for opioids for acute pain. We're pursuing legislative and regulatory mandates to require the electronic prescribing of all medications include controlled substances.

We are supporting the development of an integrated PDMP to help curb diversion and abuse. And we are working to diminish inappropriate access via safe and effective manufacture-supported disposal options for unwanted opioids and other controlled substances.

This is in addition to other initiatives we support such as increasing access to naloxone for overdose prevention, enhancing education for patients and prescribers and training for prescribers, and facilitating law enforcement efforts to shut down illegitimate internet sellers and rogue pain clinics.

Turning to the specifics of the FDA request for this particular hearing, NACDS supports the development of a REMS that would leverage electronic prescribing of controlled substances and the development of a national prescription drug monitoring program database to promote opioid prescribing practices consistent with the CDC guidelines.

Today my comments will address prescriber documentation, additional REMS approaches, as well as additional considerations such as patient education and the return of unused medications.

NACDS supports a REMS program to establish daily supply prescribing limits based on the CDC opioid prescribing guidelines and leveraging e-prescribing technology to enforce compliance. The development of such a REMS must be implemented effectively and efficiently so that any prescription transmitted to the pharmacy would have been verified to be in compliance with the CDC prescribing guidelines at the point of prescribing.

The REMS should prompt prescribers to provide an ICD-10 code with a prescription. Not only will this serve to document medical necessity, providing this information in a prescription would also help to reduce the back and forth communications between prescribers and pharmacies as this information is required for many insurers to process pharmacy claims for controlled substances.

It is critical that any REMS developed be a shared system REMS so that there is standardization across the program. As is the case with other REMS, manufacturers should delineate the different REMS requirements in accordance with the REMS standards and a structured product labeling or SPL format.

FDA might want to look to the enforcement provisions of other REMS such as i-pledge for, for examples of how to ensure compliance. NACDS recommends the development of a national PDMP solution established under a REMS applicable to all opioids that would leverage e-prescribing

technology.

Data from the national PDMP should come from e-prescribed prescription data, but it would also need to be combined with state PDMP data so that prescribers would be able to tell whether a prescribed drug had, in fact, been picked up by the patient via the sold date reported to states by pharmacies.

Potential concerns regarding proprietary pharmacy data would have to be considered and addressed. Ultimately it would be important for the national PDMP database to be used by healthcare providers to fulfill any state requirements to check the PDMP. FDA should work with SAMHSA and other federal agencies who collect and analyze drug abuse and overdose data to help assess the effectiveness of the REMS.

We believe that FDA should make prescriber education a priority as education will be critical for changing prescribing practices that have helped contribute to the crisis. Additionally, there are opportunities to improve patient

education on the risks and appropriate use of opioid medication.

FDA should move forward to develop the one-document solution which combines and streamlines the different information documents that patients receive into one concise and clear document to help patients better understand the safe and appropriate opioid medication use.

Finally, with respect to the return of unused medication, while we support the concept, we believe that FDA should leave this to the state to enact laws on this issue. Congress has already enacted federal legislation and the drug enforcement administration has finalized rules. We believe that FDA should not regulate in this area as it is already being regulated by the Drug Enforcement Administration.

Again, I want to thank the Opioid Policy Steering Committee for the opportunity to address you today and I'm happy to take your questions.

MS. TIOGO: Thank you, Mr. Nicholson. Questions from the panel? I have one. When you

reference, can you clarify what you mean by priority pharmacy data that would need to be considered?

MR. NICHOLSON: Well, right now pharmacies do have data rights for the information that they maintain in their files and there's been concerns in the past with other systems making sure that, that any, any proprietary information related to the pharmacy isn't, isn't mandated to be provided to a state or federal database.

There would be some recognition that there's proprietary information in the pharmacy databases that need to be objective. It's, yeah, I think it's something we need to flesh out a little bit more.

MS. TIOGO: Okay. I, I just wanted, as we try and think about implementing some type of solution, being aware of the concerns. I was trying to understand which proprietary pharmacy data in all of these interoperability and interconnectabilty and all of that we need to be --

MR. NICHOLSON: So it's a good question. I have to admit I don't have the full answer.

MS. TIOGO: Okay. That's, that's fine.

MR. NICHOLSON: We, we can -- I'll work through that more as we develop our comments for the docket.

MS. TIOGO: Thank you. Okay. Thank you for your comments. Our next speaker is Dr. Leland McClure from Quest Diagnostics.

DR. MCCLURE: Good afternoon to you, Steering Committee. This afternoon we'll be talking about additional REMS approaches, which is supplementing prescription drug monitoring program data with objective actual drug use information.

Quest Diagnostics appreciates the opportunity to discuss an additional strategy that can facilitate prescriber inventions and other risk evaluation and integration strategies concerning opioids.

I'm Dr. Leland McClure, Director with Quest Diagnostics, Corporate Medical Affairs Division, and coupled with the American Board of Forensic

Toxicology. I've spent 37 years in the field of toxicological services and mandatory testing and all subject matter expert for the AMA, SAMHSA, the CDC, and other agencies and groups.

Recent policy issues have focused on limiting the number of pills prescribed and we've seen a decrease in the number of prescriptions actually written and developing or enhancing prescription drug monitoring programs. Efforts to decrease opioid prescription (inaudible) successes that we've seen, but unfortunately 2016 drug overdose deaths are spiraling to an all-time high.

It is clear that while these efforts are worthwhile and provide additional tools to combat opioid abuse, they focused on prescribing patterns and that alone is not enough. Healthcare providers need accurate, objective information to help manage patients who are appropriately prescribed opioids.

In hearing those through this FDA meeting, the committee knows that healthcare providers generally have access to prescription monitoring

program data that includes prescription history and also prescribing patterns.

Today I'm responding to the section entitled additional REMS approaches for information considered (inaudible) the use opioid analgesics and should be considered as part of a long-term strategy for risk evaluation mitigation.

Quest Diagnostics is the nation's leading provider of diagnostic information and we manage the largest database, the PO identified clinical laboratory data, 40 billion tests (inaudible) annually. We partner with the CDC and government who also use our information database to help shape future healthcare policies, population messaging, and also detecting changes in trends at local state and national levels.

Our studies have been published in peer-reviewed medical journals, as well as by the company for public service. The expansive reports cover a wide range of medical commissions, including drug testing that I'm going to talk about a little today. The Quest Diagnostic drug

testing, as an example, has been utilized by the government, employers, and policymakers for more than 29 years.

For the past six years Quest Diagnostics has published an annual prescription drug monitoring report. It's an industry update on more than three million drug tests that are focused on clinicians who prescribe controlled medications and they monitor the patients for compliance.

Today we're going to focus on the utility of this prescription drug monitoring testing as a trusted source of what could be objective information for actual drug use or actual drug nonuse. For healthcare surveillance programs to be effective, it's important to understand not only drug testing, or excuse me, not only prescribing patterns, but also how these patterns relate to actual patient abuse.

Drug use and drug nonuse information provides a unique insight into the breadth and depth of what's going on with the ongoing opioid epidemic. Our 2017 prescription drug monitoring healthcare

report reflects that drug use trends are troubling and they include that more than 50% of the tests are inconsistent with the drugs tested that physicians indicate are prescribed.

Just alone, 36% of those inconsistent drugs or we see that drugs are not prescribed and the patients are using them. We see dangerous combinations of drugs and we also see that across all age groups, genders and health payers' claims, that they're at risk for misuse. Healthcare providers, again, need to be aware of potentially dangerous drug interactions that occur beyond the prescribing level to understand relationship between the drugs prescribed and the combination of drugs actually used.

We performed this study in two classes of drugs that contribute to the rising death rates, opioids and benzodiazepine medications. Both classes can depress breathing and combined use of the drugs can be dangerous and potentially fatal. We believe that our study is to be the first national examination of the concurrent use of

opioids and benzodiazepines compared to the prescribing information.

The *Journal of Addiction Medicine* published their study in November 2017 and overall our study results far exceeded what we saw of previous estimates that combining benzodiazepines and opioids based upon prescribing drug and monitoring databases only. This suggests that prescription monitoring program databases and monitoring programs do not fully reflect the extent to which individuals actually combine these drug classes in the United States.

Key findings of our four gate study data of 231,000 prescription drug monitoring tests from 144,000 patients is that we saw that prescribing information only tests indicated about 11.2% of the patients were concurrently prescribed opioids and benzodiazepine drugs. That compared favorably with a 9.6% concurrent opioid prescribing pattern that was reported by previous authors.

What we did see, though, was when we look at the drug tests compared to prescribing

information, we saw that the test results demonstrated 25.8% of results were positive for concurrent use of opioids and benzodiazepines compared to the 11.2% disclosed by the ordering physician. The use of 25.8% was startling.

While some patients might be appropriately prescribed those opioids and benzodiazepines, our study results of concurrent use of benzodiazepines and opiates is a significant public health warning that's related to the 2016 FDA issuance of box warnings of prescription opioids and benzodiazepines that alerted prescribers to the dangers of concurrent drug use.

Drug testing? Well, it helps to enhance patient safety by alerting providers that a patient may not be taking meds and could be at risk for diversion. It can also augment existing subjective tools like patient history, risk assessment. It can also support the observation of patients self-reported drug abuse as limited validity, and it also helps assist the healthcare provider who is making evidence-based decisions

prior to and throughout the treatment, including whether to use non-opioid or opioid therapies and referral for substance use disorder.

And lastly, it helps to maintain the healthcare provider relationship and it helps destigmatize patients on drug testing.

REMS should be a mechanism to ensure that patient risk for misuse of opioids is thoroughly addressed before a prescription is issued. Factors taken into consideration for REMS include population likely to use the drug, severity of disease, and expected benefit of the drug.

In conclusion, drug testing is a safe, trusted source of objective information that will enhance REMS programs by augmenting state PDMP programs and other databases with what the actual drug use is that the patient is consuming, countering the problem of over testing. All drug testing, by drug safest and everybody understands, all drug testing should be performed in a manner that is risk-relevant and the tests are ordered according to what is medically necessary to manage that

patient.

Quest Diagnostics provides clinically, physically responsible options for what's medically necessary and we appreciate the opportunity to discuss this crucial public health issue. Any questions that you want to add?

MS. TIOGO: Thank you, Dr. McClure. Any questions from the panel? We welcome Dr. White. Our next speaker is Dr. Sidney Schnoll from PinneyAssociates.

DR. SCHNOLL: Good afternoon, and thank you for having this panel. I think it's very important. I'm Sidney Schnoll with PinneyAssociates and I've been working in the field of addiction and pain for close to 50 years. I've worked as a clinician, an educator, researcher, and a health policy consultant and work for PinneyAssociates in disclosure.

One of the things that I've learned over the years and has been talked about today is that no patients are the same. And I look back at this quote from Moses Maimonides, a very famous

physician who said "The physician should not treat the disease, but the patient suffering from it." And what this says is every patient is different.

If you read this definition of pain from the International Association for the Study of Pain, you see that pain is not only a sensor problem, but it's an emotional problem. This is very important because patients have emotions secondary to the pain they have, and emotions influence the intensity of the pain they have. Also, it's associated with potential or actual tissue damage.

So this is a very complex phenomenon and there are different types of pain. All of this supports, leads us up to wondering why we set specific doses for the treatment of pain when we're dealing with this very difficult, complex phenomenon.

It is not a unified event and we don't set limits that dosage the treatment for diabetes or hypertension, but we come up with numbers for the treatment of pain and those numbers are frequently associated with something like you score a six or

a five or an eight on a pain scale and yet we know that my five and your five are not the same amount of pain and we can't equate them.

A change in my score influences something, but my change may not be the same as somebody else's. We've heard today already that one size does not fit all.

Complying with guidelines is very time intensive. We've also heard that and we haven't heard much mention of insurance companies, but they influence what is done in healthcare today. They influence it more than almost anything else.

And so when we set limits, that's a real problem. Insurers we know use these limits. They use these limits to reduce their costs, and as we heard earlier today from Dr. Henningfield with whom I work, this can increase cost to patients. So they may require more trips to the physician, more copays. Patients would come back to me and they'd say, you know, you prescribed a week's worth of medication and I paid the same copay for that that I pay for a month's supply of

medication.

It just makes sense. People want more for their money. But yet this is what the insurance companies are doing. On the other hand, pharmacies may not carry certain medications and this is particularly true in neighborhoods with a lot of minorities.

So I think when we look at this, insurance companies are a very important part of this problem that we're addressing. Packaging mandates like unit dose, we've already heard some people recommending them, but they can be a problem. What's the right dose? What's the right size of the package?

If you have arthritis, you have difficulty opening that package. I can remember myself. I don’t have it and trying to squeeze a pill out of one of these unit dose packages, it flew across the room. These are things that we need to be very careful about.

Does the REMS make sense? REMS are attempted to improve patient care. They should not inhibit

prescriber decisions about the care of that patient. And we know that payers use this and use it not to provide better patient care, but to reduce their costs.

So adding guidelines, unfortunately as we've heard today, many cases become policy and now we know that in many states these policies are becoming laws regarding prescribing. This does not allow the clinician to treat the patient. This is really problematic.

We're heard a lot about prescription data monitoring programs. I'm not going to go into that, but there are a lot of data there and I don't think we're adequately utilizing it, the data that are available in these, in these programs.

Now prescriber package inserts, have you ever tried to really read those? They're two or three point type. You need a magnifying glass. We need to separate out important facts to the clinicians and put them in bolder type where they can be easily seen. We've done that to some extent with

medication guides where for the early REMS opioids, we created a one page medication guide.

But I think it's very important when we do these things to test for literacy. Test for comprehension. Even doing that with healthcare providers. They don't all have English as their native language and they have problems and we've seen that in certain tests we've done. We may need to use icons to help people understand what's going on.

And as I've said, don't let the insurers use the REMS to limit care. And one of the important things, or two important things that I think FDA could really do, is really foster the development of less reenforcing pain relievers. Abuse deterrent formulations, we've heard have problems. They are an incremental step, but they're not the full answer.

Looking at the development of less reenforcing pain relievers, important, and we also have to do that for treatments for substance use disorders. That's a real problem.

And the FDA should not try to address areas that they can't affect. It's only going to result in failure.

So one of the things I think might be development of a new pain lab. Starting with non-opioid products and moving let's say to Schedule 4 products, Schedule 3, and then to Schedule 2. Some insurance companies now require failure of a Schedule 2 product in order to use a Schedule 3 or Schedule 4 product. It's a cost factor. It's not healthcare.

So in conclusion, I'd like you to remember Moses Maimonides, a very famous physician who said treat the patient, not the disease from which the patient suffers. Thank you.

MS. TIOGO: Thank you, Dr. Schnoll. Any questions from the panel? Okay.

DR. SCHNOLL: Thank you.

MS. TIOGO: Our next speaker is Mr. Garry Brydges from the American Association of Nurse Anesthetists.

MR. BRYDGES: Good afternoon. I'd like to

thank the committee for the opportunity to be able to speak to you today. Again, my name's Garry Brydges. I am the chief nurse anesthetist at the University of Texas MD Anderson Cancer Center in Houston, Texas, as well as the current President of the American Association of Nurse Anesthetists representing over 52,000 nurse anesthetists across the country.

Since we've heard so much today already about many of the things that I was actually going to talk about, I'm just going to sort of truncate this a little bit. You know, we deliver, nurse anesthetists over 43 million anesthetics across the country on an annual basis and certainly myself as an anesthesia provider, educator, and administrator, and in my environment, truly passionate about the solutions to try to address the opioid crisis because it has affected me on a personal level because I've lost family members to opioid addiction.

So the one that I will actually sort of by use of an example, is address the PDMP and how

important that is. Certainly heard today where the upfront cost is a concern, being able to try to implement this amongst other little barriers. I urge the committee to sort of reapproach with a thinking towards pain management as not looking at it from a single modal use as far as opioids.

And certainly the anesthesia in the perioperative continuum in our practice we've implemented opioid sparing with the goal of trying to be opioid free in our practice at MD Cancer over ten years ago and we've had tremendous success with a lot of the strategies that we've now been able to curtail a lot of opioid use in our practice, and that is moving away from the union dimensional or single modal approach to a multimodal opioid spread approach.

Just to kind of give you sort of an upfront cost prescriptive, when we used traditional anesthetic or preoperative techniques, that incorporated fentanyl. And as you all know, fentanyl is 100 times more potent than morphine. We typically in our practice historically used a

lot of sufentanil, which would be a thousand times more potent or you hear a lot of the street now is carfentieyl, is one of those agents.

That has tremendous impact postoperatively with a lot of postoperative comorbidities that we would ensure by using very potent opioids to no benefit of the patient. It delays discharge. You see certain site infections increase because of it.

We moved towards a multimodal approach which was to eliminate opioids, and here's the key, is, is if we have to rescue the patient for pain management, then you consider opioid use. But we use a whole strategic approach throughout the pain pathway to be able to hit ever one of those receptors that is an alternative to opioid use.

And certainly when we look at costs to try to translate, upfront cost is not what we should be looking at. Traditional approaches in anesthetic utilizing opioids cost about $300 on average. Multimodal approaches certainly are a little bit more expensive upfront, about 1,400, $1,450

dollars to implement one of those opioid sparing strategies. It's the back end that we need to consider, the outcomes we need to consider.

When we looked at comorbidity complications related to opioids, we found in our practice it was sixfold increase by comparison to opioid-sparing techniques or opioid-free techniques. When you look at that, every 100 patients were spending an extra million dollars on managing comorbidities postoperatively with opioid use. We will, may be able to cut that literally by a sixfold decrease by using multimodal strategies.

Give you an example of a patient I took care of. A year ago this past Christmas, comes in for a pelvic exenteration, a coloresection, colostomy, etc. Typically for these type of tumor debulkings and stuff is about a six to eight. In some cases, for this gentleman it was a 12 hour procedure. Zero opioids were used for that entire case, as well as postoperatively. We used regional techniques to be able to hit various elements of pain pathway.

When that patient woke up, he was clear-headed postop, immediately postoperative. Moved himself to the bed. Within two-and-a-half hours was actually sitting up in a chair taking in clear liquid fluids. Postop day one in the morning was already consuming solid foods. You don't see this with opioid use in the perioperative continuum.

Day one postoperatively was already doing eight laps around the nursing unit, still no pain requirements for rescue with opioid use. Postop day two, and then postop day three discharged him. Still zero requirements for opiates. Yet we did send him, not with the usual prescriptions with opiates that you would send people home with, but if he need to be rescued, then we would give him (inaudible) and then obviously aggressive follow-up for these patients.

So I urge the committee to sort of, we need to reapproach the thinking and methodologies when we're looking at pain management. Certainly this is a segment of healthcare delivery. I mean we recognize that every one single patient is

different. And certainly with our approaches we make sure that the patient is at the center. So we build a team around the patient. And interdisciplinary collaboration is critical in order to reap the successes.

So with that I'm not going to go through a lot what was already repeated today, but in conclusion, I do want to say with nurse anesthetists across the United States, these are sort of the approaches we've really been pushing our membership to look at and reduce opiate use within the practice, as well as that collaboration with the surgeon or the anesthesia care teams to make sure when we send those patients home, that they are, if not opioid free, that we've minimized the integration of opioids into the community.

So with that I want to say thank you again for the opportunity to speak today. Questions.

MS. TIOGO: Thank you, Mr. Brydges. Questions from the panel? I have one. So when you speak of your members, the nurses.

MR. BRYDGES: Yes.

MS. TIOGO: What kind of barriers are there to replicating --

MR. BRYDGES: Yeah. That's a million dollar question across the country. So the biggest barriers is people want to implement this en masse production and one of the recommendations is you pick sort of champions where you build a team around that patient. And so once you get people onboard and you get one service line that starts pushing that up, your colleagues that are not implementing these strategies will see the outcomes.

And in fact I'll tell you in our facility we started with head and neck surgeons and one specific surgeon champion. Within about two weeks when they were on call they were seeing, this particular surgeon's patients went home three to four days earlier then their patient population. Then they started asking what was going on? How are you doing this?

And so it's, you know, it's got to start somewhere. But it's, it can (inaudible). The

database which is critical for us to be able to hone our care, I get patients that come from all over the country. I can't login to some national database to tweak their care to know do I need to rescue or be cognizant of rescuing this patient, or do I need to make that or tailor that approach to the individual patient.

And this database is extremely, extremely important to make sure that we get it in our hands as far as clinicians to tailor it to the patients' needs.

MS. TIOGO: Our next speaker is Dr. Randall Lewis from MediMergent, MediMergent.

DR. LEWIS: Good afternoon. My name is Randy Lewis and I'm an orthopedic surgeon. I'm a constant for MediMergent (inaudible).

For the past few weeks due to narcotic addiction, almost 60,000 vets per year in the United States begins with a legitimate medical prescription in about half the cases. Despite their inherent dangers and the speaker that we just heard, opioids are a generally necessary

component of anesthesia pain management and will continue to be employed in most cases (inaudible).

Many of the solutions proposed to control, most of the solutions purposed to control medically-initiated opioids are simply to limit the quality, the quantity of pills that a physician's allowed to prescribe. For this one. Okay. Back this way.

However, as Comm. Gottlieb has pointed out, control of all parts of the supply chain, not just one, are really necessary for success. Specialists and primary care physicians, pharmacies, distributors, manufacturers, and the patients themselves must all buy-in for any such program to be effective.

Is this an achievable goal? A successful program of this type already exists. Under a research cooperation agreement with the FDA, MediMergent developed a national medical safety outcomes and adherence program abbreviated as NMSO, which was a three year post-market surveillance program for novel oral anticoagulants

that involved about 10,000 patients.

This innovative program collected, integrated, analyzed, customized patient-reported outcomes, medical record information, pharmacy data, and claims information, and provided real world data about the drug effects and the patient's healthcare experience. Because of the success of this program, an agreement with the FDA has now been renewed for another five years. And MediMergent has now adapted the NMSO program to address the opioid crisis.

Everyone agrees that more education is necessary for physicians and we say for patients of requiring doctors to obtain permission every time they prescribe more than a small number of pills is both demanding and impractical. Who will they contact? How much time will it take? What sort of professional will determine if the quantity prescribed is permissible for the physician? How is such a requirement (inaudible) for effective professional workflow?

Guidelines for opioid prescriptions are needed

and compliance can and should be monitored. Physicians should know, attest to knowing those guidelines before writing an opioid prescription. If the pattern of prescriptions with relative refill frequency, number of pills distributed, other things regularly exceeds those guidelines, the prescribing physician should be contacted and further education provided. And in most cases, that should remedy the situation.

If the problem persists, regulatory authorities can then be informed. As an attractive benefit of such an approach to physicians is an independent, outside monitored record of their prescriptions and it can be provided to the physician to assist if there is any question of a performance audit or investigation.

This slide reminds us of the program of compliance that was articulated by Ronald Reagan. Trust, but verify. Prior to receiving a prescription for pain control, patients receive, patients receive basic education about opioids and

must attest that they understand it. The patient signs in this program a HIPAA waiver. Information from the medical record is also collected and a predictive risk profile created assessing the likelihood if the patient might develop dependence or addiction to opioids.

This information is shared with the prescribing physician and the pharmacy and all the opioid prescriptions are monitored. The patient is informed regularly electronically if his or her opioid intake is consistent with the guidelines. This reassures the patient that the opioid intake is not a problem and it also gives early warning if a potential problem exists.

Concerns are also committed to the patient's support system, which are identified at the time the patient enters the program. Patient involvement and the use of this real world evidence are really central to the program.

Equally important in the program is the participation of the pharmacies. Pharmacists obtain some information and gets feedback from the

patients, monitors the opioid prescription and refills. Pharmacy records are reported centrally and shared with prescribers. As the patient has signed the HIPAA waiver, the primary physician, the primary physician, not necessarily the prescribing physician, is informed electronically that the patient is receiving opioids and is encouraged not to write a duplicate prescription.

If the physician does write an opioid prescription, he or she is requested to inform, and if so, which will also inform the prescribing doctor.

Orthopedic studies show that 50% of patients who continue to take narcotics long after orthopedic surgery received the prescriptions from the primary physicians and not from the surgeons. So I think you can see that that really is, is an important part of the problem.

The NMSO program can easily be instituted in hospitals and in emergency facilities where many of the opioid prescriptions are initiated. Patient education and enrollment can take place

prior to hospital discharge and the prescription information can be forwarded electronically to the patient's physician.

Monitoring of narcotic shipments with the drug manufacturers and distributers obviously can be included in the program. Inappropriately large shipments could be identified.

Because the NMSO program is entirely digital, it's possible to collect, coordinate, and monitor the information from multiple sites in real time so that a large, new bureaucracy is not required and the alerts are generated everywhere.

The system works as a block chain that has widespread distribution of information and interlocking components that monitor usage, discourages deviation from the accepted guidelines, identifies early on the situations requiring referral for suspected abuse, and/or regulatory action.

NMSO collects the voice of the patient and real world data and it should take us to a place where we can avoid these problems and hopefully

overall have better pain management.

Thank you for your attention. We appreciate the opportunity to (inaudible).

MS. TIOGO: Thank you, Dr. Lewis. Any questions from the panel?

DR. WOODCOCK: Yeah, this is Janet Woodcock. So I'm familiar with the NOAACT (ph) program, but how would this integrate with the PMPs and other data collections that are currently underway and been described all day by folks?

DR. LEWIS: Well, basically this, this is, provides some of the same, the same information and the, the PMPs would have the information. The idea is to, is to create a block chain and diffuse the information so it's very difficult to get out of, out of the system without it being regulatory, without it being -- the guidelines are set up obviously to establish expectations and we don't get into -- obviously, you can add this to the, to the PDP program and, and have it, have it happen.

But the experience in Maryland has been that it's very difficult for, for physicians to access

the program. When they talk about six minutes, that's about a fifth of what I've heard is the average time spent doing this. And I think it, it's an old maxim in medicine that the best is the enemy of the good.

I don't think any one thing is going to take away the opioid problems, but if we can make them a lot better with minimum, minimum disruption in the system, I think that will be ideal.

MS. TIOGO: Anymore questions? Okay. Thank you, Dr. Lewis. Our next speaker is Mr. Jason Leedy from Examoto.

MR. LEEDY: Good afternoon. First, thanks to the FDA for hosting this meeting and providing us an opportunity to speak. Also, thanks to all the other speakers today. I learned (inaudible).

I'll first start with just a mathematical context. You can see the human context today in some of the presentations, if you pick up a newspaper. (Inaudible) mathematical (inaudible) and it's, it's (inaudible). So for 16 years every single year more people died from opioids than in

car accidents. So, and that's the challenge, right? So that's, that's the trend we need to, to reverse.

I'm going to limit my comments today to address some of the specific questions that the FDA put and some of the ideas that they put into Docket 6502. So I'll paraphrase some of those to sort of set the stage so that we can get (inaudible).

So to paraphrase, within the agency's statutory REMS authority, how should the agency require sponsors to ensure compliance with, and then they provide two ideas. Require sponsors to ensure that the prescribers follow specific requirements outlined in the REMS for each opioid prescription above a specific quantity. So we've been talking about this all day as a threshold.

The second is require sponsors to create a system that would leverage a nationwide database and be more effective in identify misuse and abuse. Now this is the PDMP interface that we've been discussing today. And if such measures were

required, how should prescribers be made aware of these measures.

So I'm not here to render an opinion that these are the right measures, but instead I'd like to use them as a way to lay out some scenarios for highlighting strategy implementation. So even if these were the exact recommendations right now today - and I don't think based on the conversation anyone would be willing to say that - they could be directionally correct with the other measures.

The reality is if you're going to have these elements toward safe use, they'll change over time anyway. So the question is what would be a strategy for implementing these measures?

A natural first step would be to either revise or create a new opioid REMS. So imagine what would this REMS look like. One, most likely have mandatory prescriber training and certification. This mandatory prescriber training and certification would include the measures that are in, in the REMS, the attachments, right? The

thresholds or the score that comes back from PDMP, etc.

The REMS would contain the thresholds. So for a certain prescription, maybe some number of days supplied, etc. You would have a PDMP check to identify misuse and abuse, doctor shopping, etc. I'll assume in this instance that there would be a PDMP aggregator, right? So an expedient, if you will, for the PDMP databases where you can get a national score for a risk assessment back for a prescriber.

If you're going to have those things, the next logical components for REMS would be systematic verification of those elements to ensure safe use. And then the final component to make it have some teeth would be to have a noncompliance policy so prescribers that are not compliant with the REMS could lose their ability in the future to prescribe such drugs.

These are all fairly normal components and are, exist in REMS today. So again, if we were to take a look at the ideas and measures that were

provided in the docket, this is a potential REMS, a potential REMS that would result in those things.

So if you accept this as a strawman for a future opioid REMS, the next question is how would you do this. How would you implement REMS like this? What would the strategy be? The FDA mentions two approaches, traditional pharmacy-based approach for checking the elements for safe use, and an innovative approach to use prescribers to document safe use conditions.

Now let's take this diagram here and use it to evaluate these two potential approaches. So this diagram would depict the high level prescription pathway through retail pharmacy. So let's take the traditional way REMS would be implemented, relying on a pharmacy.

So we start in the top left-hand corner and in this case the patient visit would result in an opioid prescription. That prescription will be sent to the pharmacy. The patient would present at the pharmacy, and then at this point in time

the script would be sent for financial adjudication.

So while that script is in transit for financial adjudication, the REMS would pick it up, inspect it, and encroaches the elements to ensure safe use. Okay? So let's say the script is for 30 days, but this particular script has a threshold of 15 and let's say you ping the PDM aggregator and you get back a risk score, which is ten, and it's not supposed to exceed five. That script should not proceed.

The problem with this, with this approach for an opioid REMS is the following. There's a lot of work that's being done. There's people doing things. There's, there's transactions flying around. You're going all the way down the process to payment and then you have a problem. You can overcome that in a small (inaudible), but if you take that burden, lost burden and multiple it across an opioid REMS, you're not likely to succeed.

So an alternative approach would be the

following. Prescriber and patient consult and they document the safe use conditions at that point in time. The documentation of the safe use conditions are encapsulated in a crypto PDA, or a dispense authorization, and they're attached to the prescription.

That prescription is sent electronically to the pharmacy. The health information network that sends that prescription can mathematically verify that the (inaudible) in place. If it is not, return it to the prescriber with messaging consistent with what was in the training, or if it is, if it does meet the ATAZU (ph), they can send it to the pharmacy. The remainder of the process with the pharmacy thereafter is --

MS. TIOGO: So Mr. Leedy, I know you know you're over time --

MR. LEEDY: Am I? I apologize. So I will wrap up. So what I can leave you with is this. I hear a lot of varied discussion around what should be done and I think there's some work there, but I want to leave you knowing that when you determine

what should be done, it can be done. So we do not have a technology problem that can't be solved with current tools. What you have is a definition problem. Thank you for your time. I'll take any questions.

MS. TIOGO: Thank you. Questions for Mr. Leedy?

DR. WOODCOCK: Definition problem. What was this capsule that was sent from the prescriber along with the e-prescription?

MR. LEEDY: I'm sorry?

DR. WOODCOCK: The message that was sent along with the e-prescription that varies (inaudible)?

MR. LEEDY: So the idea is we've heard a lot today about the systems connecting, this system connecting, there's a problem with this system connecting, this one, so forth and so on. The idea here is that the prescriber's system would document elements to ensure safe use.

That can be turned into a mathematical block. You would attach that mathematical block to the e-prescription. It could then be verified

downstream by the health network as a secondary check.

DR. WOODCOCK: Okay. Thank you.

MS. TIOGO: Thank you very much. Our next speaker is Dr. Daniel Busch from the Northwestern University Feinberg School of Medicine.

DR. BUSCH: I'm a psychiatrist at Northwestern and have been for many years, but nothing in my life prepared me for the pain that I felt when my son died in 2011 of an oxycodone overdose. I became determined at that point to learn as much as I could about the opioid epidemic, more specifically, the epidemiology of the opioid endemic. I was very interested in what the FDA was doing about the opioid epidemic.

I attended a couple of FDA meetings, the Zohydro meeting, a meeting regarding (inaudible) combination products. I looked back at some of the previous work that the, that the FDA had done, including a 2003 deal with prescription opioid abuse, and the risk management programs that were involved at that time. And after looking at all

that and the impact of it, I realized that the FDA really wasn't going to do anything that was going to be effective to deal with the problem of the opioid endemic and the rising number of deaths.

I think there were two reasons behind this. The first one was that the FDA seemed to be dedicated primarily to getting drugs into the hands of physicians where the physicians could make the decision about what was the appropriate medication. The second had to do with FDA concerns about making sure that patients would have access to the medicines they needed.

But neither of those really included the issue of the rising tide of deaths. My concern at that time back around 2012, 2013 was I could really envision a time when this thing was going to be beyond the ability of the FDA to exercise -- sorry?

MS. TIOGO: We can't hear you.

DR. BUSCH: Sorry. When it was going to beyond the ability of the FDA to exercise any control and that we were going to be in the midst

of a heroin epidemic. I never would have thought things would have come to the fentanyl epidemic that we're in the midst of, but certainly things did pass beyond FDA control and we're at a point now where over 350,000 people have died from this opioid epidemic.

And in some ways when we're looking at these REMS, I think we have to look at starting over again. So I wanted to go on from there. The other thing that I think caused the FDA to really make the mistake, which was that it seemed to me that the FDA really saw things that there were really two groups of people who were using opioids and those were pain patients and drug abusers and those were separate groups.

I think that we now know that pain does not protect against addiction and that we've come to understand that this is not an epidemic of drug abuse; it's an epidemic of opioid addiction, and that there are different pathways to opioid addiction, both using the drugs in order to get high leading to addiction. Also pain treatment

leading to addiction.

People mentioned this morning that only about 2% of patients who are treated for pain will wind up with opioid use disorder, but if we look at the number of people that were being treated in the 2015 data showed that 92 million Americans received prescriptions for opioid in that year. Two percent of those wound up addicted. That's 1.8 million, and we have a total of 2.5 million people in this country suffering from opioid use disorder.

So a large percent of the patients could actually have been done with pain treatment. So I think we understand now with the risk of addiction, it's a function of the dose, times the duration of treatment, times individual vulnerability, and that that means that there's really no safe dose of opioids. There's no safe length of treatment and all exposure to opioids involves the risk of addiction.

We've shown among patients with chronic pain that those who are taking higher doses are more

likely to have overdoses, that were more likely to have overdose deaths. And the people with acute postsurgical pain, that the more prescriptions they received, the more refills they received for treatment of their postsurgical pain, the more likely they are to wind up having misuse of opioids.

A couple studies from 2010 and 2012, the North Carolina Initiative, showed that for people who died of prescription opioid overdose is roughly 50% had received recent pain medication treatments from their physicians.

So in terms of the issue of whether we're going to wind up not giving medicines to people who need them, first none of the things that I've talked about in terms of thresholds are designed in order to keep medicines from getting to the people who needs the medicines.

In terms of whether we're really prescribing the right amount of the medicine for pain, I don't think we know. We're still three-and-a-half times in a per capita MME from what we were in 1990.

We're four times greater than the people in Europe who consume more opioids than any other country. I'll come back to the other slide. We don't even know whether opioids are beneficial for chronic pain.

We have the clinical impression that these are useful and we certainly have a lot of people here who've spoken and said that they have been useful to them and the people that they know, but we don't have studies that show pain reduction from chronic pain treated by opioids.

We do have some studies that show decreased function. We don't even know the role of opioid-induced hyperalgesia in chronic pain and what the interaction is between that and the opioids that we're treating people with.

So with all that we come to the REMS proposals that we have right now and this is my summary of them, which is a little different from what they actually are. They include prescribing opioids for the shortest possible time at the lowest dose, a national PDPM, public education, and getting

prescription opioids out of the medicine cabinets.

There have been people who objected to the issue of threshold amounts because people show individual differences, but this is a slide that shows the amount of opioids that are prescribed and the different portals of counties in the United States. So in the top portal, so this means that counties, the top 25% of county in terms of how much opioids people are getting, the average is about 1,300 MMEs per capita annually; whereas, in the bottom portal it's around 200.

So this is a six-and-a-half-fold difference. It has nothing to do with different amounts of pain in the different counties or whether people are being treated appropriately or inappropriately. It has to do just with customs within those counties. That needs to get straightened out and threshold doses are one way we could do that.

So I think that we should require prescriber justification and that we should be using CDC guidelines where applicable. And it looks like

refills for postsurgical pain should also require justification. A national PDMP, I thought after listening to people today would be a great help, and I'll tell you in terms of the bottom one of these three things, which is it would provide easier mechanisms for a search and assessment of patterns of use abuse and misuse, as well as prescribing patterns, it's very difficult to do research on the state PDMPs.

There is a tremendous amount of data that needs to be mined, but it's, things have to be identified. You have to go through various levels of authority. The state PDMPs don't have the money to do the research. It's a big problem.

Looks like my time's up. So I think I'll stop there. And thank you very much.

MS. TIOGO: Thank you, Dr. Busch. Any questions for Dr. Busch? Thank you, Dr. Busch. Our last speaker is Mr. Al Knowles.

MR. KNOWLES: Good day. My name is Alvin Knowles. I'm here because I love someone who spends her life in chronic pain. I want to talk

about a statement on the docket. Please excuse me. I talk a little loud. I only get one shot at this and I need to be heard.

The statement I want to talk about is this. Documentation requirement would not be intended to prevent the access for patients in their chronic use of opioid analgesics is the most appropriate therapy. I'm here because that was not likely the intent of the CDC guidelines either, but that has been the effect.

You're going to hear and read many, many stories of patients in chronic pain who have now been abruptly cut off from their medically necessary pain medications by providers citing the CDC guidelines as the reason. These patients now only a few horrid choices left: to live with excruciating, agonizing, tortuous pain that most of us can't even imagine, to seek illegal and dangerous drugs through the black market, or to end their pain by ending their lives.

These are patients who have already tried pain management alternatives and found that opioids

were the only realistic choice. With the guidance of their providers, they have used opioids successfully and responsibly for years to achieve a quality of life that would not have been possible without them.

Doctors terrified of the DEA and fed up with even more new regulations are already leaving pain management in droves, leaving thousands of people in chronic pain without access to the meds that make their lives livable.

The providers prescribe alternatives; insurance companies frequently refuse to cover them. CVS is about to start practicing medicine without a license by second guessing providers with years of medical training. Most any ethical doctor will tell you that to prescribe any treatment for a patient they have not seen is a huge breach of ethics or even medical malpractice.

Yet in the current environment, the only person who has any less say in their care than the provider is the patient. Any chronic pain patient who dares to demand his or her right to

appropriate medical treatment of opioids risks being labeled by the pharmacist and/or provider as a drug seeker. If a patient seeks another doctor, well, that's doctor shopping and that patient will be to have even more evidence against them.

Once the drug seeker label goes into a patient's medical record, it will stay there and prevent and askew her from medical treatment forever. Her providers to speak up is to the DEA like waving a red flag in front of a bull. The provider may not have actually done anything to warrant the DEA's attention of why should he or she take a chance like that. As one provider put it, your quality of life is not as important to me as my medical license. His patient later killed themselves for the tortuous, agonizing pain.

The message that I'm being sent from all of these agencies I mentioned and the mainstream media is this. All patients who take opioids for any reason are drug addicts and none of their doctors can be trusted.

With consideration of these new regulations,

the FDA's about to send that same message loud and clear, giving already frightened providers even more reasons to abandon pain management and their chronic pain patients altogether.

There are 100 million Americans who suffer from chronic pain. Among them are hundreds of thousands who will themselves be using prescribed opioids to function. Now they are left with only bad choices. As you read through their e-mails, please keep in mind that at the beginning of each one of these is actually an FDA success story. The patients will tell you about how taking opioids allowed them to function and they've been productive for years. Even decades.

Now is it the FDA that made that possible for them to obtain these meds that have dramatically improved their quality of life for years. Unfortunately these success stories rarely make news and you likely didn't get many letters or phone calls that said, hey, FDA, I'm doing great now. Thanks. The true heros don’t need recognition.

And I'm here to say that for people who have chronic pain and are successfully using these meds to manage it, you guys were heros. You are hearing from chronic pain patients now because they're in serious trouble and they need your help again. Once again they need yours.

As I mentioned, many government agencies are already addressing the addiction crisis. Most of them refuse to see any difference between a chronic pain patient and a drug addict. The organizations I mentioned will deny, dismiss, minimize, or even refuse to acknowledge all the good that opioids have done for chronic pain patients for years. And again, that means your success they are disparaging.

Now the same people you once helped are committing suicide on a daily basis because they've been abandoned by the providers, lied about by the media, shamed by their pharmacists, and betrayed by the government. Many feel there is no one in the government on their side. Sadly those hit first and hardest with the new

regulations are the veterans who served this country with distinction and honor in the wars that we asked them to fight. Some suicides are mothers and fathers leaving children behind.

I'm sure all the agencies I spoke of mean well, but under enthusiastic zeal to address on public health crisis, they have created another. And to its victims, this seems like a public health crisis and no government agency is truly addressing.

Now this provides the FDA with a unique opportunity. FDA could be the agency that finally provides something rarely found in government - balance. After all, aren't you the guys who are supposed to protect consumers? Are you going to stand ideally by while the people you once saved are abandoned? Worse, are you now going to join all agencies that are torturing and killing them? You were their hero once.

I'm here to beg you to be their hero again. You can start by not imposing even more new regulations, but if you must, then they should be

primarily focused on helping the responsible chronic pain patient and providers instead of making their lives even more difficult. Let's say the first set of questions of the document. I certainly don't have an answer for those questions, but I do have a suggestion.

Why don't you start by asking the patients? If you must implement a database, then for established patients a provider should only have to sign a box that says patient reports satisfactory quality of life on current opioid regimen. No changes needed are made. Once that box is signed, a provider should not have to justify its prescription to CVS, the DEA, or anyone else.

In fact, you could probably make it illegal for any of them to require it from CVS or any pharmacy to alternate it or add additional requirements to it. Maybe you can even think of some way to allow the provider some sort of protection from the over-enthusiastic DEA. It is the FDA that has the power of law to reduce, or

where it's not already too late, even reverse the horrible damage being done to people in life long chronic pain and those of us who love them. You have been our champion before. Please be our champion again.

Thank you for having this hearing and thank you for hearing me out.

MS. TIOGO: Thank you for sharing your comments, Mr. Knowles. Any comments from the panel, question? Thank you, Mr. Knowles. So on the agenda, the next thing is the open public hearing, but the, all of the speakers that we needed to accommodate for the open public hearing participated in the morning session. So we will not have the open public hearing this afternoon. But I think the Commissioner does want to make a few closing comments. Well, I get to end that meeting, but he gets to make a few closing comments.

COMM. GOTTLIEB: Well, I thought I got to end the meeting. Thanks a lot. Good afternoon. I at least wanted to thank everyone who, who joined us

today in person or via the webcast. I'm mostly sorry that I couldn't be here for the morning session for more of the testimony. I had to testify on Capitol Hill today before the Energy and Commerce Committee or I would have, would have been here.

This remains one of my highest priorities, dealing with these challenges. I'm deeply committed to the families, and the caregivers, the patients that grapple with this crisis every day. And we've heard from some of them today. It's going to take a sustained and coordinated effort on the part of everyone involved to reduce the tide of addiction and the death afflicting communities while maintaining appropriate prescriber for a patient's medical need who we've heard from today, especially patients who suffer from seriously debilitating chronic pain.

The agency recognizes both the urgency and the complexity of this crisis and that's why we're seeking and will continue to seek feedback from a broad group of stakeholders both from public and

private. I'm encouraged by the broad engagement I know we've had here today with voices representing patients, industry, academia, and advocacy organizations, as well as medical professional societies.

Since establishing the Opioid Policy Steering Committee in May, senior FDA leaders across the agency have been hard at work to ensure that we're leaving no stone unturned in our efforts to combat this immense public health challenge. With 11.5 million Americans misusing prescription opioids in the past year and more than 40 million dying every day from overdoses, it's 40 people dying every day from overdoses involving prescription opioids, it's become abundantly clear that more vigilant action is needed from the FDA to get ahead of this crisis.

Today we heard from a very helpful spectrum of voices involved in different aspects of this challenge, from patients suffering with chronic pain, and those who have been harmed by opioids, as well as from providers who ask us for more

help, whether it's through education or systems that could help prescribing, and those who ask us to look for approaches that could address these challenges without imposing additional burdens that could also prevent patients who need access to appropriate therapy from getting that access.

I can tell you that we struggle with these challenges every day at the agency and I know my colleagues inside the drug center who work on these issues every day struggle with the challenge of trying to afford opportunities to patients to have the appropriate access to the medications they need while we also take appropriate steps and vigilant steps to address the crisis that's afflicting the country.

At the FDA we believe one of our key roles in addressing the opioid epidemic to reduce new addictions and we're exploring ways that we reduce exposure to opioids through our influence on prescribers, particularly through the REMS which you heard about today. However, we're also mindful any REMS that have mentioned have to

consider should minimize the burden on appropriate patient access and to the extent possible on the healthcare system. And that's why this feedback is so helpful to us.

Even after hearing the discussion today, we still welcome and strongly encourage you to submit electronic or written comments to the docket until March 16, 2018. Many of you already submitted comments to our previous federal registry notice and we're currently carefully reviewing more than 900 comments we received, and we look forward to reviewing the submitted comments from this meeting here today.

Our discussion will also continue on February 15th in collaboration with the Duke Margolis Center at the National Press Club through a public workshop to explore strategies for promoting the safe use and appropriate prescribing of prescription opioids. Your feedback and your continued engagement will help inform what more FDA could be doing to stem the opioid crisis while helping to maintain safe, effective, and

appropriate prescribing for patients who need it.

We're also making more information available that we believe can help address the crisis now. And so today I'm pleased to let you know that we've posted a revised blueprint, opioid analgesics REMS education blueprint, for healthcare providers involved in the treatment and monitoring of patients in pain.

In May 2017, as many of you know, we made a draft revised blueprint available for public comment via a federal registry notice. FDA received and considered nearly 700 comments from the public and other federal agencies on that blueprint and today we're posting our revisions to it.

FDA wanted to make the revised blueprint available to the public in advance of the approved REMS to facilitate the development of continuing medical education materials and other activities so that once the REMS is approved, the educational programs can be made readily available to help the professionals in a timely way.

We believe these revisions are important, but I want to highlight that the revised blueprint will not be considered final until the opioid analgesics risk evaluation mitigation strategy, the REMS, is approved later this year. When that process is complete, those REMS will apply for the first time ever to management of all extended-release and long-acting opioid drugs, as well as immediate-release formulations.

Once approved, the final blueprint will also apply to CE training for all ER and LR, and IR formulations for healthcare professionals, including nurse and pharmacists through nonrestricted grants from manufacturers. All this is to ensure appropriate use of medications as they're intended and we're working on several other ways that we can help address these goals and address these challenges.

Appropriate prescribing practices and education are important steps within our statutory authority to help address the human and financial toll that opioid addiction has taken because they

can reduce the harm while still providing effective pain management protocols and the access that patients who suffer from chronic pain leading from acute pain.

So I wanted to close by just thanking you for joining us for what I know was a long day. I'd also like to acknowledge this sustained effort and dedication by FDA colleagues here today, including the group of senior FDA leaders at the table and their staffs, and Kathleen (ph) Davies for making today possible.

We have a long road ahead all of us, but I know its supported by a lot of talented people both inside and outside the agency who have risen to challenges in the past and I know will rise to this challenge to confront both the opioid epidemic, but do it in a way that's mindful that they're a lot of patients who still need access to these medications. I want to thank you.

MS. TIOGO: Thank you, Dr. Gottlieb. You actually covered everything I needed to cover, so I don’t need to do any closing remarks other than

to thank all of attendees. And I especially want to thank the participants who signed up to speak and I especially appreciate your attention to the time limits that we set and keeping the day moving.

And so with that, have a safe trip home and we'll continue to work on this important public (inaudible). Thank you. The meeting is adjourned.

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I, KeVon Congo, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

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DATE Penny Knight