FDA - Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics

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FOOD AND DRUG ADMINISTRATION

Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics

Exploring the Path Forward – An FDA Workshop

Tuesday, May 9, 2017

8:37 a.m. to 5:03 p.m.

Sheraton Silver Spring

8777 Georgia Avenue

Silver Spring, Maryland

C O N T E N T S

C O N T E N T S (continued)

C O N T E N T S (continued)

P R O C E E D I N G S

(8:37 a.m.)

DR. THROCKMORTON: Good morning, everybody. If you could sit down we'll go ahead and get started. Today, we have a busy two-day meeting here.

My name is Doug Throckmorton. I am the deputy center director at the Center for Drugs, and I've met many of you at some of the other meetings we've had related to the opioids epidemic in the past. Welcome to you again today.

Very busy, very important two-day meeting here to talk about the place that education has, especially the place that federal education has in addressing the opioids crisis that I know that we are all very familiar with and all committed to doing something to address that that's meaningful, that makes a real difference.

The two days here are particularly exciting for me because of the broad range of groups that we have here. Mary tells me that there are 25 organizations at the state federal level, consumer

advocacy groups, and from state and local, medical boards, pharmacy boards, and the like, all scheduled to talk at one part of the meeting or the other in the next couple of days. In addition, from the federal space, we have representatives from almost the entire range of agencies that are working in this area CDC, CMS, SAMHSA, NIDA, FDA obviously. I'm probably missing -- oh, DEA is going to be coming as well.

So a really broad range of voices, something that is really important for us as an agency, as we decide where to go next in this area of federal education. And then, decide how to do it as best we can, to do the most effective job at educating and training healthcare professionals in this terribly important area.

Our intent is to listen closely and to take the things that you all say seriously. I am going to be planning on summarizing what we've heard at the end of the second day. I hope we're going to have a vigorous discussion, one that we will be able to make important use of.

Before I turn the podium over to Dr. Woodcock, I have some housekeeping things I have been asked to remind people of. One, please turn off or silence your phones. There is a one-hour lunch break. The restrooms are down the hall and to the right, important things like that.

The open public hearings are scheduled each day. If you are interested in speaking, go to the registration table. That's right outside and let them know, and we will make time for you.

There is a docket that has been set up for this. That docket will remain open until July 10th. As you'll hear, we are hoping that docket is going to be useful for you for giving us some additional information, things that we should take into consideration.

A transcript of the meeting will be posted within 30 days of the meeting. A webcast is being done, and that will be archived for later viewing. Because there is a webcast, if you make comments, please make them into a microphone so they can be captured and available for people listening on the

Web. And then finally, again, thank you very much for participating in this. We are taking this very seriously, and appreciate all of your time and attention to this matter.

With that, I am going to turn the podium over to Dr. Woodcock, who is the head of the Center for Drug Evaluation and Research to give us some opening remarks.

Janet?

Opening Remarks – Janet Woodcock

DR. WOODCOCK: Thanks Doug, and good morning, everyone. I am very happy to be here and kick this meeting off. To start, I would really like to step back a little bit and say where we are, we have come from, how did we get to this place.

Well, right now, as everyone in this room knows very well, there is an epidemic of use of prescription opioids and related substance abuse. And FDA has been executing an action plan that we published a year ago on a large number of steps we are trying to take to help control this.

I think everyone agrees that this can't be done by one entity alone. That's why there's so many different groups represented here. It is going to take concerted effort at the federal, state, local, professional society level to manage this.

But FDA's part of the plan, we try to decrease exposure, overall exposure to prescription opioids. We've been approving alternative pain medications, so that there are other tools that prescribers have when someone presents with pain.

We've been stressing education under our REMS program and offering educational programs for several years, and that's been very successful. A large number of healthcare professionals have taken CME programs, educational programs, under this.

We also have been trying to decrease the non-medical use of opioids by approving abuse-deterrent formulations of various types, and that is an experiment that we still are assessing how effective various abuse-deterrent formulations might be. We view that we have version 1.0, maybe

1.2 of abuse-deterrent formulation. We hope we get up to a very effective abuse-deterrent formulations, but of course any formulation can be overcome; this is not the entire answer.

We're also trying to decrease non-medical use by encouraging disposal and take-back practices, so that there are not so many prescription bottles available, not being used.

We are trying to decrease overdosing deaths and use of naloxone in various forms as an antidote to the respiratory depression caused by opioids, and we would like to see more treatment options for people who have opioid substance-use disorder. That is a field that probably can be explored much more and a great opportunity to treat those who already have issues.

But today we are here to talk about prescriber education. Now why is this so important? To stress the importance, I would like to go back through the history of what happened here.

This epidemic is fueled by opioids that are

legally prescribed. This epidemic of prescription opioids, generally they come from an opioid prescription that was written and somehow made its way into a problematic place.

Back in the '80s, back when I was training, and probably many of the health professionals in this room were in training in the early days, '70s, '80s, I had cancer patients who refused to take opioids for pain relief, for cancer pain relief, because they were afraid of the side effects they told me. They said they were afraid they would get addicted. That was the societal attitude at the time.

I don't know if that happened to you Doug, and maybe you are a little bit younger than I am. But for those who trained later and later in those decades, the attitudes changed.

By 2010, in contrast, there were more than 200 million outpatient prescriptions dispensed for opioids in this country, a huge number of prescriptions. So there was a sea-change between that time that was I think coming off a heroin

epidemic following the Vietnam War and so forth, where people were simply afraid to use opioids. They were used very sparingly. The public was afraid of them, to the point where 200 million prescriptions would be dispensed.

What happened is, of course societal attitudes change, and then prescribing patterns changed. There was this huge increase in prescribing over three decades. There was a shift first in medical dogma about abuse potential when used to treat pain. And I was taught that prescription for pain would not result in any untoward effects for patients as far as substance abuse.

That was the teaching at the time, and that had shifted quite a bit. And it was coupled with an increased awareness of under-treatment of pain and need for therapy of people in pain.

This is something that is still present today, that people with terrible pain are under-treated. We have heard this at our patient focus drug development meetings, where people with sickle

cell disease and other painful conditions come and talk about how they suffer terrible pain, and the pain is not adequately treated.

That recognition was a legitimate recognition, but the shift in medical dogma probably made people feel more comfortable using opioids in that case. Then opioid drugs were promoted for these uses, and all of this over several decades resulted in this massive shift in prescriber behavior.

What were the consequences of this shift? Well, the main consequence was a huge increase in population exposure to prescription opioids. Over 200 million prescriptions is massive population exposure. There was a surge in opioid-related substance abuse disorders and deaths from overdose, and this is still ongoing as we all know.

This was abetted of course by illegal practices or unethical practices such as the rise of pill mills and so forth that fueled the availability of opioids out there. And many with substance abuse disorder today state that the

source of drug is obtaining or stealing from friends or relatives.

As I said, these are prescribed drugs, these emanate from these 200 million prescriptions or what is given out post-surgery, or so forth, to patients when they leave the hospital.

Despite the general belief, the vast majority of exposure is not to the extended release or long-acting. The vast majority of exposure is to the immediate-release formulations, which people feel very comfortable about prescribing, but this is hundreds of millions of prescriptions basically.

So it turns out that that medical dogma of the late '80s and '90s was really not correct. The rate of substance abuse appears to correlate with most substances that are abused with population exposure, and brief exposure can lead to prolonged exposure, something that prescribers were not taught in those decades.

There was a recent article in JAMA Surgery that said exposure to opioids post-surgery results in extended use in about 6 percent of people. That

isn't substance abuse. That is simply the people who weren't taking opioids that came in, and they had even minor surgery unrelated to a pain condition, 6 percent of these people were still taking opioids 90 to 180 days after the surgical episode.

Similarly for opioid prescriptions for musculoskeletal or head pain indications, 6 percent had persistent opioid use one year after the initial prescription, and this increased to 30 percent if the initial prescription was for more than a month of opioids.

So people who are exposed to opioids, even briefly, some of them may become persistent users of opioids. Some fraction of them actually may develop problems with the opioid.

The consequences of 220 million prescriptions written, some proportion of those people -- and that's a lot of people exposed, although, of course some of these are refills. But some people exposed go on to chronic use, a lower proportion, but a substantive proportion develop

opioid substance abuse disorder.

A large proportion of patients who are prescribed these 220 million prescriptions take only a few doses or none, but some only take a few pills and stop because of the side effects. The side effects of dysphoria, nausea, constipation, and so forth, are relatively intolerable to many people.

The problem is what these folk do, many of them -- and there are some of you in this room I would wager -- is put these in their home medicine cabinet. In case they may have some injury, they want to have some pain medicine on hand. This is a target for adolescent use or substance abusers, or people who want to traffic in these. And that's where it comes from when people say that the vast majority of the opioids they obtain, the substance abusers, get them from friends, relatives, or steal them from people they know.

Clinicians then need good tools for pain management to control this epidemic because we still have an imperative to treat pain and manage

pain somehow. This imperative to treat pain is not going to go away. In approaching a patient with pain, though, you need to understand clearly and consider carefully the benefits and the liabilities each modality might use.

So what happened here I think is, number 1, the liabilities of prescribing opioids were not fully understood or minimized, and we have an entire generation of prescribers who were taught this. Some effective modalities as we know are limited because of reimbursement issues, for example physical therapy or cognitive behavioral therapy, so the tools clinicians have to treat pain may be somewhat limited.

Clinicians may not be aware of other drug modalities, each of which have their own liabilities. For example, for a time, it was advised by some professional societies that people with heart disease who had chronic pain be prescribed an opioid rather than an NSAID, because NSAIDs of course have some potential liabilities in the cardiovascular system.

So there are trade-offs, and choosing pain modalities should be a sophisticated decision that weighs all the costs and benefits of whatever intervention is done.

Because opioids have been inexpensive, it's easy to write a prescription, it's over and done with, they have been seen as a good way to provide relief. But the societal consequences now we are all familiar with. So this is why it comes back to basically changing prescriber behavior. We will not be able to control this epidemic unless we're able to help clinicians manage pain better and more comfortably without prescribing opioids.

Prescriber education on opioids for pain management, we have to recognize medically that opioids will continue to be the mainstay for pain relief in many situations. For example, acute trauma, post-op, immediate post-op and so forth, we're not going to probably get away from opioids. So the prescriber awareness of issues is critical.

Renewed understanding that any opioid prescription, any prescription, conveys risk, just

like any other drug. There are benefits and risks to prescribing. But these risks are either to the patients or to others if not properly dispensed. Prescribers in balancing these risks need to understand what the actual risks are.

Renewed understanding that duration of dosing of opioids and the amount prescribed is related to the risk. Often larger numbers of tablets are provided to allow the patient, if they have continuing pain, to continue to have pain relief. However, you have to consider the down sides of having these additional unconsumed opioids around, or if the patient, even as their pain becomes more manageable, continues to take opioids.

An up-to-date understanding of the modern signs of chronic pain and its management, we have come a long way from the early 1980s in our understanding of chronic pain and how to manage it, and that's been kind of a sea-change in the understanding of chronic pain. So we need to make sure that prescribers are fully informed about all this as they make their choice of a modality for

patients.

I think the question for this meeting and the question for the FDA, and the question for everyone who's trying to help manage this epidemic and also make sure that pain is adequately treated, is how can we ensure prescriber understanding of pain management? Many practitioners were not trained in the modern science of understanding pain. And how do we balance both the clear risks of opioids and the need for treatment of pain in moving forward?

This is going to require additional and extensive prescriber education and behavior change. So the question on the table is how do we enable prescriber behavior change, whether that be more explicit professional guidelines, mandatory education, whatever is needed. How do we do that so that practitioners have the tools that they need to treat their patients when they present to them with a complaint of pain?

Thank you, and good luck with this meeting.

(Applause.)

Presentation – Douglas Throckmorton

DR. THROCKMORTON: Thanks, Dr. Woodcock.

I am going to continue in the vein of just some framing comments. As you have heard, the focus of the meeting then is on the place of education in assuring that we address the opioids epidemic while continuing to make sure that pain treatment is available for patients when appropriate.

What I'm going to do is I'm going to put that discussion to a little broader context, talk a little bit first about the federal efforts that are going on.

As you are going to hear for the next couple of days of speakers, there are many, many federal efforts going on in the opioids space. The focus today and tomorrow; however, is on education, as Dr. Woodcock said. What is the role of education, especially in the federal efforts, and how can we do it most effectively?

To do that, I want to first talk a little bit about where education fits into the broader

landscape of federal activities, talking about HHS activities in particular, and then drill down to talk about FDA and FDA's activities around education.

Following that, we are going to be hearing from a series of representatives with expertise at the state, local, and healthcare system level to talk about their own work that's going on, so that we sort of have an idea of the broad landscape of things that are going on.

Then, we are going to break into panels. And at those panels, they're going to be given specific questions that we ask each of the panel members to confront, to really discuss, so that we can have a full discussion, a full understanding of their answers to those two challenging issues. What's the role of education, especially in the federal space in regards to opioids, and how can we do it effectively?

So the overall message, as I said, the broad message is one of engagement. The federal system is engaged. We are doing an enormous number of

things across a wide variety of activities related to opioids, both to assure their appropriate use and to confront their inappropriate use, and change behaviors to make that use better. FDA within that context is doing a great many things, and we need your help at this meeting to do those things as effectively as possible.

We're all familiar with this slide. We've seen these numbers from the CDC; I expect that we may see them again today. I'm the first one, so I get to show it first.

This is obviously an unacceptable trend. I show it to show that the trend is over time. This isn't something that just happened. It's something that has been going on for a significant number of years, and we're not making the progress we want to. We want to see these curves change, and we've not yet seen that trajectory change the way we all would like.

The second slide I want to show relates to overdose deaths between 1999 and 2014. I show this slide for one simple reason. We're all in it

together. This is not a problem of one county, or one state, or one region in the country. This is something that we all have to face.

I don't know how well you can see, but going from blue to red is bad on this slide. We have all gone in the wrong direction, so as a country we need to confront this.

HHS has been working for many years -- I am familiar with work now going on for more than a decade -- in a great many places. Most recently, the HHS opioid strategy has been released, and you can see here five areas that HHS is focusing on: strengthening public heath surveillance, supporting cutting-edge research, advancing the practice of pain management, targeting the availability and distribution of overdose-reversing drugs, and improving access to treatment and recovery services.

We could have two-day meetings on any of these five areas. My focus is going to be on the advancing of the practice of pain management because I think that's the place where the

educational aspects that we're going to be talking about fit most neatly.

However, from that HHS strategy, we've also arrived at a series of goals that guide us; empowering the public through education and awareness, preventing opioid abuse and related health consequences, improving function and quality of life, ensuring patient access to addiction treatments, and supporting people for long-range recovery. These things are the things that guide us day-to-day as we do our work.

But I want to return to the focus on advancing the practice of pain management. I promise I will not walk through this slide. I want you to read through it though and focus on the bolded sub-bullets there. CDC treatment prescribing guidelines, national pain strategy implementation, REMS and associate education, and research on coverage and evidence.

These are about training and education. So, within this central focus for HHS activities around opioids, you see the focus on education and

training, the recognition that this is an important aspect of addressing the opioids epidemic at the federal level.

There are other examples that we can point to, and I want to make sure that you know those were not all of the things that HHS is doing in this area. I've highlighted a few more that I'm aware of that the NIH Pain Consortium is working on through NIDA's leadership; that the Surgeon General has put out recently; that the CDC has put out; that the National Pain Strategy has articulated.

Again and again, the theme of education, the theme of making certain that the best possible information is made available to the healthcare practitioner comes up, and it's something that we're going to be talking about for the next couple of days. But I want to say just as a beginning, there is a great deal of federal effort. Part of the discussion today is how best to harness those efforts and make sure they are as effective as possible.

The FDA is obviously a part of many of those

activities. I participate in many of those groups, as do the members of the FDA team that works on opioids. We also have our own action plan that we announced in February of last year in response to the opioids epidemic. We said that we recognized that we needed to have an articulated set of goals that would drive the activities of our agency.

Here again, we put out an action plan that I will not walk through systematically. You can go and look at it at the link at the bottom. The point I wanted to focus on was in bold: updating the risk evaluation and mitigation strategy program for prescription opioids.

The activity you have today and tomorrow was identified as one of the highest priorities for my agency last February. So the work that you are going to help us with in the next couple of days is really essential to us to complete our actions under the action plan to give us the best possible information and help that we need.

We are going to do that through a series of possible activities. FDA is a regulatory agency,

so we can use the kinds of regulatory tools that Congress has given us to improve the safe use of opioids through approvals, and through rulemaking, and guidances, and the like. We can develop policies that help support the development of products that are safer, are more effective, are non-addictive potentially.

We can work with other groups and we can work internally to improve the science of the treatment of pain, identify new products that are otherwise less susceptible to abuse, improve drug take-backs, the like. And then finally, we can partner with outside groups to extend our reach to communicate to patients, communicate to prescribers, to help make sure opioids are used as safely as possible.

Today's focus then is on our efforts around training and education. We need to have comments from the panelists on the relative role of federal training and education in the larger landscape of activities aimed at improving pain management, including the use of opioids, analgesics. The

focus is on education because we believe that is a central aspect of the things that the FDA needs to do. We want to do it as effectively as possible.

Once we've framed it, once we understand -- we've heard the comments about the role of education in the activities at the federal level, the merits and challenges of particular mechanisms of education, semi-mandatory restrictive, less restrictive -- we need to understand what kind of education you believe is most effective and most necessary for the federal space to undertake.

You're going to hear a lot of different kinds of models of educational activities. The question for us is, what's the right one for the FDA to use? This will include a discussion of the role, if any, for mandatory prescriber education.

Third, the merits and challenges of utilizing partnerships. We understand the value of partnerships. I'm proud to say we have many, many partnerships with people in this room and outside the room trying to extend the reach that the FDA

has, trying to do the job that we need to do because we can't do it alone, as Dr. Woodcock said. We need your discussion about how best to manage that, how to identify those opportunities and make the best use of them.

Then finally, we would like to have some discussion about the aspects of the opioids epidemic best targeted by education. Our current blueprint or the current outline that we use to describe the education that the FDA is interested in is focused on drug-specific information. It talks specifically about products and their particular issues.

Is that the right frame, or should we be thinking about a broader framing about the use of opioids in a larger aspect of pain management?

With these kinds of discussion, these kinds of feedback, we can take back the information and make the decisions that we need to, the decisions that the later speakers this morning will lay out, the kinds of decisions that FDA has before us.

With that, I am going to end and turn this

over to Claudia Manzo -- oh sorry, let me do one other thing. I just want to summarize where we started.

We are working very hard to address the opioids epidemic as a part of this larger HHS effort. Our action plan provides the framework we are using. As I pointed out, it has a large focus, a specific focus, on education. Since the action plan was announced, we have continued to make significant progress. This meeting, I'm sure, will give us important additional information to continue that good work. And with that, I will thank you very much.

Claudia?

(Applause.)

Presentation – Claudia Manzo

DR. MANZO: Good morning. My name is Claudia Manzo. I am the director of the Office of Medication Error Prevention and Risk Management within the Center for Drug Evaluation and Research at FDA.

This morning, I will be talking about the

extended-release and long-acting opioid analgesic REMS, the evolution of how we got there, what we know about its effectiveness, and recommendations that we received from an advisory panel about a year ago, and an update on where we are today.

So as you heard some of the background by Dr. Woodcock and Dr. Throckmorton, we kind of understand where the problem came from. In the early 2000s, FDA started to receive reports of problems with prescription opioid abuse, especially involving some of these modified formulations. And these reports included information about patients crushing the tablet to defeat the extended-release properties, misusing by several different routes, and reports of addiction, overdose, and death.

Despite numerous warnings added to the label and developing individual risk management plans for the individual products, the inappropriate prescribing, misuse, and overdosed deaths continue to rise.

Also in 2009, FDA notified the manufacturers of these products, the extended-release and long-

acting opioid analgesics, that their products would require a REMS to ensure that the benefits outweigh the risks. And then between 2009 and 2011, FDA obtained stakeholder input various ways, through public meetings, advisory committee meetings, opening a docket, what the REMS program should look like.

This would be the largest REMS to date that FDA would approve. And because of this, it was really important to keep in mind what the scope of the REMS would be and the impact this type of program would have on the healthcare system and patient access.

Some of the comments or highlights of comments that we received was that if we applied a REMS only to the extended-release and long-acting products, that there would be a shift in prescribing to the immediate-release opioid analgesics.

There was general support for prescriber education. Some strongly supported mandatory training, but felt it was best accomplished if it

was linked to DEA registration or state medical licensure rather than through our REMS authorities. And some stakeholders also felt that real-time verification, the prescriber was trained before the filling of each opioid prescription, would cause some prescribers to opt-out of prescribing these products all together.

The other comments were that patient education is important, but shouldn't include patient enrollment, which would be considered overly burdensome and creates stigma and may adversely affect patient access.

I'm going to turn a little bit to information about REMS themselves and what they are. A REMS is a required risk management program or plan that utilizes strategies in addition to FDA approved labeling. The Food and Drug Administration Amendments Act added a section within the Food, Drug, and Cosmetics Act to give FDA authority to require these programs from the manufacturers. These programs can be approved either before the drug is approved or after

approval if FDA determines that this program is needed to ensure the benefits outweigh the risks.

The REMS are developed and implemented by the manufacturers, so FDA's authority is over the manufacturers. A REMS can include a medication guide or a patient package insert; a communication plan; elements to ensure safe use, which I will describe a little bit more; an implementation system; and a timetable for submission of the assessment of the REMS or how it's performing.

The elements to ensure safe use, there are a number of them that can be chosen. I will just point out that you cannot necessarily implement some of these without implementing other ones. And you'll hear more about what a REMS might look like for all of these products from Doris Auth later this morning.

So I won't go through each of these. One thing to point out though is that elements can include certification and/or specialized training of healthcare providers who prescribe the drug.

The elements to ensure safe use, or ETASU,

can either be restrictive or non-restrictive. If they're restrictive, then that means the components of the REMS are actually linked to dispensing or distribution of the product. Dispensing could not occur without somebody becoming certified for example or undergoing training.

For non-restrictive programs, it's generally required that the manufacturers make information available, such as training, but there's no specific link to training and dispensing of the product.

The ER/LA opioid analgesic REMS was approved by FDA July 9, 2012, again, after numerous input from stakeholders. This is a shared system REMS, which means it involves all of the manufacturers of these products. Right now we have about 38 sponsors that comprise the ER/LA REMS product companies or the companies that have developed and implemented the REMS. It includes approximately 67 applications, both innovator and generic products, and I've listed the ingredients that are included.

The goal of the REMS is to reduce adverse

outcomes associated with inappropriate prescribing, misuse, and abuse of these products while maintaining access to pain medications.

The primary component of the program is prescriber training. There are also materials for patients. There is a one-page medication guide for patients, and they're specific to each product, and there's a patient counseling document that prescribers can use when they are counseling their patients and to provide additional notes or instructions for patients.

At the time that the REMS was approved and implemented, FDA required sponsors to send out targeted letters to DEA registered prescribers, as well as numerous organizations and licensing boards, making them aware of the REMS and the need to take the training.

The REMS was also approved with a call center and a website that included what the requirements of the REMS were and provided links to the education that was made available. And then finally, there was an assessment piece, which

included an assessment, which we're now getting on an annual basis.

The prescriber training, this would be the first time that companies had used continuing education as the means to provide the training to prescribers. The sponsors are meeting their obligation by providing unrestricted grants to the continuing education providers, who then develop the training, and this is based upon the FDA blueprint. As I described before, this is a non-restrictive REMS, so it's not linked to the ability to prescribe or dispense.

The FDA blueprint is posted on FDA's website, and it focuses, as Dr. Throckmorton mentioned, on the safe prescribing of the extended-release and long-acting opioid analgesics. There are six domains, which I won't list or discuss. But in order to be considered REMS compliant, it would have to be offered by an accredited CE provider and include all of the elements of the FDA blueprint. It would also need to include a knowledge assessment and would be

subject to an independent audit.

At the time that the REMS was approved, there were performance targets that were specified within the REMS itself, and these were based upon an estimated number of prescribers of these products at that time. At that time the estimated number of prescribers was around 320,000, and the first CE became available about nine months after the REMS was approved, so in March of 2013. By two years, 25 percent of opioid prescribers would be trained, and you see the other targets there for the subsequent years.

The REMS assessments that are submitted on an annual basis include the number of prescribers that have been trained, information about audits and the quality of the content of the program, results of prescriber and patient surveys, surveillance studies that look at key safety outcomes, as well as drug utilization patterns, which are used to look at changes in prescriber behavior, as well as to try to determine the extent that the program might have on patient access.

On the left, you'll see the training numbers as of two years after the first CE became available. It was a relatively slower up-take. I will point out that the gray bars represent all participants, the dark blue represents participants that have completed the training, and then the light blue really represents the ER/LA opioid prescriber completers, which is the target that we were looking to train.

I will say that what you could see is between 2015 and 2016, a huge uptake of participants that were interested in taking and had started the CE training. What's not clear is why they might have completed or exactly who some of these additional participants were.

We actually did find that participation was pretty high, particularly for a program that was voluntary, and included a number of healthcare providers that were not targeted for the training. The reason that prescriber targets were not met was not entirely clear, but we do know that there are multiple sources of education, as Dr. Throckmorton

mentioned, and probably a number more that you'll hear about this afternoon.

The scope of the training might have been too narrowly focused, so participants may have started it and realized that they weren't interested in taking the rest of it. And of course this was, as we said, not linked to the ability to prescribe.

I am not going to go too much into the other findings, just to state that the other findings generally showed positive trends; however, there were a lot of limitations in the way that these assessments were conducted. Particularly with surveys and the surveillance studies, it is unclear whether these reflected the general population and whether we could really attribute any of these changes to the actual REMS program itself because we saw some of these decreases occurring particularly in adverse outcomes prior to the implementation of the REMS.

About a year ago, we took this program to a joint Drug Safety Risk Management and Anesthetic

and Analgesic Drug Products advisory committee, and we presented the findings to the committees. We sought their input on alternative methodologies for evaluating the program and also whether the blueprint should be modified and expanded or whether the program should be expanded to include the immediate-release opioid analgesics, and whether just any other modifications should be made.

There were three general recommendations from the committees about the program itself. The majority recommended extending the REMS requirements to the immediate-release opioid analgesics, broadening the education to include pain management, and extend the training to other healthcare providers that are involved in the management of patients with pain. And then, the majority recommended mandatory education though they did not believe that the REMS authorities were the best way to implement this.

Today, just providing an update on where we are, FDA did invite the applicant holders of all of

the immediate-release, extended-release, and long-acting opioid analgesics to a meeting in January to let them know that we were intending to require REMS for all of these products.

The intent of this was to have them to begin to work together. As we said with the ER/LA opioid REMS, there were 38 sponsors. This would require a number more sponsors to work with the existing sponsors.

The FDA has also been revising the blueprint to include pain management and the safe use of opioid analgesics, and is also exploring mechanisms to extend that training to the other healthcare providers. FDA is establishing a public docket, which I believe may have opened this morning, and we have the draft blueprint available on the website for this meeting.

Here I just have an outline of the draft blueprint, which includes basics of pain management and then creating the pain treatment plan, as you can see.

In summary, the ER/LA opioid analgesic REMS

was implemented in 2012 to address the growing epidemic of opioid abuse, addiction, and overdose. FDA intends to modify the REMS to evaluate the blueprint, or modify the blueprint, and intends to add the IR opioid analgesics.

We are looking for comments on the blueprint now. This public meeting, as well as comments that are submitted to the docket for this meeting, will help inform next steps on how best to implement the training for opioid prescribers. Thank you.

(Applause.)

DR. THROCKMORTON: Thanks, Claudia.

Those talks give us a general overview of the federal activities and some of the FDA activities focused especially around the REMS.

Next, we are going to turn to state and healthcare experience starting with Lisa Robin, who is the chief advocacy officer from the Federation of State Medical Boards.

Lisa?

Presentation – Lisa Robin

MS. ROBIN: Thank you.

Well, good morning, it's always a pleasure to be at these meetings and see all these familiar faces, and looking forward to these next two days. But as you can imagine, the landscapes throughout the states varies significantly. There's such a lack of any coordination it seems among the states, and what we see are some trends that I am going to kind of discuss today that you can see throughout some of the legislative proposals.

Everyone is trying to do something, looking for a lot of solutions, and our state legislatures are all wanting to do something. So it looks almost like they're throwing everything against the wall and see what sticks without really thinking about maybe what some of the unintended consequences may be.

So we certainly have our work cut out for us, but it is a wonderful step that we are all in the same room. And maybe we can come up with some guidance as we look at some ways that we can perhaps promote some harmonization among the states as far as the education and the other policies that

really guide how we take care of our patients and treating their pain.

But we do know that there's just been an explosion of legislative activity this year, but we do see changes. We know that we are reaching providers, that the number of folks that have taken education has certainly increased. We know that the number of prescriptions have decreased in every state in the country. But I am not sure -- we don't know really what that means and is that going to have an impact on patients outcomes, good and bad.

The number of physicians that are certified to provide office space treatment for opioid use disorders is certainly increased, and we see a huge increase in PDMP utilization.

We have seen over 1200 bills introduced in 2017. It certainly keeps my staff busy trying to monitor and look at these. We have 94 signed into law this year. And what we're seeing, they kind of address certain broad areas, whether that be a mandated query to the PDMP; implementing the lock-

in programs with the Medicaid programs; or requiring registration of pain clinics; increasing access to naloxone and providing immunity to those that administer; and of course mandated CME, which is I think will be a big topic of our meeting today and tomorrow.

At the same time that this was going on, the Federation of State Medical Boards over the past 15 months have been working on looking at our guidance document for opioid prescribing, and that work was completed in just this past April. We'll be promoting that to the states and hoping that that document can serve as kind of a basis as they do their policy work in this area.

We've also seen a lot of activity around the prescription drug monitoring programs with 172 bills introduced in 2017; 17 signed into law. I am not going to go through all of these; you can certainly read the slides.

Missouri, of course being the last state to not have a state prescription drug monitoring program, that bill was introduced and proceeding,

but it's in conference. And we think it's actually unlikely to pass due to time constraints this year. However, they do have some work at the local level that the state has really taken through cities and counties to have a good number percentage of the state covered.

This map demonstrates where we are with the legislative trends. As you see, certain areas of the country kind of mirrors where they have seen the worst problems, and it is interesting kind of as you look at it from a regional basis.

Here, this year we have had I think 45 bills introduced that were specific to pain management and mandating CME. Those bills, a few have passed this year. Out of the 45, we have Minnesota, New York, New Jersey, Georgia, and Utah that have actually passed legislation.

The state trends here, again, just showing the trends for the prescription drug monitoring programs. As kind of a national perspective, we see as of last month, we had 49 states and the District of Columbia and the territories that have

operational prescription drug monitoring programs. As I mentioned earlier, in Missouri I think about 45 percent of all residents are covered due to the work between the counties and the cities to adopt some sort of local programs.

We are seeing certainly a trend to have physicians register with their state prescription drug monitoring program, 35 states require some sort of access to the database for certain populations or certain circumstances, and 8 states are actually requiring access to the database prior to each prescribing of a designated substance.

This is an area that I think that the state medical boards are looking at as far as whether this is something usually being -- it's from the legislature versus being medical board driven for the most part, and trying to look at is this really an effective means by requiring it in every circumstance or when should it be required.

What we see that is actually happening, when boards are seeing a case that comes before them, if the prescription drug monitoring program was

available and they chose not to access it, it can be considered as they evaluate a case. Does it really meet -- even though it is not specific, a specific requirement, it still is becoming part of the standard of care. So it's just a tool in the toolkit for the prescriber to use in taking care of their patients.

As far as content-specific requirements, we have 40 states currently that have content-specific CME. Twenty-six of those is specific to pain management, 10 have the CME just in their primary area of practice. There are some that are specific to prescribing and a few with end-of-life care.

I think that this is a trend that we'll see continue, and I think this is an area that we can talk about as far as bringing some consistency of the programs. However, a one size fits all may not be the answer when you have different specialties with different needs of different populations of patients that they take care of.

This is a slide, and you certainly can't read this, but the federation publishes a biannual

publication on a trends and actions report, and it has a number of tables that really will look like these. It will show every board of the country on a variety about 28 different issues as to what the requirements are.

So if you have a question about some of the specific requirements in your state or around the country to get a flavor, that document is available on the federation's website.

I'm just going to conclude with that at the last annual meeting of the Federation State Medical Boards, which was last month, we had a resolution brought forward from one of our member states to look at this mandatory use of prescription drug monitoring programs.

The resolution did pass, which will require us to look at this issue. We've already established a workgroup that will be studying the use of prescription drug monitoring programs in the United States and looking at if mandatory use has a positive impact on patient outcome and prescribing practices, look at the feasibility of incorporating

the PDMP into electronical medical record systems; looking at how those systems can really be utilized to be in the workflow of the provider, and look at recommendations as how the states may look at mandatory use and whether or not this is something that should be on a select basis or more incorporated into the standard of care versus mandatory based on every prescription.

So I encourage you, if you would like to participate or if you would like to provide your comments as this workgroup gets started, we are planning to begin that work this summer and would certainly invite any of your comments and expertise.

With that, thank you and happy to have any questions later.

(Applause.)

DR. THROCKMORTON: Thanks Lisa, very much.

Next, we are going to hear from the National Governors Association. Melinda Becker, senior policy analyst health division, Nation Governors Association Center for Best Practices. Welcome.

Presentation – Melinda Becker

MS. BECKER: Thank you, and good morning. Again, Melinda Becker. I'm a senior policy analyst with the National Governors Association Center for Best Practices health division, and I'm really glad to be participating today.

I'm going to talk about how states are working to enhance education and training for opioid prescribers and other healthcare providers, and how that fits into their broader prevention efforts. I'll give a little bit of background about NGA and how we're supporting governors in addressing the opioid crisis, provide an overview of some key prevention strategies, some of which have been touched on already, and then give a couple of state examples where there are continuing education requirements for opioid prescribers and other providers.

The National Governors Association is the nation's oldest organization serving the needs of governors and their staff. This is a picture of the 1908 Conference of Governors, sort of a

precursor to NGA's annual meetings where governors came to Washington for the first time to meet with then President Teddy Roosevelt.

The organization is divided into two main parts, the Office of Government Relations, which serves as the voice of the nation's governors in Washington, and the Center for Best Practices, where I sit, which you can think of as a cross between a think-tank and a consultancy for governors and their staff.

NGAs opioid work is a partnership between our health division and our homeland security and public safety division, and it's made possible by the support of the Centers for Disease Control and Prevention. So I want to just recognize CDC for their partnership.

To underscore why NGA has been so active in this space over the last several years, you'll see on the next slide a map of age-adjusted death rates between 1999 and 2014. And Dr. Throckmorton showed us some of this earlier, but we've got a time-lapse.

Again, you can see as you are moving from the purples, blues, and greens, the problem is getting worse as you go to that yellow, orange, and red where there are higher rates across the country. Since 1999, the number of overdose death rates have quadrupled nationally, driven by an increase in overdose deaths related to prescription opioids. According to CDC, 91 people die every day of an opioid-related overdose. That's one person every 15 minutes, and more than a thousand people will visit the emergency room today for an overdose.

In addition to the human toll, the epidemic is putting pressure on state Medicaid budgets, social services, and public safety, and it is something the governors are hearing about from their residents and reading about virtually every day in their local newspapers.

This is a timeline of how NGA has been involved over the last several years, in supporting governors on this issue. Our work began in 2012, with the first of two policy academies focused on

prescription drug abuse where we helped a number of states develop and implement strategic action plans to address that problem.

Fast-forward to 2016, to the NGA winter meeting where governors expressed frustration regarding the pace of change and the number of opioid prescriptions written really recognizing that prescribing practices have been a key factor in driving this crisis.

That call to action from the governors lead to the NGA compact to fight opioid addiction. This was signed last summer by 46 governors, who committed to re-doubling their efforts in three areas by reducing inappropriate opioid prescribing, changing the nation's understanding of opioids and addiction, and ensuring pathways to treatment and recovery.

Also, in July of last year, after extensive research and consultation with states and other national experts, the NGA center released a road map to help states assess the problem and their capacity to address it, select evidence based on

promising strategies both healthcare and public safety, and evaluate the strategies that they're putting into place.

In developing the road map, we took time to assess the factors that are driving the prescription opioid and heroin epidemic to help states more effectively target their strategies. One of the three key factors identified is the wider availability of prescription opioids, as well as the lack of access to treatment for opioid use disorder and the changing economics and supply of illicit opioids like heroin and illicit fentanyl.

From that research, we developed a policy framework that integrates healthcare and public safety strategies along this continuum from prevention, through treatment, and recovery. And it's from this comprehensive framework that we have identified specific healthcare and public safety strategies for prevention and response that states could consider to address the problem.

I'm going to skip this slide for now.

This slide lays out the best and promising

healthcare strategies for prevention and early identification that we highlighted for states in our road map. One of the most prominent is developing and updating guidelines for all opioid prescribers.

To give some examples, Washington is one of the states that's really led the way on prescribing guidelines. Their guidelines along with other state efforts importantly have contributed to a 40 percent decline in prescription opioid-related deaths between 2008 and 2014. More recently, last summer Wisconsin passed legislation authorizing the State Medical Board to issue a guideline through regulation.

We have also seen states increasingly adopt new limits on first-time opioid prescriptions for acute pain with exceptions for certain patients. Over the last year, a number of states have really followed Massachusetts' lead in passing statutory limits. And most recently, Governor Bevin in Kentucky signed a bill that limits first-time opioid prescriptions to three days with certain

exceptions. I think that's the most stringent statutory limit we've seen to date.

Finally, the last of these strategies that I'll highlight, given the relevance to today's discussion, is enhancing education and training for healthcare providers through changes to curriculum and continuing education requirements.

In a first-in-the-nation effort, Governor Baker in Massachusetts, the Massachusetts Medical Society, and the Deans of the Commonwealths for Medical Schools partnered to establish core competencies for the prevention and management of prescription drug misuse, and a similar effort has been undertaken with the states dental schools, and nursing, and PA programs. Governor Bevin in Kentucky is also engaging medical and dental schools in a similar way to strengthen education for students and residents.

With regard to continuing education, I think prior to 2012, only seven states had required some or all physicians to obtain training in pain management or controlled substances prescribing.

As we heard from Lisa, that number has changed quite a bit over the last several years. And of course there are variations in the types of providers that are required to receive that training, the duration and frequency, and the topics covered.

Just to give a couple of examples of continuing education requirements in the states, in 2012, Kentucky passed a bill that focuses on the regulation of pain clinics, as well as a host of other issues related to prescription drug abuse in the state. The legislation mandated that state licensing boards issue regulations and a host of issues related to prescribing of controlled substances including continuing education related to pain management, addiction disorders, and the use of the states PDMP Kasper.

Physicians in Kentucky are required to complete 4 and a half hours of CME every three years, and there are similar requirements for nurse practitioners and dentists. Kentucky actually implemented that piece of the law with a grant from

one our first policy academies that helped them develop the trainings with a company called UK Healthcare CE Central. And now with the help of a CDC grant, they are updating those trainings and developing separate modules for the different types of providers.

In New Jersey, just recently in February, Governor Christie signed legislation to curb the opioid epidemic, which includes a continuing education requirement for certain healthcare providers, both opioid prescribers and others. Healthcare professionals with authority to prescribe opioids are required to complete one continuing education credit on topics, including responsible prescribing practices, alternatives to opioids, and the risks and signs of opioid abuse, addiction, and diversion.

Healthcare professionals that don't have prescribing authority but who frequently interact with patients who may be prescribed opioids, like pharmacists and nurses, are now required to complete one continuing education credit on topics

that include alternatives to opioids for pain management and identifying the signs and risks of abuse and diversion.

I have outlined some of the steps that states are taking with respect to prevention and education and training for healthcare providers, but I also want to highlight a recommendation that governors made last year to Congress regarding the federal role in this effort.

The recommendation issued through NGA called on Congress to require opioid prescribers to receive high-quality continuing education on pain management and safe opioid prescribing as a condition of DEA licensure, so very relevant to today's discussion.

With that, I will close and happy to take questions later. Thank you.

(Applause.)

DR. THROCKMORTON: Thanks Melinda, very much.

Joanna Katzman is next. She comes from New Mexico. She is at the University of New Mexico,

associate professor, director of UNM Pain and Project Extension for Community Healthcare Outcomes Pain and Opioid Management. Thank you, welcome.

Presentation – Joanna Katzman

DR. KATZMAN: Thank you all for having me speak here today. I was able to come last year and speak to the FDA related to the long-acting REMS issue.

I am going to tell you a little bit -- I'm going to kind of dive deep into the experience that New Mexico has had into the continuing medical education experience regarding pain and safe opioid prescribing.

I have no conflicts of interest to disclose, and what I first am going to talk to you about is the background of New Mexico. We're a unique state, we are the fifth largest state, but we are fairly low in population. We're fairly impoverished. We're populated by a large degree of Hispanics and American Indians, and we've had a heroin addiction issue for a number of generations.

Then I'm going to talk to you about the

mandated pain and addiction training that has been going on in New Mexico since 2012. I am going to talk to you about how that jump-drived the Indian Health Service clinician mandated pain and addiction training in 2015, and then a little bit about my starting project ECHO Pain and Opioid Safe Management for clinicians around the country in 2008, and how clinicians in New Mexico can actually get their mandated pain and safe opioid training through project ECHO. And then finally, I'll just close with some summary points.

Historically, New Mexico has really had one of the highest rates of opioid deaths in the country. We've really not been new to this. Unfortunately, we've really lead the country in unintentionally opiate deaths due to prescription opiates and heroin. As you know, northern New Mexico has really had a heroin problem for many, many decades. For the past decade, decade in a half, we really have been number 1, 2, 3, 4, or 5 in the country for unintentional prescription opiate overdose deaths.

In 2015, we had a marked reduction in where we stand in the country. We dropped from number 2 in the country to number 8, which was an 11 percent reduction from 2014. I think it's because of probably a three-pronged approach. We really take ourselves seriously. We have tremendous key stakeholders in the state. The University of New Mexico, our Pain Center, our Addiction Center, our Department of Health, the U.S. Attorney's Office, we all come together on a monthly basis and talk about these issues.

We have tremendous naloxone programs, required PDMP, and our mandatory continuing medical education. The diversity, as I told you, is Hispanic, American Indian. As you know, New Mexico is significant with 29 pueblos. A large part of the Navajo Nation resides in the territory of New Mexico. And as you know, the American Indian population has a very high-rate of non-medical use and misuse of opiates.

Many deaths as you know are combined with alcohol and other illicit drugs, such as cocaine

and methamphetamine, and in 2014 many of our deaths in New Mexico -- 111, to be specific -- were related to methamphetamine.

New Mexico in 2012 was one of the first states in the country that had mandatory continuing medical education, and I am going to go into detail in that in a minute. As you can see, in 2011, we had 521 deaths in the state. Again, we're a very small state. We're growing in population every year. But as soon as we had mandatory continuing medical education, our numbers dropped.

It was a little bit of a aberrancy in 2014 when our rates went up. Again, 111 of those deaths were related to methamphetamine. Again, we're not the number 1 state in the country for methamphetamine substance-use disorder, but we have a huge problem with methamphetamine-related overdose deaths. You can say that we really are a state of Breaking Bad.

Again, I am now the third person who is showing these slides from the CDC. We continue over the last decade to increase the number of drug

overdose deaths related to opioids in the country with men increasing their deaths more than women, and increasing more than prescription opioids probably because of ease of access, physicians restricting their writing of prescription opioids, and also accessibility, really seeing an increase in heroin-related overdose deaths. And we're not alone here in New Mexico that we are also seeing an increase in deaths related to heroin.

So what did we do in New Mexico? Well, a group of many key stakeholders had been meeting in 2010 and 2011, and Melinda from the National Governors Association did come down -- the NGA did come down in 2012 to meet with the governor at that time, as we were one of the leading states with unintentional opiate overdose deaths.

But Senate Bill 215 did pass unanimously in the House and the Senate that year, and Senate Bill 215 mandated that every clinical licensing board in the state promulgate rules to mandate a continuing medical education specific to pain and safe opioid prescribing, but the key word here was

pain.

The other part of the bill was that a council would be developed for key stakeholders to meet on a regular basis, and that still is going on. That council meets approximately every six weeks year round to talk about unintentional opiate overdose deaths, the epidemic of pain and addiction in the state, as well as a best practices pain management.

What happened is the New Mexico Medical Board was the first board in the state to really come online and say we really need to do something quickly. The governor had signed the bill in April of 2012. And by August of 2012, the New Mexico Medical Boards said we need to realize that this is no different -- this epidemic of unintentional opioid deaths is no different than hantavirus, than a bioterrorism threat, than a drug resistance to an antibiotic, and we need to have all of our physicians, all of our PAs take 5 hours of CME in the next 18 months, all of our physicians and all of our PAs, because that's who sits under the New

Mexico medical board.

What happened within the next three months is that every other clinical licensing board; the New Mexico Board of Pharmacy, because clinical pharmacists have authority to prescribe a controlled substance, the New Mexico Dental Board, Board of Nursing, all the boards that have any clinicians who can write a controlled substance all said we will all do the same thing. We will all synchronize with you, and we will have all of our clinicians take 5 hours of CME related to pain and safe opiate prescribing within 18 months. So that's what happened.

The 5 hours were prescribed, and I'll show you what those 5 hours was about. This is a brochure of the UNM Pain Center, which I am a part of along with our key faculty from the New Mexico VA healthcare system. Our addiction center performed many of these trainings to over 5,000 clinicians around the state. In New Mexico, many live trainings in New Mexico, these were 5-hour trainings in Farmington, Las Cruces, Santa Fe.

We did this over a course of two years, and we asked these clinicians if they want to participate in research. Ninety-nine percent of these clinicians participated in institutional review board research looking at pre-post changes in knowledge, self-efficacy, and attitudes, and I will show you these results momentarily.

The topics of these courses were mandated by the New Mexico Medical Board. So not only did our UNM Pain Center have these topics, but the New Mexico Medical Society, the Greater Albuquerque Medical Association, and all over the state had the same topics.

We wanted to educate the clinicians about the epidemic of pain and opiate overdose statewide and nationally. We wanted to teach clinicians predominantly about the use of non-opioid analgesics because we realized that that's what they needed. They needed better tools in their toolbox, not just to be prescribing opioid analgesics.

We wanted clinicians to understand screening

tools and screening practices to be able to identify who might be a patient, who could be at risk if prescribed opioid analgesics, and if they had chronic pain, how best to take care of them if they needed to be placed on opiate analgesics.

We had a section on pediatric and adolescent pain. We wanted to be able to teach about federal and state laws pertaining to controlled substances and teach clinicians about prescription drug monitoring programs. This is a perfect way to teach clinicians how to use the PDMP.

Finally, a big part of it was teaching clinicians about naloxone, about antidotes, about medication-assisted treatment. Of course not a full buprenorphine training, but also about the importance of co-prescribing naloxone, especially to your high-risk patients.

Ninety-nine percent of these clinicians opted in for our research. They took knowledge questions, self-efficacy questions, attitude questions before and after the course. It was on a voluntary basis. We published this. We studied

this just on our first 1,075 patients. Half of them were physicians, half were mid-level provides, and pharmacists and dentists. What we saw was a very significant change in knowledge, self-efficacy, and attitudes.

This is probably too small for you, but we also work very closely with the New Mexico Board of Pharmacy who works closely with the Drug Enforcement Agency, and we did not see an associated change in the number of opiate prescriptions filled as a result of these courses or as an association time wise with the result of these courses, and we were glad about that.

New Mexico's an extremely rural state, and except for three cities, the population of most cities is very small. Many of our clinicians are nurse practitioners, PAs who work in solo practices, and we did not want to cause a chilling effect and have clinicians say I'm not going to prescribe, I'm not going to renew my board of pharmacy or DEA license.

So we were glad that we did not see a change

in opiate prescriptions, but what we did see is a significant drop in morphine milligram equivalence, and we did see a significant drop in valium milligram equivalence, which is the way to see a significant drop in benzodiazepine prescribing. Had I known now, I would have looked at co-prescribing, but I would do that -- maybe I will go look at that right now.

(Laughter.)

DR. KATZMAN: Being in New Mexico, we do a lot of work with the Indian Health Service. The Indian Health Service Telebehavioral Center of Excellence is located a mile away from where I work at UNM. We have an MOU with them. I started project ECHO, a telementoring program with the Indian Health Service clinicians nationwide where a group of us, myself, and internist who specializes in pain, and an addictions psychiatrist, teach clinicians every week who come on an Adobe Connect-like network. This started in 2013.

In 2015, Susan Karol, the then CMO for the Indian Health Service in the central office here in

Rockville, said, you know what, we really want to have mandated training like you did in New Mexico. So we pretty much replicated our New Mexico trainings, but we did this virtually via video conferencing technology.

Dr. Karol and the Indian Health Service, what we've done with about 12 BTC trainings, we've trained almost 3,000 clinicians -- about 5,000 clinicians have come on the network, but 3,000 of them have been IHS specific clinicians.

We've provided over 10,000 no-cost CMEs for these Indian Health Service clinicians. We've also studied them through institutional review board. We published this. We've seen the same data, and the IHS is now looking at pharmacy data as we speak. The clinicians from the IHS came from 28 states primarily from Arizona, New Mexico, Minnesota, and Oklahoma.

Since I'm from UNM and project ECHO -- and project ECHO now, it's a telementoring program, it's a clinician-to-clinician educational program. I think it's very relevant for today and tomorrow's

discussion in that it's clinicians teaching other clinicians how to take care of their patients more effectively.

We offered this training at Project ECHO. We offered clinicians in New Mexico who need mandated pain and addiction CME hours. They are able to get their hours through our project ECHO training. Through our Project ECHO pain and safe opiate management -- here are the topics -- we offer these five 1-hour trainings. We offer it three or four times per year. We've given this training to the Army, to the Navy, as they have replicated their Army and Navy pain ECHO as well, and we've helped the VA also replicate their pain ECHO through Project ECHO.

What I would like to tell you is that we are excited because in March of 2016, New Mexico passed this naloxone standing-order, which I think also helped reduce the rates of overdose in the state. Then, just three weeks ago, the state passed really cutting-edge legislation that I was fortunate enough to help craft in that naloxone is now

required for all law enforcement, for all patients in every medication-assisted treatment facility, to have two doses of take-home naloxone, overdose education, and a prescription. And for every inmate who is released from a correctional facility to be given two doses of take-home naloxone, a prescription, and overdose education.

So I think that the combination of continuing medical education, wide distribution of naloxone, as well as law enforcement being mandated to carry it, in addition to PDMP being mandated, I think that New Mexico is going to really reduce our numbers even more. Thank you.

(Applause.)

Questions and Answers

DR. THROCKMORTON: All right. We have a few minutes for questions and discussion if people want to come to the microphones and ask questions. While people are collecting their thoughts, I am going to ask a question to Melinda and Joanna.

Both of your organizations have made some fairly aggressive recommendations or put into place

some fairly aggressive things in terms of requirements for education. I'm just curious how that's been received by your respective communities, and is it well received, have you gotten a lot of push-back, and have people seen the value.

MS. BECKER: I'll just say quickly, the strategies that we highlight, including requiring education and training for prescribers are really just us helping to lift up what we see as best in promising practices for states, rather than real recommendations, if you will.

I think generally states have gotten a lot of great feedback on the road map itself as a tool, and I think states are looking at all of these strategies as sort of part of their comprehensive work.

Related to the recommendation that came out of the Office of Federal Relations last year, I have to be honest. I don't think -- I know it's something that the previous administration had been generally supportive of, and it's not something

that we've heard a lot from our membership about.

DR. KATZMAN: What I can tell you is, New Mexico, we've had very little push-back. We've had maybe one or two clinicians at each course say -- come up to one of the faculty and personally saying why am I needing to take this. I'm a radiologist or a pathologist. I don't see patients. And we explained that it's really important that everybody takes these.

I did not mention this, but no clinician, no physician is excluded in the entire state. If you're a pain practitioner or you're a pathologist, you have to take the training. So nobody is excluded. And I would say there has been very little push-back and very little chilling effect.

Thanks, Doug.

DR. THROCKMORTON: Thanks. Go to the microphone here, and please identify yourself when you speak.

MS. CHAMBERS: My name is Jan Chambers. I'm the president of the National Fibromyalgia and Chronic Pain Association. I'm really happy to hear

of the progress and see all of the impact that we are having on safe prescribing. I know that there needs to be a lot more to make sure that all treatments for pain management need to be addressed to advance.

But I have not heard one comment about the feedback that you are receiving on the impact on patient's pain or on their function. When we look at this and we are assessing the opioid use or the overdoses and things, that's one measurement. And I'm wondering, are there measurements that you have in place, and what are they?

DR. KATZMAN: Thank you Jan. This is Joanna. Absolutely. So that's primarily what we discuss in these courses, is when we talk about screening for addiction, we teach the clinicians about screening tools and how to screen patients.

When we talk about pain management and non-opioid medications, we discuss that. When we talk about how to assess a patient for their pain, we talk about functional outcomes and not just a scale of 0 to 10 and what makes a patient -- how do you

assess improvement. So we give the tools. Thank you.

DR. THROCKMORTON: Over here?

DR. KAHN: Norman Kahn, convener of the Conjoint Committee on Continuing Education. My question is for Dr. Katzman also.

Joanna, I've heard you present before, and I'm confused by the relationship between some of the data that you showed and some of your conclusions.

You showed a slide with eight successive years and numbers of opioid deaths and concluded that they had gone down. But in reality, as I looked at that slide, they went down for three years and then they went up-and-down for three years, and then they went back up. So there's like three-year cycles where they go up-and-down.

Then, there was a slide on morphine milliequivalents and talked about a significant reduction. On the other hand, the year at the bottom was higher than the second year at the top.

So I'm confused by the conclusions and how

they relate to the data.

DR. THROCKMORTON: I might suggest maybe that you guys discuss that at the break or something, rather than -- would that be all right? Unless you have a slide in mind that we can go back to quickly. I am just mindful of time.

DR. KAHN: Doug, I am happy to do that. The reason that I bring it up is that we are all going to be talking about mandatory continuing education. And if we draw conclusions that mandatory continuing education works, then we need to have data that reveals that it works, and the data did not reveal that it worked in that particular case. I think that is something that we need to hear about.

DR. THROCKMORTON: Couldn't agree with your first statement more.

Let's go over here.

DR. BERGER: Yes. My name is Tom Berger. I am executive director of the Veterans Health Counsel for Vietnam Veterans of America, and I would like to address the following question to my

colleague from New Mexico.

First of all, we are the only veteran service organization that has chapters behind the walls in prisons throughout the country. But my question is, under the legislation passed last month, the last item, take-home naloxone, are they also required, those inmates who are being released, required to attend recovery meetings?

DR. KATZMAN: As part as Senate Bill 370 -- that's not part of Senate Bill 370, but I don't know the terms of certain inmate's probation. So I don't think I can answer that sufficiently.

DR. BERGER: Thank you.

DR. THROCKMORTON: Over here?

MS. COWAN: Penny Cowan, American Chronic Pain Association. And I'm just wondering, I've heard a lot about pain management education, and I don't know what that means. There are so many components to pain management. And what we're hearing a lot, at least at our office, is that people are being actually abandoned right now because the providers aren't willing to prescribe

opioids for them, but they're not giving them anything else.

I'm wondering, are you teaching these practitioners all the other pain management components that are really necessary for a person to live a full life in spite of their pain? It's possible, but we have to teach them. We can't just tell them. And I'm wondering, are you teaching them those skills as well? That's really important.

DR. THROCKMORTON: Actually I think that's probably for all of you to comment on that.

MS. ROBIN: Well, from the medical boards' point of view, I really appreciate it. I think that there is certainly a paucity of real good data to show that the CME and the one size fits all, CME works, and you know what the outcomes are. And I've had a number of talks with colleagues around the country at medical boards that really would like to figure out if we can do some really good research around that and look at can we really tie it to patient outcomes.

I can just speak to -- I know our recent policy work in this area, a big focus of it was really on the patient and taking care of the patient, the whole patient, and the responsibility of the prescriber to understand it is taking care of the whole patient, and that they need to look at all of these different modalities.

As medical boards, they're not specific as far as putting on the curriculum on particular programs, but more that it's the responsibility of good medical practice to be able to familiarize yourself and have the knowledge to treat the patient. With various modalities and looking at outcome and function, as you mentioned earlier, that that really is the primary focus of what the prescriber should be looking at, would be that function and patient outcome, not just one modality.

DR. THROCKMORTON: We're going to go over here, and I think we'll just end with these two here.

DR. GREENBLATT: Thank you. I'm Larry

Greenblatt, and I am a general internist at Duke and leading an opioid safety effort there. In my state, which reflects what's happening across the nation, we are seeing a slight uptake in prescription opioid overdose deaths, which we certainly are very concerned about.

But we're seeing a sharp rise, like the rest of the country, in heroin and fentanyl and fentanyl analog deaths. And those numbers are shooting up at 30 to 50 percent per year. And now when you add up the illicit drug overdose deaths, they have far surpassed prescription drug overdose deaths.

I'm wondering, are any of you looking at any strategies for reducing the numbers of people that end up on illicit drugs? I don't think I fully understand why is it that some people end up switching over and some don't, but shouldn't there be some sort of systematic effort at preventing that problem in addition to offering treatment in naloxone rescue kits?

DR. THROCKMORTON: With the focus on education, I guess I'm hearing an interest in

educating prescribers about that potential transition also?

DR. GREENBLATT: Strategies for preventing individuals from starting on illicit drugs. Do we have any, and are we teaching that?

DR. THROCKMORTON: I'm looking around. I think that's a challenging transition. I think there's a lot we don't understand, hard to know what to say other than we do know that it occurs sometimes.

I don't know if any of you have comments on that.

MS. BECKER: Yeah. I'll just say at the National Governors Association, we've been very focused on this issue of illicit opioids. And really our work with states and the various learning labs we've done over the past nine months or so has really focused on expanding access to treatment and improving screening and referral and making those linkages to treatment where possible. It is something we've been trying to wrap our heads around as well.

DR. THROCKMORTON: The point is a good one though. Prevention is obviously what we're all trying to do. But when someone is later on in addiction, it's very hard.

Go here please.

MS. KEAR: Cynthia Kear. I'm with CO*RE. CO*RE is an 11-partner organization that represents over 700,000 prescribing clinicians, not including our online partner Medscape. We've been doing this for a while, since two thousand -- well actually before that, actually 10, but anyway -- and we've had a lot of activities.

My comments are largely geared -- and they are comments for Lisa and Melinda. It seems to me as we go out and try to leverage our education to tie it in with state requirements or state opportunities, that there is so variance, whether it is in the actual topic, end-of-life, pain, opioids, or whether it is by prescriber type or by credit, unit, amount, et cetera.

It would be so wonderful if we could have much more of a focused coordinated effort there,

appreciating that there are differences, but nonetheless trying to leverage some of the basic standardization of the education so that we can make these links more tightly. And also, while this remains voluntary educational activity for clinicians, I think really appeal to them and bring in more number of those actual prescribers.

The other point that I'd just comment is, Lisa, it would be so interesting if we could also have your data that would include PAs and NPs as well. So I don't know if that's possible for the future. But anyway, as I said, it's more a comment than a question, but I think a really compelling effort that would help everybody in this.

Thank you all for your comments.

MS. ROBIN: I would just like to comment, I think that that is -- exactly. If we can come to some standardization around that, it would be a resource that we could provide. As you know, we have through our foundation a couple of years ago provided block grants to state boards to put on trainings, and it was very positively received.

I would love to see things like that where we could do resources for medical boards to be able -- and I think that that might be the link through your medical and nursing boards, because then you're really reaching all the prescribers because they would fall -- well, and you've got dentistry as well. But you are going to reach the most of the prescribers through those two boards. And the good thing about that is they reach everybody.

So some basic courses. And I think they have to be fairly basic. If we could decide on what is this level, then we would need everybody to know, and that that's a good -- it's a great forum to reach everybody and that they can do that with a nudge. Because most people do look at their license and look at things that come from their licensing board because they hold their livelihood in their hands.

I think if that's something -- but I would just encourage us to look at something. If we could come up with a basic foundation, and then

there's other add-ons, obviously. But if we really could all come to an agreement on a basic foundation of education that you want every prescriber to be familiar with -- and that that's throughout the country. I think that could be well received among the regulators because, as I said, they don't necessarily have the resources to be developing programs themselves.

DR. THROCKMORTON: Lisa, real quick follow-up question. We've talked a lot about the trends in medical boards requiring and prescriber education. What about healthcare providers, non-prescribers? What are the trends there?

MS. ROBIN: We believe that -- you look at how healthcare is delivered, it is a team effort now. We are taking care of patients as a whole team of providers, and that it should not be just limited to the prescriber because the other members of the team have a huge role in that. That's why I say if you have a basic level of a foundation, education, pull all the members of the healthcare team into offering the education. I don't think

that you can just gauge success on the actual prescriber.

DR. THROCKMORTON: Yes. I was asking you, and I guess Melinda also, is actually are there trends legislatively, trends in expanded requirement for training, or formal training for those groups too? I think we all agree with the team approach.

MS. ROBIN: I have not seen that necessarily in the mandates. And I will just say as far as the mandates, I find that oftentimes some of the mandates and legislation doesn't necessarily involve the regulators that actually do it, the boards of nursing, the boards of medicine. It's more coming from the legislature or the governors' offices. So I think in some states there's not involvement, which is unfortunate. Maybe if we had more involvement, then we could come up with better policy.

DR. THROCKMORTON: Melinda, if you had anything else.

MS. BECKER: Yeah, it's not something that

we track, but as I mentioned, New Jersey, which I think has one of the newer requirements, there's a component for non-prescribers, practitioners who are involved in the care of patients who are being treated with opioids.

DR. THROCKMORTON: Great, thanks.

One last question.

DR. MILIO: Lorraine Milio. I'm representing the Society for Maternal Fetal Medicine. One of my concerns is that a lot of the required CMEs are not addressing issues of pregnancy and prescribing opioids in pregnancy. And this is a major problem because a lot of chronic pain clinics discharge patients when they are pregnant, and obstetricians are not comfortable doing the pain management, so patients conceal their pregnancy, together with the fact that opioid misuse disorder is becoming a leading cause of maternal mortality in multiple states.

I just wanted to ask if that should be under consideration when we are looking at providing physician education on the subject?

DR. THROCKMORTON: Claudia, remind me. I believe that's in the draft blueprint.

DR. MANZO: I don't know exactly how much we get into special populations in the actual blueprint, but I think those are good comments, and we welcome you to submit those to the actual docket, blueprint docket.

DR. THROCKMORTON: Agreed, something we've worked on a lot I know.

Thank you very much. We are going to have a break now. I have 10:22, so let's come back at 10:32. Thank you very much.

(Whereupon, at 10:22 a.m., a recess was taken.)

DR. THROCKMORTON: While people are taking their seats, I'm going to start the next session. Before lunch, we have two speakers. The first speaker is Doris Auth, who's in the FDA and in the Office of Surveillance and Epidemiology. She's the associate director there, and she's going to be talking about the REMS, options and considerations.

We're starting with Fred Brason. My

apologies. I'm jumping the session here.

I think as many of you know -- Project Lazarus obviously has been engaged in this effort for many years, and I'm going to sit down before I say something else I shouldn't.

(Laughter.)

DR. THROCKMORTON: Fred, thank you.

Presentation – Fred Brason

MR. BRASON: Thank you, Dr. Throckmorton, and thank you FDA for the opportunity. And I really appreciate the comprehensive nature of what you're looking at over these two days regarding prescriber education and addressing the issue that we all find very personal in our lives and in the lives of our community.

As you can see, Project Lazarus began as a community-based, non-profit addressing the issue of prescription opioid medications. And we did that with the premise of wanting to obviously prevent the overdose deaths, but at the same time present safe and responsible pain management because we do have people with pain, and we didn't want to move

them out of the availability and accessibility of treatment. But at the same time, we wanted to make sure that we promote and establish and implement effective substance misuse treatment and support services.

We have done that in many, many communities now, utilizing this model so that we were addressing prescriber education -- yes, which is what we are talking about today -- the ED policies; diversion control, because that's where most of what unfortunately is creating havoc -- it's not from the original prescription it's how it's passed on to somebody else -- making sure that the person with pain has appropriate support and the modalities of treatment are available, accessible, and paid for; harm reduction with naloxone, that you've already heard somewhat about; addiction treatment to ensure that all modalities are available in our communities; and of course community education going forward.

I will state I have no personal conflicts regarding this. As a corporation, Project Lazarus,

we've had a charitable contribution from KemPharm, and we are currently involved in a project for medication disposal throughout the state of North Carolina with Purdue Pharma; other than that, nothing to disclose.

But as we began the approach in our own community, we initially looked at how do we reach our prescribers to gain not only their access, but to gain their attention to the issue and the problem at hand. And we found that if we could do that locally, we got more of their attention, we got more of their buy-in, and we got more of their energy to do what needed to be done to bring about change and best practice with what they were doing in prescribing every day so that they weren't opting out, so that they were continuing to prescribe, but make sure that the right elements were there.

We found that not only in our own community, but through a health director's survey throughout the entire state, it was the lunch-and-learns, it was that community based level engagement that

brought about most of the changes; not the global CMEs, not all of the other ways that it can be done, but that one-on-one or practice-to-practice within the local community.

We found that through that, there has been some comfort and the continuation of treating chronic pain. And as you can see here, it feels like now there's a guideline explaining all what needs to be done, and the prescriber felt covered by following the guidelines. And of course, we have various guidelines today, some across the nation; different states saying this, different organizations saying this. And of course, we have to come with something that's more uniform.

But again, once there's that knowledge and understanding and in putting it into practice, we not only found that the prescribers were more content and continuing to prescribe, but the patients felt validated with their condition. They felt validated in the pain that they were having, and that they did not push back against treatment agreements, or urine screens, or pill counts

because they felt that they were engaged in their own care and that interaction with patient to prescriber brought about change across the spectrums.

So it became a win-win in our own individual community, and it was this chronic pain initiative that after the pilot in our Wilkes County, North Carolina did go throughout the state through our community care networks of North Carolina.

You can see here from some of the data that shows from the evaluation that Wake Forest Medical School did in Wilkes, there were significant changes and much improvement in the single prescriber, and only one prescriber and only one pharmacy. And the number of prescribers, the number of phone calls, the number of ED visits all decreased because of more engagement at the prescriber level working with the individual that has the pain, not only the person with the pain, but their family and caregivers also, so that it was a comprehensive approach, and everybody was in tune with the risks and the benefits of the care

that was necessary for that pain whatever the cause.

Second to this, and I am really going through three scenarios that we've done in the state, is we assisted Fort Bragg at the Womack Army Medical Center, began their pain program and enhanced that dating back to 2008 after they had read about us in our own North Carolina Medical Forum.

What they have developed over time is primary prevention looking at risk stratification, doing the urine drug screens and the sole provider agreements and the opioid profiles, doing assessments on the front end to determine what are the risks, and then what are the benefits regarding that patient, continuing with the epi surveillance of that, but then the secondary prevention of education with patient and family, dispensing naloxone directly to those individuals who seemingly were at risk.

That was one of the first foremost things that we did at Fort Bragg and made a significant

change that I'll share in a minute. Then of course, we were able to implement buprenorphine as a detoxification method. And now of course, now there's buprenorphine medication assisted treatment allowed through Tricare within the military and at Fort Bragg.

But what we found through that initially, that they were having 15 overdoses per 400 soldiers, and in one year, that was reduced to 1 to 400. Of course, those that had survived overdose, they had 17 per 1,000, and that dropped to 1.4. And the contributing factor to that early on was that sitting down and the co-prescribing of naloxone with the soldier, with the soldiers, whoever was around them, whether it was a family, a spouse, whether it was their brigade sergeant, whoever was engaged with them, sitting down because it created that stop, look, and listen moment so that they could see and understand the risk that was involved but also the benefits that were involved. And it changed everybody's behavior surrounding that medication.

Because we know that prescribers can prescribe it exactly how it's supposed to for the right diagnosis, the pharmacy can dispense it, but once it walks out that door of the pharmacy, it is in the community, and the behaviors are not so easy to control at that point.

But we found that within the Army, which is a controlled atmosphere, that we were able to do that. And of course, now they're using abuse-deterrent formulations for the refills, again, just to add the insurance that diversion doesn't occur.

So it's a systematic approach, risk stratification, risk mitigation, provider education, and other modalities with opioids, including for that pain management, and again, in the military they're covered and they're accessible. That is not true across the spectrum of medical care, and we hope that that will change also.

It did result in a reduction of opioid prescribing with decreased healthcare utilization,

and an improvement with what we're all after, patient satisfaction. So pain care still continues, and satisfaction is there with or without opioids, but using all the modalities that are available to those individuals.

Just to give you an idea with the CMEs that we do -- and normally we don't create any CMEs and we're always a part of somebody else's CME. So I can state unequivocally that any donations, any contributions to Project Lazarus have never ever gone to any kind of CME support or training.

But we notice that when we do this at the local level, there is that -- I strongly agree and I agree that the presentation positively impacted my ability to provide services to patients or clients. So that one-on-one, that small group at the local level brings about that kind of change, and then of course they understand the community aspect and the engagement and the comprehensive nature of that going forward.

But who is responsible for ensuring client patient understands how to take prescribed

medication? Well, when we talked about 32 individuals at one CME, it was the prescriber, the pharmacist, the client, the patient, again where does that happen in the mix? Because we can do all the prescriber training, but if it does not transfer to the patient, family, and caregiver, then we've got a gap.

So it has to rollover to that scenario so that there is a full understanding among whatever that medication may be with that family, client, and caregiver.

How do you ensure that client patients understand how to take their medication correctly? Again, you can see most of it yes is the 42 percent at the prescribing level, that one-on-one conversation, but others have a different modality. And just handing a med-guide -- I hate to say -- who reads it? Do they understand it?

So it has to be that engagement, that conversation, again, so that the risks and benefits are balanced and bringing in the other individuals surrounding that patient.

The third component that has been evaluated in North Carolina regarding Project Lazarus, our work has been done by UNC Injury Prevention Research Center. All of the spokes that you saw on the initial model of Project Lazarus have a direct impact on the mortality, ED visits, and hospitalizations from prescription medication mainly, but now we are also in the spectrum of heroin and fentanyl.

But we realized early on when we went statewide in 2013 and 2014, the two that made the direct immediate impact were prescriber education and emergency department policies regarding the level of prescribing for the individuals that were attending there.

The third aspect of that was the addition of addiction treatment within that community, that local. That happened on basically in a short-term basis. And the other spokes of that wheel, it was over a longer period of time. But every single one has a positive impact, but we learned through the UNC evaluation that when communities do all of what

we're doing, then they have the greatest impact.

So there isn't any one thing that we can do. We can't focus in on just one thing. We can't just say it's prescriber education and prescriber education only that's going to make the difference. No, it's not. It's everything else that goes along with it.

This is a society and social issue that we're dealing with across the board, and we have to make sure that we address it that way. But to have a 9 percent and a 3 percent immediate drop in mortality and ED visits, and so forth within those communities, that is significant, and we know that it only grows from that going forward.

The most effective strategies to immediately reduce overdose rates, and this is from the study from UNC, were prescription education related to pain management and addiction treatment; policies designed to limit the amount of opioids dispensed in emergency departments, because that is what we found to be a frequent place for obtaining for right or wrong reasons; and greater utilization of

addiction treatment that has to be expanded across the board. It's sorely missing in all our communities.

But again, prescriber education has to be linked to substance-use disorder, opioid use disorder, and addiction treatment because they all have to be engaged together.

That has to be not only part of the education, but then part of what spills over to that patient, family, and caregiver and into the community from the prescribing level, and along with, again, we found that co-prescribing of naloxone is that stop, look, and listen moment that gets everybody's attention. And that changes the behavior of what we're after and what we're looking for, yet, it continues the ability and the availability of continuing to prescribe in order to meet the need of the pain.

Same local strategies to prevent overdose should consider interventions within the healthcare system, but use community based coalitions. And that's something else that we have learned through

the evaluation, is it's, again, at the local level, the coalition work builds the energy, so it builds the desire to do best practice, not only in the practitioner's office but, again, in that patient, family, and caregiver's home, that they're doing best practice with the medication, and ensuring that nobody else gets their hands on it.

Who best to inform the patient, family, and caregiver of how to take it correctly, dispose of it properly, than the prescriber and then the pharmacist because that's at the front end.

Yes, we want all of that to be done in the community, and we've been broadcasting that in communities. We've been broadcasting naloxone with law enforcement, first responders; that is all necessary. But if the patient walks out with the information as to where I need to dispose of this when I'm done with it, and that I have naloxone just in case, and I have an overdose plan, then those combined make a difference in the behaviors and changes within our community. But the energy has to come from within the community, and that has

been our approach from the beginning and our success across the board.

Now the words that I want to share, and my words are never paid for, bought for, or written, or spoken, or coerced by anybody else, but where there is a will, there is a way.

When we began the work in North Carolina to begin prescriber education across the state, it was more for us pushing that education, but now we're seeing that we are being pulled for that education. So that transformation has occurred where the prescribing community says, yes, we want guidelines, we want assistance, we want to know that best practice is. Let's get together and show us how this can be done.

Again, now we have more of a will, now let's determine what is the best way for that to done without just simply mandating and saying this what needs to be done. Well, if we mandate this, what does that look like? And if the state mandates this, what does that look like? If it is not uniform, we are missing something because there

could be gaps in that.

The training alone, we learned is not sufficient. There has to be the support for the general practice. There has to be the integration of behavioral health, addiction treatment, and all of that, because now we are looking at team-based care. So it isn't just writing the prescription, it's that holistic comprehensive approach around the patient care that we find makes a difference.

Again, the availability, the accessibility, and the covered modalities for pain management should be readily available. If our guidelines are saying begin here and not here, then we have to make sure that that beginning is easily accessible and covered and paid for in order to meet the need. Because if we fail to treat, then we have walked into the arena of mistreatment, whether it is for people with pain or whether it is somebody who does have a substance-use disorder, addiction issue, and the prescribing community has to be engaged in all of that. Thank you very much.

(Applause.)

DR. THROCKMORTON: Thanks very much.

Next, we're going to hear from another federal system from Dr. Bernie Good at the VA. He is the chair of the Medical Advisory Panel for Pharmacy Benefits Management at the Department of Veterans Affairs, also professor of medicine, and a member of the Drug Safety Board at the FDA.

Bernie, thank you.

Presentation – Chester Good

DR. GOOD: Thanks for the opportunity to speak. I am with the Department of Veterans Affairs. I have no conflicts of interest with any pharmaceutical company. I do chair the Medical Advisory Panel for Pharmacy Benefits, as Doug stated, and I co-direct the VA Center for Medication Safety, and I am a member of the FDA's Drug Safety and Oversight Board.

I want to start with pain as the fifth vital sign, and the reason I start here is because this was early pain education that VA started. It was back when the American Pain Society recommended that pain be promoted as the fifth vital sign.

James Campbell, president of the American Pain Society in 1996, said, "Vital signs are taken seriously. If pain were addressed with the same zeal as other vital signs are, it would have a much better chance of being treated properly."

The Department of Veterans Affairs was an early adopter of pain as the fifth vital sign. In 1998, we started a national pain strategy where this was incorporated. And in 2000, the VA mandated that pain be the fifth vital sign, so that every time that a patient would be seen and get blood pressure, they would be asked about their pain on a scale of 0 to 10.

This shows that at least part of the outcome of that education was that we ended up with quite a few patients on opioid medications for chronic pain. By fiscal year 2016, these are the most recent data, we had 1.2 million veterans that received at least one opioid prescription. That's 15.4 percent of all of our patients who got any prescription in that fiscal year.

This was down. It peaked in 2012. We had

more than 7 million total opioid prescriptions, and we have 30,000 VA prescribers who prescribed at least one opioid prescription. We had 35,000 veterans who remain on more than 100 morphine equivalents a day, but that is down from about 60,000 in 2012.

I think it's important to say that pain is especially prevalent in VA. Fifty to 60 percent of veterans have chronic pain. And again, 11 percent of veterans with pain get those opioids chronically. This compares to about 30 percent of the general U.S. population with chronic pain.

I have here a timeline, and I am going to focus on those areas in red, because those are part of our education system. In 2013, we started the Overdose Education and Naloxone Distribution Program, and we'll talk a little bit about that.

In 2014, we started our Academic Detailing Program with a focus on opioid prescribing. In 2016, the VA and Department of Defense Pain Guidelines were issued, the most recent iteration of those. And in 2016, we also had mandatory

opioid training for all VA prescribers.

We have an opioid safety initiative, and this is a comprehensive program, which includes individualized prescriber facility and regional reports. It includes provider tools to identify high-risk patients at high-risk for overdose. We have a comprehensive naloxone distribution program. As I mentioned, we have academic detailing and prescriber education as just some of the opioid safety initiative.

In order to provide the patient, prescriber facility, regional and national, opioid prescribing information, we have dashboards that are available to all prescribers, as well as site managers for review. We track metrics of interests, and aggregate data is routinely provided to facilities for benchmarking.

These metrics include patients prescribed opioids, presence of urine drug screens, concurrent opioid plus benzodiazepine, and patients on high-dose opioids to find there's more than 100 morphine-equivalent daily dose.

As mentioned, we started the Naloxone Distribution Program in 2013. We provide patient and provider education regarding overdose prevention. There are web-based accredited provider education modules, patient and provider handouts, YouTube videos, et cetera.

We provide free naloxone rescue kits to patients with the education and instructions for use. This program provides reports back to facilities to track the distribution. And as of March of 2017, we had 5200 VA prescribers who had distributed more than 72,000 naloxone kits across the VA. There were 172 documented opioid reversals using these kits.

Academic detailing, in 2014, VA funded this program. It's an outreach education for VA healthcare professionals. This is fashioned after the pharmaceutical industry where it's one-on-one communication by clinical pharmacists using pharmaceutical industry detailing models. Our initial focus is still on opioids and psychiatric drugs. It utilizes individualized online dashboard

metrics.

We have 285 academic detailers throughout the VA. And as of August of 2016, more than 10,000 clinical staff had been detailed regarding pain and opioid safety. We have looked at those detailed, and in those that were detailed, there's a 58 percent reduction in high-dose opioids compared to 34 percent of those without the academic detailing.

As is the case with all education, it's really hard to single out what the impact of education is. That was one attempt. So you can see here, these are the academic detailing visits focused on opioid safety and naloxone.

VA and Department of Defense published clinical practice guidelines, and there's a recent update of our clinical practice guidelines for the management of opioid therapy for chronic pain. This guideline is a departure from previous guideline in that it recommends against the initiation -- and I should have underscored that -- initiation of long-term opioids for chronic

pain; recommends setting limits; recommends short duration only; recommends risk mitigation strategy for those already on chronic opioids; and tapering those opioids when feasible.

There was also a recent clinical practice guideline for the management of low back pain with similar recommendations.

In 2015, the White House published a memorandum, which directed all federal employees who prescribe opioids to be trained in safe and effective opioid prescribing practices. The VA developed several mandatory training programs to meet this directive.

Just like everything we do, we have tracking metrics for the training. And as of April 2017, 96 percent of all VA opioid prescribers had documented meeting those training requirements, including me.

What are the results of the Opioid Safety Initiative? We have seen a dramatic improvement in every metric, which involves opioids. We have fewer patients getting opioids; fewer patients

getting concomitant opioids and benzodiazepine; fewer patients on high-dose opioids; more patients with informed consent and drug screens; and we have nearly universal use of the state PDMPs when available and opioid training of prescribers.

Here's looking at a number of unique VA patients dispensed an opioid over time by quarter, and you can see the two lines. The first is when we had our opioid safety charter, and the second is when the Opioids Safety Initiative was fully implemented. That was August of 2013.

How much of this is due to the Opioid Safety Initiative? I don't know. This is just temporal data. There were obviously national things that were going on, and I'm sure there was spill-over. So the best graph would have been to have shown national data, but that's somewhat difficult to get, surprisingly enough.

This is veterans dispensed an opioid and concomitant, benzodiazepine. You can see there has been a 60 percent reduction in that. Veterans on long-term opioid therapy over time, 39 percent

reduction over the last couple of years. High-dose opioids defined as greater than 100 morphine equivalence, a 48 percent reduction.

So the question always comes up, are there unintended consequences? It's a very valid question. In VA, we've had isolated reports of physicians who implement rapid tapers or setting arbitrary opioid dose limits for patients who are on stable, chronic opioids, and I don't think that's the right thing to do. We need to be veteran centric, and when we've heard about these things, we've tried to reach out and intervene.

But there's been the question raised, well might prescribers be denying patients appropriate pain management when an opioid might be indicated? It's a fair question. There are reports we even heard this morning. There are reports that some physicians are no longer prescribing opioids.

A fair question, is prescribing of opioids being just delegated to a diminishing number of physicians? Are few people carrying this burden of prescribing opioids for those patients who should

get them?

We actually recently looked at this question of are there fewer primary care physicians in VA who are writing for opioids? And the answer is no. We looked at a number of VA physicians who are identified as primary care specialty before and after the Opioid Safety Initiative.

We looked at the percentage of primary care physicians who prescribed opioids over time. And then we focused on the top 25 percent of opioid prescribers to see if they were now caring for more patients to see if there were some physicians sending their patients to others.

Really, the results are remarkably flat over time. So at least in VA, it does not appear that physicians are abdicating their responsibility to write for opioids. Although, in those graphs, you can see that there is a trend for all physicians to decrease their overall percentage of patients getting opioids and unsafe doses of opioids.

In conclusion, I think there's been many lessons that we've learned and continue to learn.

We continue to look for ways to assess our program and improve success. We continue to seek ways to educate opioid prescribers, as well as our patients.

I think it's really a tricky balance between creating work for providers and facilities, and maintaining the trust of our veterans who have chronic pain, and improving the safety of opioid use in the VA. And I should say improving the appropriate management of pain in the VA.

Outcomes like overdose, transitioning of veterans, to illicit drug use, these are difficult to measure, but they are also important things and things that we are trying to look for. That's all I have.

(Applause.)

DR. THROCKMORTON: Our last speaker in this session is Dr. Carol Havens, director of physical education development, Kaiser Permanente, Northern California, and a clinical lead of their opioids initiative.

Carol, thanks.

Presentation – Carol Havens

DR. HAVENS: Good morning. Just to clarify, I'm not the director of physical education; I'm the director of physician education and development.

(Laughter.)

DR. HAVENS: At one time or another, I might have wanted to be a gym teacher, but I was not nearly smart enough to do that.

Thank you for inviting me here to talk about the work that we've been doing within the Permanente Medical Group in Northern California around our opioid safety initiative.

For those of you who are not familiar with us, in Northern California, we care for over 4 million members. We have 35,000 nurses and staff located in 21 medical centers and over 200 medical offices and other outpatient facilities.

The Permanente Medical Group is an integrated multi-specialty medical group, which contracts with the Kaiser Health Plan to provide care to the members, and the medical group is composed of over 9,000 physicians, making us the

largest medical group in the nation. And we are represented by over 70 specialties and sub-specialties. So it's a pretty large group.

Our initiative goals are very similar to what you've heard already, is to ensure that we provide safe and effective and appropriate care to our patients across the region, and that we give our physicians the tools and support needed in order to be able to provide that kind of care.

We went through a multi-step process to do this. We started this in actually 2014, and we started with looking at all of the recommendations, both the evidence-based recommendations, the available evidence, best practices, expert opinion, our regulations; we looked at the California Medical Board guidelines for prescribing, all of which changed while we were in the process of developing this.

We put together a multidisciplinary team representing essentially all of the groups that were involved in this, so we had specialties. We had primary care; we had chronic pain; we had

addiction medicine; we had mental health; we had pharmacy; we had quality; we had our Health Connect, which is our electronic medical record; we had patient education; we had representatives from most of the groups.

So we put together a multidisciplinary team to review all of those recommendations and develop workflows, specialty-specific workflows. And we started with adult and family medicine, because they were the most common prescribers within Northern California, and developed a workflow for our adult and family medicine providers for how to both initiate and do ongoing monitoring for patients who are on opioids.

We developed an education curriculum in order to implement the workflow within adult and family medicine. We developed the curriculum regionally to include both why we were doing this as well as what our recommendations were, and some about how those recommendations would be implemented.

We did a Train the Trainer regionally, so

from our 21 medical centers, each sent their own multidisciplinary team, and we trained all of them on the curriculum, and they then went back and delivered it locally.

The best education is local, as has already been said, and within each of our medical centers, although we are all part of the same medical group, there are different resources and different cultures at each of the medical centers. So there were certain parts of the workflow that needed to be customized for each individual facility, so we gave them the opportunity to then customize the workflow based on their own culture and their own resources.

The in-person training, the original training was developed as a 6 to 8-hour curriculum, which was done in person, and it included the time variable, included how much communication training. We included a significant portion of patient-clinician communication, which included role playing and practice having conversations with patients.

That training was delivered at all of our medical centers by -- the Train the Trainer was done in September of 2014. It was rolled out at all of our medical centers by May of the following year.

Subsequent to that, we developed online modules to include all of the same information with the exception of doing the communication training, which is still done live. The online training is now available both for new hires, as well as a refresher for those who have already taken the course, and the online module is 3 hours long.

We also created metrics, as again you have already heard, so most of the metrics that we've included are similar to the ones that the VA does. These metrics are provided to the department chiefs on a monthly basis, which includes prescriber-level data for every member of their department on the number of prescriptions, the number of high-dose prescriptions, the number of concomitant prescriptions with sedatives, a variety of other things.

In addition, our prescribers have access to real-time data through our electronic medical record, that at any time they can go in and see their own dashboard and see which of their patients have not had a urine drug screen within the past year, which is one of our recommendations; which ones don't have medication safety agreements that are signed and on file, which is another one of our recommendations; which ones have not been seen within the past six months, which is one of our recommendations.

Our physicians have access any time to real-time data, as well as the monthly reports that are given to the chief. So our physicians can see not only what they're prescribing and their practices are like, but they can also compare it to their colleagues.

We firmly believe that one education is no education, so we have ongoing opportunities for reinforcing this, which include -- each of our facilities has established an opioid team at their own facility with an opioid lead, and they have

regular meetings.

We meet with the opioid leads on a monthly basis, and they have regular meetings at their facilities. The department chiefs, when they get their monthly reports, provide the information at department meetings. We also do academic detailing. We have been doing academic detailing for over 20 years within Northern California of a variety of things and now including opioids.

We also have pain pharmacists, so a pharmacist who specializes in working with patients who are in pain who can also help with both assuring that the recommendations for ongoing monitoring are done, can help with tapering if that is indicated, and have provided tremendous support for our providers.

Subsequent to the adult and family medicine, we have also worked with the emergency department to create recommendations for workflows within the emergency department because the way emergency departments practice and the things that they experience are significantly different than most of

our outpatient adult and family medicine providers.

We worked, again, with a multidisciplinary team, including emergency department chiefs and providers, to develop recommendations for emergency departments. We did the same kind of a process with them. Our education was a little different because most of our emergency department providers can't come to live meetings. So most of their education was done online with the exception of, again, the communication training.

The metrics that we've been following for the emergency department include both the use of parenteral opioids in the emergency room, as well as discharge opioids. We wanted to make sure that the recommendations that we made for our emergency department providers were consistent with the recommendations that we were making for our adult and family medicine providers.

It didn't make a lot of sense to us to recommend for our adult and family medicine providers that they not refill the prescriptions that the dog ate, or that were in the car that was

stolen, or any of the other things that they commonly heard if they were just going to show up in the emergency room and get their refills. So we tried to create both linkages and consistency between practices.

Our current process project is with the orthopedic surgeons and podiatrists who have been an amazing group to work with and very excited about doing this work. With them, we're creating a three-part process in terms of recommendations for both pre-op care.

The peri-op period is we've instituted ERAS, the enhanced recovery after surgery, in all of our facilities, so that covers most of the perioperative care, and then we have separate recommendations for post-op care; again, delineating expectations and rational and resources and assistance, as well as making it clear at what point handoffs occur, how those handoffs occur to make sure that patients don't get lost in the process.

Our results, as the VA has, we've shown some

pretty dramatic decreases. We've had a 43 percent reduction in opioid prescribing in the two years since we implemented the process. I don't have the slides on it, but we've seen a decrease in overdoses in the same time period.

Other measures of our success -- because we weren't really concentrating just on opioids. We really wanted to look at the overall picture of safety and monitoring for our patients. Seventy-nine percent of our patients on high-dose opioids now have an opioid agreement, a medication agreement, in their charts compared to 42 percent before we started this.

Over 75 percent have had a urine drug screen within the previous 12 months, compared to 52 percent before we started this. Both of those are recommendations for the adult and family medicine.

We have also seen a pretty significant reduction in those who are on high-dose opioids, as with the VA, defined as over 100 milligrams of morphine equivalents per day, from 21 per 10,000

patients to 13 per 10,000 patients.

Measures of success within the emergency department, our discharge opioid prescribing was reduced by one-third. The parenteral use of opioids in the emergency department was reduced by 15 percent. We were already fairly low, as 16 and a half percent of our patients received parenteral opioids in the emergency room; now 14 percent do.

Significantly, since we're talking about education here, over 95 percent of our emergency department providers have undergone the multi-hour training. This is not mandatory. This is voluntary training for both adult and family medicine, as well as for the emergency department.

For adult and family medicine, we had virtually 100 percent participation with the original training. We're having a little more trouble with the online training with the new hires, but they are getting a whole lot of things all at once, so we're working on that.

As with Project Lazarus, I'm really glad that they've seen the same kind of measures of

success or the same reasons for the success that we have. We feel that there are a number of reasons for the success that we've had within the organization.

First of all, we have strong visible leadership support. A number of our physicians said we really don't feel comfortable with prescribing, but we don't feel like we're supported to not prescribe. So what we heard was having clear, consistent guidelines, with leadership support at every level saying we support you doing the right thing, and here's what the right thing is, made a huge difference.

The clarity and the consistency of a non-judgmental message, we really tried very hard not to say it's your fault, or it's the patient's fault, or you're to blame, or you're responsible for this. There were lots of things that happened to create this issue with opioids in the country; there's lots of opportunities to intervene in a number of different ways.

The interdisciplinary workgroup we think

made a huge difference because it really brought in all of the appropriate people. And although the recommendations that we developed are not significantly different than all the other ones that you see out there, we feel having our own physicians be part of making these recommendations gave them credibility because we could say our physicians, our chiefs, our organization supports these guidelines. We've looked at them and this is what we think is appropriate for our practices and our organization.

So the interdisciplinary workgroup was really important to bring in the perspectives from all the different areas. We provide lots of coaching, education, and support for our physicians. Just explaining to physicians or just doing training on why they need to make a change doesn't really lead to change. Even telling them what they need to do will lead to some change, but unless they also know how to do it, it's not going to be as successful.

So our education was really about the why,

the what, and the how, and the how included lots of support, including tools that were built into our electronic medical record, which does some amazing things. You see a patient who is on chronic opioids, it will automatically check to see if they've had a urine drug screen in the past year. If they have not, it will order one. You can de-select that if you want to, but it will automatically include it on your order sheet.

If you have a patient who is on methadone and they have not had an EKG within the past year, it will automatically order it for you. Again, you can de-select it, but it will automatically be there. So it's a reminder system, as well as a prompt, to allow our physicians to do the right thing.

Use of physician-specific data, we had a number of physicians when we started this say this doesn't apply to me because I don't prescribe opioids. We certainly heard this from some of our surgical colleagues until we were able to show them their data. And then they kind of went, oh, on

second thought, maybe I kind of do need to talk to you about this.

So the physician-specific data has been really important and hugely valuable. Although, we don't make it mandatory and we don't penalize people for prescribing, physicians, although we love to talk about how independent we are and that nobody tells us how to practice, we also really hate being outliers. So getting your own prescribing data and being able to compare that to your colleagues creates a tremendous incentive to find out what the differences are. And in some cases, there are very good reasons for those differences, and that's just fine.

Our emphasis has really been on doing the right things, taking the right steps in terms of both evaluation of the patient prior to initiating, as well as ongoing monitoring. As long as you do all of those things and you can document all of the decisions that you made, and why you made those decisions, that's just fine. But we want to make sure that you're taking all the appropriate steps

to ensure the safety of your patients.

Identifying individuals to help colleagues with tough cases, many of our facilities have actually instituted a pain board similar to tumor boards, which brings together, again, all of the appropriate specialties. And physicians can bring their tough cases and say I've done this, I've tried this, what else should I do? Are there other medications that I should use? Are there other interventions? Are there other specialties that I need to get involved? And it's been tremendously helpful for our physicians.

The collaboration between the medical group and the pharmacy, we had some interesting experiences early on where the pharmacy had one initiative and we had a different one, and we had to get together and say we need to be measuring the same things and we need to be providing the same message and consistency about those messages. And that's been a huge part of our success.

With that, I have one minute left, so I will give it back to Doug and for questions. Thank you.

(Applause.)

Questions and Answers

DR. THROCKMORTON: All right, thank you. We do have a few minutes for questions. Start right over there.

MR. ANDERSON: Hello. I'm Jimmy Anderson. I'm a physician assistant, and I'm really glad to be here. What a great meeting. I am here as a member of the American Academy of PAs and their specialty organization, Society of PAs and Addiction Medicine.

One question I have for all of you, when you looked at some of the unintended consequences of the more restrictive opioid prescribing and achieving far lower rates of opioid prescribing, did you see an uptick in illicit use of opiates?

MR. BRASON In our individual community of just Wilkes County, our prescribing level really did not change that much, so there wasn't any significant decrease. We have a high level of social determinants, which drives the illicit aspect and may or may not have started with

opioids.

The question you have does have a role in what is occurring today, definitely, that if that person who developed a problem either accidentally or had considerable substance-use issues previously is suddenly cut off and no place to go, that cutoff could be because -- found something on the PDMP, and I'm not going to prescribe you anymore, goodbye, then that person is sent out to the street with no other alternative.

It does have a role -- we have to be attentive, too, to make sure that any individual, whether we're decreasing opioids or stopping opioids, that there is another individual we're handing them off to, to ensure appropriate care beyond that aspect.

DR. HAVENS: I think it's a little tough to know that. We've looked at -- as I've mentioned, we've seen a decrease in our overdose rate in our emergency room. That's all drugs. So at least in our emergency rooms, we've seen a decrease in overdose rates among all drugs.

We also were very fortunate that we have in every one of our hospitals -- every one of our medical centers has a chemical dependency program, so we have resources to get patients with problematic use into treatment if they're willing to go. But that's certainly one of the fears that everybody has, is are we just moving this down the road?

DR. GOOD: It's a legitimate question and concern, but it is very difficult to measure it. And we're left with these intermediate outcomes. So we try to very carefully track and trend unintentional drug overdoses, not just prescription, any, as well as unintentional death. And they are going down, but it's not the same. No doubt, there probably are some patients that do do that, and it's most unfortunate.

DR. THROCKMORTON: Here.

DR. BERGER: I'm still Tom Berger from Vietnam Veterans of America. And my question is for Dr. Havens. As you're probably aware, dissemination science has found lots of differences

between in-person training and video training. And you mentioned your training does have some challenges or problems with the video stuff.

Would you care to elaborate on the differences perhaps behind personal training and video training?

DR. HAVENS: Sure. We have a lot of video training that we do. We have not incorporated that into the opioid training. We have online training.

There are certain things that I think can only be done in a personal training. I think learning new skills requires practice and requires live training to be done. And that's why we do the communication training live because we think that that requires the ability to see and practice and get feedback on your actual performance.

For purely didactic, for knowledge-based, you just need to know what the guidelines are. You need to the why of the guidelines. That can probably be done any way, and that's what we do online. But a lot of what we do is still done in person because we do believe that it's the best way

to do it.

DR. BERGER: Thank you.

DR. THROCKMORTON: Over there.

MS. HARRIS: Patrice Harris, chair of the Board of the American Medical Association. Congratulations to you all for the work that you're doing and the success that you are having.

Dr. Good, thank you as well for noting that the data regarding the decrease is temporal data and not necessarily cause and effect. I think that's critical. Thank you all for doing the evaluation, the inspection of your expectations.

For Dr. Good and Dr. Havens, are you also tracking the utilization of non-pharmacologic alternatives to treatment, and did you have to within your systems remove some administrative barriers, such as prior authorization and fail-first for some of those, as well as medication-assisted treatment?

DR. THROCKMORTON: Great question.

DR. GOOD: Sure. So, yes.

(Laughter.)

DR. GOOD: We have looked at the uptake of non-opioid pharmacotherapies, and one of the tasks of the group that I work with is to put things on formulary and make them available. So we specifically looked at things, things like topical creams that can be used, other non-opioid/non-pain meds that augment pain therapy, and think it's an important part.

We actually also looked to see did our use of non-steroidal -- I mean, one could argue we only have so many things in our arsenal of ways to treat patients, and some of them are with drugs and some are non-drug things like physical therapy and acupuncture.

VA clearly ramped up -- I didn't present those data, but we clearly ramped up the availability of things like Tai Chi, acupuncture, non-pharmacologic means to address chronic pain.

DR. HAVENS: And we did the same thing. When we were going through this, one of the things that became very clear is you can't just say no, and you have to provide alternatives. So we had to

take a look at what alternatives we provided and realized we had to do the same thing.

We significantly increased availability to physical therapy, to group visits, to other modalities of treatment. I'd have to assume that those were increased since we didn't have them before it's really tough to know. We don't have prior authorization. We don't have such a thing, so we didn't have that barrier to start with.

DR. THROCKMORTON: Thanks. Next?

MS. CHEEK: Linda Cheek from Roanoke, Virginia. I'm a physician victim of prosecutorial misconduct in the area of pain management. I am the founder of doctorsofcourage.org, and I work for American Pain Institute as an advisor.

What I'm interested in is following cases of doctors across the country that are being attacked for doing pain management, and any information -- since mandatory laws in the states is an open door for attacking more physicians.

Also providing naloxone like is now being done and they're saying for high risk, but then if

you're a high risk and you provide pain medication to a high-risk patient, then you can very easily be attacked.

Just open to the door for you, for the speakers, and also anyone else in the room, are you following the doctors in the states that are being attacked for doing pain management? Is there any way for us to get that information so we can see that data?

Also, it's very nice to put numbers on the screen that show how well you're decreasing in the VA, how well you're decreasing pain prescribing. But what you don't show is the lack of quality of life that the VA patients now have as a result of having their medicines cut. And of course that's across the board, not just the VA, but the whole world, or United States.

I guess my main question is are you following and tracking the doctors being attacked for doing the job that you are telling them to do?

DR. GOOD: I'll start. We're not tracking the states. But it was interesting when

Dr. Schulkin, the secretary, had in his nomination hearings, and this issue of opioid use was brought up. And one of the questioners, who was a physician, also a congressman, said can you tell me how many VA physicians have been disciplined and have been de-credentialed because they are writing too many opioids?

I got the privilege of responding to that question. And the answer was there's one VA physician who was de-credentialed in the past couple years, and we think that that's the wrong way to go about it; that you don't want to do that because if you look at -- use the word high-outliers.

If you look at high-outliers, many of these physicians are running pain clinics, are taking patients with chronic pain situations that many routine providers either are incapable of taking care of or don't want to take care of. So the last thing you want to do is discipline and de-credential patients [sic].

Regarding the second question, what's the

quality of care when you do decrease the opioids? It's a very difficult question to answer. It hasn't yet been published, but it was just presented.

Dr. Aaron Krebs did a study at the Minneapolis VA. They took a large cohort of patients with chronic pain, and they either used opioids or they had a non-opioid track where they helped these veterans, and they now are publishing the results. And actually, the quality of care and physical functioning is better for those that aren't on chronic opioids.

So that's a little different question than what you're asking, and that is someone who's on a chronic stable dose of opioids, what's the effect of taking them off? And I think there's no easy answer.

I can also just tell you my own personal experience has been that in several patients that I've had who are on really dangerous doses, I was able to get them off, and in one case, the patient is now on chronic Suboxone, and the other case the

patient is off. And in both cases, once they were off or on Suboxone, had been quite grateful and said that the quality of their life is much better, their physical functioning has gotten much better.

But those are anecdotes, and I'm sure there are patients who the physician says you're on 120 morphine equivalents, and, darn it, we've got to get you under 100. So I'm dropping you to 90. On a patient who's been stable and tolerating, there's really no need to do that.

DR. THROCKMORTON: We're going to have time for one more question just briefly. Yes, I think we're going to have to -- interest of time.

MS. CHAMBERS: Jan Chambers, National Fibromyalgia and Chronic Pain Association. I appreciate this open forum to what you're doing and the progress you are making.

Our organization has been looking at that intersection between chronic pain and substance-use disorder, and particularly people who are getting in trouble with the court systems. When they are given the opportunity to go to a drug court and go

through that program, we are seeing that people with chronic pain are not receiving treatment, only their substance-use disorder is being treated.

So we're trying to develop a peer mentoring program, and I'm expanding this. We're just starting with a pilot idea. If people --

DR. THROCKMORTON: Jan, if there's a question you're going to ask, please get to that. I'm sorry.

MS. CHAMBERS: Have you used peer mentoring? Have you considered peer mentoring?

DR. HAVENS: Have we considered what?

MS. CHAMBERS: Peer mentoring.

DR. HAVENS: Peer mentoring. Well, we have lots of patient groups, and it's a wonderful opportunity to get peers involved and getting people involved and helping their colleagues. I think it's terrific. So yeah, we do use that.

DR. BRANSON: We've done the same thing, yes.

DR. THROCKMORTON: Thirty seconds or --

DR. KAHN: For Dr. Havens and Dr. Good.

You're in big systems. This is Norman Kahn from the Conjoint Committee and Continuing Education. It there anything about what you're doing that's replicable to small practices that are all over the country?

DR. BRANSON: I've spoken too much.

DR. HAVENS: Yes. Next question?

(Laughter.)

DR. THROCKMORTON: That's a great question, actually. I think that's going to be one for the second day.

DR. HAVENS: Okay, great. Then I'll just say yes, and we'll talk about it tomorrow.

DR. THROCKMORTON: I think a really important question, beyond yes I guess.

Now, Doris. I'm so excited to have Dr. Auth talking. I tried to jump the gun on her. She is going to be talking about the REMS and some of the considerations there. Thanks, Doris.

Presentation – Doris Auth

DR. AUTH: Thanks, Doug.

I was going to begin with a good morning,

but we are dangerously close to lunch, so I'm just going to say good afternoon. Again, my name is Doris Auth. I'm with the Division of Risk Management in the Center for Drug Evaluation and Research.

The Division of Risk Management is primarily tasked with reviewing new drug applications, as well as existing products when safety signals are identified for the need for a risk evaluation and mitigation strategy.

We also work with sponsors once the need for REMS is determined. We also review the periodic REMS assessments to determine if the program is meeting its goals and whether any modifications to the REMS are necessary.

I'll be providing some examples of how the FDA REMS authorities are used to ensure prescribers receive training on risks and safe-use conditions of a particular drug and how a required prescriber education or training program for prescribers of opioid analgesics could be operationalized. And finally, the potential impact of such a program on

patients, prescribers, and pharmacies.

Before I get to how an opioid analgesic REMS that requires prescriber training would operate and how it might impact stakeholders, I will provide a quick review of the REMS authorities and REMS elements; an overview of the current REMS programs and the elements of these programs.

I'll then provide two examples of REMS programs that require prescribers to complete training before prescribing; then a proposal for a possible opioid analgesic REMS and its potential impact of the REMS on stakeholders. I'll wrap up with a few issues to consider if such a program were required.

You've heard several presentations since Dr. Manzo provided a background on REMS, so I am going to quickly review her slides again.

REMS is a required risk management plan that goes beyond labeling to address a risk or risks of a product. The FDA was granted the authority to require REMS with the FDA Amendments Act of 2007. REMS can be pre-approval or post-approval, and REMS

are developed and implemented by manufacturers of drugs.

Again, a REMS can include several components, including a medication guide or patient package insert; communication plan; elements to ensure safe use, or ETASU; implantation system.

All REMS for new drug applications and biologic applications must have a timetable for submission of the assessment. This timetable is not required for generic or abbreviated new drug applications.

This slide further describes the elements to ensure safe use. I have bolded the first bullet, the certification and training of prescribers because that's the focus of this meeting.

The second bullet is also bolded. I believe that Claudia mentioned this as well earlier. Certification of pharmacies is necessary in order to verify that prescribers in a REMS program have completed training prior to dispensing.

There are currently 74 REMS programs. Thirty of these do not have elements to ensure safe

use; 42 have elements to ensure safe use. Of the 32 that don't have elements to ensure safe use, 15 are medication guide only, 12 are communication plan only, and 5 have both communication plan and medication guides.

Of the 42 programs with elements to ensure safe use, 34 of these are restrictive and 8 are non-restrictive. I would like to note that these programs can also have a medication guide or communication plan as a component.

Just a reminder, these ETASU programs that are restricted require some action on the part of prescribers, pharmacies, and possibly patients in order to prescribe, dispense, or take the drug. Most often, there is a requirement for certification or training of prescribers, as well as documentation that a safe-use condition was met prior to dispensing or administering the drug. An example of a safe-use condition would be verification that a patient has completed a patient prescriber agreement or a PPA.

The only requirement in the current

non-restrictive ETASU programs is for the manufacturers to make training available to likely prescribers. And as described earlier by Dr. Manzo, the extended-release and long-acting opioid analgesic is one of these non-restrictive programs.

The next two slides will outline the operations of a restrictive program when prescriber training is a REMS requirement.

The sponsor or drug manufacturer provides training to likely prescribers of the drug. The sponsors also notify distributors of the program requirements. Once prescribers complete training and certify into the program, they are enrolled in the program.

Dispensing pharmacies and pharmacists must also complete training, certify, and enroll the pharmacy into the REMS. Distributors must agree to only ship the REMS drug to enrolled, certified pharmacies, and a database of enrolled prescribers, pharmacies, and distributers is maintained by the sponsor.

Under the system, a patient receives a

prescription for the REMS drug, takes the prescription to the pharmacy to be filled. The pharmacy must check that database. If the prescriber is enrolled and any safe-use conditions are met, there is an authorization to dispense that is granted by the database, and the prescription is dispensed.

On the other hand, if one or more of those entities, pharmacist or prescriber, are not enrolled, then the prescription is not dispensed. This leaves the pharmacy to have to go back to the patient, and there can be delays in dispensing of the product.

I mentioned earlier that there were currently 34 REMS with elements to ensure safe use that were restrictive. The next slide provides some information on stakeholder participation in a subset of those programs. The programs that are excluded are primarily programs that are newer where we just don't have the assessment data or programs that don't require pharmacy and prescriber certification.

Recent REMS assessment data from this subset show as few as about 100 participating patients receiving a REMS drug to as many as 370,000. The prescriber range is 80 to 27,000, and that is 80 prescribers, 27,000 prescribers. The range for pharmacies is one pharmacy to 48,000 pharmacies.

While the ranges of each stakeholder participating may seem pretty large, I'd like to point out that more than half of these programs are relatively small with fewer than 10,000 patients, fewer than 10,000 prescribers, and fewer than 10,000 pharmacies that are participating. There are a number of REMS programs, as you may be aware, that are for products intended to treat orphan diseases that have relatively small patient populations.

Earlier, I gave a somewhat elementary description of how prescriber education could be required under a REMS. I am going to spend the next few minutes giving some examples of the operations of a couple of restrictive REMS programs that have been in place for several years.

The first example is the isotretinoin or iPLEDGE REMS program. It is a shared-system REMS approved in 2005 and currently has five application holders. Indication for isotretinoin is severe recalcitrant acne, and the risk that the REMS is attempting to mitigate is a risk of teratogenicity. So the goals are to prevent fetal exposure and inform prescribers, pharmacists, and patients about the serious risks and safe-use conditions.

This next slide shows an overview of the requirements. First, prescribers are required to review the educational program in order to become certified. They then enroll in the REMS program. They are required to counsel all patients on the risks of isotretinoin and enroll them by the appropriate patient risk category.

For patients in the risk category of females of reproductive potential, the prescribers have to document that safe-use conditions have been met both prior to the first prescription and again with each monthly prescription. And by safe-use condition, I mean, a negative pregnancy test.

Pharmacists also have educational materials to review in order to become certified and enroll in the REMS. Pharmacists must provide each patient with a medication guide each month. In addition, pharmacies have to obtain authorization to dispense each prescription by the REMS program.

For the iPLEDGE program, this is done through the pharmacy accessing a separate database. This is an interactive either voice or web-based system. This is outside their current work-flow. Pharmacies obtain this authorization number, and that serves to document the date and the result of the pregnancy test, and then the prescription can be dispensed.

Finally, for patients in the iPLEDGE program, if they're enrolled in iPLEDGE, they have to review and sign an informed consent. Females of reproductive potential also have to, again, have pretreatment and monthly pregnancy tests. They also have to access the REMS program on a monthly basis, complete comprehension questions on the risks, and document that they are complying with

our chosen form of contraception.

The second REMS example is a transmucosal immediate-release fentanyl, or TIRF REMS, which is also a shared-system REMS program. It was approved back in 2011. It currently includes 8 application holders.

The TIRFs are indicated for breakthrough pain in cancer patients that are already receiving and tolerant to around-the-clock opioid therapy for underlying persistent cancer pain. The majority of the products are indicated for patients 18 years and above, and the formulations include a buccal tablet, a buccal film, a lozenge, a sublingual spray, and a nasal spray.

The next slide shows an overview of the requirements for the stakeholders that are involved in the outpatient dispensing and use of the TIRF products. We do have slightly different requirements and a process for inpatient prescribing, dispensing, and use.

Again, prescribers are required to review an educational program and successfully complete a

knowledge assessment in order to become certified and enroll in the program. They must agree and attest that they will counsel each patient and complete a patient-provider agreement with each patient.

Pharmacies have very similar education and knowledge assessment requirements. They must provide patients with a medication guide with each prescription. Pharmacies actually -- it says here on the slide -- passively enrolls the patient. In this program, the pharmacies enroll patients into the program upon their initial prescription as long as the prescriber is enrolled. They're given a 10-day window that allow the patient to receive the TIRF product prior to the REMS system receiving that patient-provider agreement form and officially enrolling in the program.

In the TIRF REMS system, slightly different from in the iPLEDGE program, the pharmacies obtain this authorization to dispense by using the claims adjudication system. So this is different from the iPLEDGE system. This authorization occurs within

the normal flow of their work, and this also occurs before any sort of insurance adjudication.

However, pharmacies operating under closed system health plans, such as the VA and the DoD and some other large managed care health systems that don't use the claims adjudication system, they have to actually phone or fax in the REMS system in order to get approval for dispensing.

Finally, it's with the iPLEDGE program patients are required to sign a patient-provider agreement form as a safe-use condition. In this form they are acknowledging that they understand the risks, proper use, and safe storage and disposal of the TIRFs.

This is a lot of information. Proposal for an opioid analgesic REMS that focuses solely on prescriber education is similar -- maybe, I'm not going to say a bit simpler, but it may appear to be. Prescribers would complete training and a knowledge assessment and enroll in the REMS.

The same would happen for the pharmacies. The pharmacist would obtain authorization to

dispense each prescription. This can be done either way through the claims adjudication system as in the TIRF program, or as in the iPLEDGE program through a separate database. The pharmacists in this program would also hopefully provide the patient with a medication guide or some sort of patient materials.

Unlike the TIRF and the iPLEDGE program, this proposal does not include any specific patient requirements, such as a patient-provider agreement form or patient enrollment.

Before looking at the potential stakeholders impacted by an opioid analgesic REMS, it's helpful, as I just gave those examples of how those programs operate, to use both of those programs to give some perspective on participation in our programs.

The most recently reviewed annual REMS assessment, as well as some IMS data on TIRF prescribing, shows about 8,000 active prescribers, 42,000 active pharmacies, 63,000 prescriptions dispensed, and about 4200 newly enrolled patients.

From the most recently reviewed annual REMS

assessment for the iPLEDGE program, there were 16,000 prescribers, 48,000 pharmacies, 1.3 million prescription authorizations or prescriptions dispensed, and 370,000 patients.

In comparison, an opioid analgesic REMS program that would require prescriber training could potentially involve all the DEA registered prescribers, which is currently about 1.5 million prescribers, as many as all of the outpatient pharmacies, which is about 67,000. And despite declining prescriptions for opioid analgesics in the past four years, recent data on prescriptions dispensed showed that there were still 160 million prescriptions dispensed for opioid analgesics in 2016.

Going back a few years to look at the potential patient impact, we know that in 2014, more than 80 million patients are estimated to have received prescriptions for opioid analgesics. So as you can see, a REMS program that would require all prescribers to complete training prior to dispensing would impact significant numbers of

prescribers, pharmacies, and patients.

There are several issues to consider regarding the use of a restrictive REMS that would require training of all opioid prescribers. First, current prescribers of opioid analgesics may choose not to take the training, which I think we've heard that has been alluded to earlier this morning, that that may lead to a decrease in prescribers; although, I think some of the data that we heard this morning in some situations that has not been the case. This may happen, and this may be a positive outcome, however, this may lead to some patients scrambling to find a prescriber to write prescriptions for legitimate pain control needs.

As you heard earlier today, several states and some healthcare systems already have educational requirements on pain management and safe use of opioids for their licensed prescribers. A REMS program would duplicate these requirements, and we're not really sure what sort of waivers we could put into place that would waive them of their requirements to participate in a federal program.

A separate REMS database would need to be developed that would duplicate the existing DEA database. And as illustrated on the previous slide, the numbers required to enroll would be several-fold greater than any current REMS program, as well as all of these stakeholders that are required to enroll in the program.

We know that the number of manufacturers that would be required to participate is actually more than double what is in the current extended-release and long-acting opioid program. There's roughly 90 total manufacturers that would be involved in this program, and many of these have multiple products. So it would be close to 300 products that would be involved in an opioid REMS program.

Finally, as outlined in the two-process slides earlier, the implementation operation, maintenance, and evaluation of REMS programs are all controlled by the pharmaceutical industry. Thank you.

(Applause.)

DR. THROCKMORTON: Thanks very much.

Before we have the last talk of the morning, I just want to re-cap what we've talked about in this whirlwind run-through.

Remember the two central goals we have. One, we're interested in understanding your comments about the role of education and the larger federal efforts, so where does education fit in to all of those things? And it's federal educational activities, as well as a comparison against other kinds of activities: state, providers, various other ways of people being educated about the use of opioids.

The first part of this morning has been a whirlwind survey, if you will, of some of the various models of education around the use of opioids, and we've learned a lot I think from the speakers that we've heard.

Because there are two -- the second thing that we need to have some help with is how to make that federal education as effective as possible, and one particular interest people have had is

mandatory versus voluntary federal education.

What we wanted to do is talk a little bit about two at least possible models for mandatory prescriber education. You've just heard one of them, using the REMS authority under the Food, Drug, and Cosmetics Act, something that we've put into place for a couple of systems, so we wanted to give you some details about the impact that that kind of a system has; the kinds, if you will, the efforts that are necessary to put into place one of those and then to sustain it.

What we're going to have next is a second potential route to a mandatory education system, and this would be through the Controlled Substances Act, and we're lucky enough to have the DEA here to be talking about their views on prescriber education, too.

I think after that, I'm not sure we're going to be able to have time for a lot of questions, but I think this morning we've learned a lot about the possible models for education, and now with these last two talks, a little bit more about some of the

potential challenges in putting into place a federal system.

With that, Dr. Arnold, chief of Liaison and Policy Diversion Control Division, Drug Enforcement Administration.

Good morning. How are you, sir?

Presentation – James Arnold

MR. ARNOLD: Good morning, and thank you very much. I am not a doctor. I just wanted to clarify that. My name is Jim Arnold. I'm the chief of the Policy and Liaison Section for the diversion control division, what used to be known as the Office of Drug Control for the DEA at DEA Headquarters in Washington, DC.

I travel around the country quite a lot to speak to all kinds of organizations, professional organizations, public organizations, talk to all kinds of medical professions regarding the DEA and our perspective on the opioid epidemic.

Do we have my slides available? No, that's not it. That's okay.

There's a lot of misunderstanding, and part

of the reason that I wanted to -- that I'm glad that I'm a part of this meeting today, and the next two days, is just to provide some information regarding exactly what the DEA is and what we do.

There's a lot of misinformation out there in regards to our authority, in regards to requirements, in regards to all kinds of things and our role in the overall opioid epidemic. So I'm just going to try to give you a little bit of information regarding that role and provide you with some other stuff in regards to our ability to assist in this mandatory prescriber education situation.

Our primary mission, our primary responsibility involves the enforcement of the Controlled Substances Act. It was passed in 1970, and that's our primary role, to enforce the Controlled Substances Act. Our primary mission, to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and illicit chemicals that are used to manufacture illegal drugs, and their movement from legitimate channels

on to the street.

That's our primary role, but at the same time to make sure there's an adequate and uninterrupted supply of controlled substances to meet legitimate medical and research needs.

So we kind of have a dual role in regards to the Controlled Substances Act in regard to controlled substances, and that's our primary mission. We have this enforcement component, and we have this other component, which allows for the legitimate practice of medicine.

I would like to just share that with people, so people understand that, basically, we're not here to interfere with the legitimate practice of medicine. It's not our role. And I want to make sure that I make that very clear, the legitimate practice of medicine.

It is our role to interfere with those individuals, those medical professionals, those organizations, those individuals that are engaged in improper, illegal behavior with controlled substances.

The situations that we deal with and we come in contact with -- doctors, pharmacies, drug houses, distributers, you name it, researchers, we've had it, nurses, all kinds of situations where this kind of diversion activity takes place -- the kind of things that we see are those situations that are truly, truly bad and are large scale. That's what we get involved in.

Like I said, once again -- and you're probably going to get tired of hearing me saying this -- we're not here to interfere with the legitimate practice of medicine. That's not what we're about and that's not what we do.

The one thing, the main thing that I want to share with you this morning, and the one thing I always try to share with all medical professions, whoever I'm speaking to in the room, is this, 21 CFR 1306.4.

As long as the prescription is being written for a legitimate medical need by an individual practitioner who's acting in a usual course of professional practice, you are good to go. Once

again, legitimate medicine versus those individuals who are involved in outright illegal behavior with controlled substances. That's what we're all about, and that's what's going on.

This is the one thing. This is the most important thing in terms of sharing with you today what we're all about, legitimate medicine, legitimate medical purpose. The individuals, the doctors that we conduct surveillance on, that we conduct undercover buys on, these are people, that I could sit here and regale you with stories all day long about what goes on there and what happens in terms of physicians, in terms of pharmacies, and what kind of improper behavior that they engage in.

Most individuals do the right thing. Most individuals engage, and do the right thing, and engage in proper behavior with controlled substances. But unfortunately, we have a small percentage of the population, of registrant population -- remember, we have 1.6 million DEA registrants, all those entities, authorities, businesses that are registered with the DEA to

handle controlled substances. Of that amount, there's approximately 1.5 million prescribing practitioners. That includes mid-level practitioners.

Of that amount, like I said, there's a very, very small percentage that creates about this much of our problem, and that is unfortunate. It gives a bad name to everybody, and these are basically -- whether you want to believe me or not, these are individuals who are basically drug dealers in white coats. That is the facts. That's what we see. These things, unless you see it on a day-by-day basis and unless you see it from our perspective and see what we're engaged in and the battle that we wage on a day-to-day basis, this is the kind of activity that we see and what we're involved in.

So once again, legitimate medical need by a doctor who's acting the usual course of professional practice. That's a high standard to disprove that a doctor's not engaging in that kind of proper behavior. There are all kinds of hoops

you have to jump through in terms of the legal system in order to prove that a doctor is behaving inappropriately and outright illegally in terms of illegal distribution. So it's a whole different thing.

Our solutions to the problem. We're not going to arrest our way out of this situation or our problem. We're not going to arrest our way out of it. We realize that, and I think everybody in this room realizes that. Our problems are so important, and everybody in this room, we need to all be working together. There are so many entities and so many organizations and professional organizations, public organizations, citizens groups that are working together to attack this epidemic, and it is an epidemic. It's unfortunate, but it is an epidemic.

Like I said, it's going to take everybody working together to attack this problem, and it's a horrendous, horrendous problem that destroys individual lives, it destroys individual families, that destroys all kinds of things for an

individual.

We need prevention. There's no doubt about that whatsoever. We need to be out there talking to people, educating people. We need education. It's so, so important educating people, and not only on the proper prescribing of controlled substances but also teaching our young people about controlled substances and about how it affects their brain, and how it changes their brain physically, and that this is something that happens, and it's just not something made up, and that these opioids are not safe, and once believed by the medical community that these opioids were safe for administering, were safe for delivering to a patient for the treatment of pain and other things.

Treatment is so important. We need treatment. There's no doubt about that whatsoever. That's an important component of this overall epidemic and this problem.

Enforcement. There's no doubt whatsoever that we need enforcement as well. On a national,

and on a state, and on a local level, there are all kinds of entities engaged in illegal practices and illegal activities with opioid drugs and with other controlled substances.

We need to get the bad actors off the street. Unfortunately, they give all the doctors in this room and all the medical professionals, all the health professional in this room a bad name. And these are people who outright, like I said -- and you just have to believe me and understand how we see it on a day-to-day basis and what we are engaged in.

We're talking about doctors who are seeing patients at Starbucks and writing prescriptions for patients at Starbucks after hours. We're talking about doctors who you go into their waiting room and there's no furniture in the room, and all you have is a bunch of people sitting around waiting to see the doctor.

You have doctors where those individuals in that waiting room, with no furniture in the waiting room, are going in to see the doctor and are back

out in less than 10 minutes with three prescriptions for controlled substances. Usually that involves a narcotic, a benzodiazepine, and another item in combination.

That kind of activity is not necessarily for legitimate medical need. That's the kind of thing that we're looking at, and that's the kind of thing that we're after; not here to interfere with legitimate medical need.

I hear stories every day. I get the phone calls every day from the public, from everybody regarding my doctor says this, my pharmacy says that, he says DEA says this. And I have to tell them over-and-over again, we're not involved in legitimate practice of medicine. I could do this in my sleep, and it's unfortunate.

I've heard horrendous stories about individuals in chronic pain, and have been run over by cars and dragged a quarter of a mile down the road, and who have had four back operations. I've heard horrendous stories about this thing. Like I said, legitimate pain and addiction, and how you

handle that, and how you determine that, and how you deal with that, it must be an awful difficult job. I can only imagine. So that's what it's all about.

The DEA supports and encourages prescriber education in any form. We support it totally, that it may be required by federal or state law in regulation. Everybody has the opinion that DEA has more power than we actually do. We only have the power that comes with the Controlled Substances Act.

Basically what the Controlled Substances Act says is that if a person's applying for a registration to be a medical doctor, that unless there's some sort of lack of state license of state authority as far as a medical license is concerned or a particular controlled substance license, there's a felony conviction for controlled substances, there's a Medicaid Medicare conviction, and there are other reasons. It says you have to give them a registration. That's what the law says. This would probably take, most likely, an

act of Congress in order to give us this authority to be able to do this.

We have the ability to set up already, to assist in this prescriber education, however, that might show itself or offer itself. We have that ability. But like I said, we could not mandate it at this point, but we would be more than willing to participate if so directed.

I want to thank you for the opportunity to be here, and hopefully I will be around for the next few days. Feel free to come up and ask me any questions that you would like to. Thank you.

(Applause.)

DR. THROCKMORTON: Thank you. I think in the interest of time to make sure that everybody gets a chance to have lunch, we're going to break now. Come back at 1:00, and we'll start with the open public hearing at that point. Thanks very much.

(Whereupon, at 12:07, a lunch recess was taken)

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

(1:10 p.m.)

DR. THROCKMORTON: If everybody could sit down, we'll get started with the first open public hearing. Dr. Kahn?

Open Public Hearing

DR. KAHN: Thanks. Norman Kahn, convener of the Conjoint Committee on Continuing Education. It's 26 organizations in medicines, pharmacy, dentistry, physician assistants, and nurse practitioners. Our goal is to voluntarily educate clinicians in opioid REMS. We are the educational partners of the FDA and of the RPC.

You heard from Claudia Manzo earlier on some of the data that's most recent, so I won't repeat that. The real issue today is about the role of continuing education. I'm going to make a couple of points about mandatory continuing education.

I think if our goal is to have more people complete the training, then mandatory education would do that. If the goal is the goal that the FDA stated on July 12, 2012, which is "The goal of

REMS is to reduce serious adverse outcomes resulting from inappropriate prescribing," then we have a suggestion that there might be a better way to achieve that goal than simply mandatory continuing education.

We did some literature reviews on the evidence. The nurses did a wonderful study; it was published in 2003. I'll give you the highlight on that one.

Nurses with a CE mandate attended more hours of CE unrelated to their work or interests because they had to go to CE on what they were mandated to do. The American College of Physicians did a literature review and the physician community and found that the evidence was pretty good, that CE improves knowledge, skills, and attitudes. But there was no evidence that CE improved patient outcomes, and the evidence for improving practice behavior was self-reported.

Mandatory CE, on the other hand, was perceived as a burden. Thirteen percent of the clinicians involved in this study said, if you make

it mandatory, I'm not going to prescribe. The risk is that those are people that are not in big systems that can support them. That was part of my question this morning.

There are a couple of system recommendations that we'd like to call our attention to. We started to hear from one this morning, actually two of them, from the VA.

The VA system has four strategies that we need to take into consideration. One is education, both prescribers and teams -- we've been educating teams from the beginning -- academic detailing by pharmacists in the clinics, at the practice site; pain management team management; risk mitigation dashboards -- they use a tool called STORM so that clinicians have access to all of the data on their performance at any one time -- and a system-wide focus on addiction treatment.

Similarly, the University of Washington in Seattle has a multi-pronged approach with controlled substances agreements, urine testing, prescription drug monitoring programs, consultation

on difficult cases, again pharmacists in the clinic, access to specialists, and use of the MAT program.

So in summary, if our goal is simply to get more people educated, we could certainly make it mandatory. If the goal is to reduce adverse outcomes, I think we should -- and we think that we should -- look at the VA, we should look at Kaiser, we should look at the University of Washington for systems in which education is integrated into the practice with support.

DR. THROCKMORTON: Thank you very much.

Thomas Sullivan?

MR. SULLIVAN: Hi. I'm Thomas Sullivan. I'm founder and president of Rockpointe, a medical education company. We've recently implemented an ER/LA opioids REM and education series of live educational sessions at regional pain management programs, following the FDA blueprint. The views I express here are my own opinions.

I'd first like to thank the FDA for seeing continuing education and provider training as a

valuable tool for fighting and controlling the opioid crisis, while remaining cognizant of the needs of pain patients to have access to therapies and help them overcome and live with their pain.

During our program, we looked at the outcomes for our educational series, and we saw that 33.7 percent were more likely to practice evidence-based medicine for the 54,000 patients seen by each of them each month.

Analysis of the specific outcomes showed the following further activities: 37 percent were more likely to recognize that physicians should counsel caregivers and patients to dispose of unused opioids; 30 percent were more likely to recognize that equianalgesics tables suggest relative opioid potencies; 28 percent were more likely to recognize that opioid tolerance depends on the drug and duration of exposure when considering dosing and need for discontinued use; and 22 percent were more likely to understand that while converting patients from one ER opioid to another, the new ER/LA opioids should be started at lower doses or dosed

as if the patient is opioid-naïve.

We've also had other significant competence improvements in things like monitoring patients on opioids, methadone's initiation, toxicity, and which opioid analgesics is influenced by the P450 cytochrome system.

We believe that educating clinicians on safety and profiles of opioids, along with the six domains of the FDA blueprints, remains a priority. But despite the successes of these programs, there are several areas which I think need to be improved.

First, although it's controversial in the medical community, I recommend the DEA issue licenses required for prescribing controlled substances be linked to prescriber education. This includes courses and tests to ensure competency. Medical schools offer very little education on pain and addiction management, and physicians should be made fully aware of the proper usage and safe profiles of opioid drugs prior to writing prescriptions for them.

In America, we require education for testing for driver's license, handguns, and lifeguards at our local pools have to study and take a test to be certified. A model to follow may be the advanced cardiac life support certification for the American Heart Association, which many clinicians, nurses, and first responders take to enhance their skills in emergency cardiac treatment. It would be safe to say that opioid prescribers would benefit from education and certification.

REMS should be expanded to include all opioids, which you have stated. After reviewing the Maryland opioid death certificates for prescriptions, opioid deaths have remained relatively the same from 2011 to 2015, from 342 to 351, respectively. And at the same time, deaths from fentanyl has increased 12-fold from 26 deaths to 340 deaths, and heroin deaths have tripled from 238 to 748.

Healthcare providers need significant education to understand how to fight this epidemic, and I think you need to think about expanding it

from just opioids, but to also these other parts, and require that patients prescribed opioids are aware of all their options, including NSAIDs and physical therapy.

If a patient is prescribed an opioid, they should be required to watch a short patient education video similar to the videos offered by the University of California Davis and Irvine, which describe the risks of opioids. Also, patients should be sent home with easy-to-understand literature on opioid therapy for them and their families to review.

A further step should be taken to offer education and counseling to clinicians who write more than 10 opioid scripts per month near zip codes where opioid-related deaths are happening. The goal of this education is to reduce overdoses in those areas. Also, a prescription for naloxone or similar antidotes should be included, at least yearly, with all opioid prescriptions.

Finally, I'd be remiss if I did not address the fact that continuing education alone is

unlikely to be enough to fully impact our pain management and abuse problems. Several system changes are needed, including more comprehensive pain and addiction management education in medical, nursing schools, and pharmacy schools and increased government and private insurance coverage for other treatment modalities -- as we know, they're not covering alternative therapies including acupuncture, chiropractor, and complementary treatments -- and less stigma and punitive approaches toward pain sufferers and prescribed clinicians than is currently seen in other government agencies.

The FDA should also refrain from scaring the public on the dangers of NSAIDs and Cox-2 inhibitor use, as one has to consider the opioids are the alternative therapy. The FDA should also give priority review for new alternative, non-addictive pain treatments.

DR. THROCKMORTON: Dr. Sullivan, would you like to summarize, please?

DR. SULLIVAN: Yes, I'm summarizing right

now.

Anyway, I make these recommendations. I think you should consider them. Thank you.

DR. THROCKMORTON: Thank you.

Cynthia Kerr [ph], Kear?

MS. KEAR: Kear. That's good.

Thank you very much for the opportunity to speak. I'm with CO*RE. As I said earlier, CO*RE's about 11 organizations representing over 700,000 of the targeted learners, and that's not inclusive of Medscape, which brings considerable heft in terms of our reach.

We've been doing this work since 2010. We've had about 600 activities in four years. Probably about 90 percent of those are live; the rest of them are online. We've generated close to 200,000 targeted learners, and probably when you throw in nurses and PharmDs, whom we consider very important audiences, we're probably about 280,000.

I just want to make a couple of comments. We are not an advocacy group. We agree only to come together as an educational collaboration

because we have difference of opinions as to whether or not education should be mandatory.

That being said, I'd like to just say that should this go forward and be mandatory, there would be a couple of considerations that all of the members of CO*RE would really want attention to be paid to.

One is a consideration for all past learners. We have a fair number. You saw the numbers yourself. So we wouldn't want to offend those people; somehow figuring a way to get those people into the system to give them credit.

Secondly, we would urge great attention to a database, a common single database, that would be created, that would be streamlined, that would be standardized that all the grantees or anybody who was participating in would enter common. Right now, the database and the data information is different, and it makes the process somewhat challenging.

We would suggest that you include patients somehow, all or some of the other REMS. It's very

appropriate for them to sign/co-sign a patient prescriber agreement. We think that that is an important element. They need to have a seat at the table and to feel some accountability in this process.

Lastly, I would say that we urge consideration for a test out in the past. We would like to bring that issue up again. We know that many of our learners and many of our organizations really support it, and we think that it would be an efficient way to reach greater numbers of people and allow them yet another option in terms of engaging with this educational process.

I would also suggest, to reiterate what I said this morning, if this were to become mandatory to really closely coordinate with the states, so that we can streamline those opportunities and maximize them. I know that that would be probably a bear event and activity, but it would really be worthwhile, and standardizing content would probably be a good way to start.

One of the things I think, mandatory or not

mandatory, is a slight problem with this REMS is that we suffer -- all the stakeholders suffer from lack of a really coordinated, high-impact awareness campaign, and I would really continue to urge that as well.

The last thing that I'd like to say is just that education alone is not going to do it. Our learners continue to report that barriers remain. And the barriers to integrating this into workflow, into being more successful with this, the top two that continue to be problems are access to specialists, be they addiction or pain specialists, is a real problem. And the second one is reimbursement is not always there for non-pharmacologic or even for other types of modalities. Thanks very much.

DR. THROCKMORTON: Thank you.

Eunan Maguire?

MR. MAGUIRE: Hello. My name is Eunan Maguire, and I'm the chief operating officer of Adapt Pharma. We developed and distribute Narcan nasal spray, which is the most commonly prescribed

FDA-approved, community-used naloxone. The product is affordably priced, and that is critical to ensuring expanded access.

My comments today relate to efforts to increase naloxone co-prescribing alongside high-risk opioid prescriptions or situations. As we know, prescription opioids are involved in the majority of opioid overdose deaths, and many people who use illicit opioids have previously misused prescription opioids. There's widespread support for co-prescribing from the community and medical societies, and from HHS.

Co-prescribing provides a systematic means of targeting naloxone at the highest-risk opioid prescriptions or situations. It's also a concrete step around which to have a safe-use discussion between the provider and the patient, and I think Fred Brason spoke to that earlier on.

The challenge is not a lack of support for co-prescribing, but how to implement it. The current system is an opt-in system where co-prescribing is recommended or encouraged by many

people, but not required.

The opt-in approach has delivered an increase in naloxone prescribed in the past year, but there is still only one naloxone prescription for every 1,000 opioid prescriptions. We believe far greater levels of naloxone prescribing are necessary to impact the death rate.

We welcome the draft revised medication blueprint and the naloxone co-prescribing references therein. We've also petitioned FDA to introduce naloxone prescribing alongside high-risk opioids as a condition of safe use of those opioids, using an ETASU or an element to ensure safe use.

We can look to state experiences to see the impact a requirement can have. Two state medical boards, Virginia and Vermont, have or will shortly implement a naloxone co-prescribing requirement, and we heard of the naloxone prescribing initiative in New Mexico this morning.

In the six weeks following Virginia's rule changes in March 2017, naloxone prescriptions

increased 11-fold, and they now account for 1 in 4 of the prescriptions in the nation. Vermont will implement a similar policy in July.

So these state efforts are very encouraging in expanding access. We support mandatory training with the draft revised blueprint, and we continue to advocate that a naloxone co-prescribing ETASU be added to the opioid REMS. Thank you.

DR. THROCKMORTON: Thank you.

Katherine Cates-Wessel?

MS. CATES-WESSEL: Thank you very much for this opportunity. I am presenting on behalf of the American Academy of Addiction Psychiatry, an organization that is a leading source in translating the latest evidence-based research into clinical practices for substance-use disorders and co-occurring mental disorders.

AAAP seeks to assure that research findings are applied throughout clinical practice and in the training of health professionals. Research demonstrates that 70 percent of individuals with substance-use disorders also have a co-occurring

mental disorder.

While emerging evidence also reveals a significant number of prescription opioid deaths are suicidal in intent, rarely is mental health mentioned. In fact, a 2015 report from a national surveillance database of poison control centers from 2006 to 2013 noted an alarming 75 percent of prescription opioid-related deaths occurred with suicidal intent. The percentage rises to 86 percent in individuals 60 and older.

This is all the more alarming, as these statistics are glaringly absent from the public discourse regarding opioid risk. We strongly advocate that all prescribers and other health professionals have adequate training for screening mental disorders and substance-use disorders, as well as the risk for self-harm and suicide. This is vital to ensuring that health professionals have the necessary information and skills to avoid further opportunities for overdose and addiction.

With the rising number of opioid-related overdoses, training for opioid analgesic

prescribers should also include a recommendation for naloxone and outline steps to direct an individual to a psychiatric evaluation and appropriate treatment following an overdose.

Screening for mental and substance-use disorders as risk factors is imperative and will contribute significantly to addressing the misuse of opioids. It is important to note that prescribers should not deny opioid treatment if deemed appropriate, but should have enhanced safety practices in place and carefully monitor the patient's response to treatment.

Patients with a family history of substance-use disorders and/or mental disorders are at particularly high risk for addiction and overdose. Therefore, recommended monitoring practices should include a reassessment at regular intervals and call backs for pill counts and toxicology throughout their continuum of care.

In the spirit of best practice and overdose suicide prevention, AAAP is working collaboratively with a major primary care and addiction

professional organizations and key stakeholders, many who are represented here today; too many to mention.

We collectively represent over one million health professionals forming two coalitions called Providers Clinical Support System for Medication-Assisted Treatment and Providers Clinical Support System for Opioid Therapies, looking at the interface of chronic pain and opioid use disorders. Both projects are funded by SAMHSA.

The goal is to provide evidence-based training; clinical coaching for prevention, identification, and treatment of opioid use disorders; treatment of pain, substance-use disorders and co-occurring mental disorders, all at no cost. Thus far, we have trained close to 80,000 health professionals. We've created over 400 online courses and webinars, and we provide free clinical coaching and support.

We recognize that more is needed beyond only training the individual prescribers and a response. We're working in five pilot states to provide

clinical settings with technical assistance in how to create a system of care for implementation of evidence-based practices, focusing on MAT for opioid use disorders in a primary care setting.

We're releasing the 24-hour MAT waiver for nurse practitioners in PA, at no cost, and just released 14 new modules on chronic pain. AAAP has been working with other initiatives in the era of prescriber education, such as the AMA opioid task force and others.

We're committed to providing the education and training for all health professionals in evidence-based practices, but more needs to be done. It's clear that medication-assisted treatment is essential in reducing opioid use disorder, morbidity, and mortality, but access to care is a continuing problem, as is workforce shortage, which is why we are providing education and training free, as well as advocacy on this front.

In summary, AAAP strongly recommends expansion of the current opioid analgesic

prescriber training to include other health professionals as well, and to include key information regarding the risk of prescribing opioid medication; in addition, the importance of thorough and longitudinal mental health and substance-use screening and simultaneous mental health and addiction treatment when needed.

We urge the FDA to assist in removing barriers to access to evidence-based treatment, not just treatment, to support novel and effective alternative pain management strategies and to understand that opioid prescribing will remain a necessity for many who are severely disabled by chronic pain.

Lastly, please do not leave mental health out, as most often it is at the core of the problem for many.

DR. THROCKMORTON: Thank you.

Richard Lawhern?

MR. LAWHERN: Good afternoon. I am Richard Lawhern, known to my friends as "Red". For the past 21 years, I've supported chronic neurologic

face-ain patients and others, as a non-physician research analyst, writer, and moderator for peer-to-peer online groups. I daily interact with Facebook forums in which the membership is over 20,000 patients and family members. I have no financial conflicts of interest.

To begin this short presentation, I would draw the attention of the members in front to the fact that at present, millions of people either hyper metabolize or poorly metabolize opioid medications. This is due to variations in what is called the CYP2D6 genotype.

As a direct consequence of this reality in the patient population, there can be no universally applicable threshold of risk in MMED. Tens of thousands of patients are now stably maintained with zero opioid addiction risk on dose levels exceeding 200 MMED or even 400 MMED, and there are case reports of patients maintained stably on 2500 MMED. If you deny these people opioid therapy, you might as well shoot them because you will be killing them.

Beyond that, I wish to convey a message from those whom I support. Some FDA participants may find this a bit jarring, but if you're truly concerned with the patient safety, then the first thing you can do in this organization is to adjourn without disseminating one more guideline.

This is true because the CDC guidelines on opioid prescription are egregiously incomplete, scientifically ill-supported, and are extremely damaging to patient interests. The document, as it has been issued last March, is desperately flawed. It needs to be taken down, retracted, and done over from scratch.

Since the CDC released its guidelines, tens of thousands of patients have been summarily discharged without referral. Many have been denied medical care, and some have been deserted in opioid withdrawal. Many more have been arbitrarily tapered down from opioids, which have been effective and safe for them for years; plunged into agony and disability, losing whatever quality of life they had. Suicides due to unbearable pain

have occurred in numbers, and you may anticipate more. We are seeing evidence of that every day in social media.

Doctors are now leaving practice in part because they fear a campaign of extra judicial persecution by the DEA. DEA regularly seizes patient medical records before filing indictments, and then prolongs legal action for years in a knowing attempt to bankrupt the practitioner or bludgeon them into a consent decree. This is something widely understood and widely accepted by tens of thousands of people who have been affected.

I will conclude my remarks with three references, and I will provide my comments as written. The three references, two of which I wrote, are respectively, The CDC's Fictitious Opioid Epidemic, Parts 1 and 2 published by the Journal of Medicine of the National College of Physicians; and the third is useful and deeply referenced, the title is Neat, Plausible, and Generally Wrong: A Response to the CDC's Recommendations for Chronic Opioid Use by

Stephen A. Martin, MD, Ruth A. Potee, MD and DABAM, and Andrew Lazris, MD. This concludes my remarks. You may have a copy.

DR. THROCKMORTON: Thank you very much.

Laura Wooster?

MS. WOOSTER: Good afternoon. I'm Laura Wooster, senior vice president of public policy with the American Osteopathic Association. I speak today on behalf of the AOA's more than 129,000 osteopathic physicians and osteopathic medical students that we represent.

The AOA takes very seriously our nation's opioid epidemic and the public health emergency that it represents. Over the past years, we have worked tremendously hard to mitigate its impacts through efforts to educate our providers, including being a member of the CO*RE REMS collaborative, that we've heard about several times today; a founding partner along with the AMA and the ADA of the White House HHS Working Group on Opioids that started work in 2015; as well as the Office of the Surgeon General's Turn the Tide Rx Campaign.

We're a member of the National Association of Boards of Pharmacies Work Group to address opioid abuse, misuse, and diversion. As well, 22 of our colleges of osteopathic medicine last year committed to including opioid prescriber education based on the CDC guideline in their curricula.

I speak today to emphasize that we support any efforts by the FDA to further expand opportunities for prescribers to be educated on safe opioid prescribing practices and to better identify those who are at risk of developing substance-use disorders who may already have opioid substance-use disorders.

We urge the FDA, though, to approach with caution imposing any new mandates on prescribers. As we heard this morning, many states are already requiring physicians to complete CME-related to opioid prescribing and/or are implementing new guidelines that provide physicians with the tools to prescribe opioids safely and appropriately.

Physicians already face significant and growing administrative burdens that continue to

shorten the time they have available to spend with their patients. We are concerned that adding new mandates would further cut into that time that could instead be devoted to understanding individual patient needs and developing a personalized care plan that can better address their unique situation and therefore improve their ability to treat the underlying cause of their patient's pain, including with non-pharmacological modalities such as osteopathic manipulative treatment when appropriate.

We therefore encourage the FDA to move beyond educating providers on how to prescribe opioids themselves and to broaden educational materials to include other pain management approaches. Thank you.

DR. THROCKMORTON: Clif Knight?

DR. KNIGHT: Thank you.

Good afternoon. My name's Clif Knight. I'm a family physician and serve as the senior vice president for education for the American Academy of Family Physicians, and I'm here on the AAFP's

behalf.

I appreciate this opportunity to testify today. In my role at the AAFP, I oversee all organizational activities related to medical education and continuing medical education. The AAFP represents 129,000 family physicians and medical students.

Family medicine plays a critical role in delivering care to patients in communities across the country, and family physicians are the most visited speciality, especially in underserved areas. Family physicians conduct approximately one in five of all physician office visits in the United States, and this represents more than 192 million visits annually.

A key mission of the AAFP is to protect the health of the public, and we are deeply aware of the critical and devastating problem of prescription drug abuse. At the same time, we need to address the ongoing public health requirement to provide adequate and appropriate pain management.

The AAFP supports having programs in all

states for monitoring real-time opioid prescribing. This information should be available across state lines to address the public health problem of prescription drug abuse.

Opioid abuse and addiction has become a public health matter that needs to be addressed, and the AAFP recognizes the need for evidence-based physician education to ensure safe and effective use of both extended-release and long-acting opioids, as well as short-acting opioids. But we maintain that mandating CME for individual prescribers is not the solution for this public health crisis. We oppose policies that would require mandatory education of family physicians as a condition for prescribing opioids.

Family physicians already are deeply committed to fine tuning their ability to prescribe opioids appropriately and effectively. AAFP members reported completing more than 141,000 CME credits on this topic in 2016.

Since then, the AAFP has signed on to a number of related initiatives, including efforts by

the White House, HHS, and other federal agencies to tackle the opioid crisis, in addition to working with the AMA Task Force to reduce opioid abuse.

Recognizing the current epidemic late last year, the AAFP updated its Chronic Pain Management and Opioid Misuse, a public health concern position paper, to better equip members to combat the opioid abuse crisis while continuing to treat patients' chronic pain.

Additionally, our position paper directs members to our new opioid and pain management toolkit, which practices may use to evaluate their current practices regarding pain management and opioid prescribing.

The AAFP opposes limiting patients' access to any physician-prescribed pharmaceutical without cause, as well as any actions that limit physicians' ability to prescribe these products based on medical specialty.

The AAFP continues to believe educating physicians is an important tool, but to be impactful, the education must be designed to

address the specific and personalized needs and gaps of the learners. One-size-fits-all education is not optimal. Requiring all physicians or prescribers in this case to complete the same education, regardless of whether or not they actually have a relevant performance gap in this area, would be a disservice to that physician and their patients since it will result in unnecessary time spent away from patient care.

The AAFP and our 50-state chapters will continue working together to bring localized and state specific education to our members and their care teams in order to continue to address the nation's current epidemic.

Thank you for this opportunity to present, and I'd be happy to answer any questions, and I'll be here today and tomorrow. Thanks.

DR. THROCKMORTON: Thank you.

Ilana Hardesty?

MS. HARDESTY: Thank you. I'm Ilana Hardesty from Boston University School of Medicine. I serve as the program manager for the longest

running ER/LA opioid analgesics REMS program, the Boston University School of Medicine's safe and competent opioid prescribing education or SCOPE of Pain program.

Our case-based FDA blueprint compliant program covers the spectrum of pain management options: self-care, non-pharmacologic and non-opioid treatments, and all opioids including immediate-release formulations.

Since our launch over four years ago, we have trained over 70,000 health professionals around the country. Our two-month post-training evaluation, published in the Journal of Pain Medicine, found significant improvements in self-reported opioid prescribing practices that align with guideline-based care.

As long as opioids are available for the treatment of pain, training to maximize benefits and minimize harm is critical. Mandatory prescriber education may be required. Our experience in New York, where a recent mandate resulted in our training 30,000 individuals in

11 weeks, would indicate that mandated education can reach large numbers of clinicians in a short period of time.

However, we must be cognizant of the potential unintended consequences of federally-mandated education. Such a mandate may lead clinicians to opt out of opioid prescribing, which could result in reduced treatment access for patients who are benefiting from opioid analgesics.

There will also be a risk of burnout among the clinicians who opt in, as this is a complicated and time-consuming issue. To be a physician, one must be able to manage pain and suffering. This includes the competent use of opioid analgesics. Prescriber education is an important component of addressing concurrent crises, over prescribing opioids with the associated increases in opioid-related harms, and the ever present inadequate treatment of chronic pain.

Prescriber education improves clinician's skills to individualize patient care based on a careful benefit-risk assessment. This is the way

all chronic diseases are managed. Education empowers clinicians to make appropriate, well-informed decisions about whether to initiate, continue, modify, or discontinue any treatment for pain, including opioid analgesics for each individual patient at each clinical encounter. It also improves communication skills to educate patients about realistic treatment goals and safety monitoring strategies.

Education has the potential to both reduce opioid overprescribing and ensure that patients in need retain access to opioids. Accredited continuing medical education, such as SCOPE of Pain, ensures unbiased education based on the best, most up-to-date evidence. Thank you.

DR. THROCKMORTON: Thank you.

Dr. Passik?

DR. PASSIK: Thank you for the opportunity to comment. I'm Steven Passik. I'm vice president of scientific affairs, education, and policy at Collegium Pharmaceuticals. Prior to spending the last four years in industry, I had a 25-year

academic clinical and research career at Vanderbilt, University of Kentucky, and Memorial Sloan-Kettering, focused on cancer and non-cancer pain and their interface with substance abuse.

I'm a psychologist trained in pain and addiction and brought my expertise to expert teams, and I can tell you was involved in multimodal opioid therapy for many years with overwhelmingly positive results.

Many years ago, Dr. Douglas Gourlay suggested that every prescriber of opioids for chronic pain needed to become a talented amateur in addiction medicine; that is, we needed to create a generation of prescribers knowledgeable enough to perform an individualized assessment of addiction risk; design a unique pain management plan for the delivery of opioid therapy and additional monitoring and supportive interventions; and know how to react to and manage signs of loss of control; and finally, be equally knowledgeable about how to stop opioid therapy as they are

starting it.

Much opioid therapy heretofore has no doubt been performed over a course of time, when far too few practitioners ever became trained in performing up to this standard of care.

I applaud FDA for holding this meeting, though we must recognize that the task ahead is complex, for in addition to knowledge of opioids, pain and addiction, practitioners will also require education on how to orchestrate a range of practice variables to do this well.

Education of practitioners must be accompanied by education of payers and those who influence in how we organize and deliver pain management, so they recognize what safe opioid prescribing looks like and can be expected to cost; because, as I can tell you from my personal experience, even expert teams can have difficulty implementing well-thought-out individualized plans of care when there are many systemic forces mitigating against it.

Payers must be required to support and pay

for elements of treatment plans made by those practitioners who ultimately receive any training that we move forward to offer them, and respect that training.

Recent attempts to respond to the opioid epidemic have involved regulation over education. These efforts almost always emphasize efforts aimed at limiting the number of opioid exposures that occur, rather than improving the quality of the exposures that we do have. This approach has already started to create difficulties in access to care for those suffering with chronic pain, many of whom were deriving benefit from stable regimens.

The irony is that given the multiple advances in the assessment of addiction risk, promising psychotherapeutic approaches, monitoring tools including PDMPs and urine drug testing, give-back programs and abuse-deterrent formulations, there's quite possibly never been a safer time to prescribe an opioid to a person in pain at any point in the last 30 years.

Clinicians must be educated and acquire the

skills to use these tools in strategic ways, and the payers must support it. In the end, my colleagues and I at Collegium believe that opioid therapy can be rendered safer when it is conducted by educated prescribers, and we see it as crucial to the future of humane and safe treatment of people with pain. Thank you.

DR. THROCKMORTON: Thank you very much.

Ashley Walton.

MS. WALTON: Good afternoon. I'm Ashley Walton, and I'm here on behalf of the American Society of Anesthesiologists. On behalf of our 52,000 members, I thank you for this opportunity to provide feedback on healthcare provider training and education.

As a professional society composed of physician anesthesiologists including pain medicine specialists, the ASA is actively seeking solutions to the epidemic. We are pleased to see a recent decline in opioid prescribing, a 17 percent decrease from 2012 to 2016, yet we realize there is still much to do, both to ensure comprehensive

treatment for patients with pain and to support efforts that reduce opioid overdose deaths.

Healthcare provider training can play an important role. First, I'd like to make a brief comment regarding the FDA REMS program. ASA is fully supportive that the REMS program apply to all Schedule 2 opioid products. Although there are several different proposals to address provider education, the ASA feels that the most logical proposal is managed at the state level.

For example, linking continuing medical education to state medical board licensure would incentivize physicians to stay up to date on topics such as pain management, opioid prescribing, and addiction treatment. Many states have already begun to implement CME requirements on opioid prescribing in order to maintain a medical license. ASA is encouraged by state-level efforts and believes that this is a better option than any federal mandate.

We fear that efforts to link CME to DEA registration could prove problematic. Many

physicians may choose to no longer prescribe controlled substances and therefore not register with DEA. This would significantly reduce the number of physicians willing to manage chronic pain patients for whom opioid medications are the only source of pain relief.

Lastly, there are proposals to change medical school curriculum. ASA understands the complexities of medical school curriculum and the large amount of information that must be tailored to a short period of time. Yet, this would provide a great foundation for future physicians early on, introducing pain management including opioid prescribing and addiction training to medical school students just as they are beginning their training is a proposal that could have a big impact.

Outside of proposals to specifically address prescriber education, ASA would like to see implementation of the National Pain Strategy come to fruition. The NPS includes steps to encourage education around pain, including encouraging

accreditation bodies and professional licensure boards to require pain teaching and clinician learning at the undergraduate and graduate levels.

Thank you for the opportunity to comment on this matter. ASA appreciates the efforts of both FDA and HHS to curtail opioid abuse and misuse through education and training providers. Thank you.

DR. THROCKMORTON: Thank you very much.

Linda Cheek?

MS. CHEEK: Thank you for this opportunity to speak. My first and main point is to say that drugs are not the cause of abuse and addiction. Correlation does not mean causation. It is like a railroad track, two lines, separate, and this is demonstrated by the fact that in the last five or six years, we have really severely curtailed the prescriptions of opioids, and yet abuse is going up exponentially.

The idea of drugs causing abuse or addiction has been government propaganda for a hundred years. Attempts to contain drug abuse through control of

medications has failed for the last 50 years. The definition of insanity is repeating the same action over and over, expecting a different result. We will not succeed in curtailing the opioid epidemic until we realize the real cause of drug abuse.

I have a YouTube presentation on that, and for those who did not receive my card, you can simply go to YouTube and search my name, Linda Cheek, and pull up that Real Cause of Drug Abuse.

The second point I want to make is that mandatory federal requirements of pain management education is an avenue that the government will use to attack more doctors through government overreach. They have already found out that through their propaganda, they can incarcerate and criminalize innocent physicians for the sole purpose of confiscating their assets.

Medical regulation is, by constitutional law, reinforced through the Supreme Court decision under state regulation, and yet the federal government will use whatever inch we give them to take a mile. Do not allow any form of federal

mandatory regulation of opioid prescribing or education.

There will be no end to the innocent physicians that will end up in prison for life. Some of you might be next. Just this act of the FDA stating that doctors need training in prescribing opioids shows that the actions of the government criminalizing doctors is action for one reason, and one reason only. Money. All doctors are potential victims.

Training for doctors in the past in pain management was absent. You are admitting, through a meeting like this, that you recognize that fact, that pain has been treated for the past 15 years by doctors that are simply doing the best they can with the limited knowledge they have.

Pain management training is necessary, but it needs to be based on truth, not propaganda. If there is mandatory management, then there needs to be protection from doctors that say that they cannot be charged criminally, and it should definitely not be a part of the CSA. Thank you.

DR. THROCKMORTON: Thank you very much.

And the last speaker, Kara Gainer.

MS. GAINER: Good afternoon. My name is Kara Gainer, and I am providing comments on behalf of the American Physical Therapy Association or APTA. We greatly appreciate the opportunity to provide our input to the FDA and other stakeholders today.

I'm here to raise awareness as to how physical therapy is an alternative to opioids for the treatment of acute or chronic pain and the important role physical therapists play in managing pain by administering treatments that include strengthening and flexibility exercises, manual therapy, posture awareness, and body mechanics instruction.

As discussions evolve related to what federal effort should be undertaken to support training on pain management and the safe prescribing, dispensing, and patient use of opioids, we encourage you to also consider delegating resources to support training and

education to prescribers or others who are directly involved in the management or support of patients with pain on alternative, non-pharmacologic treatments, and how to recognize when such an alternative therapy is the safer, more effective option for the patient's condition.

As you know, the CDC recently released guidelines for prescribing opioids for chronic pain, and in their first recommendation specifically identified non-pharmacologic therapy as the preferred alternative for chronic pain. The CDC made clear that there are better, safer ways to treat chronic pain than the use of opioids, specifically stating that many non-pharmacologic therapies, including physical therapy, are a more effective option.

APTA recognizes that in some situations, prescription opioids are an appropriate part of medical treatment. However, there are many instances when an alternative treatment such as physical therapy is more effective. To ensure all treatment options are considered, however,

clinicians must be equipped with the knowledge and resources necessary to be able to examine the variety of treatments for pain that currently are in existence and provide a well-informed recommendation on the best treatment for pain management, specific to the needs of each patient.

If clinicians have not been educated on alternative, non-opioid pain management solutions and how such options may suit patients needs, goals, and desires, then alternative treatments such as physical therapy will neither be discussed or offered to patients, not only placing patients at a significant disadvantage during the course of treatment, but at the same time encouraging the over utilization of opioids to treat pain.

APTA is committed to raising awareness of the positive effect physical therapy can have on long-term pain management. As part of this effort, last year APTA engaged in a public relations campaign to educate consumers about the opioid epidemic and urged them to choose physical therapy -- hashtag, choosePT -- to manage pain

without the risks of opioids.

We strongly recommend that any future training and education provided to prescribers or others who are directly involved in the management or support of patients with pain also include training and education on non-pharmacologic therapies and when such treatment options should be recommended to patients.

We thank you for the opportunity to provide comments here today, and we look forward to working together in the future to develop policies and initiate actions to prevent and treat opiate abuse and addiction.

DR. THROCKMORTON: Thank you very much.

That closes the first public session. Should we transition, Terry, right into your session?

MS. TOIGO: Yes.

(Pause.)

Panel Discussion

MS. TOIGO: We'll introduce ourselves, because we've got five questions to cover in 90

minutes. We're not going to do a summary at the end. We're going to do our summary tomorrow. So if we don't get to cover things today that you want to make sure get included in the summary, you can email me those tonight.

But that's the plan. We're going to go through. Hopefully, it will be a robust discussion, and we'll look forward to the questions from the panel.

So Dr. Terman, do you want to start?

DR. TERMAN: Sure. I have an hour and 15 minutes to talk; is that right?

MS. TOIGO: You do.

(Laughter.)

MS. TOIGO: And I will politely cut you off if you go too long.

DR. TERMAN: You'd like to me to start by introducing --

MS. TOIGO: Yes, just very quick, just who you are in one-minute.

DR. TERMAN: Got you.

I'm Greg Terman. I'm an anesthesiologist

from the University of Washington in Seattle, a professor there in the Department of Anesthesia and Pain Medicine. And I am immediate past president of the American Pain Society.

DR. GALLUZZI: I'm Kate Galluzzi. I am an osteopathic physician. I'm the chair of geriatric medicine at the Philadelphia College of Osteopathic Medicine. I'm board certified in family medicine, geriatrics, hospice, and palliative care, and pain management. And I've been a longstanding member of the CO*RE initiative.

DR. MOORE: I'm Paul Moore. I am the representative dentist in the house. I am a pharmacologist, dentist, anesthesiologist, have trained in chronic pain management, and I'm from the University of Pittsburgh.

MS. BURNS: Good afternoon. I'm the resident pharmacist in the house. My name is Anne Burns, and I'm the vice president of professional affairs at the American Pharmacists Association.

DR. WALLER: My name is Corey Waller. I'm an emergency medicine and addiction medicine

physician, and I'm the chair of the Legislative Advocacy Committee for American Society of Addiction Medicine, and work in Camden, New Jersey, doing street medicine, as well as national system development for systems of care.

MS. TOIGO: I'm Terry Toigo, and I'm associate director for drug safety operations in the Center for Drug Evaluation and Research at FDA.

MS. NORMAN: I'm Anne Norman. I'm a family nurse practitioner. I'm also the vice president of education and accreditation at the American Association of Nurse Practitioners; also a member AANP and also a partner of the CO*RE.

MS. LEGER: Good afternoon, everyone. My name is Michele Leger. I'm the director of clinical education at AAPA, and we represent over a 115,000 physician assistants. We're also a member of the CO*RE REMS collaborative.

DR. HARRIS: Good afternoon. I'm Patrice Harris. I'm chair of the Board of the American Medical Association. I also chair our AMA opioid task force. I'm a psychiatrist from Atlanta,

former public health official, and I also have worked in addiction medicine.

DR. TWILLMAN: Good afternoon. I'm Bob Twillman. I'm a psychologist, and I'm the executive director of the Academy of Integrative Pain Management.

MS. TOIGO: Okay. Thank you, everyone.

Just before we get started, how many in the audience are health professionals? We've got almost everybody represented here.

I'm challenged today in speaking. How many in the audience are health professionals?

(Show of hands.)

MS. TOIGO: Okay. And how many are involved in the education of health professionals?

(Show of hands.)

MS. TOIGO: Okay. So good mix. So we've got five questions today to talk about related to education and training of health professionals. You can see the first three are related to mandatory training, and the other two are voluntary.

So I'm going to start with the first question, which is discuss the pros and cons of implementing a required training program for the prescribers of opioid analgesics. I'm going to take a risk here and start with Dr. Terman, but he can't have an hour and a half to answer the question.

DR. TERMAN: Okay. So as representing the American Pain Society, who we think of ourselves as the science of pain society being a U.S. chapter of the International Association for the Study of Pain, all of our members are in favor of pain training, more pain training, mandatory pain training for anyone doing prescribing, or more importantly, for anyone seeing pain patients, which is likely to be everybody.

You want me to go into cons as well?

MS. TOIGO: Yes.

DR. TERMAN: The cons are clearly if people opt out. As a multidisciplinary society, many of the members in the American Pain Society don't prescribe anything, let alone opioids. The concern

that we have after 40 years of doing this kind of education, multidisciplinary education, trying to wave the flag for better pain management, which only in a small subset of situations include opioids, the concern is we're going to have opt out. We're going to encourage people who opt out to opt out, and that is a huge issue, and it'll be a huge issue for folks in my society.

Even the basic scientists who may not think it's going to be a huge issue, we all may have pain in the future, and we want people to be trained to do that in a good way, rather than in a bad way.

MS. TOIGO: Who else would like to expand on what Dr. Terman has talked about? Dr. Galluzzi?

DR. GALLUZZI: Should we go down the line?

DR. TOIGO: Go ahead.

DR. GALLUZZI: Okay. I would just like to speak to my agreement with Dr. Terman that pain is a universal experience, and every single person in this room who hasn't experienced pain may yet feel that. Therefore, we as providers need to be able to address it, and address it well and safely.

So of course, pain management education is necessary. The pros for mandating this are that it gives us the potential for developing and implementing best practices. It will give us enhanced understanding, and sharing of the multidisciplinary and multimodal therapies that are available for managing pain. And it may also give us the potential for expansion of patient education, which I think is an area that has been under recognized and under utilized.

As an osteopathic physician, I believe in holistic care, and I feel that the patient is at the center of that care, and that the individual who's suffering pain, especially high-impact chronic pain, which is an area of significant impact on quality of life and function, needs to be able to access self-management techniques. And they have to be accessible, they have to be affordable, and they have to be paid for by the payers, the reimbursements.

The cons are exactly as Dr. Terman said, and these are huge unintended consequences. The big

one being, of course, that providers will, and already are, opting out of prescribing C2 medications.

I work at a medical school. I interact with medical residents and family medicine residents routinely, and a number of them have already said, I don't have to worry about this. I'm just not going to prescribe opioids. That is not an option at a time when the population of senior citizens is burgeoning, and it is the largest, most rapidly growing population. Seniors are, of course, the ones who will be having significant chronic high impact pain.

I think that if and when mandatory -- and I hope that this is not the case, but if mandatory, education does seems to be the way we're going. It certainly has to be provider specific. Not every discipline requires the same types of education.

Of course there's a minimum level of competency, but it has to be specific to the providers. And it clearly needs to involve not only physicians, physician assistants, and nurse

practitioners, but also psychologists, physical therapists, and all the other ancillary personnel who can help with this big problem of pain.

MS. TOIGO: Thank you, Dr. Galluzzi.

Dr. Moore, do you want to talk a little bit about the dental perspective?

DR. MOORE: Well, you just stole my thunder, I think, and that is we have mandatory education in Pennsylvania at this point for safe and responsible use of opioids. And that's required both in the curriculum at dental schools in Pennsylvania, as well as a requirement for re-licensure.

So we are mandated, at this point, for education. And whether there's a redundancy in what policies FDA creates, that's an administrative problem.

My only comment would be that acute pain, acute inflammatory pain, not neuropathic pain, 99.7 percent of our prescriptions are for Vicodin and Percocet for immediate-release analgesics. We are not using opioids to treat chronic pain. And as such, I would hope that education, both by the

state as well as considerations with the FDA, address educational processes that are specific to the needs of the provider. Thank you.

MS. TOIGO: Thank you, Dr. Moore. Dr. Burns?

MS. BURNS: I would agree with many of the comments that have already been made. From the pharmacists' perspective, we approach this from a very interesting point because as you heard earlier this morning, pharmacists can be prescribers. In some states, pharmacists can prescribe opioids under collaborative practice agreements. They get DEA licenses.

Then our members at APHA span the gamut of practice settings and are often on the final endpoint, or at the final endpoint, before the patient leaves with the opioid medication.

So the types of education that are needed for pharmacists can be variable, and as was discussed, having education that is tailored for the provider.

Then this isn't really education, but trying

to establish better connections between providers -- and we've talked about the team-based approach to care. But oftentimes for pharmacists, they have a lot of medication expertise already. That's where the core of their training is. But they oftentimes don't have the information they need in order to interact with the patient effectively.

So the different aspects of training that are needed are quite broad and much more complex than any other required program that is currently being offered through FDA. Those would just be some of I guess our asks and our concerns.

MS. TOIGO: Thank you. Dr. Waller?

DR. WALLER: So I'm going to dissent on a few of these things at some level. With the American Society of Addiction Medicine, the vast majority of our members, and me as an emergency medicine doctor, and one who actually works in the streets of Camden, New Jersey, I see the failed attempts at utilization of opioids every single day.

We have to remember the number one cause of injury-related death in this country is related to a controlled substance, and that is overdose. So to just belie that whole fact is a little bit odd to me to hear the most educated people in the country push against education.

So if education doesn't work, because that's something that comes up on a regular basis, then I wonder if we should dismantle the requirements within residency programs and just let residents tailor their own pathways to education, or medical students.

I mean, the logical fallacies that consistently come up start to become a little bit frustrating as someone who educates medical students on a regular basis.

The other fallacy that I worry about in a setting is the one that says, we're going to lose active prescribers if they opt out. Good. I say that because right now would you want someone not willing to take a 2-hour course on opioids who's going to prescribe the most deadly prescribed

substance that we have out there?

If they don't want to take 2 hours of extra education, do they really actually manage patients with chronic pain? I don't think they're managing anything. They're managing the electronic medical record and the refill pathway.

So I think we have to make sure that what we're asking for is for a loved one who needs that care. And I prescribe opioids as well for chronic pain management, for patients with debilitating diseases, like sickle cell and all of these, and so there are places for it, and then there are places not for it.

But without the education, the difference between a physician and a healthcare provider making a decision that saves a life and one that kills someone is the education that they get. So without it, I am concerned that we're going down this pathway that is filled with logical fallacies.

MS TOIGO: Okay. Thank you, Dr. Waller. Dr. Norman?

MS. NORMAN: I would just say that nurses

and nurse practitioners, and the advanced practice nurse, are lifelong learners. They also historically have been very good patient educators. I think they are very much involved in the learning of what they need to do to provide evidence-based care.

I think that the pros would be to encourage and prepare more nurse practitioners to safely prescribe and treat pain, and thereby increasing the access of care for those patients who do need pain management.

I think the cons, I would agree with what most people said. But I would say that it's not really about taking the 2 or 3-hour course. It's more about the fear that might be implied by the necessity to have that course, and to have -- I think that they just might begin to think that they were just a little bit frightened by the fear of what might result if they didn't provide the care that they needed to adequately.

MS. TOIGO: Thank you. Dr. Leger?

MS. LEGER: It's actually Ms. Leger.

MS. TOIGO: You can be a doctor today.

MS. LEGER: I'm speaking on behalf of AAPA, and actually AAPA does not agree with mandated education. Having said that, being in the Department of Education, we are always providing education and education materials to our constituents.

One of the concerns that we have is that we don't want people going in taking a course just to fill a box. I think that's doing a disservice to the clinician. It's doing a disservice to the patients. And I think one of the things that we want to be very cognizant about -- I mean, we have been part of the REMS collaborative for the last four years. It's a very long, arduous course.

A lot of our constituents are saying it's too much information in a 2-hour course. I don't think 2 hours is actually the right answer. I think Anne actually hit the nail on the head. Clinicians should be lifelong learners, that this is something that's going to be an ongoing process. And we learn from day-to-day practice. We learn

from day-to-day management of our patients. So just mandating a 1-hour or 2-hour course is not going to meet, I think, the needs of clinicians in the big scheme of things.

The other thing that I really want to highlight is that we already have state mandate CMEs. So how is this going to fit with the state mandate CMEs? Each state has their own wants. Again, we have the REMS CO*RE. So when a PA calls and says, I need to fill my need for New York and I have them look at the objectives of the CO*RE REMS, they say, I don't know if that meets the New York requirements.

That's real. So they have to go back to their states. They have to go back to their state legislation, their medical boards, and see, does this meet my need, and not all individuals are getting the answers that they want.

MS. TOIGO: Thank you. Dr. Harris?

DR. HARRIS: Yes. So I think there is a general agreement that education is necessary, and the AMA -- I don't think I've heard one person in

this room this morning, or actually as I've traveled across the country talking about this issue, say that education is not important.

The critical issue or critical issues are the what and the how, and many folks have made the point that you can aspire to meaningful education when it is tailored to the physicians or the prescriber's specialty, their patient population, and their practice.

So I look at the answer to this question, and I say it depends on what your outcome is; what you want your outcome to be. If you want your outcome to be simply a checkbox, then perhaps someone would argue for mandatory education. But if you want true, meaningful, improvement and impact on patients, and if you really want your prescribers -- by the way, a term I don't like to use, but I'll use it today, because we're using it -- if you want your "health professionals" to really get the necessary education that will work for them -- we've seen it this morning with example after example, that health professionals are

willing, ready, and able to get the education they need when it's tailored to their own practice. I think our colleague from Kaiser said there was 95 percent uptake.

So I think those are the pros of voluntary education.

DR. TWILLMAN: I would say that I think there is certain core body of knowledge that everyone who works with a patient needs to have with respect to opioids and with respect to pain management. The trouble is I think that while that education is necessary, didactic types of education as we have generally done in this area, that's necessary, but not sufficient.

I could go and take a 3-hour flight school course, and you still wouldn't want to see me in the cockpit. There's a whole lot more to it than just that, and that's part of the challenge. How do you provide people with this basic information that is so necessary before you can move on, but ensure that that actually turns into a meaningful change? And that's I think a huge part of the

challenge.

I am concerned about people opting out if this is made mandatory. We've already seen that happening to people, even without mandates. Even without anything coming from their medical boards, people are opting out of treating patients with pain.

My concern is that while we might see a reduced number of overdose deaths, we might offset that by an increased number of suicides in people who are no longer having their pain adequately treated, and I'm not sure that that's a bargain we want to make either.

So I'm not sure I have an answer for how to do this. I certainly would like to see the education incentivized, rather than mandated, if that's possible, but I think the challenge there becomes how do you design a meaningful incentive.

MS. TOIGO: Okay. Thank you very much. And I think we've pretty much covered question 2 as well, unless there's something somebody wants to add that we haven't covered there, which is the

impact on your members if a required training program were implemented.

Anne?

MS. NORMAN: Sure. Just one additional comment related to impact if a required program was mandated. As was highlighted in the FDA presentation this morning, depending on how the required elements are integrated into the workflow for the providers, it can either be very burdensome or not.

So any required program and the checks that would need to be made, and especially from the pharmacy perspective at the dispensing pharmacy, making sure that it's done through electronic means, maybe through a switch or something like that, where everything is verified and it doesn't require phone calls or checking alternative websites, would be desired.

MS. TOIGO: Okay. Dr. Galluzzi?

DR. GALLUZZI: I just wanted to comment, with respect to -- of course everyone up here agrees that education is important. The question

at hand is should it be mandatory? I just want to ask the obvious question, is there any evidence that shows that individuals who are required to do something, who are mandated to do something, actually performed better after they've gone through that mandatory educational process?

I don't think we have that evidence, and I want to expand on what Anne said, which is simply to say -- or what a number of people said. A 2-hour or a 3-hour or 4-hour course is certainly not ever going to be adequate. And indeed, this type of education I believe needs to be iterative.

So how that is able to be accomplished, I think is really the big question.

MS. TOIGO: Dr. Waller?

DR. WALLER: Just very quickly. Education, if you look at the Bloom's Taxonomy, has six different layers. We're only trying to get to the apply layer. So that means you have to remember, understand, and apply. If you already have the base of a medical education, then actually didactic information has been shown to be helpful when we

have surgeons watching a YouTube video before they go in and try a new procedure.

So when you have a base of knowledge, didactics applied on top of it actually can be effective and actually move people up Bloom's Taxonomy to apply, and that's been shown over and over through many different versions of it, not just in medicine.

I think earlier, we did actually have research that showed, at least in the Army, that they did see a significant decrease in opioid overdose deaths just with the education alone, and it by itself was the single most impactful piece. And I think I looked at that slide twice to make sure, but I'm pretty sure that that was shown in that study, that we actually have seen an outcome that's significantly improved by just the education alone, and it was mandated to those professionals.

DR. TOIGO: Anyone else want to comment?

Dr. Harris, were you going to say something?

DR. HARRIS: Just a point that was made earlier, but I think it's worth repeating regarding

the duplicative nature of perhaps a federal program. From a public health perspective, you want to look at this from a systems approach. And if states are already doing this well -- and this gets into the next question a bit. But if states have a system, we certainly wouldn't want to spend federal dollars duplicating work that's already being done in the states.

I would also say that we should really look at rather than creating a new system, a new layer, it seems to me to make more sense to improve what's already out there. You've heard that the medical schools are involved in this. I know I went to Brown. I visited Brown, and they have a wonderful program for the medical students and the residents.

So it seems to me that where you get the most bang for your buck is improving systems that are already in play versus creating a whole new layer that would then add to the bureaucracy.

MS. TOIGO: Just to add to this question a little bit, we heard this morning a question -- and then I think when Dr. Kahn spoke in the public

hearing, he made a comment about mandatory being more burdensome when you're not in a big system.

So the presentations this morning were from the VA, and Kaiser, and a lot of people getting trained. I wonder if any of you have any thoughts on the burden when you're an individual practitioner versus the burden when you're part of a system, and mandatory versus voluntary education there.

DR. MOORE: Well, since I'm representing dentistry, which in fact 50 percent of it is a cottage industry, solo practitioners, I feel sure that our members, the ADA's membership, will have a certain amount of pushback with added mandated burden, in part because they have to go find it. It's not easy for them to access. On the other hand, life's tough, you know?

I would point out that we have child abuse requirements for our licensure, and those programs are certified. Not anybody can teach them. You have to become certified so that your curriculum fulfills the requirements for that continuing

education.

So I see the requirements for a mandated opioid education to fit within that model in the state, so I really agree with Dr. Harris with that regard. We have a system in place there I think.

MS. TOIGO: Okay. Did you want to add something, Dr. Waller?

DR. WALLER: Always, but I'll hold back.

MS. TOIGO: Okay. There will be another opportunity.

Okay. Just before we move to question 3, I want to make sure nobody has any other comments on number 2.

MS. LEGER: Terry?

FEMALE AUDIENCE MEMBER: We just cannot hear you.

MS. TOIGO: You can't? Okay, is that better? Okay.

MS. LEGER: I just want to add that I think in a closed system things are easier than individuals in a private practice or in a community health center, and unfortunately you cannot equate

those two.

In the VA, in a Kaiser -- I used to work in the hospital where basically every year you had to have your annual competencies to be done. That was in a hospital-based setting. But when I worked in an outpatient setting, those were not done. So I think, again, one size does not fit all.

MS. TOIGO: Okay. Thank you.

Yes, Dr. Galluzzi?

DR. GALLUZZI: I don't want to monopolize this point, but I'm not sure that I made my point clearly enough, that if we're talking about what organizations need to be involved in this education, of course the AOA, the AMA, AAPM, AANP, AAPA, et cetera, have to all be involved, and this has to be a coordinated effort.

But I just want to say again, this is a public health crisis. And if we eliminate the public from the problem, then I think we're missing the boat. We need to really initiate significant educational imperatives at the level of the public, the individuals, children, adolescents,

preschoolers.

I had adult children who went through the D.A.R.E. program and who mocked it because they were already so sophisticated that they thought it was ridiculous for them to do learning about drugs. And in fact, they used the D.A.R.E program to inform them about some new things that they could try.

I just want to continue to say, again, that the onus is being placed on the prescribers, when in fact this is a public health crisis affecting everyone, and the education needs to involve, therefore, everyone.

MS. TOIGO: Okay. Thank you for that. And I think everybody's agrees with that. We're just focusing on the education piece of it today.

So why don't we move to question number 3?

Number 3 is discuss which organizations, federal agencies, state medical boards, others, that are best situated to register and track completion of a required training program. We heard some presentations this morning around this

topic. I'd be interested in going down the panel on this one and having everybody have an opportunity to comment.

DR. TERMAN: Okay. Eight years ago, I was brand new on the board of the American Pain Society, and we talked about opioid REMS. What are those? And I said, oh, sounds like medical school. And the president at the time said, "Oh well, if you're so smart, you take this on."

So I found myself a few months later at an FDA REMS meeting in 2009, and I suggested, on behalf of the American Pain Society, that mandatory education would be important, that it should be across all opioids, not just extended release, and that it be linked to the DEA certification.

There was no other certification that I'm aware of in healthcare where you get the certification without any demonstration that you can do what they're certifying you for, use controlled substances. I realized that that might require some work politically, but that seems like a reasonable first -- even if it's a short test

that leads people through good pain management before they get their certification, that seems like a reasonable thing.

The disadvantage of a federal approach is that federal institutions seem to be all about prescribing. They're not really about practice of medicine. That's what the state boards are supposed to be doing, reasonably enough. That would not keep the state boards from doing what they need to do, but when you figure six boards, every state, that's a lot of diversity, and it's going to be a long time before there's any agreement on what needs to be done to improve pain management.

I'm happy to see it moving towards something, but I'm not sure that that would keep us -- not necessarily teaching long courses, doing many pain fellowships for every DEA licensure, but some sort of competency test that suggests, gee, it might not be a great idea to co-prescribe benzodiazepines and opioids.

That seems like a reasonable way to -- I

mean, I spend a lot of time on my Internet connection doing everything from IRB, animal care, ACLS, central-line placement, asbestos abatement training, everything comes across as a [indiscernible].

So there's an unlimited number of people who want me as a physician, an academic physician, not just private practice physician, to do stuff. But we're talking about what we think is a public health crisis. Maybe it's okay to have physicians understand what they're doing before they're given license to do it.

MS. TOIGO: Dr. Galluzzi?

DR. GALLUZZI: We're talking about bullet number 3, describe mechanisms. So what are the mechanisms whereby this type of education can be successfully rolled out? I think the CO*RE initiative has shown that there's a successful uptake of volunteers.

MS. TOIGO: We're doing number 3 on this screen, so it's organizations that are best situated to register and track.

DR. GALLUZZI: I'm sorry? I can't hear you.

MS. TOIGO: So I'm going to try it again. It's discuss which organizations, that is federal agency, or state medical board, or others, are best situated to register and track completion of a required training program?

DR. GALLUZZI: Oh, I think I agree with Greg then. I think the state medical boards are probably a good place to start. The problem I think is coordinating them because there's been a paradigm shift in treating patients, and we need to come out of our silos.

The one doc on the block treating everything is no longer the model. We are working with physician assistant, nurse practitioners, physical therapists, and so I'm not sure that there is a central clearinghouse, a repository where everyone can come together.

But I do feel like we need to come out of our silos and work toward a coordinated effort, and that may be through the state boards. I'm not sure.

MS. TOIGO: Did you also agree with Dr. Terman on DEA?

DR. GALLUZZI: I would agree with Dr. Terman.

MS. TOIGO: That was his main point, I think initially that required through DEA registration.

DR. GALLUZZI: Oh.

MS. TOIGO: Okay. I just wanted to clarify if you did or when you were talking about agreeing with him whether it was all or part.

DR. GALLUZZI: I guess for the most part, yes.

DR. TERMAN: Could I take a giant step backwards? Just one sentence. The reason why DEA -- I don't think most people opt out of DEA registration. Anything done by the FDA on the opioid class, I worry about people opting out. But if you take all of the controlled substances, I don't think people will opt out.

DR. GALLUZZI: We're talking about a huge range of possible medications, and I think, clearly, most people are going to opt in.

MS. TOIGO: Okay. Thank you. Dr. Moore?

DR. MOORE: DEA.

MS. TOIGO: Dr. Burns?

MS. BURNS: I was going to say DEA, and one of the -- and this would be a for consideration. But I think one of the important positive aspects of DEA would be it would take some of the actual administrative burdens that happen at the patient level away, potentially, and allow the providers to actually work with their patients and take care of them.

MS. TOIGO: So just to clarify, the question on the table is not whether DEA is the solution to the problem; it's just on federal, state medical boards, or others. Just because it was mentioned, it's not -- okay, I just wanted to clarify that. If I didn't, probably Dr. Waller will, right?

DR. WALLER: It's the J-O-B, right?

I would say that whenever you're going to look for a point in which you can hit the most people at the most time, it would be the one place in which they have to go to either obtain initially

or renew a DEA license, because that's where everybody eventually has to go is to the DEA diversion website. So with that, that allows for actually a place where we already have a database of every person who has a DEA license.

One of the issues that you find when you start to deep dive into the states and what they have the capability to do and don't do, is you find that there's a distinct heterogeneity around the country of the level of capability of a state medical board.

So some very small states have less sophistication at the state medical licensing board to set up a unique database of people to do this. I mean, there are a couple of states that I've been to that literally, it's a hard drive where they have the list of their people. It's not even an Access database. It's an Excel spreadsheet where they have all of their providers who have a license to practice in the state.

They're not going to be able to stand up a REMS program and be able to maintain that, so that

we can know that people are doing it, turning it in, and following it. And the locality -- I live in New Jersey, which has now one of the stronger requirements for CEs.

So it can be an either or, but there would need to be an undertaking by either the FDA or the DEA to determine which of these courses actually meet the criteria and say it's either you take this one that's provided through the federal means and meets the requirements, or the state ones, which also meet it. But either way, you would have to sign up with that certificate, specifically the DEA website where they already have the database.

MS. TOIGO: Thank you. Dr. Norman?

MS. NORMAN: I think I'll be in agreement with everyone else. I think it has to be the agencies that authorize providers to prescribe; therefore, the DEA. But I also think that it will have to be a collaborative effort with the state boards, since many of those do require state education on controlled substance for relicensure. So I think it will have to be a collaborative

effort.

MS. TOIGO: Ms. Leger?

MS. LEGER: And I was going to expand from the collaboration perspective. We actually have a model, and PAs are new to that model. It's the buprenorphine waiver, and it's a collaboration between SAMHSA and DEA. I think, again, there's a model that is already in place for physicians, has now been enabled for PAs and NPs, where PAs and NPs who get their buprenorphine waiver training, their information is sent to SAMHSA, who codifies it with the DEA, and then they get their X waiver.

So I think that could be a model that you may want to investigate.

MS. TOIGO: Thank you. Dr. Harris?

DR. HARRIS: So the practice of medicine is regulated at the state level, and as we've heard today, some states have decided to mandate training. And those states, their medical boards or probably maybe some other entity in the state, are managing that.

The solution to the opioid crisis is a local

solution. We saw that this morning. I'm originally from West Virginia, Mercer County, which is right new to McDowell County, which has been significantly impacted by the opioid epidemic. Recently, I went to the prescription drug abuse summit and heard from folks from Marin County. And I imagine everyone in this room knows how different Marin County is from McDowell County, West Virginia.

So the solutions are local. So I believe that if states decide to mandate, they know best, working with their state partners, the state public health department, state medical societies, know best what the needs are for that particular state, and even further down to the local level.

So I will continue to say that if there is required training, that should come from the state level, and then the state should regulate that as it regulates the practice of medicine.

MS. TOIGO: Thank you.

DR. TWILLMAN: I would very much like for it to be a local solution handled by the licensing

boards, but I think it's impractical to do that. You're talking about 70 medical boards, 51 nursing boards, 51 dental boards, some unknown number of pharmacy boards, optometry boards, naturopathic medicine boards. It just begins to be too much to manage. And furthermore, I'm not sure what authority any federal agency has to direct all of those licensing boards to mandate this kind of education.

I'm not sure that that's the solution that's going to work. I think it does have to be a federal agency. I don't mind it being DEA that's keeping track of that, so long as it's not DEA that's determining the content of the education. As long as it's determined by someone in healthcare, not someone in law enforcement, I would be okay with that.

With respect to people not opting out of DEA registrations, I may be wrong about this, and correct me if I am, but I think it's possible to opt out of a Schedule 2 registration only, and keep your Schedule 3, 4, and 5. So I'm not sure that

that gets us to the point where we won't have anyone opting out. But to me, it's the best of some non-optimal solutions.

MS. TOIGO: Okay. Thank you. Before we move to question 4, is there anybody that wants to add anything on question 3?

(No response.)

MS. TOIGO: Okay. So we'll move to question 4, and we've got 20 minutes left for the last two questions.

Question 4 is discuss which organizations, federal agencies, state medical board, healthcare system, or others, that are best situated to incentivize a voluntary education program?

So now we're moving from the mandatory to the voluntary. The last two questions are on voluntary. Which organizations are best situated to incentivize a voluntary program?

How about we start down this way this time?

DR. TWILLMAN: I think the answer to that depends on what kind of incentive you come up with. Obviously the most powerful incentive for most

people is money. So if you're going to go down that route, I'm not sure that we have an agency other than CMS that might be able to do that. And again, that's only going to cover folks who are Medicare and Medicaid prescribers.

I'm a little challenged by this because outside of a financial incentive, I'm not sure what other incentives we can come up with. And I'll leave it to the rest of the panel to suggest some things I'm ignorant of.

MS. TOIGO: Dr. Harris?

DR. HARRIS: So I do agree that it does depend on the program. But in the last question, everyone answered DEA. In this question, I'm going to answer DEA, and I'm going to say would DEA consider a 10 percent reduction of -- I see my DEA colleague looking up when I'm talking about this.

(Laughter.)

DR. HARRIS: Definitely don't have to answer today -- a 10 percent reduction in registration fees for those who have taken whatever courses, either maybe their state or they can demonstrate

some course in that.

So for this question I might say let's put DEA on the table here to incentivize those courses.

MS. TOIGO: Thank you, Dr. Harris. Ms. Leger?

MS. LEGER: I think payers have a big role to play in this. And I know that there are some programs for some of the chronic disease models and how clinicians are able to apply evidence-based practice, and they're able to move the needle in their patient management.

I think if you look at the payers who are able to give a better reimbursement rate for the visits, that would be the place to go.

MS. TOIGO: Dr. Norman?

MS. NORMAN: So I just agree with the two former colleagues up here that I would really like to see that reduction in the DEA fee. If they were to do that, I think that would be a good incentive. And then I agree also with the payers. However, there are some people out there who are not involved in that with their boutique practices or

whatever, so they're not involved with insurance or any type of reimbursement plan like that. I think it needs to be an overall organization that would have the power to incentivize everyone.

MS. TOIGO: Thank you. Dr. Waller?

DR. WALLER: I would say that I did like the idea of the DEA that Dr. Harris had mentioned, but I think it's a combination of the payer and the hospital systems, because hospital systems are who ubiquitously receive money from CMS. So they could be given a bonus on their CMS reimbursements, if they had a certain portion of their medical staff that had taken the CME there. And I know that they have the capacity to do this because it took exactly two weeks for the entire country's health systems to stand up Ebola screening, and we saw entirely two cases.

So I think with that, we know that they have the capacity to do this. And the incentive doesn't necessarily need to be to the individual provider, but to the system, and then they can internally incentivize in many different ways for medical

staff.

Someone who is a medical staff, chief of pain medicine for four years in a large health system, I could not incentivize one person to do anything, but the health system can magically snap their fingers, and a lot of people were standing in line to get stuff done.

MS. TOIGO: Thank you, Dr. Waller. Dr. Burns?

MS. BURNS: And I agree the comments that have been made. At the national level, there's a lot of focus on public-private partnerships, so I'm hearing payers. I'm hearing DEA. So there may be some opportunity for some collaborations.

I would just add for the education component, collaboration among the members of the team, as has been stated will be critical moving forward.

MS. TOIGO: Thank you. Dr. Moore?

DR. MOORE: Continuing education in dentistry is supported by fees by the dentist to take continuing education. And I think as long as

these programs are within the total number of hours that you're required to take, it probably doesn't have a disincentive factor.

So I don't think we're -- we don't have hospitals; we don't have those kinds of sources. So I think it is not really a significant problem.

MS. TOIGO: Thank you. Dr. Galluzzi?

DR. GALLUZZI: I just want to reiterate, I'm in favor of the carrot much more so than the stick, so that the incentivization of getting this training, and ongoing continuing education I think is really where I would like to see this going.

I'm not sure. I don't have the public policy background to say that the DEA would be the right place versus CMS. But when you think about interdisciplinary training, I think that CMS would have more oversight for different disciplines, more so than the DEA, a law enforcement agency.

MS. TOIGO: Thank you. Dr. Terman?

DR. TERMAN: Yes, I am not as excited about the DEA for $10 getting off of your license fee. I'm not quite willing to get FDA off the hook here.

Frankly, I don't think the ER/LA REMS thus far have been a failure. I think they were not expansive enough, and I think they were aimed at the wrong categories of prescribers.

Calling a successful completer someone who has prescribed long-acting opioids in the last few months, those aren't the people we're trying to teach. Those are the people that probably aren't going to care about what I have to say.

It's everybody else that hasn't been prescribing them and is wondering whether they should, and why would you? Those are the people that we want to teach in the same way that you like to get the medical students fresh. You like to get students in general who don't come in with their own agenda.

So when I saw that 400,000 -- did I misread that? Is that right? Does that make sense?

MS. TOIGO: They were not completers, but there were 400,000 who --

DR. TERMAN: I understand, that took training. And then he tells me that 1.5 million

are DEA registrants. I mean, I'm less pessimistic about that. Now, I realize that some of those people took it multiple times and perhaps --

MS. TOIGO: Or not prescribers -- it was all -- I think that number was all healthcare professionals.

Doris, is that --

DR. AUTH: We don't know that gap, the people that started and never finished. We don't know [inaudible - off mic].

DR. TERMAN: But they did take it. They signed up for it.

DR. AUTH: Yes.

DR. TERMAN: Okay. So again, I'm not sure in terms of the voluntary -- if you're not going to make it mandatory, I like what the FDA has done so far. And there's a lot of throwing the FDA under the bus. It's like blaming CDC for Zika virus. It makes no sense.

(Laughter.)

DR. TERMAN: And there are reasons why we ran into problems with this opiate crisis, and it's

because people are not doing good pain medicine. And boy, is it easy to write a prescription and send them on their way. It's not because people wanted to create a bunch of problems with opioids. It's that it's hard to do, and apart from addiction medicine, there's nothing that doctors like to do less than pain medicine, and that's where the connection is, actually.

MS. TOIGO: So I'm not --

DR. TERMAN: What question did I answer?

(Laughter.)

MS. TOIGO: No, I just wanted one point of clarification to make sure I understood what your main point was, that you're not going to let FDA off the hook. You think voluntary training is a good idea, but it should be broader than ER/LA opioid analgesics.

Is that what you were saying?

DR. TERMAN: Correct. That's correct.

MS. TOIGO: Okay. I got it. Thank you.

Okay. So we've got one question left before we go to questions from the audience. So what I'd

like to do is go to the last question, which is describe mechanisms your organization has successfully used or potentially could be used to support prescriber training that is voluntary in nature.

I'm going to start with Dr. Waller.

DR. WALLER: I'll just get it out of the way. It's like pulling off a band-aid. No, fair enough.

So I'm the medical director -- one of my roles is a medical director of an ACO in Camden, and recently we rolled out a plan to expand medication assisted treatment in the city of Camden by paying providers $500 to take the free 8-hour course, plus write their first prescription. So that's 8 hours and write their first prescription for buprenorphine for a patient, then they would get $500.

Eighty-four percent of the providers signed up for that. I think it's going to end up being a hundred, or pretty close to that, for peer-pressure basis. And that's all voluntary. And $500 is not

enough money to really say that that's a true incentivization. So we may not have to honestly pay that much to get a lot of benefit. But I think the biggest piece was we said, after this, for your first 10 patients, we will have somebody on call to help you, meaning that they have somebody to call.

So I can't say whether it was just the $500 or the fact that they feel like somebody's there to back them up. And with AAAP, PCSSO, and PCSSMAT, we have a wonderful number of mentor providers that this already exists nationally that we could tap right into with opioids, because there's already the PCSSO mechanism to tap into for that mentorship that they put together really well.

So I think it's doable, but the incentives have to be weighed out. Money's hopeful, but help is I think more appreciated.

MS. TOIGO: Okay. Thank you. Dr. Burns?

MS. BURNS: From a professional association perspective and specifically for pharmacists, APHA has really ramped up our efforts to train pharmacists in a more integrative approach to pain

management. I think I could speak across the board for the organizations, the CE programs that organizations offer.

We have really increased the number of in-depth CE offerings, so not just 1 and 2-hour programs, but day-long programs via a pain institute, really to help to drive the message that pharmacists need to be up to speed on the latest as it relates to pain management.

The other thing that associations can do is use their communications vehicles to make pharmacists or other healthcare providers in our case, aware of programs that exist, requirements for those programs and so forth. So there we have the opportunity for broad reach using organizational input.

MS. TOIGO: Thank you. Dr. Moore?

DR. MOORE: The American Dental Association is organized as a national organization, as well as state organizations, as well as local organizations. So when you belong to the ADA, you belong to all three of those organizations, and

they all provide continuing education.

Clearly, the American Dental Association is really trying to be as proactive as dentists can be. So I think there is going to be lots of programming available, either free or for minimal costs through those organizations.

But I think without a mandate, I think you have a situation in our profession where getting trained to do something you do already doesn't make you any more money.

Unlike training that you can now use Suboxone and like that, where in fact that adds to your practice, I'm not sure that there is a particularly financial advantage. And I suspect the people who would be involved in an unmandated CE requirement would be the people who are interested in that information and are taking it anyway. I'm not sure if it would really go to the people who we are targeting with regard to proper and responsible prescribing.

So I'm kind of at a loss there. Did you hear me kind of say a lot of words and not come up

with an answer?

MS. TOIGO: No, but I got the difference between what Dr. Waller was describing and what you were describing in the realm of voluntary programs and how appealing they might be.

DR. MOORE: People take CE courses to learn about how we can whiten teeth -- there's a money-maker -- or how we can straighten teeth, or how we can fill teeth. I'm not sure that there are those kinds of incentives, inherent incentives, that exist there.

MS. TOIGO: Thank you. Those are helpful comments. Dr. Galluzzi?

DR. GALLUZZI: The AOA was actually a founding member of the CO*RE initiative, which is an 11-member group and includes Medscape as a commercial partner, if you will. And I have to say having given a number of those lectures over the years, I have been edified with the response from the volunteers who attend the lectures. Admittedly, some of it is arduous. Some of the programs are 3 hours long, and there's a great deal

of engagement. I think that that's one of the best things AOA has partnered with.

AOA has also developed an initiative and 22 of the colleges of osteopathic medicine have signed on in agreement to expand the amount of opioid education at the undergraduate level. There is an attempt to expand it beyond the use of just basic science, pharmacology, and to bring in the other disciplines like psychology, physical therapy, physician assistant studies, et cetera.

AOA has also worked with the surgeon general on the Turn the Tide initiative, and with the National Association of Boards of Pharmacy workgroup to assist with education on identification of red flags and interprofessional education.

So I think these have been some very successful initiatives, and I hope that we can expand on them and have them grow in the future.

MS. TOIGO: Thank you. Dr. Terman?

DR. TERMAN: Sure. The American Pain Society will continue to do voluntary education, as

we have for 40 years, a multidisciplinary group, including next week in Pittsburgh, our annual scientific meeting, where we'll be describing one of my conflicts of interest, which is $2 million from Pfizer to fund three major grants on better pain management, none of which involve pharmacology.

But to be perfectly honest, our best efforts in educating has been through collaboration, and our outstanding collaborations with CO*RE and the other members there have been very good. Our pain care for primary care conferences with Global Academy of Medical Education have been packed. So we are certainly happy to collaborate with anybody interested in educating people about pain medicine.

MS. TOIGO: Thank you. Dr. Norman?

MS. NORMAN: So I said earlier that nurse practitioners were lifelong learners, and I would just say that the American Association of Nurse Practitioners is the only national organization for all NPs in all specialties. We serve and support the 222,000 nurse practitioners in the United

States.

We have offered continuing education for many, many years. We offer three live conferences a year, and then we have a very robust LMS where we maintain 170 to 180 programs in there, and we have educated lots of NPs.

At two of our conferences, we always have a pain management track. This year at our Specialty in Leadership conference in September, we'll have a pain management and opioid use disorder track. We always get good attendance for those.

At our health policy conference this year, we've also focused on -- actually, the last few years have focused on the opioid epidemic. This past February, we did have the surgeon general come and speak.

So we're addressing the epidemic across several avenues and venues. We're, of course, a proud member of the 11-partner interprofessional multidisciplinary CO*RE collaboration. Within that curriculum, AANP has taught or had more than 19,584 NP learners.

When we look at those, how many of those were licensed to prescribe, 13,760 were licensed to prescribe. Then how many had prescribed within the last 12 months was 5,996 of those that have taken the CO*RE program through AANP.

We also offer several other related CE programs, including substance-use disorder for adolescents. We will soon be in partnership with NIDA on another substance-use disorder program for adolescents that will be coming out soon. And again, like I said, we offer a lot of live sessions at our conferences on this topic.

AANP also participates on the advisory council for Harvard Medical and NIDA who are creating three 8-hour modules on the opioid topic, and we have already begun to promote that to our members. And then also, we serve on steering committee for the PPCSO and PCCSMAT to influence that, so that we can insure that nurse practitioners are getting the education that they need.

Other than that, we serve on a lot of opioid

initiatives both at the national and federal level, including the surgeon general, HHS, and others.

MS. TOIGO: Thank you. Ms. Leger?

MS. LEGER: AAPA has several national initiatives of which one is the opioid epidemic. We actually have on our webpage an opioid page, and it has all the activities that PAs can go to for continuing medical education, of which one of them is the CO*RE REMS.

But the other thing that we're doing is that I purposefully placed one of our lectures in Kentucky. Kentucky is the only state of the nation where PAs are not allowed to prescribe controlled substances, and we know that there's a tremendous epidemic in Kentucky.

When I placed that course, no one said why are you doing it? And it wasn't because we were not chasing the numbers for FDA at this point in time, because FDA, it's not just the number of individuals who are in the room attending the session; it's the number of individuals who are licensed to prescribe and has prescribed in the

last year.

Doris has heard me say that over and over and over, that they need to change their definition. But I really felt that clinicians, whether they are prescribers or not, are part of the team that are managing patients who may be on an opioid.

NPAs are prescribers in Kentucky of other products, and they manage patients who may be on an opioid. So to tell me that they cannot benefit from an education program because they don't meet the FDA definition, I'm not going to say what I think.

The other thing that we do also is that from a legislation perspective is -- Florida was one of the last states that recently enabled PAs to prescribe controlled substances. And I told the Florida chapter that we need to -- what's the word?

I'm sorry. I'm thinking in French; one second. We need to leverage education and show to the legislation, to legislators, that PAs in Florida were educated.

Before a bill was introduced and passed in Florida, they could prove that they had a fair number of the PAs if Florida had taken the opioid REMS course. And that was, again, without it being mandated, so it was all voluntary.

The last thing that I'm going to say is we are continuing to provide other programs. Similar to Anne, we're part of the NIDA CME for pediatric and adolescent substance use. We've collaborated with the Harvard Medical School also.

So it's not just REMS. It's just addressing the epidemic in totality, I think is really where we really need to look at, the public health impact of the epidemic on the clinicians and the patients.

MS. TOIGO: Thank you.

So I'm mindful of time. We're a little bit over.

DR. HARRIS: Okay. The AMA is very active in this area. We create our own CME courses and offer these at our two policy meetings per year, as well as our advocacy meeting. We're involved in development of webinars, having national partner

calls where we are constantly urging our physicians to enhance our education and training, not only on opioids, but on substance-use disorders and pain, and pain management.

We're working on two pilots right now in Rhode Island and Alabama. These pilot projects are toolkits that have many resources on multiple levels, including education and training for physicians.

Of course, we have our AMA opioid task force. Many of our partners are in the room, anesthesiology, OAO, ADA, AAFP, addiction psychiatry, ASAM, so we have really elevated all of our courses.

We have 200 courses on that website because we had heard that physicians weren't sure where to go when their own specialty didn't offer the courses. So now folks can have that website to go to, and we know that recently over 118,000 physicians have taken courses from that. So AMA is very active, and we will continue to be active in making sure that physicians lead on the issue of

furthering our education and training.

Also, one more thing that I think we should keep in mind as we go forward. This epidemic has evolved, and the factors that are currently sustaining this epidemic are different from the factors that were probably involved.

We have to make sure -- I'll just say that we are constantly looking at what we are doing, and evolving with the epidemic, and staying ahead of the epidemic, if you will, for whatever solutions we propose. So I just wanted to make that point.

MS. TOIGO: Thank you. Dr. Twillman?

DR. TWILLMAN: Of course we would do the same thing that we do with all of our education courses, make them available, our LMS, advertise them widely, have content at our annual meeting.

But they might be interested in doing some creative things. It would be nice if we could get a grant that would allow us to give members a discount off their membership fee for the next year if they completed the course.

Or maybe since Dr. Terman and I both have

psychology degrees from the same fine educational institution, I'd call up APS and say, let's have a competition. Let's see which percentage of APS or AAPM prescribers can take this course and see who wins. And then when APS loses, he'd wear our logo T-shirt at his meeting or something.

(Laughter.)

DR. TERMAN: No, we'd lose you as a member.

(Laughter.)

DR. TWILLMAN: But I think doing all the usual things is obvious. I think it's time to get a little bit creative maybe and think about some new and interesting things, too.

Questions and Answers

MS. TOIGO: So if you all get creative before our docket closes, we'd love to hear those creative solutions to the docket.

So I think we've got a little bit of time left for questions, so I'd like to open it up to the meeting participants, if you have any questions. And I'd also like to apologize for -- from having kids who tell me they hold the

phone over here when their mother is speaking, this clearly is not how I usually speak. I thank you for bearing with me in not being able to hear completely.

DR. HAVENS: I have a comment and a suggestion. Comment is CME has always been a part of licensure, and that's where it should stay. Putting it in the hands of the DEA is putting the fox in charge of the henhouse.

By keeping it at the state level with licensure, which even though there might be five different licensure groups, they're doing it already. It's part of their job. Then all the DEA has to do is look to see if that little box has been checked, and then they get their DEA certificate. That's one suggestion.

The second thing is that for an incentive, since innocent doctors are being attacked all over this country, make it in these statements that if you take this CME and are taught how to prescribe controlled drugs, they cannot use the CSA illegally, like they're doing now, using that 1304

or whatever it is, against doctors. Doctors are immune to prosecution, and you will guarantee that you'll have doctors again treating pain appropriately.

We treat pain appropriately as it is. And having our licenses taken away and our lives destroyed for money is not right. And that would be a way of getting people back the care that they have without putting innocent people in prison. Thank you.

MS. TOIGO: Thank you. Over here?

FEMALE AUDIENCE MEMBER: Yes. Hi. A question that may have no answer. I wonder whether, since there are already 20 some states that have opioid prescribing or pain management prescribing education as a requirement of licensure, is there some way, without creating a new mandate, sort of a new level, a new layer on top of that, that the states could maybe -- we could herd the cats a little bit and create some sort of a standardization across states, so that the requirements don't vary as widely as they do

now. I think that's a frustration for us as CME providers, as well as for the people who are learning.

DR. WALLER: I think that's a definition of a federal standard. I mean, I'm just saying -- which I agree with. I think that in order to standardize across all 50 states and the territories, because we also have people that are licensed outside of the Continental United States in Puerto Rico and Mariana Island --

I mean, there are complicated issues that go along with those. And the big thing is that, yes, there should be a baseline, and if the state meets it, then it seems logical that if the state meets it, that box has been checked. Then the only thing that the DEA does is not say yes or no; they just keep the database.

They're not in charge of building the education, making sure that that education was done by that person in that state, but purely just the allocation of those names and the check box that's there, but heterogeneity is a reality, especially

the deeper you get into localities.

FEMALE AUDIENCE MEMBER: Thank you.

MS. TOIGO: Norm?

DR. KAHN: Norman Kahn, Conjoint Committee on Continuing Education. First of all, I want to thank the panel. I have two pages of notes. This is terrific.

You know, a lot of times people come to the microphone and they pretend to ask a question, but in reality they're making a statement. I don't have a question.

(Laughter.)

DR. KAHN: I have a really quick statement that I want your reaction to. And I think we have a window of opportunity here with regard to incentives, and that is the Center for Medicare and Medicaid Services is right now writing a rule on improvement activities.

You talk about collaborations, there are a number of us in the audience here who are working with them right now on certain kinds of continuing education, fulfilling the criteria for an

improvement activity. If it can be shown to change practice behaviors and be related to improved outcomes, this seems to be perfect. This would be a great incentive.

MS. TOIGO: So are you asking for other partners to come see you? Is that --

DR. KAHN: Sure.

MS. TOIGO: Okay. Steve?

DR. PASSIK: Steve Passik, Collegium. So continuing on my theme of holding the payer's feet to the fire a bit on this, Fred in his slides had an outcome that would really matter to the physicians I used to practice with, and that is fewer phone calls.

So I'm wondering if there's any mechanism that anybody knows of, or could you fathom an incentive that if someone got this training, insurance companies would offer them an opportunity to be exempted from prior auth, not have their judgment questioned quite as often, and not have to be on the phone with the insurance companies constantly if they wanted to institute a certain

visit schedule, a certain particular drug, a urine drug test on a particular frequency.

Right now, people trying to do that in their practice and trying to -- when I did it, I would say, I want to see this person once a week. I want them to have psychotherapy. I want to do a urine drug test every month. I want my prescribing colleagues to give out only 7 days worth of medicine at a time, and so on, and the answer you got back was, no, no, no, no, copay every time.

There are significant payer barriers. So if you really wanted to incentivize people, if there was a way to say if someone was certified in this way, the payers would have to honor it in some way, that would matter to the physicians I used to practice with.

MS. TOIGO: Dr. Harris wants to comment.

DR. HARRIS: Just wanted to comment that your point about payer barriers is a good point. And I would argue that actually payers need to get rid of those barriers, separate and apart from an incentive from these courses.

The good news is I know the AMA has had some conversations. At our task force meeting, we had Blue Cross/Blue Shield. So payers I think are beginning to look at barriers, particularly to medication -assisted treatment, as well as the barriers to the non-pharmacologic alternatives for pain. So that's happening, but they need to do more.

MS. TOIGO: Okay. Can you identify yourself?

DR. MILIO: Lorraine Milio, Society for Maternal Fetal Medicine. Two comments, questions. One is whether it's incentivized or mandated, my concern is limiting training to people who are prescribing opioids only, because we live in such a fragmented care situation where I'm amazed at how many physicians do not know that they shouldn't prescribe benzos to patients who are on opioids, et cetera. I would encourage us to think about training all physicians who can contribute to the problem and not just those who are prescribing opioids. So that's one question.

The second thing is I sometimes feel that this is static, like it's a training module. And it seems that some of the best ways of incentivizing providers is really allowing for ongoing training and the availability of expertise, as I think was presented this morning by Kaiser, and having people accessible who practitioners, whether they're in small groups or a big organization, can contact easily, frequently ask questions, an easy-to-access website, so that if they do training, they know that they are not left alone after that training.

MS. TOIGO: Thank you. Last question or comment and then we'll --

MR. BRASON: It is a question. Fred Brason, Project Lazarus. And we'll probably discuss this in the next panel, but you as representatives of professional organizations, I ask you this, because you were talking about incentives and -- if you're already doing the practice, what's my incentive to go do more training for what I'm already doing?

What if the training had to do

with -- because we're already asking them to do mindfulness, and motivational interviewing, and all the other things that they're trying to add their 7 to 8 minutes that they don't have time for.

But if we wrap this around, and you start to look at it as holistically as the whole practice, how can we show them economically how you can integrate behavioral health into your practice? You can have someone else, the social workers and so forth, doing all of that.

We've been able to show that that is economically viable for a practice, so that now they're able to see even possibly more patients, but have the support mechanisms within that practice because of the dual diagnosis or whatever external issues and comorbid issues are going on; that if we looked at training around that also, then I think there would be somewhat of incentive for them to take it.

But I'm just kind of presenting that as a question. Your thoughts?

MS. TOIGO: Dr. Harris?

FEMALE AUDIENCE MEMBER: We agree, but it has to be paid for.

MR. BRASON: Right. Well, that's my point, that it isn't easy, but I know in one CMS innovations grant that we had in North Carolina, we were able to show it's economically viable and you can do that kind of care in a general medical practice. You can do the behavioral health, you can do the buprenorphine, and wrap that into all of your services and make it economically viable.

DR. HARRIS: Those are the types of best practices that we need to disseminate and share.

MR. BRASON: Right.

DR. HARRIS: Yes.

MR. BRASON: Let's not create another infrastructure and using what we've already got. Thanks.

MS. TOIGO: Okay. I think that ends this panel, the health professional panel. Thank you all very much for your thoughtful tones.

(Applause.)

(Whereupon, at 3:20 p.m., a recess was

taken.)

State Panel Discussion

MR. LURIE: Welcome back. The focus this latter part of the afternoon shifts to the states and what the states can do, should do, might have done. You heard some data this morning presented by Lisa, describing some of the state activities.

So I think the purpose of this panel then is to consider some of those state activities and the context of potential federal activities, how they might fit together, how they might be inconsistent with one another, how one might react to the other, and how one might encourage them or discourage them as the case may be.

I think what we'll do is I'm going to introduce myself and ask the others in the panel to introduce themselves. And then the last person to my left here is David Brown from the Virginia Department of Health Professions, and he's going to get special treatment, because everybody else you've already heard from before, and he wasn't on the morning panel. So he's going to make some

short comments before we jump into the questions themselves.

I'm Peter Lurie. I'm with the Office of Public Health Strategy and Analysis at FDA. Joanna?

DR. KATZMAN: I'm Joanna Katzman. I'm associate professor at the University of New Mexico. I direct the UNM Pain Center and Project ECHO Pain and Opioid Management. Thank you.

MR. BRASON: Fred Brason from Project Lazarus.

MS. BECKER: Melina Becker from the National Governors Association.

MS. ROBIN: I'm Lisa Robin with the Federation of State Medical Boards.

Presentation – David Brown

MR. BROWN: I'm David Brown, and I love special treatment, so I'm very appreciative. I'm the director of the Virginia Department of Health Professions. The Department of Health Professions, we have 13 health regulatory boards, including the Board of Medicine, the Board of Pharmacy, the Board

of Dentistry, the Board of Nursing. So we pretty much license all the prescribers, and we license all the dispensers, and we also have Virginia's Prescription Drug Monitoring Program.

This morning, we've talk about how active the legislatures have been, and I thought I'd talk for a second about some of the things that have happened in Virginia in this past year that really involve prescriber education that were mandated by legislature.

The first thing is the Virginia legislature passed a bill this year directing my boss, the Secretary of Health in Virginia, Bill Hazel, to convene a work group to study the curricula involving pain management, prescribing, and addiction in our professional schools in Virginia.

It mandated that this would include a representative from every medical school, the School of Dentistry, every pharmacy school, nursing schools, and physician-assistant programs.

We've expanded that to also look at patient education with the idea that later on in this

workgroup, we'll bring in other professions, again like we talked about this morning, who interact with patients, who may be pain sufferers, and may be on opioid medications, to make sure they can have appropriate input.

So that would involve certainly the behavioral sciences, would include physical therapy, other types of professions.

The first meeting of this workgroup is going to be May 19th, and we're hopeful that this is going to really lead to what is a real gap, which is the standardization in the area of prescribing and addiction in professional education.

The second thing that happened this year is a bill was introduced requiring the Board of Medicine and the Board of Dentistry in Virginia to enact regulations for the use of opioids in the treatment of acute and chronic pain.

As part of this, this bill ended up incorporating other bills that would have mandated limits on prescribing. In other words, the legislature was persuaded, since the Board of

Medicine has now been directed to do regulations, let's go ahead and have them incorporate -- have professionals, as opposed to legislators, look at what those requirements should be.

So the Board of Medicine convened a panel of experts in the area of addiction and pain management that pretty much looked at the CDC guidelines, and the treatment of chronic pain, and other evidence-based practices to create regulations.

I would like to argue that these regulations in some way are a way of educating all prescribers in Virginia, anyone who prescribes opioids, as to what the best practices are. Certainly a part of what we want with education is for all prescribers to understand what the CDC guidelines are, and these regulations are based on that.

Now, that's not everything that are in these regulations. Some of what's in these regulations is exceedingly obvious because what they're designed for, in part, is to give the board a clear and unequivocal regulatory handle on pill mills; in

other words, practices which aren't doing what are just normal practices in any healthcare field in terms of examination, history taking, the rudimentaries of good patient care, which don't happen in a practice which is seeing patient after patient after patient and simply writing a prescription.

These regulations include things such as a 7-day limit on prescribing of opioids for acute pain, but because they were crafted by physicians they include unless extenuating circumstances are clearly documented in the patient record. So they really allow for good practice of medicine without having the hard limits that a prescribing bill might have had.

They also require, for example, co-prescribing of naloxone if certain circumstances are met, such as an MME over 110, or concomitant use of benzodiazepines, a history of drug abuse, or overdose.

In addition to this providing, I like to think education on best practices. I also think

that these type of limits at the front end of prescribing is what we really need to do to really stop people from entering the pipeline of addiction.

I think this morning Dr. Woodcock really talked about that this epidemic is fueled by legally prescribed opioids. And if we can get our prescribers to understand appropriate use, I think we can end up in an environment where we have fewer people entering and either having a well-stocked medicine cabinet because they didn't use them, or developing a dependence or an addiction because they've filled the entire prescription.

Also, these regulations support people providing acute care, emergency physicians in the sense that they clearly give someone the ability to say, I'm sorry, I can't write you more than that because these are the regulations I have to practice under.

The concern we have is concern that's been addressed here numerous times, which is will prescribers opt-out rather than -- will they see

these regulations to be cumbersome and opt-out of treatment of patients who may be stable and may have had ongoing opioid use in a way that's effectively managed their pain, and what happens then? And do we inadvertently have an increase in deaths if some of those people end up moving towards the street for their medications?

DR. LURIE: Okay. Great. Thank you.

Now everything's fair. Thanks, those are very helpful comments.

I'm going to start with the following question, not on the slide, and it's a question to each of you.

All of you are involved, to one extent or another, in state activities related to continuing education on opioids or pain for physicians and other prescribers. Under what conditions would you conclude that what the state was doing was insufficient?

Is that clear? What would lead you to say that what we are doing at the state level is not enough and we need somebody to help us out? How

would you go about answering that question?

Because what we've heard, Lisa, from you is that 29 states are taking a stab at this. Right? So how might some of those 29 states say that's not enough? Might some of the 21 other states acknowledge that they haven't so far done anything?

MS. ROBIN: Well, I would like to comment on that. I'll start out by saying we had just done a recent survey of all of our state medical and osteopathic boards to really identify what their priorities are.

Well, opioid prescribing was number two of everything that's of concern to state medical and osteopathic boards. This is clearly an area that they wanted to be an active participant. I think things vary from state to state as far as capacity and resources, but I would say a couple of things.

I think one thing that we are seeing are the use of guidelines, and now we have our new guidelines because I think that they're very good. We had a very broad based group of folks working on them from the regulatory boards, from CDC, FDA,

AMA, AOA, and I think we have a document that really sets that baseline as a good practice, as you were talking about in Virginia, these type of things that would cross all specialties.

I would just encourage all states to look at how they can implement some sort of guidance document and guidelines, whether they do it by regulation or do it by guidelines, and then really get it out to -- because if physicians and other health professionals practice within those guidelines, then certainly it would be applied across the health professions.

I think that goes a long way because you can use them in two ways. You can use them to educate, and then you can also use them to help evaluate care. So clearly, you have two levels -- you have some well-meaning professionals that need to come up to speed, then you have that all the education in the world not's going to make a difference. But I think that that's a good start.

There are certain reasons, whether it's resources, which I would say that that is less than

just the political environment and the support that they may or may not get from their legislature and the authority that they have within the state to implement some of the guidelines.

So I don't know as far as resources, from a federal perspective, what they can do to provide those resources. But to support those, I think the use of grants is great. We've worked with SAMHSA in the past to be able to provide education at the state level and regional level, so you can look at that local -- and the needs are different, different populations of people.

The other area I think is data. I think we are talking about looking at education and mandating education, voluntary or not voluntary. I would say that's just one piece. We have the ability now -- we have data from so many sources, we should be able to identify those populations that need specific training, education, or other resources to better take care of their patients.

DR. LURIE: Okay. Who else would like to comment?

MR. BRASON: I'll comment. I think one of the problems that we're seeing about what's missing is everybody talks about the opioid epidemic, so states who look at legislating, mandating education, mandating prescribing, most of the time is based on we have to stop the epidemic.

Are they really looking at it from are we bettering best practice, or are we just doing limits on that practice to ensure that there's no diversion and the like, which to me, creates more opt out rather than opt in.

I'm always very careful about -- I don't want a legislator telling my doctor how to treat me. So I think we have that, and part of that's media driven and all of the above. I'm saying that generally, not for every state, but I know in some states, because I'm been in enough of them, it is basically -- it's a move and a measure in order to stop the opioid epidemic, rather than what is best care, best practice for the patient of what their need may be. And I think that's part of some of the missing element that we have.

DR. LURIE: Let me ask you about that. One reason a person might say there's no need for federal intervention is because, A, there's a lot of education out there. And we've heard today about all kinds of -- much more than I ever knew about, going on at the state level, private providers, et cetera, very diverse in FDA's REMS program.

Are we at a stage of the epidemic that we can say that the level of education being provided is commensurate with the epidemic and its direction?

MR. BRASON: It's much greater than what it was. As I said earlier today --

DR. LURIE: The education level?

MR. BRASON: Yes, the education. In the four years that we were doing statewide in North Carolina, again, we had to initially push the education. Now they're pulling the education. So I think that tide has turned, so that if all of the organizations that were up here and everything that they're presenting, I think that is meeting a

greater part of the need that might prohibit federal intervention as long as there's validation in every state that it is happening.

DR. LURIE: What do we do about the 21 states that don't have anything?

MR. BRASON: That's my point. They have to do something, but that doesn't mean that they have to mandate. If a state can say, okay, we know that this is occurring with all our professional organizations, the medical board, the licensing board, and all of that is laid out, and they're showing that the vast majority of their practitioners, nurse practitioners, PAs, everybody, are engaged in that in whatever infrastructure they're using, rather than mandating from the legislature, then I think they're meeting the need.

MR. BROWN: I would comment that of the states that have mandatory CE, I'd be skeptical that all of that is meaningful. And I'll say that because I think Virginia's is not. Virginia requires every two years a prescriber to get two years of continuing education in a fairly broad

category. Doesn't say exactly where; it doesn't say exactly who provides it. It has to be category 1 CME credits. That is a pretty small amount of education, and we haven't necessarily targeted what we need.

Looking at the bigger picture of who ends up coming before licensing boards, I think that on this issue, my impression -- and there's no data to really back this up -- but my impression is that prescribers who practice for the big systems, kind of like the Kaiser presentation earlier today, those systems are helping to make sure that they are well educated.

In all of our boards, disproportionately practitioners in small practices or solo practices are the ones that come in. And on opioid prescribing, they kind of come in, in two different paths. They come in on the path where they have not kept up their education. They're doing what they've been doing for years with patients for whom they've been prescribing this way. And they probably learned to prescribe because when they

were a resident, this is what the chief resident did, or this is what the attending did.

Then you have the prescribers who are knowingly making a lot of money by violating the law. So you're not going to reach them anyway, but we need to find a way to reach the prescribers who aren't part of the big systems, who are receiving the education, but are part of the smaller practices and smaller systems that may not be getting it as part of their credentialing. And for that reason I think having a more structured program could be beneficial.

DR. LURIE: Joanna, what can you tell us about an experience in New Mexico that might be like that?

DR. KATZMAN: I can tell you that experience in New Mexico has really been -- there has not been a chilling effect with the mandated pain and safe opiate prescribing education in the past five, six years. It's now an audited program, and all the clinical licensing boards, meaning 10 percent of the clinicians are audited. There's been no

chilling effect as I said.

As Lisa has alluded to and so has Peter, there are very different requirements among the 29 states who now do require some pain CME, and it is very different among states. Some require pain for certain clinicians, and not others. Some require pain in end of life. Some require pain just if you have a pain practice, and some not others.

I think if there was a way to create a common denominator among the states -- I don't think it's going to be easy, but I especially think if we could get the other 21 states on board with some key leadership from Lisa's shop creating the CO*RE curriculum with educating about screening for opiate addiction, non-pharmacotherapy/ pharmacotherapy related to non-opiate management, all of the good things that we've talked about, I do think that a local solution is the optimal way to go.

There are huge cultural differences across this country, whether or not you're teaching clinicians how to take care of their patients in a

rural setting, in an urban underserved setting, in a setting with predominantly Hispanic population, in a setting with predominantly African Americans or American Indians, there's huge cultural differences.

I think if we go to the DEA checkbox, it would have to be all by Schedule 2 through Schedule 5; that would work as well. And I think that the issues there would be just actually as difficult and may take just as long. I do think ultimately it is going to be more optimal to have a state solution. That's just my thinking.

DR. LURIE: Let me push back on that for a second. You point to various -- I don't want to call them unique, but specific circumstances that exist in New Mexico, and those are undeniable. But the question in deciding whether or not to have a national standard, in part, seems to me is whether or not those differences are so substantial that you might produce a wholly different curriculum in a different place.

I mean, do you think that's the case?

DR. KATZMAN: No. I apologize, Dr. Lurie. That's not what I'm saying at all.

DR. LURIE: Okay.

DR. KATZMAN: What I'm suggesting is creating a curriculum, a national curriculum that the states would adopt that would be a common denominator for all the states, but that there would be flexibility, wiggle room, to incorporate components of cultural sensitivity for different patient populations that might be seen in some states or more than other states, where the clinical licensing boards had relationship with their clinicians.

What I know from working with Project ECHO for seven, eight years now, is that clinicians who come for training, they're much more likely to come to you if they know you. If you're going to take a training with a checkbox with the DEA, you're not going to nearly be as invested in what that training is, whereas if you're in your home state taking a training, you might get the training in a different state related to pain society, your

addiction society, the AMA, AAFP.

That's great because it relates to you. But if you're getting it from your home state, it means something more to you, and that's just my feeling about it, the local solution.

DR. LURIE: Let me push back on even that, though, since I seem to be making a habit of pushing back. Do you think the physicians even know, in general, where the education comes from? Do they even know who's requiring it? Do they know who laid out the blueprint for it?

They certainly don't take it in the state, necessarily in the state, where they licensed. In fact, they typically head to Hawaii as far as I can tell, or if they have good judgment, New Mexico. But is there even their identity at the local level along the lines that you're describing?

DR. KATZMAN: Well, my hope is that within the next five, six years when pre-licensure education catches up to where we are right now with the epidemic, with medical schools, pharmacy schools, dental schools, and nursing schools, my

hope is that this conversation won't be as critical because we are not going to be teaching so many clinicians who are so delinquent in their post-licensure education in pain and opiate management because they will have gotten it in all of their medical education, which by the way is delivered at a local level as well.

I think either solution is fair. I just think that it's been successful locally in New Mexico, and I think it can be successful locally elsewhere.

DR. LURIE: Melinda? You haven't had a chance to jump in yet.

MS. BECKER: Sure, yes. I think that we would certainly agree that a locally driven solution is typically ideal and certainly ideal in this situation. As Lisa outlined, states are increasingly working through their medical and other licensing boards to establish these types of education and training requirements.

I think I mentioned earlier that NGA last year expressed support for the idea that there

would be a national requirement tied to DEA registration. But I think certainly resources and some sort of national standard being developed at the federal level that states could then adopt on their own and tailor would also be very welcomed.

DR. LURIE: I know in the past, the federal government has put out model acts. I know the model Drug Paraphernalia Act is the one I'm most familiar with. That's I suppose, a possibility, and people could adopt it to the extent they did.

I think we're seeing from a FDA, the beginnings of an initial blueprint, and now a revised blueprint, upon which, as was pointed out, we'd love to receive comment. I'm not hearing a lot of disagreement about the blueprint. We haven't gotten the comments into the docket yet, and I'm sure there'll be nuances. But are we at a place now that people, generally speaking, agree on what ought to be the contents of an educational program? You want to take that, Lisa?

MS. ROBIN: I can. I'm not sure. I don't think one course and one size fits all makes sense.

I think it loses its meaning and that it needs individual physicians and professionals that prescribe having their self-assessment data to know where their gaps of learning are. I think that's the way we need to go.

I do, however, firmly believe that there is a basic set of good practice that goes across all specialties, and that that certainly could be a national standard, and I think that that's the direction that we're going.

I think that we have to be careful also that you have all of these different requirements. Not only do you have requirements for the mandated CME from the state, which vary. You also have 24 states that have a state-controlled substance regulation. Texas is the Department of Public Safety. Some states have tied education to that registration.

Then you have the systems, and they're going to have requirements for their own medical staff privileges, and you're seeing more and more -- now we're to the point I think more than 50 percent of

physicians are employed, which is of benefit, because you're exactly right. When we look at disciplinary data, the people that get in trouble for -- I'm not talking about the criminal behavior, but otherwise, are really practicing in more of an isolated area. They don't have that support. They don't have the toolkits to be able to have their -- they can't compare themselves with their peers and all of those questions. And then you have a good number of physicians that are licensed in multiple states.

So that's another thing that would drive a national standard. You have 6 percent that have licenses in three or more states. So you're getting up to 20 percent of physicians in the country, and now with telemedicine, that is only going to grow. And they have different renewal requirements in all those states.

So I think that an education -- and I think that we are moving in that direction. And I'll just add one thing.

There's a tri-regulator collaborative of the

Federation of State Medical Boards, the National Council of State Boards of Nursing, and the National Association of Boards of Pharmacy. We have been, for just the last few years, been meeting. The leadership's been meeting. But this year in July, we're having a conference, and the whole conference is exactly focusing on how we can address this.

These are the forums where you have all of the state boards, various boards represented, that you can look at can we come to an agreement on a way to whether it's voluntary or mandated. But if it becomes the standard of care, I think that's going to drive it.

As I said, state medical boards, without mandating can still mandate because it's considered professional conduct that you are competent to treat whatever condition that you're treating. I mean, it's affirmatively stated in our new guidelines. So it's the responsibility that lifelong learning is part of their responsibility of good practice.

So I think that it's moving in that direction without a mandate. I am really more of a carrots person as well, but I think that we can move in that direction. But I do firmly believe that that needs to happen at the local level for it to be well-received, otherwise, if it's a checkbox on the DEA registration, I'm not sure how meaningful and how engaged the individuals will be in the educational programming.

DR. LURIE: Okay.

MS. BECKER: Can I just add something quickly?

DR. LURIE: Yes, please.

MS. BECKER: I just want to draw a parallel, and I'm curious if others think this is relevant, but thinking about the CDC's weird prescribing guideline released last year, a voluntary guideline, sort of a national standard, and thinking about how states have used that to update their own guidelines or develop new guidelines, as we're thinking about is there some national model or curriculum that could be put forward and how

states might use that going forward.

I think we've seen some examples of how states have reacted to the guideline, but I'm not sure that there's been necessarily a lot of -- I mean, others may know more, but I don't know that there's necessarily been a lot direct action on the part of states in response to guideline.

MS. ROBIN: I think it's a huge topic of discussion among the medical boards. You see it on their agendas. I do think that the guidelines -- and now that we're looking across, a number of people are developing guidelines. There is a movement to make those all in alignment. We were really careful with ours, that they are aligned.

So I think there are certain -- you leave enough room for states to be able to adjust. We don't have hard stops recommended. But I think that that really -- those type of guidelines, that's the basis of your national standard. And I think you're seeing those CDC guidelines quoted and used by medical boards I know as they're looking at

cases, because I hear them quoted over and over again.

MS. BECKER: Yeah. And it certainly inspired some of the statutory limits, I know. But sorry. Go ahead.

MR. BROWN: If I could comment, certainly the CDC guidelines were the basis of the regulations that the Board of Medicine in Virginia, Board of Dentistry in Virginia created. But at the same time, there's another agency, the state Medicaid agency in Virginia has embarked on an effort to influence prescribing behavior through its pre-authorization process, and they also used the Board of Medicine guidelines and the CDC guidelines in their process.

Specifically, they do things like if it's a non-opioid, no pre-authorization. If it's a short-acting opioid for less than 14 days, no pre-authorization. And then the authorization form itself tracks the CDC guidelines. So the authorization, the person is attesting that they have co-prescribed naloxone if there's a

concomitant benzo use, or that they have followed other parts that are in those guidelines.

What's come out of that, they have great data on how they've had about a 30 percent decrease in the number of pills prescribed in the first quarter since this was enacted. But at the same time, the number of patients receiving a prescription only went down like 15 percent.

So in other words, it wasn't a matter of people being cutoff; it was a matter of prescribing behavior changing. And my personal opinion is in Virginia, this is going to spread beyond Medicaid because at the end of the day, Medicaid saves money doing that.

So I think that's going to be attractive to other health plans to look at this as a mechanism for good practice using the CDC guidelines and at the same time saving money.

DR. LURIE: Another reason why one might prefer the state-based solution would be if the epidemics were very different from one another. One's got a methamphetamine epidemic, one's got a

large epidemic, one's got a small one, one's got heroin.

Does anybody on the panel think that the epidemics are different enough from state to state that that in and of itself justifies a state-based solution?

MR. BRASON: There are two ways to look at that. If you're looking at strictly from a prescribing level and making opioids available and that is the culprit of the epidemic, or you look at social determinants of poverty, trauma, all of those factors that lead to coping mechanisms that lead to substance use, those are different in various population groups in various states. So that convolutes the question in that to be able to answer.

I think states know themselves the best. You asked the question earlier, do people really know where their curriculum is coming from, who's doing this? I'd say, yes, they do. There's a handful. You've either got your health system doing it. You either have a few universities.

People become accustomed to who they go to for their CMEs and for their education outside of their professional group, so that I think helps.

I think some of the REMS that have been brought forth and made available already, that question's true. I don't know who's doing this. I just know that it's available. I'm going to this conference. They're going to give me 8 hours, but I have no clue who's doing it.

So how much of that really tracked into general practice, I don't know, but I know from the local level, it does track into general practice.

DR. LURIE: Just a follow-up on my question. What is there about the North Carolina, since that's where you're from, opioid epidemic and related prescribing issues that would be so irrelevant that you wouldn't mention it in New Mexico? Could there be anything like that?

MR. BRASON: Yes, because we have that from certain counties in North Carolina. "Oh, we've only had two deaths. What are you talking about? There's no issue here." And then we have to show

them, yes, there is, because they're not looking at everything.

So I think you would have that. I know from just with Indian Health's --

DR. LURIE: But those folks are wrong though, right?

MR. BRASON: Right. Right, but --

DR. LURIE: There may be disagreements about certain facts, but we deal in actual facts, not alternative ones. So if they're not right about that, then okay, I want to know about something that's factually different that would --

MR. BRASON: Yes, like Indian Health Services, I've worked with enough reservations that some, "We don't have an opioid problem. It's all methamphetamine." It's just not evident on the opioid side, but look at our methamphetamine problem and it's huge. Therefore, it doesn't --

DR. LURIE: So would you not mention heroin to them?

MR. BRASON: I'd mention everything to them.

DR. LURIE: Right.

MR. BRASON: Yes. Yes.

DR. LURIE: Joanna?

DR. KATZMAN: I would say that I think what you're asking is a little bit different, Dr. Lurie, in that I would pose it like, of course there are going to be differences among states that require some cultural sensitivity and some flexibility among states. But by far and away, there is going to be a common curriculum that would cover all states.

Of course every clinician who has prescribing authority and even clinicians perhaps that don't have prescriptive authority, nurses and the healthcare team in general, need to have training in the core content areas that we've talked about many times. I do think it is important that at the local level, people go to conferences together. The five of us might go to a conference together on a Saturday morning. If it was a DEA thing or a REMS thing where you're at a conference, you might not go with a friend.

Also, who you're getting the training from

locally, you might know the speaker. We've shown this over and over again in many studies with ECHO, many learning studies, with a learning curriculum and education learning loops and feedback, who you get the curriculum from counts. Who you get the curriculum from matters. You can contact that person. You can ask them a question.

Those are differences at the local level. But I do agree with you, Peter, that by far and away, the content is going to be exactly the same. There are going to be little differences here and there.

MR. BROWN: If I could just briefly comment, I agree that the content can be the same for different states. I don't think the differences are so much between states as within a state. Certainly in Virginia, southwest Virginia where the opioid deaths are worse, it's almost entirely prescription drugs. If you go into Tidewater and parts of Northern Virginia, it's heroin. And that does mean that there's some tailoring of education that can occur within a state.

DR. LURIE: Okay. Lisa?

MS. ROBIN: I just wonder, if looking at the presentations we heard this morning, and then also looking at the states that have shown some pretty significant progress of late, they all have -- it's not just one program. It's not just CME. And there are many different learning modalities and individual coaching.

It seems like that's where the success is going to lie, versus one curriculum for one delivery, means I don't how effective that -- and I think we just need to be a little more open. And we should have the ability to have -- I mean, I think that there is some basic principles, but then on top of that, there are different groups of healthcare professionals that have different needs and different levels of need of training.

I think we should be able to -- I can't imagine that if we're able to use our resources -- I know many states are using prescribing data and other things to identify who those people are that need -- they may need some

intervention, may need individual coaching.

I think if it's left to the local level, there are medical boards I know that do that to some degree. They identify people working with their PDMP data. They go, and they will travel to southwest Virginia and have individual meetings, if you will.

So I think we just have to cautious about that. Then also the ability to repurpose whatever type of education that they are continuing professional development, that they are participating in, should be able to meet the needs on all these different requirements that you may, however, whatever we wind up with, whether it's mandatory, DEA, or state level, to make it less of a burden. I think that that's something that we really have to be cautious about.

DR. LURIE: Another dimension to this debate is the mandatory, voluntary part, right? It tracks to a degree with the federal/state in some respects because you might implement -- we might be more tempted to put something in mandatorily if you

thought it was more serious. And the same thing might be true, that it might be a criterion for federal involvement if you thought the problem was more serious. On the other hand, if you thought the problem was going away, then you might be willing to wait.

Are there folks on this stage who feel that the current level of education is adequate, looked at nationally? Do we feel that we're currently in a place that we can look at what we have, either in terms of the content or in terms of the extent of it, or in terms of its dissemination throughout the medical prescribing community, that we're satisfied right now?

Is anybody happy?

MR. BROWN: No.

MS. ROBIN: No.

MS. BECKER: No.

MR. BRASON: Adequate in what way? I mean, adequate to meet the need? Because I think there's a great deal out there on prescribing, but how much is out there on actual pain management that

actually can even transfer to -- there's nothing else available but me writing a prescription.

DR. LURIE: No. I don't think there's a problem of availability. What I feel like I've learned from this meeting is that actually there's a ton of stuff out there. There's a ton of stuff. There's a choice. You can get bad [indiscernible] education, and you can get it in Hawaii. I mean, there's a lot of choice.

I don't think -- you can quibble its content for sure, but I'm asking is the current level of physician education on this question, satisfactory? I hope that's the question you answered. But that's what I mean by that, Fred.

MR. BRASON: Okay. All right. I'd say no, also, because it hasn't reached everybody who needs to be reached yet.

DR. KATZMAN: Same.

DR. LURIE: What about the question of -- within a state, one of the things that I've also looked at, as you have Lisa, some states have requirements for all prescribers and some have for

controlled substances prescribers only.

Do people on the panel have a view on that? Because that is an area of inconsistency between states. Again, a criterion, if you ask the Supreme Court, when does the Supreme Court step in at a federal level? It steps in when there's a split in the circuits. We have a split in the circuits here. Right? Half the states don't have anything, and within the other half, there are very large differences. That can be a criterion.

Do people have a view on that? Is focusing on the controlled substance prescribers sufficient or is this -- I suppose it depends on what this is, but I guess the packet of pain and opioid. Let’s call it that packet.

Is it something that we can cabin off just for the controlled substance prescribers, or is it really for everybody?

MR. BROWN: I'll just agree with the point Fred brought up a little while ago, which is I think that as a society, if we're only focusing on prescribers and what they do, and we don't figure

out a way to address the socioeconomic factors that are driving some communities to be desperate -- suicide, methamphetamine, alcoholism -- it's just going to be whack-a-mole.

To that degree, just focusing on prescribers, I think it's important to do. I think it's a good first step. But in the long run, if we don't bring in behavioral health and other healthcare providers, if we don't extend it to social services, to the court systems, and if we don't have -- I mean, the only -- if I look at Virginia, the things that give me hope are communities where they've formed effective coalitions that involve healthcare, involve social services, involve the courts, involve criminal justice. Those are places where you can actually see differences being made.

DR. LURIE: That brings up another question. I think everybody on the panel would agree that education on its own is insufficient. In fact, I think everybody in this room would agree to that. You need a multicomponent, comprehensive approach.

I think everybody will agree, whether you're getting into much more elaborate approach, and not to negate it, but I think in terms -- most people would say a bit of PDMP, a bit of methadone treatment, a bit of what have you, bit of education, bit of DUR. Between those things, you might come up with a reasonable package.

We heard some conversation this morning saying education, it probably doesn't even work. And Joanna, you've got some data that -- Fred, both of you really -- that argue otherwise. But my question to you all is how sure do we need to be that education is effective before we require it?

What is the evidence bar? Do we need a randomized trial that shows reductions in overdoses? Do we need just a well-intentioned, good argument put together by educators? Or is it someplace in between?

How do we decide how much evidence we need before we go about mandatorily requiring something? Joanna?

DR. KATZMAN: Well, first I might add -- do

you mind if I speak, Fred? First, I might add that education through other venues, in addition to our UNM courses, our Indian Health Service virtual courses, through are Project ECHO courses for which we've given, many have shown significant increases in knowledge, self-efficacy, and practice change over the past eight years. And this has been related to chronic pain and safe opioid management. I think education definitely does work.

Also, the VA has published several papers on their SCAN ECHO, and this is voluntary on their SCAN ECHO pain telemetry program, showing that their education program does work. It also drops opiate prescribing, saves a lot of money, and increases prescriptions for naloxone and other benefits. And I think also Dr. Good showed that as well. And again, that's an organization, not a state level.

So I'll just leave it at that. I do think that education does work. That's why we all go through -- we all end up where we're ending up after our post-licensure training.

MR. BROWN: I think the fact that we're in a crisis, that this is an emergency, the Health Commissioner of Virginia declared a public health emergency, means you don't really have the luxury of waiting when you have common-sense solutions that are not that burdensome or expensive to try.

DR. LURIE: You're saying it seems to make sense. If there's no reason to expect an adverse consequence --

MR. BROWN: Yes.

DR. LURIE: -- that those things lower the evidence bar. Is that a fair statement?

MR. BROWN: Yes, in a state of emergency.

DR. LURIE: And being a state of emergency --

MR. BROWN: Yes, being something else, you might say, well, we can wait five years and do some trials and figure something out. Well, I feel like with this, no, we can't.

DR. LURIE: Let me ask you a practical question. Let's say that tomorrow either the DEA or FDA stepped in, and there was some federal

requirement for mandatory education. What would the states do?

Would you say, all right, that's a job done. We're going to cancel the state CME requirement. Would you make it lineup with the federal requirement? We've heard a lot about duplicativeness and confusion.

What would the states' reaction on day one be? Why don't I put it to you, David.

MR. BROWN: Well, certainly in Virginia, we will align with federal requirements. We don't buck them. But at the same time, I think we're aware, sometimes there's federal requirements we agree with, and sometimes there are federal requirements we think don't quite make the mark. And if they don't quite make the mark, we may accept a federal requirement, but at the same time have other requirements of our own.

I don’t think it would in any way lessen our efforts to create something, unless we felt like going, wow, this is exactly what we were looking for.

DR. LURIE: Okay. Lisa?

MS. ROBIN: I think I would certainly not speak for how the reaction from Massachusetts would be versus Texas.

(Laugher.)

MS. ROBIN: I think you'd find it to be very different. But I do want to correct one thing, because we keep saying, well, 21 states don't do anything. I disagree with that.

Just because there's not a specified mandate, that does not mean that there's not education and all sorts of work going on to educate and put strategies in place to address opioid issues.

Absolutely. The mandate, you can discuss that all day, if that's really effective or not, and if it should be targeted. But I do think that we need some more research to look at what really does work. We need to look at outcomes, not just a reduction in the number of prescriptions, but look at the metrics. And I think that, certainly, we need to pour some resources into that.

I know that that is where we could -- the states could use that to do some studies. There's certainly a willingness of them looking at how you can do some predicative modeling, too, with looking at the discipline and who comes before the medical board, what were they trained in and were they trained.

You're making headway with the medical schools and residency programs because that was a real problem with the lack of education, and now that we're trying to get it. And to carry it through to continue is really important. But I really encourage that to put some federal resources toward that would be well spent, I believe.

DR. LURIE: Okay.

MS. BECKER: I agree with both David and Lisa. I think certainly the response would vary by state for a number of reasons, depending on what requirements they have in place, their general relationship with the federal government.

I do think it would be really important to create a mechanism. And I think Doris alluded to

this as a possibility earlier, where a state could potentially seek a waiver from the federal requirement if they one had one in place already that met certain standards.

As David said, I think there'd be some states that would look to align their programs. There would be other states that would see this as sort of another layer, or their state requirements rather add another layer to federal foundation.

MR. BRASON: I agree also. In some states, it would be problematic. Other states it would not. I like the waiver idea, because then you have that opt out but still doing scenario. I think that would make it more palatable in that regard.

But if you look at, okay, it's a legislative act, this is mandated right now, then you've got to go back to those legislatures to undo that to bring about change. That's not quick, nor is it easy. In that, logistically it becomes problematic.

Then if you've got, like you said, practitioners in multiple states, then you've got another possible layer there that they have to work

through that becomes problematic, almost needing their own individual admin assistant just to work through all that.

So I think it would not be easy and could create potential consequences that we don't want.

DR. KATZMAN: I agree.

DR. LURIE: If a more voluntary approach were to be taken, and this question was asked to the previous panel, who do you see as those entities that would be best suited to deliver that form of education? Who'd like to take a crack at that?

You nodded. I'm tempted to call on you, Lisa, because you nodded.

MS. ROBIN: No, that wasn't a nod.

(Laughter).

DR. LURIE: It could be quite dangerous to that in a situation like this. David?

MR. BROWN: I think we've already kind of covered the way in which healthcare systems can do a very good job of -- well, it's voluntary for them, it's not voluntary for their members

necessarily, their prescribers.

The problem a state medical board has is it doesn't necessarily have in-house expertise on pain, on addiction. In fact, looking at the current Board of Medicine in Virginia, we don't have any of that. So when we did our regs, we had to bring in an advisory panel of experts to help us craft that.

Unlike say a health system, which, by its nature, probably has experts in each of these areas, to create something that's voluntary, I'm not exactly sure how the state boards would create an incentive for anyone to do anything. We mainly create disincentives by having regulations to say if you fail to do this and we find out about it, you could be in trouble; you're putting your license at risk. So we have disincentives more than we have incentives.

DR. LURIE: Lisa, in your survey of the states, have you seen states that have tried to incentivize the education, as opposed to just coming with a stick?

MS. ROBIN: Well, I don't know that it is the state boards that would be the people to incentivize a voluntary program. I think there's plenty of other people that could incentivize, and I think it's their responsibility to incentivize.

You have the payers and you have the professional liability carriers. I think that there are ways to incentivize through the new payment models. We're going to looking at new payment models. I think that is where you incorporate the incentives for the programs.

I do see that the state boards are more in the area -- if it is something mandated in the states, they're responsible for making sure that's reported, and they mostly do a random audit or something like that. But they're not going to be the -- that's not going to be the place where you go to register for a program. That's the responsibility of the specialty societies and all the CME providers that develop these programs. I don't know that they even have the ability to incentivize.

MR. BRASON: But I agree with those that you're talking about that can and should.

MS. ROBIN: They can, and they should.

MR. BRASON: Yes. The liability malpractice and all of that, that you've completed this much education, you've got no dings, then you should have a reduced -- and that is an incentive.

DR. LURIE: Joanna?

DR. KATZMAN: I can just say that I guess I'm a little bit of a skeptic, that if the thought at the conclusion at the end of tomorrow is that we should bring it back to the state level with perhaps an FDA blueprint as the core with some wiggle room for the states to decide how they want to do the rest of the training because of cultural diversity or what have you -- I really think that if there was a core 2 to 3 hours of training, it would not be too burdensome, if you could show the clinicians across the state with prescriptive authority that this an emergency, this is a healthcare crisis with chronic pain and the opioid epidemic.

What I can tell is anecdotal -- not even anecdotal, for the past five years at Project ECHO, we've had two insurance companies say that they will give clinicians $100, one $100, one $150, if they present a case to Project ECHO. So a clinician anywhere in the country, if they present a case to Project ECHO, that clinician will get a free CME for every hour that they come on board.

It has been extremely unsuccessful, and I can get you the numbers for that. It's not been very successful, the incentivization from insurance companies for clinical education, and that's been voluntary even. We had 100 percent participation when we needed to get all clinicians in New Mexico prescribe -- the 5-hour training. That's just been my experience.

DR. LURIE: Just a factual matter, Lisa. Those requirements at the state level when they exist, they're typically of the 50 hours over 2 years that people typically are required --

MS. ROBIN: On the renewal cycle, yes.

DR. LURIE: Right. But what I'm trying to

say is these things are not add-ons. If you've got to do 50 hours over 2 years and you have 3 hours of opioid, let's say, that then you've got 47 fewer hours to go, right?

MS. ROBIN: Usually, yes, it would be part of the overall --

DR. LURIE: The burdensome argument applies -- I mean, if it were a DEA requirement on top of it, then that's some increment of burden, 3 hours on top of say 50 over 2 years, so 6 percent. But within the states, it's burdensome to the extent that you don't want to take that CME; you want to be learning about Wilson's disease, right?

MS. ROBIN: Yes, choose, yes.

DR. LURIE: Right.

MS. ROBIN: Right. And I mean, some states have particular things that they need everyone in their state to know about. For instance, in Kentucky, it's required that they know about their PDMP. There's specific curriculum around that. We had to build it in to some programs we did for

them. Well, someone that's practicing in Oklahoma doesn't need to know how to use the Kentucky system. So there are certain elements that are definitely state specific.

MR. BROWN: To talk about the incentive structure, the fact of the matter is that organized medicine, organized dentistry, organized whatever field it is, hate to have the legislature tell them what to do, and with good reason. To legislate the practice of healthcare is looked down upon. But they actually also dislike anyone telling them what to do.

To some degree, that stems from the fact that the people who participate in organized medicine in the state medical society, in the AMA, state dental association, whichever, typically are well-educated, well-informed, active participants, and who have a different viewpoint than say the state board who frequently sees those practitioners who go through the motions, who practice remotely, and get in trouble for doing ridiculously stupid things.

So creating an incentive structure voluntarily goes against the very nature of some of the people, anyway, you're expecting to step forward. For example, we would not have the pain regs we have if the legislature hadn't told us to. So having that type of structure --

Now, I will back up and say because of this crisis, I think in the Virginia, the medical side of Virginia's been a very willing partner to fix, to try to address this problem. The dental association has been a very willing partner.

So I think it's a little bit different climate in general, but I think having someone make us do something, and I say me as health professionals, it's not a bad idea.

Questions and Answers

DR. LURIE: I think it's time for questions from the audience. Hopefully, we've stimulated you to ask some good ones.

DR. KAHN: Yeah, you really did stimulate some thinking. Norman Kahn from the Conjoint Committee.

I'm going to ask you if the states would accept something like the following. It's based on much of what I've learned from listening to you all, which is that standardization is an issue. Having the states require what they want is an issue.

Not all clinicians need the same level of training. They want to be incentivized to learn, and they want whatever they're doing to align with whatever else they have to do, and not be an added burden.

So that if we develop modules that were based on the FDA blueprint, that used an adaptive learning model? For those of you that are physicians participating in maintenance of certification, this is what used to be MoC part 2.

Just to describe it briefly, I'm a family physician. I participate in maintenance of certification. Every year, I have to go online, and I have to choose a module, take several hours, and it's all questions. And eventually, I have to get 80 percent of the questions right.

But I was just telling my colleague over there, I never stop until I get them all right, because I want to know, even if I pass the 80 percent, what the right answers were. And if I don't get it right, it asks me again. And if I don't get it right, it gives me the answer and it gives me the references. And I still have to go back and take the test until I get it right.

Now we have something that is designed based on the individual clinicians starting point, wherever they are. It would count for MoC. It would count maintenance of certification. It would count for relicensure.

We talked with Doug and others earlier about we're going to submit this to Medicare for a MIPS improvement activity, or maybe in patient safety, so it would align with what they have to do for CMS. And they would definitely be learning, and they would demonstrate their learning.

Would the states accept that?

MS. ROBIN: I think so. I don't know -- if you can show that -- they're looking at the end

result of that program. You have something that's the adaptive model, I think it's great, as long as they complete it. The states aren't specific enough on -- they just want so much credit. They want to see the outcome. So I do think that that is definitely the way to go.

DR. KAHN: Virginia?

MR. BROWN: It sounds like it has good potential to me.

MS. BECKER: And you're talking about a voluntary program, to clarify, right?

DR. KAHN: It is. On the other hand, it aligns with all of these things that clinicians in their practices have to do. And if they do this, then they'll get credit for being relicensed. They'll get credit for their CME credit. They'll get credit for maintenance certification. They can use it for a MIPS improvement activity.

You can say it's voluntary, but there's so much incentive there, that I'm going to do it.

DR. LURIE: There's a question over here.

DR. GREENBLATT: Larry Greenblatt from Duke,

internal medicine physician. First I want to thank the panel for a lot of really deep thinking and great ideas that came up during this discussion. I want to make a comment, and then I have a question.

The comment is just I think we need to be careful not to target these efforts at the people who come in front of state medical boards only. I think that's absolutely the tip of the iceberg. There's a huge number of people who need to change their practice patterns, not just the ones who are being called out.

But here's my question. I think if we're going to do this, we have to focus not on clinician knowledge, but on clinician behavior. I think it's very easy to give CME that allows people to do better on a test, or to demonstrate in some way they learn the material, but are they actually changing what they do?

While we're dealing with this huge opioid epidemic, we have another epidemic, which I think is important to talk about in this room, and that's an epidemic of burnout and depression amongst

healthcare providers. It's really bad. It's more than half.

If you're asking people to change behavior and to implement new practices that are time consuming, and aren't reimbursed, and are burdensome, you've got to remember that the people that you're asking to do this, they're exhausted.

So how do we make sure that whatever we're going to try to do results in better patient care? I welcome anyone to try to answer that question.

(Laughter.)

DR. LURIE: Anybody want to take a crack at it?

MS. ROBIN: No, I'm just saying it's a huge issue, and we know that for a variety of reasons. There's so much stressors on physicians, and it's a huge issue: suicide, and burnout, and wellness issues. And to do whatever we can to put a system in that is not redundant and is not an additional burden on what is already a burdensome system, I think it's really, really important.

MR. BROWN: I think going back to what the

physician from Kaiser mentioned, having something that much of this can be integrated into the workflow as possible with automatically checking the PMP, unless you say no, or automatically doing other things, so it becomes less of a burden and the good practices are followed.

MR. BRASON: And I'll just toss it back to you a little bit that, yes, we have to be sensitive to that, but why are we in the place that we are now in the healthcare systems with so much depression and burnout? What is the causation of that, that we need to address at the same time?

DR. LURIE: It's probably not 3 hours of CME. On numerous December 31st's, when I was there trying to finish off my state mandated CME on HIV, it was a pain in the neck.

MR. BROWN: I did procrastinator CMEs.

MS. KEAR: Cynthia Kear with CO*RE. That was a great discussion. I took lots of notes and really appreciated everyone's insights and efforts. Just a couple of observations or responses to some points that came up, and then kind of a big

opinion; I'll just be honest about it.

One thing is that I think really inclusion of other audiences is really important, and we made this point to the FDA. But we've done surveys of nurses. They are the ones that are doing so much of the counseling and patient education. To not include them is a travesty.

Pharmacists. I mean, who does consistently tell people how to do their meds? But I also think patients. I mean, I think patients have got to belly up to the bar here. We've got to educate them. They've got to be active in this. Somehow that has got to be included in this education.

I'm not sure the blueprint is the right place for it, but they do have to be. They're off the stage right now, yet they're center stage to the problem.

Someone was saying about quality of education isn't sufficient. Education, we know from principles of adult education, it takes seven effective educational interventions before you'll see somebody change their behavior. So knowledge

is fairly easy, but what we want to see people do is change behavior. If that's true, then we should be looking at this from a very, very different point of view.

The question was about the states; maybe this was your point, about people like to hear at a local level. Our experience is that people like to hear from a similar clinician. An FP wants to hear from an FP. They don't want some fancy schmancy pain specialist coming in and talking down to them. I think that's true around all clinician types. So that's something I would suggest that we look at.

Two other points that relate to kind of now process. In California, a number of years ago, they developed out of reactivity from the state legislature, 12 hours of mandated pain education. It was just pick something up and throw it against the wall, and it required a tremendous amount of time and a tremendous amount of effort, and we know nothing about it. Marsha Stanton [ph] asked me about 10 years later, "What did we learn?" I said, "No one knows."

So the one thing that I would really suggest that we consider in terms of this issue of national versus state is not all state mandates are the same, and will it be easier to actually have quality control if something is implemented and launched at a national level, so you can get common information on practice gaps.

Yes, there might be variances depending upon what the substance is or the particular cultural background, but you can do some things that really are going to help us to develop education that's really targeted toward those most egregious practice gaps, which are creating so much of the problem.

We can also then create content to address that, and then we can come up with a common design program, so across all the states it could be measured. Right now, California can't be measured. Maybe Maryland can be. Maybe New York will be. I have no idea who's developing these programs?

I appreciate pain expertise, I appreciate addiction expertise, all kinds of clinical

expertise, but there's also educational expertise, and that would be a nice voice to have sitting at the table as we try and come up with something that's going to really be quite meaningful.

So for me it's a question of making sure that the processes have some sort of comparable quality. Maybe it doesn't really matter who implements it or how it implements, but really that they're really kind of a standardization in terms of basic things we know about how to deliver design and deliver and assess quality education.

DR. LURIE: Let me give the panel a chance to react. You've said a lot and --

MS. KEAR: I've said a lot. I'll stop. That's time for me to be quiet then. Thank you.

DR. LURIE: Does anybody on the panel want to react to some elements of that?

(No response.)

DR. LURIE: It's an endorsement.

MALE AUDIENCE MEMBER: A quick comment and a question. The comment is I wonder whether there's a mortality rate associated with education, so

delivering that is not going to really hurt anyone to actually get extra education. However, there's a significant mortality rate with the control substances at around 50,000 per year.

I just want to make sure we keep it in scope. As a physician who makes a lot of money, I have to take 4 extra hours of education to not kill people? I think we just need to make sure and keep it in perspective.

But realizing that better is sometimes the enemy of good, what would you see as the minimum viable product that the FDA and the national or the federal system would be able to put out to the states in order to move forward quickly as the longer that we wait.

What is the minimum viable construct that you think would be helpful for the states to be able to start directing education within those states?

DR. LURIE: Okay. Fair enough. Joanna?

DR. KATZMAN: Thank you for your question. Our content that we delivered to most of the

clinicians in New Mexico, to most of the clinicians in the Indian Health Service, to many that we've trialed and tested with the Army and Navy pain clinicians, and primary care clinicians, the Army and Navy has been 5 hours. Part of that has been because we've also used standardized patients with vignettes and so on.

I think that in order to deliver an overview of the epidemic, include regulations pertaining to state and federal requirements, and to be able to offer content regarding pediatric and adolescent pain in addition to the core content, which is how to treat pain non-pharmacologically, how to treat pain with non-opiate pharmacotherapy, and how to screen for opioid addiction, and then how to treat pain with opioids safely, my feeling having done this for eight years, is a minimum of 4 hours, 3, 4 hours. If you're going to do it live or via BTC, it is intensive, so 3 to 4 hours.

DR. LURIE: Over a two-year cycle, right? Is that what you mean?

DR. KATZMAN: However you want to do it.

DR. LURIE: That's how most do it.

(Crosstalk.) DR. KATZMAN: That's my feeling. We did 5 hours because we added breakout sessions and such.

DR. LURIE: Okay. Is there agreement that any --

DR. KATZMAN: I forgot to mention, Peter, that we also did -- we also added naloxone take-back. We also incorporated dental specifics on acute pain. The full first class would be a 5-hour course.

DR. LURIE: Is there agreement on the panel that separating opioid prescribing from pain management would be a mistake?

DR. KATZMAN: Can I just start with that? I think that would be a significant mistake.

MR. BROWN: Agreed.

MS. ROBIN: Agreed.

DR. TERMAN: Greg Terman from University of Washington and American Pain Society. My question is for Lisa and Melinda specifically, and you may have almost touched on it. But my question is, if

there was a miraculous best education product out there, do you think that the states would gather around it or try and improve on it?

Having been involved in three Washington state guidelines and CDC guidelines, it seems sometimes that governors or legislators in the states, maybe even boards, play the I can restrict prescribing to 40 MED. I can restrict it to 20 MED. And of course, it's the numbers that people remember.

What do you think about that? Are they interested in collaborating, or are they trying to get themselves in the news as yet another decrease in restrictive practices?

MS. ROBIN: I can say that I think you've got different audiences that you're talking about. I think that from the boards, from the regulatory boards, I would say that they are looking, and yes, that resources would be well received.

I would say that the REMS blueprint before was well received from the states. There was not any pushback on the state boards wanting to get

that education out to their licensees. We didn't have any. They were anxious to -- if I had had more resources to be able to provide more grants, those boards would have done additional education.

Now, that doesn't mean that there is not every legislator or -- they want their hands on something and looking for a very quick fix, and whether it's okay, well, we're just going to stop. And they're not medical professionals, but it looks like that's an easy thing. Let's say, well it's going to have a hard stop here, and nobody can -- and without necessarily looking at what the evidence really is to support that, what are our patient outcomes?

So I think you've got two different people. Whether the governors and the legislators are really looking for that common resource, and looking at it from an education perspective versus more of a prescriptive -- let's tell the doctors and nurses and pharmacists how to practice -- or are the regulators, who not only -- they have to look at access. They have to look at they're

trying to raise a whole standard of practice, and at the same time take out the folks that are misbehaving.

So I think you have two different varied people there.

MS. BECKER: I agree completely. I'll just say I think there will always be -- whether it's governors or state legislatures who are trying to be more visible and more publicly on the forefront, if you will, on this issue. But I think, by and large, they have varying capacities to develop these evidence-based programs on their own, and I think would really welcome the resources. I think that you would see a very positive response from the states if something like that were to come together.

DR. LURIE: Okay. Great. I think we've exhausted the expertise or insights of this panel. We might have exhausted the audience. At that point, I think it's time to stop.

Doug, you have some closing comments to make, and then I think that we'll end the day.

Closing Remarks – Douglas Throckmorton

DR. THROCKMORTON: That was terrific, and I'll just start by thanking the panels, both the panels this afternoon, in keeping the focus on education, which is, again, really the thing that we're looking for help on in this particular area. There's a lot that we could be talking about. Thank you for especially this last panel staying laser-focused on that and not other activities that we could be talking about.

I heard some things where consensus seemed to emerge, so I'm going to say them, and just we'll see how it goes. I heard some things that I don't believe we've yet gotten to consensus on, so I'm going to just try to summarize what I've heard.

One, Peter as you said, there is just an enormous amount of educational activity going on at the federal/state healthcare system local levels, a large change over where we were when we first talked about needing the REMS, I would say; this last few years, really just an explosion in terms of the amount of focus on education and training.

The first question was is education enough? Okay, if anyone thinks that it is, please raise your hand. But I think consensus was it's one aspect of this. It's important but not sufficient.

Is the current level of physician education satisfactory? And Peter, you elicited the answer to that question, at least to this panel, that there is a consensus that given everything that's happening both in pain management and, in particular, in the field of opioids, really there is additional education that we all could benefit from. We all could do that.

Is the current level of education focused on prescribers the right one? Here the consensus was no. Yes, prescriber focus is important, but there needs to be a focus on additional elements of the healthcare system, the nurse practitioners; other non-prescriber groups play a critical role in supporting this. Someone mentioned the courts. We didn't get a chance to mention that, but I heard that. That was an interesting editorial I won't explore further.

Are there improvements in the federal -- I'll say federal, I'm guessing all educational activities -- that could occur to improve their impact? So could we be doing better with education?

Here again, it seemed pretty straightforward. Everyone agreed. Dr. Kahn mentioned the idea of modules. I mean, there was some various ideas that people had for taking the kinds of education that we put in place, now speaking about the REMS specifically, the content we put in place in 2012, updating it for our current state where we know more about how to educate prescribers or educate practitioners. We know more about how to do that better to be more likely to be successful.

Then I would say the place I've heard consensus, is there a need for additional federal action? So given that we have all of this new activity going on from where we were in 2012, is there a need for additional federal action? And that can be either mandatory or not obviously.

Two advantages people suggested, one was to make a common educational content that the states could then draw on. I think there was broad -- it sounded as though a lot of people thought that was useful.

Another suggestion that was made was that it would provide a common standard of data collection, data sharing. It would make it possible for us to understand better what was going on, if there was a federal architecture, if you will.

Before answering that question, though, I think everybody acknowledged there's a lot of other things going on, other non-education things, or education things other than the REMS going on. We have the CDC treatment guidelines. CMS and states are using reimbursement strategies that some of you mentioned to modify prescriber behavior.

Healthcare systems are working to modify prescriber behavior. I know this because I know people that are having their practice modified by those behaviors, the chits and the flags, and that kind of thing.

The comment was made that those things are directed to large practices and are not likely to be impacting the solo practitioner that I trained in the sandhills of Nebraska with, was not going to be affected by that kind of stuff, because he was out there on his own, and he was not going to be getting that information.

Then there was this long discussion, I would say really fruitful discussion, on how to understand state-to-state variability. Lisa, I take your point that not choosing to make mandatory prescriber education is only one aspect of what the states are doing, but we have to recognize there is a broad range of state choices that have been made. And before we decide whether or not the next level up, federal requirement is necessary, it's important to understand the source of that variability.

Is it because states are fundamentally that different, or is there something else going on there? And Dr. Katzman talked about huge cultural differences, and having come from the Midwest, I

understand that. I think there are those things. That's true. I don't know whether that fully explains the broad range of choices the states have made or not. I think that's something I hope we have a chance to talk about a little bit.

People have talked about how a common curriculum with flexibility, a model act, or a waiver or something, might be a compromise in that sense; if you decided some federal activity was necessary, how to reflect those cultural differences.

Then the last question, and I am absolutely not answering, what I think I've heard so far today about the need for additional mandatory federal action. I would say I haven't heard a consensus or even -- people have stated their views.

I hope tomorrow we're able to talk about it more systematically, a little bit more in the framework that we've been talking about it late this afternoon, really talking about how to make a choice about additional federal activity, given all of the state and local and healthcare system

activities that have been going on because I think that's how our decision-making is going to ultimately have to be framed.

In the context of the things going on now, do we need to do more? And if so, whether that more needs to be mandatory or if it needs to be an improved version of what we're doing now, with understanding better that we have now.

I'll end by just -- I'm sorry, I don't know who spoke at the very end there. There are two challenges that have been raised that we really do have to keep in mind. The first is the physician burnout, and we have to acknowledge that that burden is important. Not having a prescriber is infinitely worse than most other options we can be thinking about here.

So that just absolutely does need to be thought about, the healthcare system burnout. Actually, I shouldn't have said physician, because I have very good friends that are nurse practitioners. I know very much the burden they bear in these sorts of discussions for instance.

The other thing we just have to remember is those 91 people. We are losing people daily to this. So yes, we all acknowledge there's a lot of things we don't know. At the end of the day, though, everything about this epidemic is going in the wrong direction. And we've seen some small improvements. The VA system data were very compelling and things, but we need to make a difference.

So yes, additional research is important, and yes those things are important. But at the end of the day, perfect being the enemy of the good, sometimes we're going to be obliged to act without all of the data we might ideally like to have.

So with that, I'm going to close the session. Thanks to everyone that participated. Thanks to the two panels this afternoon for really terrific discussion. And I hope to see all of you tomorrow.

(Applause.)

(Whereupon, at 5:03 p.m., the meeting was adjourned.)

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