

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

May 9, 2017

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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

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1 PROCEEDINGS

2 (8:37 a.m.)

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

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

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

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

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

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

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

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

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

11 There is a docket that has been set up for
12 this. That docket will remain open until July
13 10th. As you'll hear, we are hoping that docket is
14 going to be useful for you for giving us some
15 additional information, things that we should take
16 into consideration.

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

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

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

9 Janet?

10 Opening Remarks - Janet Woodcock

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

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

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

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

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

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

1 1.2 of abuse-deterrent formulation. We hope we get
2 up to a very effective abuse-deterrent
3 formulations, but of course any formulation can be
4 overcome; this is not the entire answer.

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

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

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

22 This epidemic is fueled by opioids that are

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

5 Back in the '80s, back when I was training,
6 and probably many of the health professionals in
7 this room were in training in the early days, '70s,
8 '80s, I had cancer patients who refused to take
9 opioids for pain relief, for cancer pain relief,
10 because they were afraid of the side effects they
11 told me. They said they were afraid they would get
12 addicted. That was the societal attitude at the
13 time.

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

18 By 2010, in contrast, there were more than
19 200 million outpatient prescriptions dispensed for
20 opioids in this country, a huge number of
21 prescriptions. So there was a sea-change between
22 that time that was I think coming off a heroin

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

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

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

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

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

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

11 What were the consequences of this shift?
12 Well, the main consequence was a huge increase in
13 population exposure to prescription opioids. Over
14 200 million prescriptions is massive population
15 exposure. There was a surge in opioid-related
16 substance abuse disorders and deaths from overdose,
17 and this is still ongoing as we all know.

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

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

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

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

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

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

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

7 Similarly for opioid prescriptions for
8 musculoskeletal or head pain indications, 6 percent
9 had persistent opioid use one year after the
10 initial prescription, and this increased to
11 30 percent if the initial prescription was for more
12 than a month of opioids.

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

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

1 opioid substance abuse disorder.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 patients.

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

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

21 Thank you, and good luck with this meeting.

22 (Applause.)

1 Presentation - Douglas Throckmorton

2 DR. THROCKMORTON: Thanks, Dr. Woodcock.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 The FDA is obviously a part of many of those

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 With that, I am going to end and turn this

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

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

14 Claudia?

15 (Applause.)

16 Presentation - Claudia Manzo

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

22 This morning, I will be talking about the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 The elements to ensure safe use, or ETASU,

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

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

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

22 The goal of the REMS is to reduce adverse

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

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

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

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

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

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

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

1 subject to an independent audit.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 In summary, the ER/LA opioid analgesic REMS

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

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

11 (Applause.)

12 DR. THROCKMORTON: Thanks, Claudia.

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

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

20 Lisa?

21 Presentation - Lisa Robin

22 MS. ROBIN: Thank you.

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

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

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

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

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

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

17 We have seen over 1200 bills introduced in
18 2017. It certainly keeps my staff busy trying to
19 monitor and look at these. We have 94 signed into
20 law this year. And what we're seeing, they kind of
21 address certain broad areas, whether that be a
22 mandated query to the PDMP; implementing the lock-

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

7 At the same time that this was going on, the
8 Federation of State Medical Boards over the past
9 15 months have been working on looking at our
10 guidance document for opioid prescribing, and that
11 work was completed in just this past April. We'll
12 be promoting that to the states and hoping that
13 that document can serve as kind of a basis as they
14 do their policy work in this area.

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

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

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

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

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

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

1 operational prescription drug monitoring programs.
2 As I mentioned earlier, in Missouri I think about
3 45 percent of all residents are covered due to the
4 work between the counties and the cities to adopt
5 some sort of local programs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 (Applause.)

18 DR. THROCKMORTON: Thanks Lisa, very much.

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

1 Presentation - Melinda Becker

2 MS. BECKER: Thank you, and good morning.

3 Again, Melinda Becker. I'm a senior policy analyst
4 with the National Governors Association Center for
5 Best Practices health division, and I'm really glad
6 to be participating today.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 I'm going to skip this slide for now.

22 This slide lays out the best and promising

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

6 To give some examples, Washington is one of
7 the states that's really led the way on prescribing
8 guidelines. Their guidelines along with other
9 state efforts importantly have contributed to a
10 40 percent decline in prescription opioid-related
11 deaths between 2008 and 2014. More recently, last
12 summer Wisconsin passed legislation authorizing the
13 State Medical Board to issue a guideline through
14 regulation.

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

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

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

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

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

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

7 Just to give a couple of examples of
8 continuing education requirements in the states, in
9 2012, Kentucky passed a bill that focuses on the
10 regulation of pain clinics, as well as a host of
11 other issues related to prescription drug abuse in
12 the state. The legislation mandated that state
13 licensing boards issue regulations and a host of
14 issues related to prescribing of controlled
15 substances including continuing education related
16 to pain management, addiction disorders, and the
17 use of the states PDMP Kasper.

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

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

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

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

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

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

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

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

18 (Applause.)

19 DR. THROCKMORTON: Thanks Melinda, very
20 much.

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

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

4 Presentation - Joanna Katzman

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

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

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

22 Then I'm going to talk to you about the

1 mandated pain and addiction training that has been
2 going on in New Mexico since 2012. I am going to
3 talk to you about how that jump-driven the Indian
4 Health Service clinician mandated pain and
5 addiction training in 2015, and then a little bit
6 about my starting project ECHO Pain and Opioid Safe
7 Management for clinicians around the country in
8 2008, and how clinicians in New Mexico can actually
9 get their mandated pain and safe opioid training
10 through project ECHO. And then finally, I'll just
11 close with some summary points.

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

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

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

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

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

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

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

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

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

10 So what did we do in New Mexico? Well, a
11 group of many key stakeholders had been meeting in
12 2010 and 2011, and Melinda from the National
13 Governors Association did come down -- the NGA did
14 come down in 2012 to meet with the governor at that
15 time, as we were one of the leading states with
16 unintentional opiate overdose deaths.

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

1 pain.

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

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

1 Mexico medical board.

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

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

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

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

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

22 We wanted clinicians to understand screening

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

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

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

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

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

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

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

22 So we were glad that we did not see a change

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

9 (Laughter.)

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

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

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

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

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

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

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

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

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

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

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

14 (Applause.)

15 Questions and Answers

16 DR. THROCKMORTON: All right. We have a few
17 minutes for questions and discussion if people want
18 to come to the microphones and ask questions.

19 While people are collecting their thoughts, I am
20 going to ask a question to Melinda and Joanna.

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

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

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

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

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

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

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

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

16 Thanks, Doug.

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

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

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

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

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

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

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

3 DR. THROCKMORTON: Over here?

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

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

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

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

22 So I'm confused by the conclusions and how

1 they relate to the data.

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

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

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

18 Let's go over here.

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

1 colleague from New Mexico.

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

9 DR. KATZMAN: As part as Senate Bill
10 370 -- that's not part of Senate Bill 370, but I
11 don't know the terms of certain inmate's probation.
12 So I don't think I can answer that sufficiently.

13 DR. BERGER: Thank you.

14 DR. THROCKMORTON: Over here?

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

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

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

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

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

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

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

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

22 DR. GREENBLATT: Thank you. I'm Larry

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

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

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

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

1 educating prescribers about that potential
2 transition also?

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

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

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

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

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

5 Go here please.

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

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

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

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

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

15 Thank you all for your comments.

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

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

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

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

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

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

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

1 that you can just gauge success on the actual
2 prescriber.

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

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

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

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

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

6 DR. THROCKMORTON: Great, thanks.

7 One last question.

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

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

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

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

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

10 Thank you very much. We are going to have a
11 break now. I have 10:22, so let's come back at
12 10:32. Thank you very much.

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

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

22 We're starting with Fred Brason. My

1 apologies. I'm jumping the session here.

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

6 (Laughter.)

7 DR. THROCKMORTON: Fred, thank you.

8 Presentation - Fred Brason

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 that was necessary for that pain whatever the
2 cause.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2 So there isn't any one thing that we can do.

3 We can't focus in on just one thing. We can't just

4 say it's prescriber education and prescriber

5 education only that's going to make the difference.

6 No, it's not. It's everything else that goes along

7 with it.

8 This is a society and social issue that

9 we're dealing with across the board, and we have to

10 make sure that we address it that way. But to have

11 a 9 percent and a 3 percent immediate drop in

12 mortality and ED visits, and so forth within those

13 communities, that is significant, and we know that

14 it only grows from that going forward.

15 The most effective strategies to immediately

16 reduce overdose rates, and this is from the study

17 from UNC, were prescription education related to

18 pain management and addiction treatment; policies

19 designed to limit the amount of opioids dispensed

20 in emergency departments, because that is what we

21 found to be a frequent place for obtaining for

22 right or wrong reasons; and greater utilization of

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

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

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

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

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

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

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

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

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

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

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

1 could be gaps in that.

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

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

22 (Applause.)

1 DR. THROCKMORTON: Thanks very much.

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

8 Bernie, thank you.

9 Presentation - Chester Good

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

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

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

6 The Department of Veterans Affairs was an
7 early adopter of pain as the fifth vital sign. In
8 1998, we started a national pain strategy where
9 this was incorporated. And in 2000, the VA
10 mandated that pain be the fifth vital sign, so that
11 every time that a patient would be seen and get
12 blood pressure, they would be asked about their
13 pain on a scale of 0 to 10.

14 This shows that at least part of the outcome
15 of that education was that we ended up with quite a
16 few patients on opioid medications for chronic
17 pain. By fiscal year 2016, these are the most
18 recent data, we had 1.2 million veterans that
19 received at least one opioid prescription. That's
20 15.4 percent of all of our patients who got any
21 prescription in that fiscal year.

22 This was down. It peaked in 2012. We had

1 more than 7 million total opioid prescriptions, and
2 we have 30,000 VA prescribers who prescribed at
3 least one opioid prescription. We had 35,000
4 veterans who remain on more than 100 morphine
5 equivalents a day, but that is down from about
6 60,000 in 2012.

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

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

18 In 2014, we started our Academic Detailing
19 Program with a focus on opioid prescribing. In
20 2016, the VA and Department of Defense Pain
21 Guidelines were issued, the most recent iteration
22 of those. And in 2016, we also had mandatory

1 opioid training for all VA prescribers.

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

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

18 These metrics include patients prescribed
19 opioids, presence of urine drug screens, concurrent
20 opioid plus benzodiazepine, and patients on
21 high-dose opioids to find there's more than
22 100 morphine-equivalent daily dose.

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

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

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

1 metrics.

2 We have 285 academic detailers throughout
3 the VA. And as of August of 2016, more than 10,000
4 clinical staff had been detailed regarding pain and
5 opioid safety. We have looked at those detailed,
6 and in those that were detailed, there's a
7 58 percent reduction in high-dose opioids compared
8 to 34 percent of those without the academic
9 detailing.

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

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

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

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

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

14 Just like everything we do, we have tracking
15 metrics for the training. And as of April 2017,
16 96 percent of all VA opioid prescribers had
17 documented meeting those training requirements,
18 including me.

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

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

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

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

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

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

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

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

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

1 get them?

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

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

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

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

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

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

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

16 (Applause.)

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

22 Carol, thanks.

1 Presentation - Carol Havens

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

5 (Laughter.)

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

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

13 For those of you who are not familiar with
14 us, in Northern California, we care for over
15 4 million members. We have 35,000 nurses and staff
16 located in 21 medical centers and over 200 medical
17 offices and other outpatient facilities.

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

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

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

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

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

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

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

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

22 We did a Train the Trainer regionally, so

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

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

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

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

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

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

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

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

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

1 regular meetings.

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

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

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

1 our outpatient adult and family medicine providers.

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

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

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

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

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

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

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

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

6 Other measures of our success -- because we
7 weren't really concentrating just on opioids. We
8 really wanted to look at the overall picture of
9 safety and monitoring for our patients.

10 Seventy-nine percent of our patients on high-dose
11 opioids now have an opioid agreement, a medication
12 agreement, in their charts compared to 42 percent
13 before we started this.

14 Over 75 percent have had a urine drug screen
15 within the previous 12 months, compared to
16 52 percent before we started this. Both of those
17 are recommendations for the adult and family
18 medicine.

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

1 patients to 13 per 10,000 patients.

2 Measures of success within the emergency
3 department, our discharge opioid prescribing was
4 reduced by one-third. The parenteral use of
5 opioids in the emergency department was reduced by
6 15 percent. We were already fairly low, as 16 and
7 a half percent of our patients received parenteral
8 opioids in the emergency room; now 14 percent do.

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

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

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

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

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

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

22 The interdisciplinary workgroup we think

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

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

22 So our education was really about the why,

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

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

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

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

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

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

1 to ensure the safety of your patients.

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

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

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

1 (Applause.)

2 Questions and Answers

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

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

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

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

1 opioids.

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

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

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

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

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

18 DR. THROCKMORTON: Here.

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

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

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

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

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

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

1 to do it.

2 DR. BERGER: Thank you.

3 DR. THROCKMORTON: Over there.

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

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

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

20 DR. THROCKMORTON: Great question.

21 DR. GOOD: Sure. So, yes.

22 (Laughter.)

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

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

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

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

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

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

10 DR. THROCKMORTON: Thanks. Next?

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

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

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

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

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

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

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

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

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

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

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

22 Regarding the second question, what's the

1 quality of care when you do decrease the opioids?

2 It's a very difficult question to answer. It
3 hasn't yet been published, but it was just
4 presented.

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

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

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

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

5 But those are anecdotes, and I'm sure there
6 are patients who the physician says you're on
7 120 morphine equivalents, and, darn it, we've got
8 to get you under 100. So I'm dropping you to 90.
9 On a patient who's been stable and tolerating,
10 there's really no need to do that.

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

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

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

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

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

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

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

12 DR. HAVENS: Have we considered what?

13 MS. CHAMBERS: Peer mentoring.

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

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

21 DR. THROCKMORTON: Thirty seconds or --

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

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

6 DR. BRANSON: I've spoken too much.

7 DR. HAVENS: Yes. Next question?

8 (Laughter.)

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

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

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

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

20 Presentation - Doris Auth

21 DR. AUTH: Thanks, Doug.

22 I was going to begin with a good morning,

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

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

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

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

1 patients, prescribers, and pharmacies.

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

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

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

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

1 are developed and implemented by manufacturers of
2 drugs.

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

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

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

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

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

1 use; 42 have elements to ensure safe use. Of the
2 32 that don't have elements to ensure safe use, 15
3 are medication guide only, 12 are communication
4 plan only, and 5 have both communication plan and
5 medication guides.

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

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

22 The only requirement in the current

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

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

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

15 Dispensing pharmacies and pharmacists must
16 also complete training, certify, and enroll the
17 pharmacy into the REMS. Distributors must agree to
18 only ship the REMS drug to enrolled, certified
19 pharmacies, and a database of enrolled prescribers,
20 pharmacies, and distributors is maintained by the
21 sponsor.

22 Under the system, a patient receives a

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

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

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

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

7 While the ranges of each stakeholder
8 participating may seem pretty large, I'd like to
9 point out that more than half of these programs are
10 relatively small with fewer than 10,000 patients,
11 fewer than 10,000 prescribers, and fewer than
12 10,000 pharmacies that are participating. There
13 are a number of REMS programs, as you may be aware,
14 that are for products intended to treat orphan
15 diseases that have relatively small patient
16 populations.

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

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

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

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

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

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

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

1 our chosen form of contraception.

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

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

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

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

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

6 Pharmacies have very similar education and
7 knowledge assessment requirements. They must
8 provide patients with a medication guide with each
9 prescription. Pharmacies actually -- it says here
10 on the slide -- passively enrolls the patient. In
11 this program, the pharmacies enroll patients into
12 the program upon their initial prescription as long
13 as the prescriber is enrolled. They're given a
14 10-day window that allow the patient to receive the
15 TIRF product prior to the REMS system receiving
16 that patient-provider agreement form and officially
17 enrolling in the program.

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

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

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

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

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

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

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

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

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

17 The most recently reviewed annual REMS
18 assessment, as well as some IMS data on TIRF
19 prescribing, shows about 8,000 active prescribers,
20 42,000 active pharmacies, 63,000 prescriptions
21 dispensed, and about 4200 newly enrolled patients.

22 From the most recently reviewed annual REMS

1 assessment for the iPLEDGE program, there were
2 16,000 prescribers, 48,000 pharmacies, 1.3 million
3 prescription authorizations or prescriptions
4 dispensed, and 370,000 patients.

5 In comparison, an opioid analgesic REMS
6 program that would require prescriber training
7 could potentially involve all the DEA registered
8 prescribers, which is currently about 1.5 million
9 prescribers, as many as all of the outpatient
10 pharmacies, which is about 67,000. And despite
11 declining prescriptions for opioid analgesics in
12 the past four years, recent data on prescriptions
13 dispensed showed that there were still 160 million
14 prescriptions dispensed for opioid analgesics in
15 2016.

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

1 prescribers, pharmacies, and patients.

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

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

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

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

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

21 Thank you.

22 (Applause.)

1 DR. THROCKMORTON: Thanks very much.

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

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

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

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

1 mandatory versus voluntary federal education.

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

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

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

1 potential challenges in putting into place a
2 federal system.

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

6 Good morning. How are you, sir?

7 Presentation - James Arnold

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

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

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

22 There's a lot of misunderstanding, and part

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

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

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

1 on to the street.

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

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

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

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

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

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

14 The one thing, the main thing that I want to
15 share with you this morning, and the one thing I
16 always try to share with all medical professions,
17 whoever I'm speaking to in the room, is this,
18 21 CFR 1306.4.

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

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

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

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

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

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

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

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

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

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

1 individual.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 (Applause.)

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

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

22

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

2 (1:10 p.m.)

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

6 Open Public Hearing

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

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

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

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

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

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

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

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

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

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

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

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

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

12 DR. THROCKMORTON: Thank you very much.

13 Thomas Sullivan?

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

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

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

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

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

1 as if the patient is opioid-naïve.

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

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

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

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

11 REMS should be expanded to include all
12 opioids, which you have stated. After reviewing
13 the Maryland opioid death certificates for
14 prescriptions, opioid deaths have remained
15 relatively the same from 2011 to 2015, from 342 to
16 351, respectively. And at the same time, deaths
17 from fentanyl has increased 12-fold from 26 deaths
18 to 340 deaths, and heroin deaths have tripled from
19 238 to 748.

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

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

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

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

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

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

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

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

22 DR. SULLIVAN: Yes, I'm summarizing right

1 now.

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

4 DR. THROCKMORTON: Thank you.

5 Cynthia Kerr [ph], Kear?

6 MS. KEAR: Kear. That's good.

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

13 We've been doing this work since 2010.
14 We've had about 600 activities in four years.
15 Probably about 90 percent of those are live; the
16 rest of them are online. We've generated close to
17 200,000 targeted learners, and probably when you
18 throw in nurses and PharmDs, whom we consider very
19 important audiences, we're probably about 280,000.

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

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

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

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

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

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

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

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

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

22 One of the things I think, mandatory or not

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

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

17 DR. THROCKMORTON: Thank you.

18 Eunan Maguire?

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

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

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

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

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

1 people, but not required.

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

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

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

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

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

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

9 DR. THROCKMORTON: Thank you.

10 Katherine Cates-Wessel?

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

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

1 mental disorder.

2 While emerging evidence also reveals a
3 significant number of prescription opioid deaths
4 are suicidal in intent, rarely is mental health
5 mentioned. In fact, a 2015 report from a national
6 surveillance database of poison control centers
7 from 2006 to 2013 noted an alarming 75 percent of
8 prescription opioid-related deaths occurred with
9 suicidal intent. The percentage rises to
10 86 percent in individuals 60 and older.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 DR. THROCKMORTON: Thank you.

19 Richard Lawhern?

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

1 face-ain patients and others, as a non-physician
2 research analyst, writer, and moderator for
3 peer-to-peer online groups. I daily interact with
4 Facebook forums in which the membership is over
5 20,000 patients and family members. I have no
6 financial conflicts of interest.

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

13 As a direct consequence of this reality in
14 the patient population, there can be no universally
15 applicable threshold of risk in MMED. Tens of
16 thousands of patients are now stably maintained
17 with zero opioid addiction risk on dose levels
18 exceeding 200 MMED or even 400 MMED, and there are
19 case reports of patients maintained stably on
20 2500 MMED. If you deny these people opioid
21 therapy, you might as well shoot them because you
22 will be killing them.

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

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

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

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

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

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

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

4 DR. THROCKMORTON: Thank you very much.
5 Laura Wooster?

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

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

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

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

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

21 Physicians already face significant and
22 growing administrative burdens that continue to

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

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

17 DR. THROCKMORTON: Clif Knight?

18 DR. KNIGHT: Thank you.

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

1 behalf.

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

8 Family medicine plays a critical role in
9 delivering care to patients in communities across
10 the country, and family physicians are the most
11 visited speciality, especially in underserved
12 areas. Family physicians conduct approximately one
13 in five of all physician office visits in the
14 United States, and this represents more than
15 192 million visits annually.

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

22 The AAFP supports having programs in all

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

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

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

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

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

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

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

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

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

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

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

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

18 DR. THROCKMORTON: Thank you.

19 Ilana Hardesty?

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

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

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

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

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

1 11 weeks, would indicate that mandated education
2 can reach large numbers of clinicians in a short
3 period of time.

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

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

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

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

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

16 DR. THROCKMORTON: Thank you.

17 Dr. Passik?

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

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

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

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

1 starting it.

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

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

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

22 Payers must be required to support and pay

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

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

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

22 Clinicians must be educated and acquire the

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

8 DR. THROCKMORTON: Thank you very much.
9 Ashley Walton.

10 MS. WALTON: Good afternoon. I'm Ashley
11 Walton, and I'm here on behalf of the American
12 Society of Anesthesiologists. On behalf of our
13 52,000 members, I thank you for this opportunity to
14 provide feedback on healthcare provider training
15 and education.

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

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

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

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

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

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

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

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

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

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

9 DR. THROCKMORTON: Thank you very much.

10 Linda Cheek?

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

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

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

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

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

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

1 mandatory regulation of opioid prescribing or
2 education.

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

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

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

1 DR. THROCKMORTON: Thank you very much.

2 And the last speaker, Kara Gainer.

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

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

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

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

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

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

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

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

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

1 without the risks of opioids.

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

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

14 DR. THROCKMORTON: Thank you very much.

15 That closes the first public session.

16 Should we transition, Terry, right into your
17 session?

18 MS. TOIGO: Yes.

19 (Pause.)

20 Panel Discussion

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

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

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

10 So Dr. Terman, do you want to start?

11 DR. TERMAN: Sure. I have an hour and 15
12 minutes to talk; is that right?

13 MS. TOIGO: You do.

14 (Laughter.)

15 MS. TOIGO: And I will politely cut you off
16 if you go too long.

17 DR. TERMAN: You'd like to me to start by
18 introducing --

19 MS. TOIGO: Yes, just very quick, just who
20 you are in one-minute.

21 DR. TERMAN: Got you.

22 I'm Greg Terman. I'm an anesthesiologist

1 from the University of Washington in Seattle, a
2 professor there in the Department of Anesthesia and
3 Pain Medicine. And I am immediate past president
4 of the American Pain Society.

5 DR. GALLUZZI: I'm Kate Galluzzi. I am an
6 osteopathic physician. I'm the chair of geriatric
7 medicine at the Philadelphia College of Osteopathic
8 Medicine. I'm board certified in family medicine,
9 geriatrics, hospice, and palliative care, and pain
10 management. And I've been a longstanding member of
11 the CO*RE initiative.

12 DR. MOORE: I'm Paul Moore. I am the
13 representative dentist in the house. I am a
14 pharmacologist, dentist, anesthesiologist, have
15 trained in chronic pain management, and I'm from
16 the University of Pittsburgh.

17 MS. BURNS: Good afternoon. I'm the
18 resident pharmacist in the house. My name is Anne
19 Burns, and I'm the vice president of professional
20 affairs at the American Pharmacists Association.

21 DR. WALLER: My name is Corey Waller. I'm
22 an emergency medicine and addiction medicine

1 physician, and I'm the chair of the Legislative
2 Advocacy Committee for American Society of
3 Addiction Medicine, and work in Camden, New Jersey,
4 doing street medicine, as well as national system
5 development for systems of care.

6 MS. TOIGO: I'm Terry Toigo, and I'm
7 associate director for drug safety operations in
8 the Center for Drug Evaluation and Research at FDA.

9 MS. NORMAN: I'm Anne Norman. I'm a family
10 nurse practitioner. I'm also the vice president of
11 education and accreditation at the American
12 Association of Nurse Practitioners; also a member
13 AANP and also a partner of the CO*RE.

14 MS. LEGER: Good afternoon, everyone. My
15 name is Michele Leger. I'm the director of
16 clinical education at AAPA, and we represent over a
17 115,000 physician assistants. We're also a member
18 of the CO*RE REMS collaborative.

19 DR. HARRIS: Good afternoon. I'm Patrice
20 Harris. I'm chair of the Board of the American
21 Medical Association. I also chair our AMA opioid
22 task force. I'm a psychiatrist from Atlanta,

1 former public health official, and I also have
2 worked in addiction medicine.

3 DR. TWILLMAN: Good afternoon. I'm Bob
4 Twillman. I'm a psychologist, and I'm the
5 executive director of the Academy of Integrative
6 Pain Management.

7 MS. TOIGO: Okay. Thank you, everyone.

8 Just before we get started, how many in the
9 audience are health professionals? We've got
10 almost everybody represented here.

11 I'm challenged today in speaking. How many
12 in the audience are health professionals?

13 (Show of hands.)

14 MS. TOIGO: Okay. And how many are involved
15 in the education of health professionals?

16 (Show of hands.)

17 MS. TOIGO: Okay. So good mix. So we've
18 got five questions today to talk about related to
19 education and training of health professionals.
20 You can see the first three are related to
21 mandatory training, and the other two are
22 voluntary.

1 So I'm going to start with the first
2 question, which is discuss the pros and cons of
3 implementing a required training program for the
4 prescribers of opioid analgesics. I'm going to
5 take a risk here and start with Dr. Terman, but he
6 can't have an hour and a half to answer the
7 question.

8 DR. TERMAN: Okay. So as representing the
9 American Pain Society, who we think of ourselves as
10 the science of pain society being a U.S. chapter of
11 the International Association for the Study of
12 Pain, all of our members are in favor of pain
13 training, more pain training, mandatory pain
14 training for anyone doing prescribing, or more
15 importantly, for anyone seeing pain patients, which
16 is likely to be everybody.

17 You want me to go into cons as well?

18 MS. TOIGO: Yes.

19 DR. TERMAN: The cons are clearly if people
20 opt out. As a multidisciplinary society, many of
21 the members in the American Pain Society don't
22 prescribe anything, let alone opioids. The concern

1 that we have after 40 years of doing this kind of
2 education, multidisciplinary education, trying to
3 wave the flag for better pain management, which
4 only in a small subset of situations include
5 opioids, the concern is we're going to have opt
6 out. We're going to encourage people who opt out
7 to opt out, and that is a huge issue, and it'll be
8 a huge issue for folks in my society.

9 Even the basic scientists who may not think
10 it's going to be a huge issue, we all may have pain
11 in the future, and we want people to be trained to
12 do that in a good way, rather than in a bad way.

13 MS. TOIGO: Who else would like to expand on
14 what Dr. Terman has talked about? Dr. Galluzzi?

15 DR. GALLUZZI: Should we go down the line?

16 DR. TOIGO: Go ahead.

17 DR. GALLUZZI: Okay. I would just like to
18 speak to my agreement with Dr. Terman that pain is
19 a universal experience, and every single person in
20 this room who hasn't experienced pain may yet feel
21 that. Therefore, we as providers need to be able
22 to address it, and address it well and safely.

1 So of course, pain management education is
2 necessary. The pros for mandating this are that it
3 gives us the potential for developing and
4 implementing best practices. It will give us
5 enhanced understanding, and sharing of the
6 multidisciplinary and multimodal therapies that are
7 available for managing pain. And it may also give
8 us the potential for expansion of patient
9 education, which I think is an area that has been
10 under recognized and under utilized.

11 As an osteopathic physician, I believe in
12 holistic care, and I feel that the patient is at
13 the center of that care, and that the individual
14 who's suffering pain, especially high-impact
15 chronic pain, which is an area of significant
16 impact on quality of life and function, needs to be
17 able to access self-management techniques. And
18 they have to be accessible, they have to be
19 affordable, and they have to be paid for by the
20 payers, the reimbursements.

21 The cons are exactly as Dr. Terman said, and
22 these are huge unintended consequences. The big

1 one being, of course, that providers will, and
2 already are, opting out of prescribing C2
3 medications.

4 I work at a medical school. I interact with
5 medical residents and family medicine residents
6 routinely, and a number of them have already said,
7 I don't have to worry about this. I'm just not
8 going to prescribe opioids. That is not an option
9 at a time when the population of senior citizens is
10 burgeoning, and it is the largest, most rapidly
11 growing population. Seniors are, of course, the
12 ones who will be having significant chronic high
13 impact pain.

14 I think that if and when mandatory -- and I
15 hope that this is not the case, but if mandatory,
16 education does seem to be the way we're going. It
17 certainly has to be provider specific. Not every
18 discipline requires the same types of education.

19 Of course there's a minimum level of
20 competency, but it has to be specific to the
21 providers. And it clearly needs to involve not
22 only physicians, physician assistants, and nurse

1 practitioners, but also psychologists, physical
2 therapists, and all the other ancillary personnel
3 who can help with this big problem of pain.

4 MS. TOIGO: Thank you, Dr. Galluzzi.

5 Dr. Moore, do you want to talk a little bit
6 about the dental perspective?

7 DR. MOORE: Well, you just stole my thunder,
8 I think, and that is we have mandatory education in
9 Pennsylvania at this point for safe and responsible
10 use of opioids. And that's required both in the
11 curriculum at dental schools in Pennsylvania, as
12 well as a requirement for re-licensure.

13 So we are mandated, at this point, for
14 education. And whether there's a redundancy in
15 what policies FDA creates, that's an administrative
16 problem.

17 My only comment would be that acute pain,
18 acute inflammatory pain, not neuropathic pain,
19 99.7 percent of our prescriptions are for Vicodin
20 and Percocet for immediate-release analgesics. We
21 are not using opioids to treat chronic pain. And
22 as such, I would hope that education, both by the

1 state as well as considerations with the FDA,
2 address educational processes that are specific to
3 the needs of the provider. Thank you.

4 MS. TOIGO: Thank you, Dr. Moore.
5 Dr. Burns?

6 MS. BURNS: I would agree with many of the
7 comments that have already been made. From the
8 pharmacists' perspective, we approach this from a
9 very interesting point because as you heard earlier
10 this morning, pharmacists can be prescribers. In
11 some states, pharmacists can prescribe opioids
12 under collaborative practice agreements. They get
13 DEA licenses.

14 Then our members at APHA span the gamut of
15 practice settings and are often on the final
16 endpoint, or at the final endpoint, before the
17 patient leaves with the opioid medication.

18 So the types of education that are needed
19 for pharmacists can be variable, and as was
20 discussed, having education that is tailored for
21 the provider.

22 Then this isn't really education, but trying

1 to establish better connections between
2 providers -- and we've talked about the team-based
3 approach to care. But oftentimes for pharmacists,
4 they have a lot of medication expertise already.
5 That's where the core of their training is. But
6 they oftentimes don't have the information they
7 need in order to interact with the patient
8 effectively.

9 So the different aspects of training that
10 are needed are quite broad and much more complex
11 than any other required program that is currently
12 being offered through FDA. Those would just be
13 some of I guess our asks and our concerns.

14 MS. TOIGO: Thank you. Dr. Waller?

15 DR. WALLER: So I'm going to dissent on a
16 few of these things at some level. With the
17 American Society of Addiction Medicine, the vast
18 majority of our members, and me as an emergency
19 medicine doctor, and one who actually works in the
20 streets of Camden, New Jersey, I see the failed
21 attempts at utilization of opioids every single
22 day.

1 We have to remember the number one cause of
2 injury-related death in this country is related to
3 a controlled substance, and that is overdose. So
4 to just belie that whole fact is a little bit odd
5 to me to hear the most educated people in the
6 country push against education.

7 So if education doesn't work, because that's
8 something that comes up on a regular basis, then I
9 wonder if we should dismantle the requirements
10 within residency programs and just let residents
11 tailor their own pathways to education, or medical
12 students.

13 I mean, the logical fallacies that
14 consistently come up start to become a little bit
15 frustrating as someone who educates medical
16 students on a regular basis.

17 The other fallacy that I worry about in a
18 setting is the one that says, we're going to lose
19 active prescribers if they opt out. Good. I say
20 that because right now would you want someone not
21 willing to take a 2-hour course on opioids who's
22 going to prescribe the most deadly prescribed

1 substance that we have out there?

2 If they don't want to take 2 hours of extra
3 education, do they really actually manage patients
4 with chronic pain? I don't think they're managing
5 anything. They're managing the electronic medical
6 record and the refill pathway.

7 So I think we have to make sure that what
8 we're asking for is for a loved one who needs that
9 care. And I prescribe opioids as well for chronic
10 pain management, for patients with debilitating
11 diseases, like sickle cell and all of these, and so
12 there are places for it, and then there are places
13 not for it.

14 But without the education, the difference
15 between a physician and a healthcare provider
16 making a decision that saves a life and one that
17 kills someone is the education that they get. So
18 without it, I am concerned that we're going down
19 this pathway that is filled with logical fallacies.

20 MS TOIGO: Okay. Thank you, Dr. Waller.

21 Dr. Norman?

22 MS. NORMAN: I would just say that nurses

1 and nurse practitioners, and the advanced practice
2 nurse, are lifelong learners. They also
3 historically have been very good patient educators.
4 I think they are very much involved in the learning
5 of what they need to do to provide evidence-based
6 care.

7 I think that the pros would be to encourage
8 and prepare more nurse practitioners to safely
9 prescribe and treat pain, and thereby increasing
10 the access of care for those patients who do need
11 pain management.

12 I think the cons, I would agree with what
13 most people said. But I would say that it's not
14 really about taking the 2 or 3-hour course. It's
15 more about the fear that might be implied by the
16 necessity to have that course, and to have -- I
17 think that they just might begin to think that they
18 were just a little bit frightened by the fear of
19 what might result if they didn't provide the care
20 that they needed to adequately.

21 MS. TOIGO: Thank you. Dr. Leger?

22 MS. LEGER: It's actually Ms. Leger.

1 MS. TOIGO: You can be a doctor today.

2 MS. LEGER: I'm speaking on behalf of AAPA,
3 and actually AAPA does not agree with mandated
4 education. Having said that, being in the
5 Department of Education, we are always providing
6 education and education materials to our
7 constituents.

8 One of the concerns that we have is that we
9 don't want people going in taking a course just to
10 fill a box. I think that's doing a disservice to
11 the clinician. It's doing a disservice to the
12 patients. And I think one of the things that we
13 want to be very cognizant about -- I mean, we have
14 been part of the REMS collaborative for the last
15 four years. It's a very long, arduous course.

16 A lot of our constituents are saying it's
17 too much information in a 2-hour course. I don't
18 think 2 hours is actually the right answer. I
19 think Anne actually hit the nail on the head.
20 Clinicians should be lifelong learners, that this
21 is something that's going to be an ongoing process.
22 And we learn from day-to-day practice. We learn

1 from day-to-day management of our patients. So
2 just mandating a 1-hour or 2-hour course is not
3 going to meet, I think, the needs of clinicians in
4 the big scheme of things.

5 The other thing that I really want to
6 highlight is that we already have state mandate
7 CMEs. So how is this going to fit with the state
8 mandate CMEs? Each state has their own wants.
9 Again, we have the REMS CO*RE. So when a PA calls
10 and says, I need to fill my need for New York and I
11 have them look at the objectives of the CO*RE REMS,
12 they say, I don't know if that meets the New York
13 requirements.

14 That's real. So they have to go back to
15 their states. They have to go back to their state
16 legislation, their medical boards, and see, does
17 this meet my need, and not all individuals are
18 getting the answers that they want.

19 MS. TOIGO: Thank you. Dr. Harris?

20 DR. HARRIS: Yes. So I think there is a
21 general agreement that education is necessary, and
22 the AMA -- I don't think I've heard one person in

1 this room this morning, or actually as I've
2 traveled across the country talking about this
3 issue, say that education is not important.

4 The critical issue or critical issues are
5 the what and the how, and many folks have made the
6 point that you can aspire to meaningful education
7 when it is tailored to the physicians or the
8 prescriber's specialty, their patient population,
9 and their practice.

10 So I look at the answer to this question,
11 and I say it depends on what your outcome is; what
12 you want your outcome to be. If you want your
13 outcome to be simply a checkbox, then perhaps
14 someone would argue for mandatory education. But
15 if you want true, meaningful, improvement and
16 impact on patients, and if you really want your
17 prescribers -- by the way, a term I don't like to
18 use, but I'll use it today, because we're using
19 it -- if you want your "health professionals" to
20 really get the necessary education that will work
21 for them -- we've seen it this morning with example
22 after example, that health professionals are

1 willing, ready, and able to get the education they
2 need when it's tailored to their own practice. I
3 think our colleague from Kaiser said there was
4 95 percent uptake.

5 So I think those are the pros of voluntary
6 education.

7 DR. TWILLMAN: I would say that I think
8 there is certain core body of knowledge that
9 everyone who works with a patient needs to have
10 with respect to opioids and with respect to pain
11 management. The trouble is I think that while that
12 education is necessary, didactic types of education
13 as we have generally done in this area, that's
14 necessary, but not sufficient.

15 I could go and take a 3-hour flight school
16 course, and you still wouldn't want to see me in
17 the cockpit. There's a whole lot more to it than
18 just that, and that's part of the challenge. How
19 do you provide people with this basic information
20 that is so necessary before you can move on, but
21 ensure that that actually turns into a meaningful
22 change? And that's I think a huge part of the

1 challenge.

2 I am concerned about people opting out if
3 this is made mandatory. We've already seen that
4 happening to people, even without mandates. Even
5 without anything coming from their medical boards,
6 people are opting out of treating patients with
7 pain.

8 My concern is that while we might see a
9 reduced number of overdose deaths, we might offset
10 that by an increased number of suicides in people
11 who are no longer having their pain adequately
12 treated, and I'm not sure that that's a bargain we
13 want to make either.

14 So I'm not sure I have an answer for how to
15 do this. I certainly would like to see the
16 education incentivized, rather than mandated, if
17 that's possible, but I think the challenge there
18 becomes how do you design a meaningful incentive.

19 MS. TOIGO: Okay. Thank you very much. And
20 I think we've pretty much covered question 2 as
21 well, unless there's something somebody wants to
22 add that we haven't covered there, which is the

1 impact on your members if a required training
2 program were implemented.

3 Anne?

4 MS. NORMAN: Sure. Just one additional
5 comment related to impact if a required program was
6 mandated. As was highlighted in the FDA
7 presentation this morning, depending on how the
8 required elements are integrated into the workflow
9 for the providers, it can either be very burdensome
10 or not.

11 So any required program and the checks that
12 would need to be made, and especially from the
13 pharmacy perspective at the dispensing pharmacy,
14 making sure that it's done through electronic
15 means, maybe through a switch or something like
16 that, where everything is verified and it doesn't
17 require phone calls or checking alternative
18 websites, would be desired.

19 MS. TOIGO: Okay. Dr. Galluzzi?

20 DR. GALLUZZI: I just wanted to comment,
21 with respect to -- of course everyone up here
22 agrees that education is important. The question

1 at hand is should it be mandatory? I just want to
2 ask the obvious question, is there any evidence
3 that shows that individuals who are required to do
4 something, who are mandated to do something,
5 actually performed better after they've gone
6 through that mandatory educational process?

7 I don't think we have that evidence, and I
8 want to expand on what Anne said, which is simply
9 to say -- or what a number of people said. A
10 2-hour or a 3-hour or 4-hour course is certainly
11 not ever going to be adequate. And indeed, this
12 type of education I believe needs to be iterative.

13 So how that is able to be accomplished, I
14 think is really the big question.

15 MS. TOIGO: Dr. Waller?

16 DR. WALLER: Just very quickly. Education,
17 if you look at the Bloom's Taxonomy, has six
18 different layers. We're only trying to get to the
19 apply layer. So that means you have to remember,
20 understand, and apply. If you already have the
21 base of a medical education, then actually didactic
22 information has been shown to be helpful when we

1 have surgeons watching a YouTube video before they
2 go in and try a new procedure.

3 So when you have a base of knowledge,
4 didactics applied on top of it actually can be
5 effective and actually move people up Bloom's
6 Taxonomy to apply, and that's been shown over and
7 over through many different versions of it, not
8 just in medicine.

9 I think earlier, we did actually have
10 research that showed, at least in the Army, that
11 they did see a significant decrease in opioid
12 overdose deaths just with the education alone, and
13 it by itself was the single most impactful piece.
14 And I think I looked at that slide twice to make
15 sure, but I'm pretty sure that that was shown in
16 that study, that we actually have seen an outcome
17 that's significantly improved by just the education
18 alone, and it was mandated to those professionals.

19 DR. TOIGO: Anyone else want to comment?

20 Dr. Harris, were you going to say something?

21 DR. HARRIS: Just a point that was made
22 earlier, but I think it's worth repeating regarding

1 the duplicative nature of perhaps a federal
2 program. From a public health perspective, you
3 want to look at this from a systems approach. And
4 if states are already doing this well -- and this
5 gets into the next question a bit. But if states
6 have a system, we certainly wouldn't want to spend
7 federal dollars duplicating work that's already
8 being done in the states.

9 I would also say that we should really look
10 at rather than creating a new system, a new layer,
11 it seems to me to make more sense to improve what's
12 already out there. You've heard that the medical
13 schools are involved in this. I know I went to
14 Brown. I visited Brown, and they have a wonderful
15 program for the medical students and the residents.

16 So it seems to me that where you get the
17 most bang for your buck is improving systems that
18 are already in play versus creating a whole new
19 layer that would then add to the bureaucracy.

20 MS. TOIGO: Just to add to this question a
21 little bit, we heard this morning a question -- and
22 then I think when Dr. Kahn spoke in the public

1 hearing, he made a comment about mandatory being
2 more burdensome when you're not in a big system.

3 So the presentations this morning were from
4 the VA, and Kaiser, and a lot of people getting
5 trained. I wonder if any of you have any thoughts
6 on the burden when you're an individual
7 practitioner versus the burden when you're part of
8 a system, and mandatory versus voluntary education
9 there.

10 DR. MOORE: Well, since I'm representing
11 dentistry, which in fact 50 percent of it is a
12 cottage industry, solo practitioners, I feel sure
13 that our members, the ADA's membership, will have a
14 certain amount of pushback with added mandated
15 burden, in part because they have to go find it.
16 It's not easy for them to access. On the other
17 hand, life's tough, you know?

18 I would point out that we have child abuse
19 requirements for our licensure, and those programs
20 are certified. Not anybody can teach them. You
21 have to become certified so that your curriculum
22 fulfills the requirements for that continuing

1 education.

2 So I see the requirements for a mandated
3 opioid education to fit within that model in the
4 state, so I really agree with Dr. Harris with that
5 regard. We have a system in place there I think.

6 MS. TOIGO: Okay. Did you want to add
7 something, Dr. Waller?

8 DR. WALLER: Always, but I'll hold back.

9 MS. TOIGO: Okay. There will be another
10 opportunity.

11 Okay. Just before we move to question 3, I
12 want to make sure nobody has any other comments on
13 number 2.

14 MS. LEGER: Terry?

15 FEMALE AUDIENCE MEMBER: We just cannot hear
16 you.

17 MS. TOIGO: You can't? Okay, is that
18 better? Okay.

19 MS. LEGER: I just want to add that I think
20 in a closed system things are easier than
21 individuals in a private practice or in a community
22 health center, and unfortunately you cannot equate

1 those two.

2 In the VA, in a Kaiser -- I used to work in
3 the hospital where basically every year you had to
4 have your annual competencies to be done. That was
5 in a hospital-based setting. But when I worked in
6 an outpatient setting, those were not done. So I
7 think, again, one size does not fit all.

8 MS. TOIGO: Okay. Thank you.

9 Yes, Dr. Galluzzi?

10 DR. GALLUZZI: I don't want to monopolize
11 this point, but I'm not sure that I made my point
12 clearly enough, that if we're talking about what
13 organizations need to be involved in this
14 education, of course the AOA, the AMA, AAPM, AANP,
15 AAPA, et cetera, have to all be involved, and this
16 has to be a coordinated effort.

17 But I just want to say again, this is a
18 public health crisis. And if we eliminate the
19 public from the problem, then I think we're missing
20 the boat. We need to really initiate significant
21 educational imperatives at the level of the public,
22 the individuals, children, adolescents,

1 preschoolers.

2 I had adult children who went through the
3 D.A.R.E. program and who mocked it because they
4 were already so sophisticated that they thought it
5 was ridiculous for them to do learning about drugs.
6 And in fact, they used the D.A.R.E program to
7 inform them about some new things that they could
8 try.

9 I just want to continue to say, again, that
10 the onus is being placed on the prescribers, when
11 in fact this is a public health crisis affecting
12 everyone, and the education needs to involve,
13 therefore, everyone.

14 MS. TOIGO: Okay. Thank you for that. And
15 I think everybody's agrees with that. We're just
16 focusing on the education piece of it today.

17 So why don't we move to question number 3?

18 Number 3 is discuss which organizations,
19 federal agencies, state medical boards, others,
20 that are best situated to register and track
21 completion of a required training program. We
22 heard some presentations this morning around this

1 topic. I'd be interested in going down the panel
2 on this one and having everybody have an
3 opportunity to comment.

4 DR. TERMAN: Okay. Eight years ago, I was
5 brand new on the board of the American Pain
6 Society, and we talked about opioid REMS. What are
7 those? And I said, oh, sounds like medical school.
8 And the president at the time said, "Oh well, if
9 you're so smart, you take this on."

10 So I found myself a few months later at an
11 FDA REMS meeting in 2009, and I suggested, on
12 behalf of the American Pain Society, that mandatory
13 education would be important, that it should be
14 across all opioids, not just extended release, and
15 that it be linked to the DEA certification.

16 There was no other certification that I'm
17 aware of in healthcare where you get the
18 certification without any demonstration that you
19 can do what they're certifying you for, use
20 controlled substances. I realized that that might
21 require some work politically, but that seems like
22 a reasonable first -- even if it's a short test

1 that leads people through good pain management
2 before they get their certification, that seems
3 like a reasonable thing.

4 The disadvantage of a federal approach is
5 that federal institutions seem to be all about
6 prescribing. They're not really about practice of
7 medicine. That's what the state boards are
8 supposed to be doing, reasonably enough. That
9 would not keep the state boards from doing what
10 they need to do, but when you figure six boards,
11 every state, that's a lot of diversity, and it's
12 going to be a long time before there's any
13 agreement on what needs to be done to improve pain
14 management.

15 I'm happy to see it moving towards
16 something, but I'm not sure that that would keep
17 us -- not necessarily teaching long courses, doing
18 many pain fellowships for every DEA licensure, but
19 some sort of competency test that suggests, gee, it
20 might not be a great idea to co-prescribe
21 benzodiazepines and opioids.

22 That seems like a reasonable way to -- I

1 mean, I spend a lot of time on my Internet
2 connection doing everything from IRB, animal care,
3 ACLS, central-line placement, asbestos abatement
4 training, everything comes across as a
5 [indiscernible].

6 So there's an unlimited number of people who
7 want me as a physician, an academic physician, not
8 just private practice physician, to do stuff. But
9 we're talking about what we think is a public
10 health crisis. Maybe it's okay to have physicians
11 understand what they're doing before they're given
12 license to do it.

13 MS. TOIGO: Dr. Galluzzi?

14 DR. GALLUZZI: We're talking about bullet
15 number 3, describe mechanisms. So what are the
16 mechanisms whereby this type of education can be
17 successfully rolled out? I think the CO*RE
18 initiative has shown that there's a successful
19 uptake of volunteers.

20 MS. TOIGO: We're doing number 3 on this
21 screen, so it's organizations that are best
22 situated to register and track.

1 DR. GALLUZZI: I'm sorry? I can't hear you.

2 MS. TOIGO: So I'm going to try it again.

3 It's discuss which organizations, that is federal
4 agency, or state medical board, or others, are best
5 situated to register and track completion of a
6 required training program?

7 DR. GALLUZZI: Oh, I think I agree with Greg
8 then. I think the state medical boards are
9 probably a good place to start. The problem I
10 think is coordinating them because there's been a
11 paradigm shift in treating patients, and we need to
12 come out of our silos.

13 The one doc on the block treating everything
14 is no longer the model. We are working with
15 physician assistant, nurse practitioners, physical
16 therapists, and so I'm not sure that there is a
17 central clearinghouse, a repository where everyone
18 can come together.

19 But I do feel like we need to come out of
20 our silos and work toward a coordinated effort, and
21 that may be through the state boards. I'm not
22 sure.

1 MS. TOIGO: Did you also agree with
2 Dr. Terman on DEA?

3 DR. GALLUZZI: I would agree with
4 Dr. Terman.

5 MS. TOIGO: That was his main point, I think
6 initially that required through DEA registration.

7 DR. GALLUZZI: Oh.

8 MS. TOIGO: Okay. I just wanted to clarify
9 if you did or when you were talking about agreeing
10 with him whether it was all or part.

11 DR. GALLUZZI: I guess for the most part,
12 yes.

13 DR. TERMAN: Could I take a giant step
14 backwards? Just one sentence. The reason why
15 DEA -- I don't think most people opt out of DEA
16 registration. Anything done by the FDA on the
17 opioid class, I worry about people opting out. But
18 if you take all of the controlled substances, I
19 don't think people will opt out.

20 DR. GALLUZZI: We're talking about a huge
21 range of possible medications, and I think,
22 clearly, most people are going to opt in.

1 MS. TOIGO: Okay. Thank you. Dr. Moore?

2 DR. MOORE: DEA.

3 MS. TOIGO: Dr. Burns?

4 MS. BURNS: I was going to say DEA, and one
5 of the -- and this would be a for consideration.
6 But I think one of the important positive aspects
7 of DEA would be it would take some of the actual
8 administrative burdens that happen at the patient
9 level away, potentially, and allow the providers to
10 actually work with their patients and take care of
11 them.

12 MS. TOIGO: So just to clarify, the question
13 on the table is not whether DEA is the solution to
14 the problem; it's just on federal, state medical
15 boards, or others. Just because it was mentioned,
16 it's not -- okay, I just wanted to clarify that.
17 If I didn't, probably Dr. Waller will, right?

18 DR. WALLER: It's the J-O-B, right?

19 I would say that whenever you're going to
20 look for a point in which you can hit the most
21 people at the most time, it would be the one place
22 in which they have to go to either obtain initially

1 or renew a DEA license, because that's where
2 everybody eventually has to go is to the DEA
3 diversion website. So with that, that allows for
4 actually a place where we already have a database
5 of every person who has a DEA license.

6 One of the issues that you find when you
7 start to deep dive into the states and what they
8 have the capability to do and don't do, is you find
9 that there's a distinct heterogeneity around the
10 country of the level of capability of a state
11 medical board.

12 So some very small states have less
13 sophistication at the state medical licensing board
14 to set up a unique database of people to do this.
15 I mean, there are a couple of states that I've been
16 to that literally, it's a hard drive where they
17 have the list of their people. It's not even an
18 Access database. It's an Excel spreadsheet where
19 they have all of their providers who have a license
20 to practice in the state.

21 They're not going to be able to stand up a
22 REMS program and be able to maintain that, so that

1 we can know that people are doing it, turning it
2 in, and following it. And the locality -- I live
3 in New Jersey, which has now one of the stronger
4 requirements for CEs.

5 So it can be an either or, but there would
6 need to be an undertaking by either the FDA or the
7 DEA to determine which of these courses actually
8 meet the criteria and say it's either you take this
9 one that's provided through the federal means and
10 meets the requirements, or the state ones, which
11 also meet it. But either way, you would have to
12 sign up with that certificate, specifically the DEA
13 website where they already have the database.

14 MS. TOIGO: Thank you. Dr. Norman?

15 MS. NORMAN: I think I'll be in agreement
16 with everyone else. I think it has to be the
17 agencies that authorize providers to prescribe;
18 therefore, the DEA. But I also think that it will
19 have to be a collaborative effort with the state
20 boards, since many of those do require state
21 education on controlled substance for relicensure.
22 So I think it will have to be a collaborative

1 effort.

2 MS. TOIGO: Ms. Leger?

3 MS. LEGER: And I was going to expand from
4 the collaboration perspective. We actually have a
5 model, and PAs are new to that model. It's the
6 buprenorphine waiver, and it's a collaboration
7 between SAMHSA and DEA. I think, again, there's a
8 model that is already in place for physicians, has
9 now been enabled for PAs and NPs, where PAs and NPs
10 who get their buprenorphine waiver training, their
11 information is sent to SAMHSA, who codifies it with
12 the DEA, and then they get their X waiver.

13 So I think that could be a model that you
14 may want to investigate.

15 MS. TOIGO: Thank you. Dr. Harris?

16 DR. HARRIS: So the practice of medicine is
17 regulated at the state level, and as we've heard
18 today, some states have decided to mandate
19 training. And those states, their medical boards
20 or probably maybe some other entity in the state,
21 are managing that.

22 The solution to the opioid crisis is a local

1 solution. We saw that this morning. I'm
2 originally from West Virginia, Mercer County, which
3 is right new to McDowell County, which has been
4 significantly impacted by the opioid epidemic.
5 Recently, I went to the prescription drug abuse
6 summit and heard from folks from Marin County. And
7 I imagine everyone in this room knows how different
8 Marin County is from McDowell County, West
9 Virginia.

10 So the solutions are local. So I believe
11 that if states decide to mandate, they know best,
12 working with their state partners, the state public
13 health department, state medical societies, know
14 best what the needs are for that particular state,
15 and even further down to the local level.

16 So I will continue to say that if there is
17 required training, that should come from the state
18 level, and then the state should regulate that as
19 it regulates the practice of medicine.

20 MS. TOIGO: Thank you.

21 DR. TWILLMAN: I would very much like for it
22 to be a local solution handled by the licensing

1 boards, but I think it's impractical to do that.
2 You're talking about 70 medical boards, 51 nursing
3 boards, 51 dental boards, some unknown number of
4 pharmacy boards, optometry boards, naturopathic
5 medicine boards. It just begins to be too much to
6 manage. And furthermore, I'm not sure what
7 authority any federal agency has to direct all of
8 those licensing boards to mandate this kind of
9 education.

10 I'm not sure that that's the solution that's
11 going to work. I think it does have to be a
12 federal agency. I don't mind it being DEA that's
13 keeping track of that, so long as it's not DEA
14 that's determining the content of the education.
15 As long as it's determined by someone in
16 healthcare, not someone in law enforcement, I would
17 be okay with that.

18 With respect to people not opting out of DEA
19 registrations, I may be wrong about this, and
20 correct me if I am, but I think it's possible to
21 opt out of a Schedule 2 registration only, and keep
22 your Schedule 3, 4, and 5. So I'm not sure that

1 that gets us to the point where we won't have
2 anyone opting out. But to me, it's the best of
3 some non-optimal solutions.

4 MS. TOIGO: Okay. Thank you. Before we
5 move to question 4, is there anybody that wants to
6 add anything on question 3?

7 (No response.)

8 MS. TOIGO: Okay. So we'll move to
9 question 4, and we've got 20 minutes left for the
10 last two questions.

11 Question 4 is discuss which organizations,
12 federal agencies, state medical board, healthcare
13 system, or others, that are best situated to
14 incentivize a voluntary education program?

15 So now we're moving from the mandatory to
16 the voluntary. The last two questions are on
17 voluntary. Which organizations are best situated
18 to incentivize a voluntary program?

19 How about we start down this way this time?

20 DR. TWILLMAN: I think the answer to that
21 depends on what kind of incentive you come up with.
22 Obviously the most powerful incentive for most

1 people is money. So if you're going to go down
2 that route, I'm not sure that we have an agency
3 other than CMS that might be able to do that. And
4 again, that's only going to cover folks who are
5 Medicare and Medicaid prescribers.

6 I'm a little challenged by this because
7 outside of a financial incentive, I'm not sure what
8 other incentives we can come up with. And I'll
9 leave it to the rest of the panel to suggest some
10 things I'm ignorant of.

11 MS. TOIGO: Dr. Harris?

12 DR. HARRIS: So I do agree that it does
13 depend on the program. But in the last question,
14 everyone answered DEA. In this question, I'm going
15 to answer DEA, and I'm going to say would DEA
16 consider a 10 percent reduction of -- I see my DEA
17 colleague looking up when I'm talking about this.

18 (Laughter.)

19 DR. HARRIS: Definitely don't have to answer
20 today -- a 10 percent reduction in registration
21 fees for those who have taken whatever courses,
22 either maybe their state or they can demonstrate

1 some course in that.

2 So for this question I might say let's put
3 DEA on the table here to incentivize those courses.

4 MS. TOIGO: Thank you, Dr. Harris.

5 Ms. Leger?

6 MS. LEGER: I think payers have a big role
7 to play in this. And I know that there are some
8 programs for some of the chronic disease models and
9 how clinicians are able to apply evidence-based
10 practice, and they're able to move the needle in
11 their patient management.

12 I think if you look at the payers who are
13 able to give a better reimbursement rate for the
14 visits, that would be the place to go.

15 MS. TOIGO: Dr. Norman?

16 MS. NORMAN: So I just agree with the two
17 former colleagues up here that I would really like
18 to see that reduction in the DEA fee. If they were
19 to do that, I think that would be a good incentive.
20 And then I agree also with the payers. However,
21 there are some people out there who are not
22 involved in that with their boutique practices or

1 whatever, so they're not involved with insurance or
2 any type of reimbursement plan like that. I think
3 it needs to be an overall organization that would
4 have the power to incentivize everyone.

5 MS. TOIGO: Thank you. Dr. Waller?

6 DR. WALLER: I would say that I did like the
7 idea of the DEA that Dr. Harris had mentioned, but
8 I think it's a combination of the payer and the
9 hospital systems, because hospital systems are who
10 ubiquitously receive money from CMS. So they could
11 be given a bonus on their CMS reimbursements, if
12 they had a certain portion of their medical staff
13 that had taken the CME there. And I know that they
14 have the capacity to do this because it took
15 exactly two weeks for the entire country's health
16 systems to stand up Ebola screening, and we saw
17 entirely two cases.

18 So I think with that, we know that they have
19 the capacity to do this. And the incentive doesn't
20 necessarily need to be to the individual provider,
21 but to the system, and then they can internally
22 incentivize in many different ways for medical

1 staff.

2 Someone who is a medical staff, chief of
3 pain medicine for four years in a large health
4 system, I could not incentivize one person to do
5 anything, but the health system can magically snap
6 their fingers, and a lot of people were standing in
7 line to get stuff done.

8 MS. TOIGO: Thank you, Dr. Waller.
9 Dr. Burns?

10 MS. BURNS: And I agree the comments that
11 have been made. At the national level, there's a
12 lot of focus on public-private partnerships, so I'm
13 hearing payers. I'm hearing DEA. So there may be
14 some opportunity for some collaborations.

15 I would just add for the education
16 component, collaboration among the members of the
17 team, as has been stated will be critical moving
18 forward.

19 MS. TOIGO: Thank you. Dr. Moore?

20 DR. MOORE: Continuing education in
21 dentistry is supported by fees by the dentist to
22 take continuing education. And I think as long as

1 these programs are within the total number of hours
2 that you're required to take, it probably doesn't
3 have a disincentive factor.

4 So I don't think we're -- we don't have
5 hospitals; we don't have those kinds of sources.
6 So I think it is not really a significant problem.

7 MS. TOIGO: Thank you. Dr. Galluzzi?

8 DR. GALLUZZI: I just want to reiterate, I'm
9 in favor of the carrot much more so than the stick,
10 so that the incentivization of getting this
11 training, and ongoing continuing education I think
12 is really where I would like to see this going.

13 I'm not sure. I don't have the public
14 policy background to say that the DEA would be the
15 right place versus CMS. But when you think about
16 interdisciplinary training, I think that CMS would
17 have more oversight for different disciplines, more
18 so than the DEA, a law enforcement agency.

19 MS. TOIGO: Thank you. Dr. Terman?

20 DR. TERMAN: Yes, I am not as excited about
21 the DEA for \$10 getting off of your license fee.
22 I'm not quite willing to get FDA off the hook here.

1 Frankly, I don't think the ER/LA REMS thus far have
2 been a failure. I think they were not expansive
3 enough, and I think they were aimed at the wrong
4 categories of prescribers.

5 Calling a successful completer someone who
6 has prescribed long-acting opioids in the last few
7 months, those aren't the people we're trying to
8 teach. Those are the people that probably aren't
9 going to care about what I have to say.

10 It's everybody else that hasn't been
11 prescribing them and is wondering whether they
12 should, and why would you? Those are the people
13 that we want to teach in the same way that you like
14 to get the medical students fresh. You like to get
15 students in general who don't come in with their
16 own agenda.

17 So when I saw that 400,000 -- did I misread
18 that? Is that right? Does that make sense?

19 MS. TOIGO: They were not completers, but
20 there were 400,000 who --

21 DR. TERMAN: I understand, that took
22 training. And then he tells me that 1.5 million

1 are DEA registrants. I mean, I'm less pessimistic
2 about that. Now, I realize that some of those
3 people took it multiple times and perhaps --

4 MS. TOIGO: Or not prescribers -- it was
5 all -- I think that number was all healthcare
6 professionals.

7 Doris, is that --

8 DR. AUTH: We don't know that gap, the
9 people that started and never finished. We don't
10 know [inaudible - off mic].

11 DR. TERMAN: But they did take it. They
12 signed up for it.

13 DR. AUTH: Yes.

14 DR. TERMAN: Okay. So again, I'm not sure
15 in terms of the voluntary -- if you're not going to
16 make it mandatory, I like what the FDA has done so
17 far. And there's a lot of throwing the FDA under
18 the bus. It's like blaming CDC for Zika virus. It
19 makes no sense.

20 (Laughter.)

21 DR. TERMAN: And there are reasons why we
22 ran into problems with this opiate crisis, and it's

1 because people are not doing good pain medicine.
2 And boy, is it easy to write a prescription and
3 send them on their way. It's not because people
4 wanted to create a bunch of problems with opioids.
5 It's that it's hard to do, and apart from addiction
6 medicine, there's nothing that doctors like to do
7 less than pain medicine, and that's where the
8 connection is, actually.

9 MS. TOIGO: So I'm not --

10 DR. TERMAN: What question did I answer?

11 (Laughter.)

12 MS. TOIGO: No, I just wanted one point of
13 clarification to make sure I understood what your
14 main point was, that you're not going to let FDA
15 off the hook. You think voluntary training is a
16 good idea, but it should be broader than ER/LA
17 opioid analgesics.

18 Is that what you were saying?

19 DR. TERMAN: Correct. That's correct.

20 MS. TOIGO: Okay. I got it. Thank you.

21 Okay. So we've got one question left before
22 we go to questions from the audience. So what I'd

1 like to do is go to the last question, which is
2 describe mechanisms your organization has
3 successfully used or potentially could be used to
4 support prescriber training that is voluntary in
5 nature.

6 I'm going to start with Dr. Waller.

7 DR. WALLER: I'll just get it out of the
8 way. It's like pulling off a band-aid. No, fair
9 enough.

10 So I'm the medical director -- one of my
11 roles is a medical director of an ACO in Camden,
12 and recently we rolled out a plan to expand
13 medication assisted treatment in the city of Camden
14 by paying providers \$500 to take the free 8-hour
15 course, plus write their first prescription. So
16 that's 8 hours and write their first prescription
17 for buprenorphine for a patient, then they would
18 get \$500.

19 Eighty-four percent of the providers signed
20 up for that. I think it's going to end up being a
21 hundred, or pretty close to that, for peer-pressure
22 basis. And that's all voluntary. And \$500 is not

1 enough money to really say that that's a true
2 incentivization. So we may not have to honestly
3 pay that much to get a lot of benefit. But I think
4 the biggest piece was we said, after this, for your
5 first 10 patients, we will have somebody on call to
6 help you, meaning that they have somebody to call.

7 So I can't say whether it was just the \$500
8 or the fact that they feel like somebody's there to
9 back them up. And with AAAP, PCSSO, and PCSSMAT,
10 we have a wonderful number of mentor providers that
11 this already exists nationally that we could tap
12 right into with opioids, because there's already
13 the PCSSO mechanism to tap into for that mentorship
14 that they put together really well.

15 So I think it's doable, but the incentives
16 have to be weighed out. Money's hopeful, but help
17 is I think more appreciated.

18 MS. TOIGO: Okay. Thank you. Dr. Burns?

19 MS. BURNS: From a professional association
20 perspective and specifically for pharmacists, APHA
21 has really ramped up our efforts to train
22 pharmacists in a more integrative approach to pain

1 management. I think I could speak across the board
2 for the organizations, the CE programs that
3 organizations offer.

4 We have really increased the number of in-
5 depth CE offerings, so not just 1 and 2-hour
6 programs, but day-long programs via a pain
7 institute, really to help to drive the message that
8 pharmacists need to be up to speed on the latest as
9 it relates to pain management.

10 The other thing that associations can do is
11 use their communications vehicles to make
12 pharmacists or other healthcare providers in our
13 case, aware of programs that exist, requirements
14 for those programs and so forth. So there we have
15 the opportunity for broad reach using
16 organizational input.

17 MS. TOIGO: Thank you. Dr. Moore?

18 DR. MOORE: The American Dental Association
19 is organized as a national organization, as well as
20 state organizations, as well as local
21 organizations. So when you belong to the ADA, you
22 belong to all three of those organizations, and

1 they all provide continuing education.

2 Clearly, the American Dental Association is
3 really trying to be as proactive as dentists can
4 be. So I think there is going to be lots of
5 programming available, either free or for minimal
6 costs through those organizations.

7 But I think without a mandate, I think you
8 have a situation in our profession where getting
9 trained to do something you do already doesn't make
10 you any more money.

11 Unlike training that you can now use
12 Suboxone and like that, where in fact that adds to
13 your practice, I'm not sure that there is a
14 particularly financial advantage. And I suspect
15 the people who would be involved in an unmandated
16 CE requirement would be the people who are
17 interested in that information and are taking it
18 anyway. I'm not sure if it would really go to the
19 people who we are targeting with regard to proper
20 and responsible prescribing.

21 So I'm kind of at a loss there. Did you
22 hear me kind of say a lot of words and not come up

1 with an answer?

2 MS. TOIGO: No, but I got the difference
3 between what Dr. Waller was describing and what you
4 were describing in the realm of voluntary programs
5 and how appealing they might be.

6 DR. MOORE: People take CE courses to learn
7 about how we can whiten teeth -- there's a money-
8 maker -- or how we can straighten teeth, or how we
9 can fill teeth. I'm not sure that there are those
10 kinds of incentives, inherent incentives, that
11 exist there.

12 MS. TOIGO: Thank you. Those are helpful
13 comments. Dr. Galluzzi?

14 DR. GALLUZZI: The AOA was actually a
15 founding member of the CO*RE initiative, which is
16 an 11-member group and includes Medscape as a
17 commercial partner, if you will. And I have to say
18 having given a number of those lectures over the
19 years, I have been edified with the response from
20 the volunteers who attend the lectures.
21 Admittedly, some of it is arduous. Some of the
22 programs are 3 hours long, and there's a great deal

1 of engagement. I think that that's one of the best
2 things AOA has partnered with.

3 AOA has also developed an initiative and 22
4 of the colleges of osteopathic medicine have signed
5 on in agreement to expand the amount of opioid
6 education at the undergraduate level. There is an
7 attempt to expand it beyond the use of just basic
8 science, pharmacology, and to bring in the other
9 disciplines like psychology, physical therapy,
10 physician assistant studies, et cetera.

11 AOA has also worked with the surgeon general
12 on the Turn the Tide initiative, and with the
13 National Association of Boards of Pharmacy
14 workgroup to assist with education on
15 identification of red flags and interprofessional
16 education.

17 So I think these have been some very
18 successful initiatives, and I hope that we can
19 expand on them and have them grow in the future.

20 MS. TOIGO: Thank you. Dr. Terman?

21 DR. TERMAN: Sure. The American Pain
22 Society will continue to do voluntary education, as

1 we have for 40 years, a multidisciplinary group,
2 including next week in Pittsburgh, our annual
3 scientific meeting, where we'll be describing one
4 of my conflicts of interest, which is \$2 million
5 from Pfizer to fund three major grants on better
6 pain management, none of which involve
7 pharmacology.

8 But to be perfectly honest, our best efforts
9 in educating has been through collaboration, and
10 our outstanding collaborations with CO*RE and the
11 other members there have been very good. Our pain
12 care for primary care conferences with Global
13 Academy of Medical Education have been packed. So
14 we are certainly happy to collaborate with anybody
15 interested in educating people about pain medicine.

16 MS. TOIGO: Thank you. Dr. Norman?

17 MS. NORMAN: So I said earlier that nurse
18 practitioners were lifelong learners, and I would
19 just say that the American Association of Nurse
20 Practitioners is the only national organization for
21 all NPs in all specialties. We serve and support
22 the 222,000 nurse practitioners in the United

1 States.

2 We have offered continuing education for
3 many, many years. We offer three live conferences
4 a year, and then we have a very robust LMS where we
5 maintain 170 to 180 programs in there, and we have
6 educated lots of NPs.

7 At two of our conferences, we always have a
8 pain management track. This year at our Specialty
9 in Leadership conference in September, we'll have a
10 pain management and opioid use disorder track. We
11 always get good attendance for those.

12 At our health policy conference this year,
13 we've also focused on -- actually, the last few
14 years have focused on the opioid epidemic. This
15 past February, we did have the surgeon general come
16 and speak.

17 So we're addressing the epidemic across
18 several avenues and venues. We're, of course, a
19 proud member of the 11-partner interprofessional
20 multidisciplinary CO*RE collaboration. Within that
21 curriculum, AANP has taught or had more than 19,584
22 NP learners.

1 When we look at those, how many of those
2 were licensed to prescribe, 13,760 were licensed to
3 prescribe. Then how many had prescribed within the
4 last 12 months was 5,996 of those that have taken
5 the CO*RE program through AANP.

6 We also offer several other related CE
7 programs, including substance-use disorder for
8 adolescents. We will soon be in partnership with
9 NIDA on another substance-use disorder program for
10 adolescents that will be coming out soon. And
11 again, like I said, we offer a lot of live sessions
12 at our conferences on this topic.

13 AANP also participates on the advisory
14 council for Harvard Medical and NIDA who are
15 creating three 8-hour modules on the opioid topic,
16 and we have already begun to promote that to our
17 members. And then also, we serve on steering
18 committee for the PPCSO and PCCSMAT to influence
19 that, so that we can insure that nurse
20 practitioners are getting the education that they
21 need.

22 Other than that, we serve on a lot of opioid

1 initiatives both at the national and federal level,
2 including the surgeon general, HHS, and others.

3 MS. TOIGO: Thank you. Ms. Leger?

4 MS. LEGER: AAPA has several national
5 initiatives of which one is the opioid epidemic.
6 We actually have on our webpage an opioid page, and
7 it has all the activities that PAs can go to for
8 continuing medical education, of which one of them
9 is the CO*RE REMS.

10 But the other thing that we're doing is that
11 I purposefully placed one of our lectures in
12 Kentucky. Kentucky is the only state of the nation
13 where PAs are not allowed to prescribe controlled
14 substances, and we know that there's a tremendous
15 epidemic in Kentucky.

16 When I placed that course, no one said why
17 are you doing it? And it wasn't because we were
18 not chasing the numbers for FDA at this point in
19 time, because FDA, it's not just the number of
20 individuals who are in the room attending the
21 session; it's the number of individuals who are
22 licensed to prescribe and has prescribed in the

1 last year.

2 Doris has heard me say that over and over
3 and over, that they need to change their
4 definition. But I really felt that clinicians,
5 whether they are prescribers or not, are part of
6 the team that are managing patients who may be on
7 an opioid.

8 NPAs are prescribers in Kentucky of other
9 products, and they manage patients who may be on an
10 opioid. So to tell me that they cannot benefit
11 from an education program because they don't meet
12 the FDA definition, I'm not going to say what I
13 think.

14 The other thing that we do also is that from
15 a legislation perspective is -- Florida was one of
16 the last states that recently enabled PAs to
17 prescribe controlled substances. And I told the
18 Florida chapter that we need to -- what's the word?

19 I'm sorry. I'm thinking in French; one
20 second. We need to leverage education and show to
21 the legislation, to legislators, that PAs in
22 Florida were educated.

1 Before a bill was introduced and passed in
2 Florida, they could prove that they had a fair
3 number of the PAs if Florida had taken the opioid
4 REMS course. And that was, again, without it being
5 mandated, so it was all voluntary.

6 The last thing that I'm going to say is we
7 are continuing to provide other programs. Similar
8 to Anne, we're part of the NIDA CME for pediatric
9 and adolescent substance use. We've collaborated
10 with the Harvard Medical School also.

11 So it's not just REMS. It's just addressing
12 the epidemic in totality, I think is really where
13 we really need to look at, the public health impact
14 of the epidemic on the clinicians and the patients.

15 MS. TOIGO: Thank you.

16 So I'm mindful of time. We're a little bit
17 over.

18 DR. HARRIS: Okay. The AMA is very active
19 in this area. We create our own CME courses and
20 offer these at our two policy meetings per year, as
21 well as our advocacy meeting. We're involved in
22 development of webinars, having national partner

1 calls where we are constantly urging our physicians
2 to enhance our education and training, not only on
3 opioids, but on substance-use disorders and pain,
4 and pain management.

5 We're working on two pilots right now in
6 Rhode Island and Alabama. These pilot projects are
7 toolkits that have many resources on multiple
8 levels, including education and training for
9 physicians.

10 Of course, we have our AMA opioid task
11 force. Many of our partners are in the room,
12 anesthesiology, OAO, ADA, AAFP, addiction
13 psychiatry, ASAM, so we have really elevated all of
14 our courses.

15 We have 200 courses on that website because
16 we had heard that physicians weren't sure where to
17 go when their own specialty didn't offer the
18 courses. So now folks can have that website to go
19 to, and we know that recently over 118,000
20 physicians have taken courses from that. So AMA is
21 very active, and we will continue to be active in
22 making sure that physicians lead on the issue of

1 furthering our education and training.

2 Also, one more thing that I think we should
3 keep in mind as we go forward. This epidemic has
4 evolved, and the factors that are currently
5 sustaining this epidemic are different from the
6 factors that were probably involved.

7 We have to make sure -- I'll just say that
8 we are constantly looking at what we are doing, and
9 evolving with the epidemic, and staying ahead of
10 the epidemic, if you will, for whatever solutions
11 we propose. So I just wanted to make that point.

12 MS. TOIGO: Thank you. Dr. Twillman?

13 DR. TWILLMAN: Of course we would do the
14 same thing that we do with all of our education
15 courses, make them available, our LMS, advertise
16 them widely, have content at our annual meeting.

17 But they might be interested in doing some
18 creative things. It would be nice if we could get
19 a grant that would allow us to give members a
20 discount off their membership fee for the next year
21 if they completed the course.

22 Or maybe since Dr. Terman and I both have

1 psychology degrees from the same fine educational
2 institution, I'd call up APS and say, let's have a
3 competition. Let's see which percentage of APS or
4 AAPM prescribers can take this course and see who
5 wins. And then when APS loses, he'd wear our logo
6 T-shirt at his meeting or something.

7 (Laughter.)

8 DR. TERMAN: No, we'd lose you as a member.

9 (Laughter.)

10 DR. TWILLMAN: But I think doing all the
11 usual things is obvious. I think it's time to get
12 a little bit creative maybe and think about some
13 new and interesting things, too.

14 Questions and Answers

15 MS. TOIGO: So if you all get creative
16 before our docket closes, we'd love to hear those
17 creative solutions to the docket.

18 So I think we've got a little bit of time
19 left for questions, so I'd like to open it up to
20 the meeting participants, if you have any
21 questions. And I'd also like to apologize
22 for -- from having kids who tell me they hold the

1 phone over here when their mother is speaking, this
2 clearly is not how I usually speak. I thank you
3 for bearing with me in not being able to hear
4 completely.

5 DR. HAVENS: I have a comment and a
6 suggestion. Comment is CME has always been a part
7 of licensure, and that's where it should stay.
8 Putting it in the hands of the DEA is putting the
9 fox in charge of the henhouse.

10 By keeping it at the state level with
11 licensure, which even though there might be five
12 different licensure groups, they're doing it
13 already. It's part of their job. Then all the DEA
14 has to do is look to see if that little box has
15 been checked, and then they get their DEA
16 certificate. That's one suggestion.

17 The second thing is that for an incentive,
18 since innocent doctors are being attacked all over
19 this country, make it in these statements that if
20 you take this CME and are taught how to prescribe
21 controlled drugs, they cannot use the CSA
22 illegally, like they're doing now, using that 1304

1 or whatever it is, against doctors. Doctors are
2 immune to prosecution, and you will guarantee that
3 you'll have doctors again treating pain
4 appropriately.

5 We treat pain appropriately as it is. And
6 having our licenses taken away and our lives
7 destroyed for money is not right. And that would
8 be a way of getting people back the care that they
9 have without putting innocent people in prison.
10 Thank you.

11 MS. TOIGO: Thank you. Over here?

12 FEMALE AUDIENCE MEMBER: Yes. Hi. A
13 question that may have no answer. I wonder
14 whether, since there are already 20 some states
15 that have opioid prescribing or pain management
16 prescribing education as a requirement of
17 licensure, is there some way, without creating a
18 new mandate, sort of a new level, a new layer on
19 top of that, that the states could maybe -- we
20 could herd the cats a little bit and create some
21 sort of a standardization across states, so that
22 the requirements don't vary as widely as they do

1 now. I think that's a frustration for us as CME
2 providers, as well as for the people who are
3 learning.

4 DR. WALLER: I think that's a definition of
5 a federal standard. I mean, I'm just
6 saying -- which I agree with. I think that in
7 order to standardize across all 50 states and the
8 territories, because we also have people that are
9 licensed outside of the Continental United States
10 in Puerto Rico and Mariana Island --

11 I mean, there are complicated issues that go
12 along with those. And the big thing is that, yes,
13 there should be a baseline, and if the state meets
14 it, then it seems logical that if the state meets
15 it, that box has been checked. Then the only thing
16 that the DEA does is not say yes or no; they just
17 keep the database.

18 They're not in charge of building the
19 education, making sure that that education was done
20 by that person in that state, but purely just the
21 allocation of those names and the check box that's
22 there, but heterogeneity is a reality, especially

1 the deeper you get into localities.

2 FEMALE AUDIENCE MEMBER: Thank you.

3 MS. TOIGO: Norm?

4 DR. KAHN: Norman Kahn, Conjoint Committee
5 on Continuing Education. First of all, I want to
6 thank the panel. I have two pages of notes. This
7 is terrific.

8 You know, a lot of times people come to the
9 microphone and they pretend to ask a question, but
10 in reality they're making a statement. I don't
11 have a question.

12 (Laughter.)

13 DR. KAHN: I have a really quick statement
14 that I want your reaction to. And I think we have
15 a window of opportunity here with regard to
16 incentives, and that is the Center for Medicare and
17 Medicaid Services is right now writing a rule on
18 improvement activities.

19 You talk about collaborations, there are a
20 number of us in the audience here who are working
21 with them right now on certain kinds of continuing
22 education, fulfilling the criteria for an

1 improvement activity. If it can be shown to change
2 practice behaviors and be related to improved
3 outcomes, this seems to be perfect. This would be
4 a great incentive.

5 MS. TOIGO: So are you asking for other
6 partners to come see you? Is that --

7 DR. KAHN: Sure.

8 MS. TOIGO: Okay. Steve?

9 DR. PASSIK: Steve Passik, Collegium. So
10 continuing on my theme of holding the payer's feet
11 to the fire a bit on this, Fred in his slides had
12 an outcome that would really matter to the
13 physicians I used to practice with, and that is
14 fewer phone calls.

15 So I'm wondering if there's any mechanism
16 that anybody knows of, or could you fathom an
17 incentive that if someone got this training,
18 insurance companies would offer them an opportunity
19 to be exempted from prior auth, not have their
20 judgment questioned quite as often, and not have to
21 be on the phone with the insurance companies
22 constantly if they wanted to institute a certain

1 visit schedule, a certain particular drug, a urine
2 drug test on a particular frequency.

3 Right now, people trying to do that in their
4 practice and trying to -- when I did it, I would
5 say, I want to see this person once a week. I want
6 them to have psychotherapy. I want to do a urine
7 drug test every month. I want my prescribing
8 colleagues to give out only 7 days worth of
9 medicine at a time, and so on, and the answer you
10 got back was, no, no, no, no, copay every time.

11 There are significant payer barriers. So if
12 you really wanted to incentivize people, if there
13 was a way to say if someone was certified in this
14 way, the payers would have to honor it in some way,
15 that would matter to the physicians I used to
16 practice with.

17 MS. TOIGO: Dr. Harris wants to comment.

18 DR. HARRIS: Just wanted to comment that
19 your point about payer barriers is a good point.
20 And I would argue that actually payers need to get
21 rid of those barriers, separate and apart from an
22 incentive from these courses.

1 The good news is I know the AMA has had some
2 conversations. At our task force meeting, we had
3 Blue Cross/Blue Shield. So payers I think are
4 beginning to look at barriers, particularly to
5 medication -assisted treatment, as well as the
6 barriers to the non-pharmacologic alternatives for
7 pain. So that's happening, but they need to do
8 more.

9 MS. TOIGO: Okay. Can you identify
10 yourself?

11 DR. MILIO: Lorraine Milio, Society for
12 Maternal Fetal Medicine. Two comments, questions.
13 One is whether it's incentivized or mandated, my
14 concern is limiting training to people who are
15 prescribing opioids only, because we live in such a
16 fragmented care situation where I'm amazed at how
17 many physicians do not know that they shouldn't
18 prescribe benzos to patients who are on opioids,
19 et cetera. I would encourage us to think about
20 training all physicians who can contribute to the
21 problem and not just those who are prescribing
22 opioids. So that's one question.

1 The second thing is I sometimes feel that
2 this is static, like it's a training module. And
3 it seems that some of the best ways of
4 incentivizing providers is really allowing for
5 ongoing training and the availability of expertise,
6 as I think was presented this morning by Kaiser,
7 and having people accessible who practitioners,
8 whether they're in small groups or a big
9 organization, can contact easily, frequently ask
10 questions, an easy-to-access website, so that if
11 they do training, they know that they are not left
12 alone after that training.

13 MS. TOIGO: Thank you. Last question or
14 comment and then we'll --

15 MR. BRASON: It is a question. Fred Brason,
16 Project Lazarus. And we'll probably discuss this
17 in the next panel, but you as representatives of
18 professional organizations, I ask you this, because
19 you were talking about incentives and -- if you're
20 already doing the practice, what's my incentive to
21 go do more training for what I'm already doing?

22 What if the training had to do

1 with -- because we're already asking them to do
2 mindfulness, and motivational interviewing, and all
3 the other things that they're trying to add their 7
4 to 8 minutes that they don't have time for.

5 But if we wrap this around, and you start to
6 look at it as holistically as the whole practice,
7 how can we show them economically how you can
8 integrate behavioral health into your practice?
9 You can have someone else, the social workers and
10 so forth, doing all of that.

11 We've been able to show that that is
12 economically viable for a practice, so that now
13 they're able to see even possibly more patients,
14 but have the support mechanisms within that
15 practice because of the dual diagnosis or whatever
16 external issues and comorbid issues are going on;
17 that if we looked at training around that also,
18 then I think there would be somewhat of incentive
19 for them to take it.

20 But I'm just kind of presenting that as a
21 question. Your thoughts?

22 MS. TOIGO: Dr. Harris?

1 FEMALE AUDIENCE MEMBER: We agree, but it
2 has to be paid for.

3 MR. BRASON: Right. Well, that's my point,
4 that it isn't easy, but I know in one CMS
5 innovations grant that we had in North Carolina, we
6 were able to show it's economically viable and you
7 can do that kind of care in a general medical
8 practice. You can do the behavioral health, you
9 can do the buprenorphine, and wrap that into all of
10 your services and make it economically viable.

11 DR. HARRIS: Those are the types of best
12 practices that we need to disseminate and share.

13 MR. BRASON: Right.

14 DR. HARRIS: Yes.

15 MR. BRASON: Let's not create another
16 infrastructure and using what we've already got.
17 Thanks.

18 MS. TOIGO: Okay. I think that ends this
19 panel, the health professional panel. Thank you
20 all very much for your thoughtful tones.

21 (Applause.)

22 (Whereupon, at 3:20 p.m., a recess was

1 taken.)

2 State Panel Discussion

3 MR. LURIE: Welcome back. The focus this
4 latter part of the afternoon shifts to the states
5 and what the states can do, should do, might have
6 done. You heard some data this morning presented
7 by Lisa, describing some of the state activities.

8 So I think the purpose of this panel then is
9 to consider some of those state activities and the
10 context of potential federal activities, how they
11 might fit together, how they might be inconsistent
12 with one another, how one might react to the other,
13 and how one might encourage them or discourage them
14 as the case may be.

15 I think what we'll do is I'm going to
16 introduce myself and ask the others in the panel to
17 introduce themselves. And then the last person to
18 my left here is David Brown from the Virginia
19 Department of Health Professions, and he's going to
20 get special treatment, because everybody else
21 you've already heard from before, and he wasn't on
22 the morning panel. So he's going to make some

1 short comments before we jump into the questions
2 themselves.

3 I'm Peter Lurie. I'm with the Office of
4 Public Health Strategy and Analysis at FDA.
5 Joanna?

6 DR. KATZMAN: I'm Joanna Katzman. I'm
7 associate professor at the University of New
8 Mexico. I direct the UNM Pain Center and Project
9 ECHO Pain and Opioid Management. Thank you.

10 MR. BRASON: Fred Brason from Project
11 Lazarus.

12 MS. BECKER: Melina Becker from the National
13 Governors Association.

14 MS. ROBIN: I'm Lisa Robin with the
15 Federation of State Medical Boards.

16 Presentation - David Brown

17 MR. BROWN: I'm David Brown, and I love
18 special treatment, so I'm very appreciative. I'm
19 the director of the Virginia Department of Health
20 Professions. The Department of Health Professions,
21 we have 13 health regulatory boards, including the
22 Board of Medicine, the Board of Pharmacy, the Board

1 of Dentistry, the Board of Nursing. So we pretty
2 much license all the prescribers, and we license
3 all the dispensers, and we also have Virginia's
4 Prescription Drug Monitoring Program.

5 This morning, we've talk about how active
6 the legislatures have been, and I thought I'd talk
7 for a second about some of the things that have
8 happened in Virginia in this past year that really
9 involve prescriber education that were mandated by
10 legislature.

11 The first thing is the Virginia legislature
12 passed a bill this year directing my boss, the
13 Secretary of Health in Virginia, Bill Hazel, to
14 convene a work group to study the curricula
15 involving pain management, prescribing, and
16 addiction in our professional schools in Virginia.

17 It mandated that this would include a
18 representative from every medical school, the
19 School of Dentistry, every pharmacy school, nursing
20 schools, and physician-assistant programs.

21 We've expanded that to also look at patient
22 education with the idea that later on in this

1 workgroup, we'll bring in other professions, again
2 like we talked about this morning, who interact
3 with patients, who may be pain sufferers, and may
4 be on opioid medications, to make sure they can
5 have appropriate input.

6 So that would involve certainly the
7 behavioral sciences, would include physical
8 therapy, other types of professions.

9 The first meeting of this workgroup is going
10 to be May 19th, and we're hopeful that this is
11 going to really lead to what is a real gap, which
12 is the standardization in the area of prescribing
13 and addiction in professional education.

14 The second thing that happened this year is
15 a bill was introduced requiring the Board of
16 Medicine and the Board of Dentistry in Virginia to
17 enact regulations for the use of opioids in the
18 treatment of acute and chronic pain.

19 As part of this, this bill ended up
20 incorporating other bills that would have mandated
21 limits on prescribing. In other words, the
22 legislature was persuaded, since the Board of

1 Medicine has now been directed to do regulations,
2 let's go ahead and have them incorporate -- have
3 professionals, as opposed to legislators, look at
4 what those requirements should be.

5 So the Board of Medicine convened a panel of
6 experts in the area of addiction and pain
7 management that pretty much looked at the CDC
8 guidelines, and the treatment of chronic pain, and
9 other evidence-based practices to create
10 regulations.

11 I would like to argue that these regulations
12 in some way are a way of educating all prescribers
13 in Virginia, anyone who prescribes opioids, as to
14 what the best practices are. Certainly a part of
15 what we want with education is for all prescribers
16 to understand what the CDC guidelines are, and
17 these regulations are based on that.

18 Now, that's not everything that are in these
19 regulations. Some of what's in these regulations
20 is exceedingly obvious because what they're
21 designed for, in part, is to give the board a clear
22 and unequivocal regulatory handle on pill mills; in

1 other words, practices which aren't doing what are
2 just normal practices in any healthcare field in
3 terms of examination, history taking, the
4 rudimentaries of good patient care, which don't
5 happen in a practice which is seeing patient after
6 patient after patient and simply writing a
7 prescription.

8 These regulations include things such as a
9 7-day limit on prescribing of opioids for acute
10 pain, but because they were crafted by physicians
11 they include unless extenuating circumstances are
12 clearly documented in the patient record. So they
13 really allow for good practice of medicine without
14 having the hard limits that a prescribing bill
15 might have had.

16 They also require, for example,
17 co-prescribing of naloxone if certain circumstances
18 are met, such as an MME over 110, or concomitant
19 use of benzodiazepines, a history of drug abuse, or
20 overdose.

21 In addition to this providing, I like to
22 think education on best practices. I also think

1 that these type of limits at the front end of
2 prescribing is what we really need to do to really
3 stop people from entering the pipeline of
4 addiction.

5 I think this morning Dr. Woodcock really
6 talked about that this epidemic is fueled by
7 legally prescribed opioids. And if we can get our
8 prescribers to understand appropriate use, I think
9 we can end up in an environment where we have fewer
10 people entering and either having a well-stocked
11 medicine cabinet because they didn't use them, or
12 developing a dependence or an addiction because
13 they've filled the entire prescription.

14 Also, these regulations support people
15 providing acute care, emergency physicians in the
16 sense that they clearly give someone the ability to
17 say, I'm sorry, I can't write you more than that
18 because these are the regulations I have to
19 practice under.

20 The concern we have is concern that's been
21 addressed here numerous times, which is will
22 prescribers opt-out rather than -- will they see

1 these regulations to be cumbersome and opt-out of
2 treatment of patients who may be stable and may
3 have had ongoing opioid use in a way that's
4 effectively managed their pain, and what happens
5 then? And do we inadvertently have an increase in
6 deaths if some of those people end up moving
7 towards the street for their medications?

8 DR. LURIE: Okay. Great. Thank you.

9 Now everything's fair. Thanks, those are
10 very helpful comments.

11 I'm going to start with the following
12 question, not on the slide, and it's a question to
13 each of you.

14 All of you are involved, to one extent or
15 another, in state activities related to continuing
16 education on opioids or pain for physicians and
17 other prescribers. Under what conditions would you
18 conclude that what the state was doing was
19 insufficient?

20 Is that clear? What would lead you to say
21 that what we are doing at the state level is not
22 enough and we need somebody to help us out? How

1 would you go about answering that question?

2 Because what we've heard, Lisa, from you is
3 that 29 states are taking a stab at this. Right?
4 So how might some of those 29 states say that's not
5 enough? Might some of the 21 other states
6 acknowledge that they haven't so far done anything?

7 MS. ROBIN: Well, I would like to comment on
8 that. I'll start out by saying we had just done a
9 recent survey of all of our state medical and
10 osteopathic boards to really identify what their
11 priorities are.

12 Well, opioid prescribing was number two of
13 everything that's of concern to state medical and
14 osteopathic boards. This is clearly an area that
15 they wanted to be an active participant. I think
16 things vary from state to state as far as capacity
17 and resources, but I would say a couple of things.

18 I think one thing that we are seeing are the
19 use of guidelines, and now we have our new
20 guidelines because I think that they're very good.
21 We had a very broad based group of folks working on
22 them from the regulatory boards, from CDC, FDA,

1 AMA, AOA, and I think we have a document that
2 really sets that baseline as a good practice, as
3 you were talking about in Virginia, these type of
4 things that would cross all specialties.

5 I would just encourage all states to look at
6 how they can implement some sort of guidance
7 document and guidelines, whether they do it by
8 regulation or do it by guidelines, and then really
9 get it out to -- because if physicians and other
10 health professionals practice within those
11 guidelines, then certainly it would be applied
12 across the health professions.

13 I think that goes a long way because you can
14 use them in two ways. You can use them to educate,
15 and then you can also use them to help evaluate
16 care. So clearly, you have two levels -- you have
17 some well-meaning professionals that need to come
18 up to speed, then you have that all the education
19 in the world not's going to make a difference. But
20 I think that that's a good start.

21 There are certain reasons, whether it's
22 resources, which I would say that that is less than

1 just the political environment and the support that
2 they may or may not get from their legislature and
3 the authority that they have within the state to
4 implement some of the guidelines.

5 So I don't know as far as resources, from a
6 federal perspective, what they can do to provide
7 those resources. But to support those, I think the
8 use of grants is great. We've worked with SAMHSA
9 in the past to be able to provide education at the
10 state level and regional level, so you can look at
11 that local -- and the needs are different,
12 different populations of people.

13 The other area I think is data. I think we
14 are talking about looking at education and
15 mandating education, voluntary or not voluntary. I
16 would say that's just one piece. We have the
17 ability now -- we have data from so many sources,
18 we should be able to identify those populations
19 that need specific training, education, or other
20 resources to better take care of their patients.

21 DR. LURIE: Okay. Who else would like to
22 comment?

1 MR. BRASON: I'll comment. I think one of
2 the problems that we're seeing about what's missing
3 is everybody talks about the opioid epidemic, so
4 states who look at legislating, mandating
5 education, mandating prescribing, most of the time
6 is based on we have to stop the epidemic.

7 Are they really looking at it from are we
8 bettering best practice, or are we just doing
9 limits on that practice to ensure that there's no
10 diversion and the like, which to me, creates more
11 opt out rather than opt in.

12 I'm always very careful about -- I don't
13 want a legislator telling my doctor how to treat
14 me. So I think we have that, and part of that's
15 media driven and all of the above. I'm saying that
16 generally, not for every state, but I know in some
17 states, because I'm been in enough of them, it is
18 basically -- it's a move and a measure in order to
19 stop the opioid epidemic, rather than what is best
20 care, best practice for the patient of what their
21 need may be. And I think that's part of some of
22 the missing element that we have.

1 DR. LURIE: Let me ask you about that. One
2 reason a person might say there's no need for
3 federal intervention is because, A, there's a lot
4 of education out there. And we've heard today
5 about all kinds of -- much more than I ever knew
6 about, going on at the state level, private
7 providers, et cetera, very diverse in FDA's REMS
8 program.

9 Are we at a stage of the epidemic that we
10 can say that the level of education being provided
11 is commensurate with the epidemic and its
12 direction?

13 MR. BRASON: It's much greater than what it
14 was. As I said earlier today --

15 DR. LURIE: The education level?

16 MR. BRASON: Yes, the education. In the
17 four years that we were doing statewide in North
18 Carolina, again, we had to initially push the
19 education. Now they're pulling the education. So
20 I think that tide has turned, so that if all of the
21 organizations that were up here and everything that
22 they're presenting, I think that is meeting a

1 greater part of the need that might prohibit
2 federal intervention as long as there's validation
3 in every state that it is happening.

4 DR. LURIE: What do we do about the 21
5 states that don't have anything?

6 MR. BRASON: That's my point. They have to
7 do something, but that doesn't mean that they have
8 to mandate. If a state can say, okay, we know that
9 this is occurring with all our professional
10 organizations, the medical board, the licensing
11 board, and all of that is laid out, and they're
12 showing that the vast majority of their
13 practitioners, nurse practitioners, PAs, everybody,
14 are engaged in that in whatever infrastructure
15 they're using, rather than mandating from the
16 legislature, then I think they're meeting the need.

17 MR. BROWN: I would comment that of the
18 states that have mandatory CE, I'd be skeptical
19 that all of that is meaningful. And I'll say that
20 because I think Virginia's is not. Virginia
21 requires every two years a prescriber to get two
22 years of continuing education in a fairly broad

1 category. Doesn't say exactly where; it doesn't
2 say exactly who provides it. It has to be
3 category 1 CME credits. That is a pretty small
4 amount of education, and we haven't necessarily
5 targeted what we need.

6 Looking at the bigger picture of who ends up
7 coming before licensing boards, I think that on
8 this issue, my impression -- and there's no data to
9 really back this up -- but my impression is that
10 prescribers who practice for the big systems, kind
11 of like the Kaiser presentation earlier today,
12 those systems are helping to make sure that they
13 are well educated.

14 In all of our boards, disproportionately
15 practitioners in small practices or solo practices
16 are the ones that come in. And on opioid
17 prescribing, they kind of come in, in two different
18 paths. They come in on the path where they have
19 not kept up their education. They're doing what
20 they've been doing for years with patients for whom
21 they've been prescribing this way. And they
22 probably learned to prescribe because when they

1 were a resident, this is what the chief resident
2 did, or this is what the attending did.

3 Then you have the prescribers who are
4 knowingly making a lot of money by violating the
5 law. So you're not going to reach them anyway, but
6 we need to find a way to reach the prescribers who
7 aren't part of the big systems, who are receiving
8 the education, but are part of the smaller
9 practices and smaller systems that may not be
10 getting it as part of their credentialing. And for
11 that reason I think having a more structured
12 program could be beneficial.

13 DR. LURIE: Joanna, what can you tell us
14 about an experience in New Mexico that might be
15 like that?

16 DR. KATZMAN: I can tell you that experience
17 in New Mexico has really been -- there has not been
18 a chilling effect with the mandated pain and safe
19 opiate prescribing education in the past five, six
20 years. It's now an audited program, and all the
21 clinical licensing boards, meaning 10 percent of
22 the clinicians are audited. There's been no

1 chilling effect as I said.

2 As Lisa has alluded to and so has Peter,
3 there are very different requirements among the 29
4 states who now do require some pain CME, and it is
5 very different among states. Some require pain for
6 certain clinicians, and not others. Some require
7 pain in end of life. Some require pain just if you
8 have a pain practice, and some not others.

9 I think if there was a way to create a
10 common denominator among the states -- I don't
11 think it's going to be easy, but I especially think
12 if we could get the other 21 states on board with
13 some key leadership from Lisa's shop creating the
14 CO*RE curriculum with educating about screening for
15 opiate addiction, non-pharmacotherapy/
16 pharmacotherapy related to non-opiate management,
17 all of the good things that we've talked about, I
18 do think that a local solution is the optimal way
19 to go.

20 There are huge cultural differences across
21 this country, whether or not you're teaching
22 clinicians how to take care of their patients in a

1 rural setting, in an urban underserved setting, in
2 a setting with predominantly Hispanic population,
3 in a setting with predominantly African Americans
4 or American Indians, there's huge cultural
5 differences.

6 I think if we go to the DEA checkbox, it
7 would have to be all by Schedule 2 through
8 Schedule 5; that would work as well. And I think
9 that the issues there would be just actually as
10 difficult and may take just as long. I do think
11 ultimately it is going to be more optimal to have a
12 state solution. That's just my thinking.

13 DR. LURIE: Let me push back on that for a
14 second. You point to various -- I don't want to
15 call them unique, but specific circumstances that
16 exist in New Mexico, and those are undeniable. But
17 the question in deciding whether or not to have a
18 national standard, in part, seems to me is whether
19 or not those differences are so substantial that
20 you might produce a wholly different curriculum in
21 a different place.

22 I mean, do you think that's the case?

1 DR. KATZMAN: No. I apologize, Dr. Lurie.
2 That's not what I'm saying at all.

3 DR. LURIE: Okay.

4 DR. KATZMAN: What I'm suggesting is
5 creating a curriculum, a national curriculum that
6 the states would adopt that would be a common
7 denominator for all the states, but that there
8 would be flexibility, wiggle room, to incorporate
9 components of cultural sensitivity for different
10 patient populations that might be seen in some
11 states or more than other states, where the
12 clinical licensing boards had relationship with
13 their clinicians.

14 What I know from working with Project ECHO
15 for seven, eight years now, is that clinicians who
16 come for training, they're much more likely to come
17 to you if they know you. If you're going to take a
18 training with a checkbox with the DEA, you're not
19 going to nearly be as invested in what that
20 training is, whereas if you're in your home state
21 taking a training, you might get the training in a
22 different state related to pain society, your

1 addiction society, the AMA, AAFP.

2 That's great because it relates to you. But
3 if you're getting it from your home state, it means
4 something more to you, and that's just my feeling
5 about it, the local solution.

6 DR. LURIE: Let me push back on even that,
7 though, since I seem to be making a habit of
8 pushing back. Do you think the physicians even
9 know, in general, where the education comes from?
10 Do they even know who's requiring it? Do they know
11 who laid out the blueprint for it?

12 They certainly don't take it in the state,
13 necessarily in the state, where they licensed. In
14 fact, they typically head to Hawaii as far as I can
15 tell, or if they have good judgment, New Mexico.
16 But is there even their identity at the local level
17 along the lines that you're describing?

18 DR. KATZMAN: Well, my hope is that within
19 the next five, six years when pre-licensure
20 education catches up to where we are right now with
21 the epidemic, with medical schools, pharmacy
22 schools, dental schools, and nursing schools, my

1 hope is that this conversation won't be as critical
2 because we are not going to be teaching so many
3 clinicians who are so delinquent in their
4 post-licensure education in pain and opiate
5 management because they will have gotten it in all
6 of their medical education, which by the way is
7 delivered at a local level as well.

8 I think either solution is fair. I just
9 think that it's been successful locally in New
10 Mexico, and I think it can be successful locally
11 elsewhere.

12 DR. LURIE: Melinda? You haven't had a
13 chance to jump in yet.

14 MS. BECKER: Sure, yes. I think that we
15 would certainly agree that a locally driven
16 solution is typically ideal and certainly ideal in
17 this situation. As Lisa outlined, states are
18 increasingly working through their medical and
19 other licensing boards to establish these types of
20 education and training requirements.

21 I think I mentioned earlier that NGA last
22 year expressed support for the idea that there

1 would be a national requirement tied to DEA
2 registration. But I think certainly resources and
3 some sort of national standard being developed at
4 the federal level that states could then adopt on
5 their own and tailor would also be very welcomed.

6 DR. LURIE: I know in the past, the federal
7 government has put out model acts. I know the
8 model Drug Paraphernalia Act is the one I'm most
9 familiar with. That's I suppose, a possibility,
10 and people could adopt it to the extent they did.

11 I think we're seeing from a FDA, the
12 beginnings of an initial blueprint, and now a
13 revised blueprint, upon which, as was pointed out,
14 we'd love to receive comment. I'm not hearing a
15 lot of disagreement about the blueprint. We
16 haven't gotten the comments into the docket yet,
17 and I'm sure there'll be nuances. But are we at a
18 place now that people, generally speaking, agree on
19 what ought to be the contents of an educational
20 program? You want to take that, Lisa?

21 MS. ROBIN: I can. I'm not sure. I don't
22 think one course and one size fits all makes sense.

1 I think it loses its meaning and that it needs
2 individual physicians and professionals that
3 prescribe having their self-assessment data to know
4 where their gaps of learning are. I think that's
5 the way we need to go.

6 I do, however, firmly believe that there is
7 a basic set of good practice that goes across all
8 specialties, and that that certainly could be a
9 national standard, and I think that that's the
10 direction that we're going.

11 I think that we have to be careful also that
12 you have all of these different requirements. Not
13 only do you have requirements for the mandated CME
14 from the state, which vary. You also have 24
15 states that have a state-controlled substance
16 regulation. Texas is the Department of Public
17 Safety. Some states have tied education to that
18 registration.

19 Then you have the systems, and they're going
20 to have requirements for their own medical staff
21 privileges, and you're seeing more and more -- now
22 we're to the point I think more than 50 percent of

1 physicians are employed, which is of benefit,
2 because you're exactly right. When we look at
3 disciplinary data, the people that get in trouble
4 for -- I'm not talking about the criminal behavior,
5 but otherwise, are really practicing in more of an
6 isolated area. They don't have that support. They
7 don't have the toolkits to be able to have
8 their -- they can't compare themselves with their
9 peers and all of those questions. And then you
10 have a good number of physicians that are licensed
11 in multiple states.

12 So that's another thing that would drive a
13 national standard. You have 6 percent that have
14 licenses in three or more states. So you're
15 getting up to 20 percent of physicians in the
16 country, and now with telemedicine, that is only
17 going to grow. And they have different renewal
18 requirements in all those states.

19 So I think that an education -- and I think
20 that we are moving in that direction. And I'll
21 just add one thing.

22 There's a tri-regulator collaborative of the

1 Federation of State Medical Boards, the National
2 Council of State Boards of Nursing, and the
3 National Association of Boards of Pharmacy. We
4 have been, for just the last few years, been
5 meeting. The leadership's been meeting. But this
6 year in July, we're having a conference, and the
7 whole conference is exactly focusing on how we can
8 address this.

9 These are the forums where you have all of
10 the state boards, various boards represented, that
11 you can look at can we come to an agreement on a
12 way to whether it's voluntary or mandated. But if
13 it becomes the standard of care, I think that's
14 going to drive it.

15 As I said, state medical boards, without
16 mandating can still mandate because it's considered
17 professional conduct that you are competent to
18 treat whatever condition that you're treating. I
19 mean, it's affirmatively stated in our new
20 guidelines. So it's the responsibility that
21 lifelong learning is part of their responsibility
22 of good practice.

1 So I think that it's moving in that
2 direction without a mandate. I am really more of a
3 carrots person as well, but I think that we can
4 move in that direction. But I do firmly believe
5 that that needs to happen at the local level for it
6 to be well-received, otherwise, if it's a checkbox
7 on the DEA registration, I'm not sure how
8 meaningful and how engaged the individuals will be
9 in the educational programming.

10 DR. LURIE: Okay.

11 MS. BECKER: Can I just add something
12 quickly?

13 DR. LURIE: Yes, please.

14 MS. BECKER: I just want to draw a parallel,
15 and I'm curious if others think this is relevant,
16 but thinking about the CDC's weird prescribing
17 guideline released last year, a voluntary
18 guideline, sort of a national standard, and
19 thinking about how states have used that to update
20 their own guidelines or develop new guidelines, as
21 we're thinking about is there some national model
22 or curriculum that could be put forward and how

1 states might use that going forward.

2 I think we've seen some examples of how
3 states have reacted to the guideline, but I'm not
4 sure that there's been necessarily a lot of -- I
5 mean, others may know more, but I don't know that
6 there's necessarily been a lot direct action on the
7 part of states in response to guideline.

8 MS. ROBIN: I think it's a huge topic of
9 discussion among the medical boards. You see it on
10 their agendas. I do think that the
11 guidelines -- and now that we're looking across, a
12 number of people are developing guidelines. There
13 is a movement to make those all in alignment. We
14 were really careful with ours, that they are
15 aligned.

16 So I think there are certain -- you leave
17 enough room for states to be able to adjust. We
18 don't have hard stops recommended. But I think
19 that that really -- those type of guidelines,
20 that's the basis of your national standard. And I
21 think you're seeing those CDC guidelines quoted and
22 used by medical boards I know as they're looking at

1 cases, because I hear them quoted over and over
2 again.

3 MS. BECKER: Yeah. And it certainly
4 inspired some of the statutory limits, I know. But
5 sorry. Go ahead.

6 MR. BROWN: If I could comment, certainly
7 the CDC guidelines were the basis of the
8 regulations that the Board of Medicine in Virginia,
9 Board of Dentistry in Virginia created. But at the
10 same time, there's another agency, the state
11 Medicaid agency in Virginia has embarked on an
12 effort to influence prescribing behavior through
13 its pre-authorization process, and they also used
14 the Board of Medicine guidelines and the CDC
15 guidelines in their process.

16 Specifically, they do things like if it's a
17 non-opioid, no pre-authorization. If it's a
18 short-acting opioid for less than 14 days, no
19 pre-authorization. And then the authorization form
20 itself tracks the CDC guidelines. So the
21 authorization, the person is attesting that they
22 have co-prescribed naloxone if there's a

1 concomitant benzo use, or that they have followed
2 other parts that are in those guidelines.

3 What's come out of that, they have great
4 data on how they've had about a 30 percent decrease
5 in the number of pills prescribed in the first
6 quarter since this was enacted. But at the same
7 time, the number of patients receiving a
8 prescription only went down like 15 percent.

9 So in other words, it wasn't a matter of
10 people being cutoff; it was a matter of prescribing
11 behavior changing. And my personal opinion is in
12 Virginia, this is going to spread beyond Medicaid
13 because at the end of the day, Medicaid saves money
14 doing that.

15 So I think that's going to be attractive to
16 other health plans to look at this as a mechanism
17 for good practice using the CDC guidelines and at
18 the same time saving money.

19 DR. LURIE: Another reason why one might
20 prefer the state-based solution would be if the
21 epidemics were very different from one another.
22 One's got a methamphetamine epidemic, one's got a

1 large epidemic, one's got a small one, one's got
2 heroin.

3 Does anybody on the panel think that the
4 epidemics are different enough from state to state
5 that that in and of itself justifies a state-based
6 solution?

7 MR. BRASON: There are two ways to look at
8 that. If you're looking at strictly from a
9 prescribing level and making opioids available and
10 that is the culprit of the epidemic, or you look at
11 social determinants of poverty, trauma, all of
12 those factors that lead to coping mechanisms that
13 lead to substance use, those are different in
14 various population groups in various states. So
15 that convolutes the question in that to be able to
16 answer.

17 I think states know themselves the best.
18 You asked the question earlier, do people really
19 know where their curriculum is coming from, who's
20 doing this? I'd say, yes, they do. There's a
21 handful. You've either got your health system
22 doing it. You either have a few universities.

1 People become accustomed to who they go to for
2 their CMEs and for their education outside of their
3 professional group, so that I think helps.

4 I think some of the REMS that have been
5 brought forth and made available already, that
6 question's true. I don't know who's doing this. I
7 just know that it's available. I'm going to this
8 conference. They're going to give me 8 hours, but
9 I have no clue who's doing it.

10 So how much of that really tracked into
11 general practice, I don't know, but I know from the
12 local level, it does track into general practice.

13 DR. LURIE: Just a follow-up on my question.
14 What is there about the North Carolina, since
15 that's where you're from, opioid epidemic and
16 related prescribing issues that would be so
17 irrelevant that you wouldn't mention it in New
18 Mexico? Could there be anything like that?

19 MR. BRASON: Yes, because we have that from
20 certain counties in North Carolina. "Oh, we've
21 only had two deaths. What are you talking about?
22 There's no issue here." And then we have to show

1 them, yes, there is, because they're not looking at
2 everything.

3 So I think you would have that. I know from
4 just with Indian Health's --

5 DR. LURIE: But those folks are wrong
6 though, right?

7 MR. BRASON: Right. Right, but --

8 DR. LURIE: There may be disagreements about
9 certain facts, but we deal in actual facts, not
10 alternative ones. So if they're not right about
11 that, then okay, I want to know about something
12 that's factually different that would --

13 MR. BRASON: Yes, like Indian Health
14 Services, I've worked with enough reservations that
15 some, "We don't have an opioid problem. It's all
16 methamphetamine." It's just not evident on the
17 opioid side, but look at our methamphetamine
18 problem and it's huge. Therefore, it doesn't --

19 DR. LURIE: So would you not mention heroin
20 to them?

21 MR. BRASON: I'd mention everything to them.

22 DR. LURIE: Right.

1 MR. BRASON: Yes. Yes.

2 DR. LURIE: Joanna?

3 DR. KATZMAN: I would say that I think what
4 you're asking is a little bit different, Dr. Lurie,
5 in that I would pose it like, of course there are
6 going to be differences among states that require
7 some cultural sensitivity and some flexibility
8 among states. But by far and away, there is going
9 to be a common curriculum that would cover all
10 states.

11 Of course every clinician who has
12 prescribing authority and even clinicians perhaps
13 that don't have prescriptive authority, nurses and
14 the healthcare team in general, need to have
15 training in the core content areas that we've
16 talked about many times. I do think it is
17 important that at the local level, people go to
18 conferences together. The five of us might go to a
19 conference together on a Saturday morning. If it
20 was a DEA thing or a REMS thing where you're at a
21 conference, you might not go with a friend.

22 Also, who you're getting the training from

1 locally, you might know the speaker. We've shown
2 this over and over again in many studies with ECHO,
3 many learning studies, with a learning curriculum
4 and education learning loops and feedback, who you
5 get the curriculum from counts. Who you get the
6 curriculum from matters. You can contact that
7 person. You can ask them a question.

8 Those are differences at the local level.
9 But I do agree with you, Peter, that by far and
10 away, the content is going to be exactly the same.
11 There are going to be little differences here and
12 there.

13 MR. BROWN: If I could just briefly comment,
14 I agree that the content can be the same for
15 different states. I don't think the differences
16 are so much between states as within a state.
17 Certainly in Virginia, southwest Virginia where the
18 opioid deaths are worse, it's almost entirely
19 prescription drugs. If you go into Tidewater and
20 parts of Northern Virginia, it's heroin. And that
21 does mean that there's some tailoring of education
22 that can occur within a state.

1 DR. LURIE: Okay. Lisa?

2 MS. ROBIN: I just wonder, if looking at the
3 presentations we heard this morning, and then also
4 looking at the states that have shown some pretty
5 significant progress of late, they all have -- it's
6 not just one program. It's not just CME. And
7 there are many different learning modalities and
8 individual coaching.

9 It seems like that's where the success is
10 going to lie, versus one curriculum for one
11 delivery, means I don't know how effective that -- and I
12 think we just need to be a little more open. And
13 we should have the ability to have -- I mean, I
14 think that there is some basic principles, but then
15 on top of that, there are different groups of
16 healthcare professionals that have different needs
17 and different levels of need of training.

18 I think we should be able to -- I can't
19 imagine that if we're able to use our
20 resources -- I know many states are using
21 prescribing data and other things to identify who
22 those people are that need -- they may need some

1 intervention, may need individual coaching.

2 I think if it's left to the local level,
3 there are medical boards I know that do that to
4 some degree. They identify people working with
5 their PDMP data. They go, and they will travel to
6 southwest Virginia and have individual meetings, if
7 you will.

8 So I think we just have to cautious about
9 that. Then also the ability to repurpose whatever
10 type of education that they are continuing
11 professional development, that they are
12 participating in, should be able to meet the needs
13 on all these different requirements that you may,
14 however, whatever we wind up with, whether it's
15 mandatory, DEA, or state level, to make it less of
16 a burden. I think that that's something that we
17 really have to be cautious about.

18 DR. LURIE: Another dimension to this debate
19 is the mandatory, voluntary part, right? It tracks
20 to a degree with the federal/state in some respects
21 because you might implement -- we might be more
22 tempted to put something in mandatorily if you

1 thought it was more serious. And the same thing
2 might be true, that it might be a criterion for
3 federal involvement if you thought the problem was
4 more serious. On the other hand, if you thought
5 the problem was going away, then you might be
6 willing to wait.

7 Are there folks on this stage who feel that
8 the current level of education is adequate, looked
9 at nationally? Do we feel that we're currently in
10 a place that we can look at what we have, either in
11 terms of the content or in terms of the extent of
12 it, or in terms of its dissemination throughout the
13 medical prescribing community, that we're satisfied
14 right now?

15 Is anybody happy?

16 MR. BROWN: No.

17 MS. ROBIN: No.

18 MS. BECKER: No.

19 MR. BRASON: Adequate in what way? I mean,
20 adequate to meet the need? Because I think there's
21 a great deal out there on prescribing, but how much
22 is out there on actual pain management that

1 actually can even transfer to -- there's nothing
2 else available but me writing a prescription.

3 DR. LURIE: No. I don't think there's a
4 problem of availability. What I feel like I've
5 learned from this meeting is that actually there's
6 a ton of stuff out there. There's a ton of stuff.
7 There's a choice. You can get bad [indiscernible]
8 education, and you can get it in Hawaii. I mean,
9 there's a lot of choice.

10 I don't think -- you can quibble its content
11 for sure, but I'm asking is the current level of
12 physician education on this question, satisfactory?
13 I hope that's the question you answered. But
14 that's what I mean by that, Fred.

15 MR. BRASON: Okay. All right. I'd say no,
16 also, because it hasn't reached everybody who needs
17 to be reached yet.

18 DR. KATZMAN: Same.

19 DR. LURIE: What about the question
20 of -- within a state, one of the things that I've
21 also looked at, as you have Lisa, some states have
22 requirements for all prescribers and some have for

1 controlled substances prescribers only.

2 Do people on the panel have a view on that?

3 Because that is an area of inconsistency between
4 states. Again, a criterion, if you ask the Supreme
5 Court, when does the Supreme Court step in at a
6 federal level? It steps in when there's a split in
7 the circuits. We have a split in the circuits
8 here. Right? Half the states don't have anything,
9 and within the other half, there are very large
10 differences. That can be a criterion.

11 Do people have a view on that? Is focusing
12 on the controlled substance prescribers sufficient
13 or is this -- I suppose it depends on what this is,
14 but I guess the packet of pain and opioid. Let's
15 call it that packet.

16 Is it something that we can cabin off just
17 for the controlled substance prescribers, or is it
18 really for everybody?

19 MR. BROWN: I'll just agree with the point
20 Fred brought up a little while ago, which is I
21 think that as a society, if we're only focusing on
22 prescribers and what they do, and we don't figure

1 out a way to address the socioeconomic factors that
2 are driving some communities to be
3 desperate -- suicide, methamphetamine,
4 alcoholism -- it's just going to be whack-a-mole.

5 To that degree, just focusing on
6 prescribers, I think it's important to do. I think
7 it's a good first step. But in the long run, if we
8 don't bring in behavioral health and other
9 healthcare providers, if we don't extend it to
10 social services, to the court systems, and if we
11 don't have -- I mean, the only -- if I look at
12 Virginia, the things that give me hope are
13 communities where they've formed effective
14 coalitions that involve healthcare, involve social
15 services, involve the courts, involve criminal
16 justice. Those are places where you can actually
17 see differences being made.

18 DR. LURIE: That brings up another question.
19 I think everybody on the panel would agree that
20 education on its own is insufficient. In fact, I
21 think everybody in this room would agree to that.
22 You need a multicomponent, comprehensive approach.

1 I think everybody will agree, whether you're
2 getting into much more elaborate approach, and not
3 to negate it, but I think in terms -- most people
4 would say a bit of PDMP, a bit of methadone
5 treatment, a bit of what have you, bit of
6 education, bit of DUR. Between those things, you
7 might come up with a reasonable package.

8 We heard some conversation this morning
9 saying education, it probably doesn't even work.
10 And Joanna, you've got some data that -- Fred, both
11 of you really -- that argue otherwise. But my
12 question to you all is how sure do we need to be
13 that education is effective before we require it?

14 What is the evidence bar? Do we need a
15 randomized trial that shows reductions in
16 overdoses? Do we need just a well-intentioned,
17 good argument put together by educators? Or is it
18 someplace in between?

19 How do we decide how much evidence we need
20 before we go about mandatorily requiring something?
21 Joanna?

22 DR. KATZMAN: Well, first I might add -- do

1 you mind if I speak, Fred? First, I might add that
2 education through other venues, in addition to our
3 UNM courses, our Indian Health Service virtual
4 courses, through are Project ECHO courses for which
5 we've given, many have shown significant increases
6 in knowledge, self-efficacy, and practice change
7 over the past eight years. And this has been
8 related to chronic pain and safe opioid management.
9 I think education definitely does work.

10 Also, the VA has published several papers on
11 their SCAN ECHO, and this is voluntary on their
12 SCAN ECHO pain telemetry program, showing that
13 their education program does work. It also drops
14 opiate prescribing, saves a lot of money, and
15 increases prescriptions for naloxone and other
16 benefits. And I think also Dr. Good showed that as
17 well. And again, that's an organization, not a
18 state level.

19 So I'll just leave it at that. I do think
20 that education does work. That's why we all go
21 through -- we all end up where we're ending up
22 after our post-licensure training.

1 MR. BROWN: I think the fact that we're in a
2 crisis, that this is an emergency, the Health
3 Commissioner of Virginia declared a public health
4 emergency, means you don't really have the luxury
5 of waiting when you have common-sense solutions
6 that are not that burdensome or expensive to try.

7 DR. LURIE: You're saying it seems to make
8 sense. If there's no reason to expect an adverse
9 consequence --

10 MR. BROWN: Yes.

11 DR. LURIE: -- that those things lower the
12 evidence bar. Is that a fair statement?

13 MR. BROWN: Yes, in a state of emergency.

14 DR. LURIE: And being a state of
15 emergency --

16 MR. BROWN: Yes, being something else, you
17 might say, well, we can wait five years and do some
18 trials and figure something out. Well, I feel like
19 with this, no, we can't.

20 DR. LURIE: Let me ask you a practical
21 question. Let's say that tomorrow either the DEA
22 or FDA stepped in, and there was some federal

1 requirement for mandatory education. What would
2 the states do?

3 Would you say, all right, that's a job done.
4 We're going to cancel the state CME requirement.
5 Would you make it lineup with the federal
6 requirement? We've heard a lot about
7 duplicativeness and confusion.

8 What would the states' reaction on day one
9 be? Why don't I put it to you, David.

10 MR. BROWN: Well, certainly in Virginia, we
11 will align with federal requirements. We don't
12 buck them. But at the same time, I think we're
13 aware, sometimes there's federal requirements we
14 agree with, and sometimes there are federal
15 requirements we think don't quite make the mark.
16 And if they don't quite make the mark, we may
17 accept a federal requirement, but at the same time
18 have other requirements of our own.

19 I don't think it would in any way lessen our
20 efforts to create something, unless we felt like
21 going, wow, this is exactly what we were looking
22 for.

1 DR. LURIE: Okay. Lisa?

2 MS. ROBIN: I think I would certainly not
3 speak for how the reaction from Massachusetts would
4 be versus Texas.

5 (Laughter.)

6 MS. ROBIN: I think you'd find it to be very
7 different. But I do want to correct one thing,
8 because we keep saying, well, 21 states don't do
9 anything. I disagree with that.

10 Just because there's not a specified
11 mandate, that does not mean that there's not
12 education and all sorts of work going on to educate
13 and put strategies in place to address opioid
14 issues.

15 Absolutely. The mandate, you can discuss
16 that all day, if that's really effective or not,
17 and if it should be targeted. But I do think that
18 we need some more research to look at what really
19 does work. We need to look at outcomes, not just a
20 reduction in the number of prescriptions, but look
21 at the metrics. And I think that, certainly, we
22 need to pour some resources into that.

1 I know that that is where we could -- the
2 states could use that to do some studies. There's
3 certainly a willingness of them looking at how you
4 can do some predicative modeling, too, with looking
5 at the discipline and who comes before the medical
6 board, what were they trained in and were they
7 trained.

8 You're making headway with the medical
9 schools and residency programs because that was a
10 real problem with the lack of education, and now
11 that we're trying to get it. And to carry it
12 through to continue is really important. But I
13 really encourage that to put some federal resources
14 toward that would be well spent, I believe.

15 DR. LURIE: Okay.

16 MS. BECKER: I agree with both David and
17 Lisa. I think certainly the response would vary by
18 state for a number of reasons, depending on what
19 requirements they have in place, their general
20 relationship with the federal government.

21 I do think it would be really important to
22 create a mechanism. And I think Doris alluded to

1 this as a possibility earlier, where a state could
2 potentially seek a waiver from the federal
3 requirement if they one had one in place already
4 that met certain standards.

5 As David said, I think there'd be some
6 states that would look to align their programs.
7 There would be other states that would see this as
8 sort of another layer, or their state requirements
9 rather add another layer to federal foundation.

10 MR. BRASON: I agree also. In some states,
11 it would be problematic. Other states it would
12 not. I like the waiver idea, because then you have
13 that opt out but still doing scenario. I think
14 that would make it more palatable in that regard.

15 But if you look at, okay, it's a legislative
16 act, this is mandated right now, then you've got to
17 go back to those legislatures to undo that to bring
18 about change. That's not quick, nor is it easy.
19 In that, logistically it becomes problematic.

20 Then if you've got, like you said,
21 practitioners in multiple states, then you've got
22 another possible layer there that they have to work

1 through that becomes problematic, almost needing
2 their own individual admin assistant just to work
3 through all that.

4 So I think it would not be easy and could
5 create potential consequences that we don't want.

6 DR. KATZMAN: I agree.

7 DR. LURIE: If a more voluntary approach
8 were to be taken, and this question was asked to
9 the previous panel, who do you see as those
10 entities that would be best suited to deliver that
11 form of education? Who'd like to take a crack at
12 that?

13 You nodded. I'm tempted to call on you,
14 Lisa, because you nodded.

15 MS. ROBIN: No, that wasn't a nod.

16 (Laughter).

17 DR. LURIE: It could be quite dangerous to
18 that in a situation like this. David?

19 MR. BROWN: I think we've already kind of
20 covered the way in which healthcare systems can do
21 a very good job of -- well, it's voluntary for
22 them, it's not voluntary for their members

1 necessarily, their prescribers.

2 The problem a state medical board has is it
3 doesn't necessarily have in-house expertise on
4 pain, on addiction. In fact, looking at the
5 current Board of Medicine in Virginia, we don't
6 have any of that. So when we did our regs, we had
7 to bring in an advisory panel of experts to help us
8 craft that.

9 Unlike say a health system, which, by its
10 nature, probably has experts in each of these
11 areas, to create something that's voluntary, I'm
12 not exactly sure how the state boards would create
13 an incentive for anyone to do anything. We mainly
14 create disincentives by having regulations to say
15 if you fail to do this and we find out about it,
16 you could be in trouble; you're putting your
17 license at risk. So we have disincentives more
18 than we have incentives.

19 DR. LURIE: Lisa, in your survey of the
20 states, have you seen states that have tried to
21 incentivize the education, as opposed to just
22 coming with a stick?

1 MS. ROBIN: Well, I don't know that it is
2 the state boards that would be the people to
3 incentivize a voluntary program. I think there's
4 plenty of other people that could incentivize, and
5 I think it's their responsibility to incentivize.

6 You have the payers and you have the
7 professional liability carriers. I think that
8 there are ways to incentivize through the new
9 payment models. We're going to looking at new
10 payment models. I think that is where you
11 incorporate the incentives for the programs.

12 I do see that the state boards are more in
13 the area -- if it is something mandated in the
14 states, they're responsible for making sure that's
15 reported, and they mostly do a random audit or
16 something like that. But they're not going to be
17 the -- that's not going to be the place where you
18 go to register for a program. That's the
19 responsibility of the specialty societies and all
20 the CME providers that develop these programs. I
21 don't know that they even have the ability to
22 incentivize.

1 MR. BRASON: But I agree with those that
2 you're talking about that can and should.

3 MS. ROBIN: They can, and they should.

4 MR. BRASON: Yes. The liability malpractice
5 and all of that, that you've completed this much
6 education, you've got no dings, then you should
7 have a reduced -- and that is an incentive.

8 DR. LURIE: Joanna?

9 DR. KATZMAN: I can just say that I guess
10 I'm a little bit of a skeptic, that if the thought
11 at the conclusion at the end of tomorrow is that we
12 should bring it back to the state level with
13 perhaps an FDA blueprint as the core with some
14 wiggle room for the states to decide how they want
15 to do the rest of the training because of cultural
16 diversity or what have you -- I really think that
17 if there was a core 2 to 3 hours of training, it
18 would not be too burdensome, if you could show the
19 clinicians across the state with prescriptive
20 authority that this an emergency, this is a
21 healthcare crisis with chronic pain and the opioid
22 epidemic.

1 What I can tell is anecdotal -- not even
2 anecdotal, for the past five years at Project ECHO,
3 we've had two insurance companies say that they
4 will give clinicians \$100, one \$100, one \$150, if
5 they present a case to Project ECHO. So a
6 clinician anywhere in the country, if they present
7 a case to Project ECHO, that clinician will get a
8 free CME for every hour that they come on board.

9 It has been extremely unsuccessful, and I
10 can get you the numbers for that. It's not been
11 very successful, the incentivization from insurance
12 companies for clinical education, and that's been
13 voluntary even. We had 100 percent participation
14 when we needed to get all clinicians in New Mexico
15 prescribe -- the 5-hour training. That's just been
16 my experience.

17 DR. LURIE: Just a factual matter, Lisa.
18 Those requirements at the state level when they
19 exist, they're typically of the 50 hours over
20 2 years that people typically are required --

21 MS. ROBIN: On the renewal cycle, yes.

22 DR. LURIE: Right. But what I'm trying to

1 say is these things are not add-ons. If you've got
2 to do 50 hours over 2 years and you have 3 hours of
3 opioid, let's say, that then you've got 47 fewer
4 hours to go, right?

5 MS. ROBIN: Usually, yes, it would be part
6 of the overall --

7 DR. LURIE: The burdensome argument
8 applies -- I mean, if it were a DEA requirement on
9 top of it, then that's some increment of burden,
10 3 hours on top of say 50 over 2 years, so
11 6 percent. But within the states, it's burdensome
12 to the extent that you don't want to take that CME;
13 you want to be learning about Wilson's disease,
14 right?

15 MS. ROBIN: Yes, choose, yes.

16 DR. LURIE: Right.

17 MS. ROBIN: Right. And I mean, some states
18 have particular things that they need everyone in
19 their state to know about. For instance, in
20 Kentucky, it's required that they know about their
21 PDMP. There's specific curriculum around that. We
22 had to build it in to some programs we did for

1 them. Well, someone that's practicing in Oklahoma
2 doesn't need to know how to use the Kentucky
3 system. So there are certain elements that are
4 definitely state specific.

5 MR. BROWN: To talk about the incentive
6 structure, the fact of the matter is that organized
7 medicine, organized dentistry, organized whatever
8 field it is, hate to have the legislature tell them
9 what to do, and with good reason. To legislate the
10 practice of healthcare is looked down upon. But
11 they actually also dislike anyone telling them what
12 to do.

13 To some degree, that stems from the fact
14 that the people who participate in organized
15 medicine in the state medical society, in the AMA,
16 state dental association, whichever, typically are
17 well-educated, well-informed, active participants,
18 and who have a different viewpoint than say the
19 state board who frequently sees those practitioners
20 who go through the motions, who practice remotely,
21 and get in trouble for doing ridiculously stupid
22 things.

1 So creating an incentive structure
2 voluntarily goes against the very nature of some of
3 the people, anyway, you're expecting to step
4 forward. For example, we would not have the pain
5 regs we have if the legislature hadn't told us to.
6 So having that type of structure --

7 Now, I will back up and say because of this
8 crisis, I think in the Virginia, the medical side
9 of Virginia's been a very willing partner to fix,
10 to try to address this problem. The dental
11 association has been a very willing partner.

12 So I think it's a little bit different
13 climate in general, but I think having someone make
14 us do something, and I say me as health
15 professionals, it's not a bad idea.

16 Questions and Answers

17 DR. LURIE: I think it's time for questions
18 from the audience. Hopefully, we've stimulated you
19 to ask some good ones.

20 DR. KAHN: Yeah, you really did stimulate
21 some thinking. Norman Kahn from the Conjoint
22 Committee.

1 I'm going to ask you if the states would
2 accept something like the following. It's based on
3 much of what I've learned from listening to you
4 all, which is that standardization is an issue.
5 Having the states require what they want is an
6 issue.

7 Not all clinicians need the same level of
8 training. They want to be incentivized to learn,
9 and they want whatever they're doing to align with
10 whatever else they have to do, and not be an added
11 burden.

12 So that if we develop modules that were
13 based on the FDA blueprint, that used an adaptive
14 learning model? For those of you that are
15 physicians participating in maintenance of
16 certification, this is what used to be MoC part 2.

17 Just to describe it briefly, I'm a family
18 physician. I participate in maintenance of
19 certification. Every year, I have to go online,
20 and I have to choose a module, take several hours,
21 and it's all questions. And eventually, I have to
22 get 80 percent of the questions right.

1 But I was just telling my colleague over
2 there, I never stop until I get them all right,
3 because I want to know, even if I pass the
4 80 percent, what the right answers were. And if I
5 don't get it right, it asks me again. And if I
6 don't get it right, it gives me the answer and it
7 gives me the references. And I still have to go
8 back and take the test until I get it right.

9 Now we have something that is designed based
10 on the individual clinicians starting point,
11 wherever they are. It would count for MoC. It
12 would count maintenance of certification. It would
13 count for relicensure.

14 We talked with Doug and others earlier about
15 we're going to submit this to Medicare for a MIPS
16 improvement activity, or maybe in patient safety,
17 so it would align with what they have to do for
18 CMS. And they would definitely be learning, and
19 they would demonstrate their learning.

20 Would the states accept that?

21 MS. ROBIN: I think so. I don't know -- if
22 you can show that -- they're looking at the end

1 result of that program. You have something that's
2 the adaptive model, I think it's great, as long as
3 they complete it. The states aren't specific
4 enough on -- they just want so much credit. They
5 want to see the outcome. So I do think that that
6 is definitely the way to go.

7 DR. KAHN: Virginia?

8 MR. BROWN: It sounds like it has good
9 potential to me.

10 MS. BECKER: And you're talking about a
11 voluntary program, to clarify, right?

12 DR. KAHN: It is. On the other hand, it
13 aligns with all of these things that clinicians in
14 their practices have to do. And if they do this,
15 then they'll get credit for being relicensed.
16 They'll get credit for their CME credit. They'll
17 get credit for maintenance certification. They can
18 use it for a MIPS improvement activity.

19 You can say it's voluntary, but there's so
20 much incentive there, that I'm going to do it.

21 DR. LURIE: There's a question over here.

22 DR. GREENBLATT: Larry Greenblatt from Duke,

1 internal medicine physician. First I want to thank
2 the panel for a lot of really deep thinking and
3 great ideas that came up during this discussion. I
4 want to make a comment, and then I have a question.

5 The comment is just I think we need to be
6 careful not to target these efforts at the people
7 who come in front of state medical boards only. I
8 think that's absolutely the tip of the iceberg.
9 There's a huge number of people who need to change
10 their practice patterns, not just the ones who are
11 being called out.

12 But here's my question. I think if we're
13 going to do this, we have to focus not on clinician
14 knowledge, but on clinician behavior. I think it's
15 very easy to give CME that allows people to do
16 better on a test, or to demonstrate in some way
17 they learn the material, but are they actually
18 changing what they do?

19 While we're dealing with this huge opioid
20 epidemic, we have another epidemic, which I think
21 is important to talk about in this room, and that's
22 an epidemic of burnout and depression amongst

1 healthcare providers. It's really bad. It's more
2 than half.

3 If you're asking people to change behavior
4 and to implement new practices that are time
5 consuming, and aren't reimbursed, and are
6 burdensome, you've got to remember that the people
7 that you're asking to do this, they're exhausted.

8 So how do we make sure that whatever we're
9 going to try to do results in better patient care?
10 I welcome anyone to try to answer that question.

11 (Laughter.)

12 DR. LURIE: Anybody want to take a crack at
13 it?

14 MS. ROBIN: No, I'm just saying it's a huge
15 issue, and we know that for a variety of reasons.
16 There's so much stressors on physicians, and it's a
17 huge issue: suicide, and burnout, and wellness
18 issues. And to do whatever we can to put a system
19 in that is not redundant and is not an additional
20 burden on what is already a burdensome system, I
21 think it's really, really important.

22 MR. BROWN: I think going back to what the

1 physician from Kaiser mentioned, having something
2 that much of this can be integrated into the
3 workflow as possible with automatically checking
4 the PMP, unless you say no, or automatically doing
5 other things, so it becomes less of a burden and
6 the good practices are followed.

7 MR. BRASON: And I'll just toss it back to
8 you a little bit that, yes, we have to be sensitive
9 to that, but why are we in the place that we are
10 now in the healthcare systems with so much
11 depression and burnout? What is the causation of
12 that, that we need to address at the same time?

13 DR. LURIE: It's probably not 3 hours of
14 CME. On numerous December 31st's, when I was there
15 trying to finish off my state mandated CME on HIV,
16 it was a pain in the neck.

17 MR. BROWN: I did procrastinator CMEs.

18 MS. KEAR: Cynthia Kear with CO*RE. That
19 was a great discussion. I took lots of notes and
20 really appreciated everyone's insights and efforts.
21 Just a couple of observations or responses to some
22 points that came up, and then kind of a big

1 opinion; I'll just be honest about it.

2 One thing is that I think really inclusion
3 of other audiences is really important, and we made
4 this point to the FDA. But we've done surveys of
5 nurses. They are the ones that are doing so much
6 of the counseling and patient education. To not
7 include them is a travesty.

8 Pharmacists. I mean, who does consistently
9 tell people how to do their meds? But I also think
10 patients. I mean, I think patients have got to
11 belly up to the bar here. We've got to educate
12 them. They've got to be active in this. Somehow
13 that has got to be included in this education.

14 I'm not sure the blueprint is the right
15 place for it, but they do have to be. They're off
16 the stage right now, yet they're center stage to
17 the problem.

18 Someone was saying about quality of
19 education isn't sufficient. Education, we know
20 from principles of adult education, it takes seven
21 effective educational interventions before you'll
22 see somebody change their behavior. So knowledge

1 is fairly easy, but what we want to see people do
2 is change behavior. If that's true, then we should
3 be looking at this from a very, very different
4 point of view.

5 The question was about the states; maybe
6 this was your point, about people like to hear at a
7 local level. Our experience is that people like to
8 hear from a similar clinician. An FP wants to hear
9 from an FP. They don't want some fancy schmancy
10 pain specialist coming in and talking down to them.
11 I think that's true around all clinician types. So
12 that's something I would suggest that we look at.

13 Two other points that relate to kind of now
14 process. In California, a number of years ago,
15 they developed out of reactivity from the state
16 legislature, 12 hours of mandated pain education.
17 It was just pick something up and throw it against
18 the wall, and it required a tremendous amount of
19 time and a tremendous amount of effort, and we know
20 nothing about it. Marsha Stanton [ph] asked me
21 about 10 years later, "What did we learn?" I said,
22 "No one knows."

1 So the one thing that I would really suggest
2 that we consider in terms of this issue of national
3 versus state is not all state mandates are the
4 same, and will it be easier to actually have
5 quality control if something is implemented and
6 launched at a national level, so you can get common
7 information on practice gaps.

8 Yes, there might be variances depending upon
9 what the substance is or the particular cultural
10 background, but you can do some things that really
11 are going to help us to develop education that's
12 really targeted toward those most egregious
13 practice gaps, which are creating so much of the
14 problem.

15 We can also then create content to address
16 that, and then we can come up with a common design
17 program, so across all the states it could be
18 measured. Right now, California can't be measured.
19 Maybe Maryland can be. Maybe New York will be. I
20 have no idea who's developing these programs?

21 I appreciate pain expertise, I appreciate
22 addiction expertise, all kinds of clinical

1 expertise, but there's also educational expertise,
2 and that would be a nice voice to have sitting at
3 the table as we try and come up with something
4 that's going to really be quite meaningful.

5 So for me it's a question of making sure
6 that the processes have some sort of comparable
7 quality. Maybe it doesn't really matter who
8 implements it or how it implements, but really that
9 they're really kind of a standardization in terms
10 of basic things we know about how to deliver design
11 and deliver and assess quality education.

12 DR. LURIE: Let me give the panel a chance
13 to react. You've said a lot and --

14 MS. KEAR: I've said a lot. I'll stop.
15 That's time for me to be quiet then. Thank you.

16 DR. LURIE: Does anybody on the panel want
17 to react to some elements of that?

18 (No response.)

19 DR. LURIE: It's an endorsement.

20 MALE AUDIENCE MEMBER: A quick comment and a
21 question. The comment is I wonder whether there's
22 a mortality rate associated with education, so

1 delivering that is not going to really hurt anyone
2 to actually get extra education. However, there's
3 a significant mortality rate with the control
4 substances at around 50,000 per year.

5 I just want to make sure we keep it in
6 scope. As a physician who makes a lot of money, I
7 have to take 4 extra hours of education to not kill
8 people? I think we just need to make sure and keep
9 it in perspective.

10 But realizing that better is sometimes the
11 enemy of good, what would you see as the minimum
12 viable product that the FDA and the national or the
13 federal system would be able to put out to the
14 states in order to move forward quickly as the
15 longer that we wait.

16 What is the minimum viable construct that
17 you think would be helpful for the states to be
18 able to start directing education within those
19 states?

20 DR. LURIE: Okay. Fair enough. Joanna?

21 DR. KATZMAN: Thank you for your question.
22 Our content that we delivered to most of the

1 clinicians in New Mexico, to most of the clinicians
2 in the Indian Health Service, to many that we've
3 trialed and tested with the Army and Navy pain
4 clinicians, and primary care clinicians, the Army
5 and Navy has been 5 hours. Part of that has been
6 because we've also used standardized patients with
7 vignettes and so on.

8 I think that in order to deliver an overview
9 of the epidemic, include regulations pertaining to
10 state and federal requirements, and to be able to
11 offer content regarding pediatric and adolescent
12 pain in addition to the core content, which is how
13 to treat pain non-pharmacologically, how to treat
14 pain with non-opiate pharmacotherapy, and how to
15 screen for opioid addiction, and then how to treat
16 pain with opioids safely, my feeling having done
17 this for eight years, is a minimum of 4 hours, 3,
18 4 hours. If you're going to do it live or via BTC,
19 it is intensive, so 3 to 4 hours.

20 DR. LURIE: Over a two-year cycle, right?
21 Is that what you mean?

22 DR. KATZMAN: However you want to do it.

1 DR. LURIE: That's how most do it.

2 (Crosstalk.) DR. KATZMAN: That's my
3 feeling. We did 5 hours because we added breakout
4 sessions and such.

5 DR. LURIE: Okay. Is there agreement that
6 any --

7 DR. KATZMAN: I forgot to mention, Peter,
8 that we also did -- we also added naloxone
9 take-back. We also incorporated dental specifics
10 on acute pain. The full first class would be a
11 5-hour course.

12 DR. LURIE: Is there agreement on the panel
13 that separating opioid prescribing from pain
14 management would be a mistake?

15 DR. KATZMAN: Can I just start with that? I
16 think that would be a significant mistake.

17 MR. BROWN: Agreed.

18 MS. ROBIN: Agreed.

19 DR. TERMAN: Greg Terman from University of
20 Washington and American Pain Society. My question
21 is for Lisa and Melinda specifically, and you may
22 have almost touched on it. But my question is, if

1 there was a miraculous best education product out
2 there, do you think that the states would gather
3 around it or try and improve on it?

4 Having been involved in three Washington
5 state guidelines and CDC guidelines, it seems
6 sometimes that governors or legislators in the
7 states, maybe even boards, play the I can restrict
8 prescribing to 40 MED. I can restrict it to
9 20 MED. And of course, it's the numbers that
10 people remember.

11 What do you think about that? Are they
12 interested in collaborating, or are they trying to
13 get themselves in the news as yet another decrease
14 in restrictive practices?

15 MS. ROBIN: I can say that I think you've
16 got different audiences that you're talking about.
17 I think that from the boards, from the regulatory
18 boards, I would say that they are looking, and yes,
19 that resources would be well received.

20 I would say that the REMS blueprint before
21 was well received from the states. There was not
22 any pushback on the state boards wanting to get

1 that education out to their licensees. We didn't
2 have any. They were anxious to -- if I had had
3 more resources to be able to provide more grants,
4 those boards would have done additional education.

5 Now, that doesn't mean that there is not
6 every legislator or -- they want their hands on
7 something and looking for a very quick fix, and
8 whether it's okay, well, we're just going to stop.
9 And they're not medical professionals, but it looks
10 like that's an easy thing. Let's say, well it's
11 going to have a hard stop here, and nobody
12 can -- and without necessarily looking at what the
13 evidence really is to support that, what are our
14 patient outcomes?

15 So I think you've got two different people.
16 Whether the governors and the legislators are
17 really looking for that common resource, and
18 looking at it from an education perspective versus
19 more of a prescriptive -- let's tell the doctors
20 and nurses and pharmacists how to practice -- or
21 are the regulators, who not only -- they have to
22 look at access. They have to look at they're

1 trying to raise a whole standard of practice, and
2 at the same time take out the folks that are
3 misbehaving.

4 So I think you have two different varied
5 people there.

6 MS. BECKER: I agree completely. I'll just
7 say I think there will always be -- whether it's
8 governors or state legislatures who are trying to
9 be more visible and more publicly on the forefront,
10 if you will, on this issue. But I think, by and
11 large, they have varying capacities to develop
12 these evidence-based programs on their own, and I
13 think would really welcome the resources. I think
14 that you would see a very positive response from
15 the states if something like that were to come
16 together.

17 DR. LURIE: Okay. Great. I think we've
18 exhausted the expertise or insights of this panel.
19 We might have exhausted the audience. At that
20 point, I think it's time to stop.

21 Doug, you have some closing comments to
22 make, and then I think that we'll end the day.

1 Closing Remarks - Douglas Throckmorton

2 DR. THROCKMORTON: That was terrific, and
3 I'll just start by thanking the panels, both the
4 panels this afternoon, in keeping the focus on
5 education, which is, again, really the thing that
6 we're looking for help on in this particular area.
7 There's a lot that we could be talking about.
8 Thank you for especially this last panel staying
9 laser-focused on that and not other activities that
10 we could be talking about.

11 I heard some things where consensus seemed
12 to emerge, so I'm going to say them, and just we'll
13 see how it goes. I heard some things that I don't
14 believe we've yet gotten to consensus on, so I'm
15 going to just try to summarize what I've heard.

16 One, Peter as you said, there is just an
17 enormous amount of educational activity going on at
18 the federal/state healthcare system local levels, a
19 large change over where we were when we first
20 talked about needing the REMS, I would say; this
21 last few years, really just an explosion in terms
22 of the amount of focus on education and training.

1 The first question was is education enough?
2 Okay, if anyone thinks that it is, please raise
3 your hand. But I think consensus was it's one
4 aspect of this. It's important but not sufficient.

5 Is the current level of physician education
6 satisfactory? And Peter, you elicited the answer
7 to that question, at least to this panel, that
8 there is a consensus that given everything that's
9 happening both in pain management and, in
10 particular, in the field of opioids, really there
11 is additional education that we all could benefit
12 from. We all could do that.

13 Is the current level of education focused on
14 prescribers the right one? Here the consensus was
15 no. Yes, prescriber focus is important, but there
16 needs to be a focus on additional elements of the
17 healthcare system, the nurse practitioners; other
18 non-prescriber groups play a critical role in
19 supporting this. Someone mentioned the courts. We
20 didn't get a chance to mention that, but I heard
21 that. That was an interesting editorial I won't
22 explore further.

1 Are there improvements in the
2 federal -- I'll say federal, I'm guessing all
3 educational activities -- that could occur to
4 improve their impact? So could we be doing better
5 with education?

6 Here again, it seemed pretty
7 straightforward. Everyone agreed. Dr. Kahn
8 mentioned the idea of modules. I mean, there was
9 some various ideas that people had for taking the
10 kinds of education that we put in place, now
11 speaking about the REMS specifically, the content
12 we put in place in 2012, updating it for our
13 current state where we know more about how to
14 educate prescribers or educate practitioners. We
15 know more about how to do that better to be more
16 likely to be successful.

17 Then I would say the place I've heard
18 consensus, is there a need for additional federal
19 action? So given that we have all of this new
20 activity going on from where we were in 2012, is
21 there a need for additional federal action? And
22 that can be either mandatory or not obviously.

1 Two advantages people suggested, one was to
2 make a common educational content that the states
3 could then draw on. I think there was broad -- it
4 sounded as though a lot of people thought that was
5 useful.

6 Another suggestion that was made was that it
7 would provide a common standard of data collection,
8 data sharing. It would make it possible for us to
9 understand better what was going on, if there was a
10 federal architecture, if you will.

11 Before answering that question, though, I
12 think everybody acknowledged there's a lot of other
13 things going on, other non-education things, or
14 education things other than the REMS going on. We
15 have the CDC treatment guidelines. CMS and states
16 are using reimbursement strategies that some of you
17 mentioned to modify prescriber behavior.

18 Healthcare systems are working to modify
19 prescriber behavior. I know this because I know
20 people that are having their practice modified by
21 those behaviors, the chits and the flags, and that
22 kind of thing.

1 The comment was made that those things are
2 directed to large practices and are not likely to
3 be impacting the solo practitioner that I trained
4 in the sandhills of Nebraska with, was not going to
5 be affected by that kind of stuff, because he was
6 out there on his own, and he was not going to be
7 getting that information.

8 Then there was this long discussion, I would
9 say really fruitful discussion, on how to
10 understand state-to-state variability. Lisa, I
11 take your point that not choosing to make mandatory
12 prescriber education is only one aspect of what the
13 states are doing, but we have to recognize there is
14 a broad range of state choices that have been made.
15 And before we decide whether or not the next level
16 up, federal requirement is necessary, it's
17 important to understand the source of that
18 variability.

19 Is it because states are fundamentally that
20 different, or is there something else going on
21 there? And Dr. Katzman talked about huge cultural
22 differences, and having come from the Midwest, I

1 understand that. I think there are those things.
2 That's true. I don't know whether that fully
3 explains the broad range of choices the states have
4 made or not. I think that's something I hope we
5 have a chance to talk about a little bit.

6 People have talked about how a common
7 curriculum with flexibility, a model act, or a
8 waiver or something, might be a compromise in that
9 sense; if you decided some federal activity was
10 necessary, how to reflect those cultural
11 differences.

12 Then the last question, and I am absolutely
13 not answering, what I think I've heard so far today
14 about the need for additional mandatory federal
15 action. I would say I haven't heard a consensus or
16 even -- people have stated their views.

17 I hope tomorrow we're able to talk about it
18 more systematically, a little bit more in the
19 framework that we've been talking about it late
20 this afternoon, really talking about how to make a
21 choice about additional federal activity, given all
22 of the state and local and healthcare system

1 activities that have been going on because I think
2 that's how our decision-making is going to
3 ultimately have to be framed.

4 In the context of the things going on now,
5 do we need to do more? And if so, whether that
6 more needs to be mandatory or if it needs to be an
7 improved version of what we're doing now, with
8 understanding better that we have now.

9 I'll end by just -- I'm sorry, I don't know
10 who spoke at the very end there. There are two
11 challenges that have been raised that we really do
12 have to keep in mind. The first is the physician
13 burnout, and we have to acknowledge that that
14 burden is important. Not having a prescriber is
15 infinitely worse than most other options we can be
16 thinking about here.

17 So that just absolutely does need to be
18 thought about, the healthcare system burnout.
19 Actually, I shouldn't have said physician, because
20 I have very good friends that are nurse
21 practitioners. I know very much the burden they
22 bear in these sorts of discussions for instance.

1 The other thing we just have to remember is
2 those 91 people. We are losing people daily to
3 this. So yes, we all acknowledge there's a lot of
4 things we don't know. At the end of the day,
5 though, everything about this epidemic is going in
6 the wrong direction. And we've seen some small
7 improvements. The VA system data were very
8 compelling and things, but we need to make a
9 difference.

10 So yes, additional research is important,
11 and yes those things are important. But at the end
12 of the day, perfect being the enemy of the good,
13 sometimes we're going to be obliged to act without
14 all of the data we might ideally like to have.

15 So with that, I'm going to close the
16 session. Thanks to everyone that participated.
17 Thanks to the two panels this afternoon for really
18 terrific discussion. And I hope to see all of you
19 tomorrow.

20 (Applause.)

21 (Whereupon, at 5:03 p.m., the meeting was
22 adjourned.)

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