

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

May 10, 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

Wednesday, May 10, 2017

8:26 a.m. to 4:30 p.m.

Sheraton Silver Spring
8777 Georgia Avenue
Silver Spring, Maryland

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1 P R O C E E D I N G S

2 (8:26 a.m.)

3 Opening Remarks

4 DR. THROCKMORTON: Good morning, everybody.
5 I'm going to sit down this morning rather than stand
6 up. I hope that's all right. We might as well go
7 ahead and get started. I think we've got most of
8 the people for the open public hearing. We've got
9 the names. We'll make sure that no one is left out
10 there.

11 I hope everyone had an interesting
12 afternoon. I thought it was a great day yesterday,
13 the morning setting the stage, giving some
14 information, and then the afternoon, two really
15 lively discussions about where the FDA, where
16 federal educational efforts fit into the broader
17 efforts that I know we're all working on.

18 I don't know if you heard the news
19 yesterday. Along the theme of broader efforts
20 ongoing, the governors of Maryland, Virginia, and
21 the mayor of D.C. met yesterday, also. I couldn't
22 find it on the news in print, but the radio said

1 that they agreed to share their PDMP data. People
2 in the audience who know more about those things
3 than I do would know whether --

4 (Applause.)

5 DR. THROCKMORTON: -- how far away they are,
6 but that's good news, I think, for all of us. So
7 again, just lots of efforts, both in the
8 educational space, in other areas to address this.
9 I thought that was a good piece of news.

10 Mary, should we go ahead and get started, or
11 do you want to wait a minute?

12 Okay. Why don't we then go ahead and get
13 started. You guys want to introduce yourselves,
14 please?

15 DR. AUTH: Doris Auth from the Division of
16 Risk Management in CDER.

17 DR. MANZO: Good morning. Claudia Manzo,
18 director, Office of Medication Error Prevention and
19 Risk Management in CDER.

20 MS. TOIGO: Terry Toigo, associate director
21 of Drug Safety Operations in CDER.

22 Open Public Hearing

1 DR. THROCKMORTON: All right. With that,
2 why don't we go ahead and get started on the second
3 open public hearing for this. Again, appreciate
4 all of the comments that people are going to make.

5 I'll just start at the top. Dean Beals is
6 the first speaker.

7 MR. BEALS: Good morning, and thank you. As
8 you said, my name is Dean Beals. I'm the president
9 and CEO of DKBmed. We're a New York-based medical
10 education company. Thank you for allowing me the
11 opportunity to speak today.

12 I wanted to disclose that we have been
13 awarded several opioid REMS grants in partnership
14 with the Postgraduate Institute for Medicine, the
15 Practicing Clinicians Exchange, and Johns Hopkins.

16 Under the Get Smart moniker, we've developed
17 18 live meetings, a home study program, webcasts,
18 online learning, and most recently a smartphone app
19 for IOS and Android. We have educated over 4800
20 clinicians. Last time, I spoke about our live
21 programs; this time, I'd like to speak briefly
22 about our smartphone app.

1 We took all the components of the blueprint,
2 and we put them into the app, and we customized it
3 for a number of different specialties. The app
4 uses text, video, short quizzes, interactive
5 features, and in-app reminders to keep learners
6 engaged. Since launching, we've educated about
7 1700 clinicians via this mobile app.

8 By all measures, it's been successful. More
9 than 70 percent of participants indicated that they
10 have made changes in their practice. Many
11 commented on the utility of the format, and one
12 said, "This is a very important topic, and this app
13 is an outstanding way to teach. Bravo."

14 I'd like to spend the rest of my time
15 discussing some recommended challenges from our
16 perspectives as well as improvements. First, let
17 me say that I commend the FDA and everyone in this
18 room for supporting these efforts. As we heard
19 yesterday, this is an enormous, enormous problem
20 that will take all of us working together to solve.

21 I also commend the FDA for considering the
22 addition of short-acting opioids. That so, we do

1 have to be mindful that this could lengthen the
2 curriculum, and I'll talk about that in a moment,
3 and we need to carefully manage that.

4 Despite our success, we all recognize that
5 the supported activities have not yet achieved the
6 intended number of learners, and I think this is a
7 result of three issues: number one, the length of
8 the curriculum; number two, the FDA's definition of
9 a completer; and three, as we talked a lot about
10 yesterday, the lack of an educational mandate or an
11 incentive.

12 While the FDA blueprint is incredibly well-
13 written and thorough, it is simply too long. It
14 takes between 3 and 4 hours in a live meeting
15 setting, somewhat less if you do it on an app or
16 some other mobile platform. At first glance and I
17 haven't reviewed it in detail, but the draft
18 blueprint really seems to be a step in the right
19 direction to simplifying that.

20 Secondly, and this is really important, just
21 because a participant is not an opioid prescriber
22 today, it does mean that they won't be tomorrow, or

1 importantly, having an impact on patients who take
2 opioids. Many of our learners were not prescribers
3 but decided to participate anyway. Why? Because
4 they think it's really important.

5 Finally, there were many discussions
6 yesterday about mandating education via REMS, state
7 boards, the DEA, or some other mechanism. There
8 were also talks of incentives. While other
9 approach would likely increase participation, we do
10 need to be mindful not to inadvertently cause
11 providers to opt out of treating their patients'
12 pain. That would be a serious disservice.

13 In summary, I'd like to recommend shortening
14 the blueprint; carefully expanding the education to
15 include short-acting opioids; thoroughly and
16 thoughtfully mandating or incentivizing education;
17 redefining a completer to include anyone achieving
18 competence; and finally, continuing to support a
19 variety of innovative learning platforms so that
20 the CME community can spread this important and
21 lifesaving education. Thank you very much.

22 DR. THROCKMORTON: Thank you very much.

1 Pat deCosta.

2 DR. deCOSTA: Good morning. I'm Pat
3 deCosta. I'm a clinical pharmacist by training and
4 experience, and I appreciate this opportunity for
5 making a public comment.

6 The requirement of REMS to have regular
7 assessments to evaluate whether a REMS is meeting
8 its goals or needs changes is working in this
9 situation as the current REMS for ER/LA opioids did
10 not meet education goals.

11 At first glance, the next step does appear
12 to be to update the REMS requirements to mandatory
13 prescriber training. However, the original
14 concerns voiced years ago regarding the resulting
15 burden of such a REMS on a class of drugs that
16 produces incredible prescription volume now becomes
17 relevant again.

18 We need to ask ourselves what have we solved
19 in all these years of money and time spent if we
20 simply now move to the mandatory requirement for
21 prescriber education without including tools to
22 support that prescriber in practice.

1 While I believe that education of
2 prescribers would be beneficial, and while I agree
3 that there must be some burden on the healthcare
4 system when balancing patient safety, I'm not sure
5 that a plan for mandatory education alone will
6 produce the results the industry, the public, and
7 patients are ultimately looking for. In five years
8 from now, will we find ourselves back here asking
9 what have we solved in all these years of money and
10 time spent?

11 The prescriber-reported barriers for
12 applying the REMS CE information learned remain,
13 which are insufficient time during clinical
14 encounters, patient noncompliance, and patients
15 continuing to identify new ways of drug-seeking
16 behavior not addressed in the training.

17 Of those who've completed training,
18 prescriber surveys indicate knowledge gaps
19 regarding initiation, modification, and
20 discontinuation of opioid therapy, and further
21 education of doctors will likely not address
22 illegal transfers of opioids from patients to

1 others or the misuse that is driving this epidemic.

2 A recent IMS study indicates that a
3 prescriber or pharmacist intervention is only
4 required 7 percent of the time when controlled
5 substances are being prescribed. While education
6 is important, workflow solutions such as DUR,
7 support the education that pharmacists and
8 prescribers have received and facilitate a reminder
9 of the education at the moment they need it.

10 Can we take a cue from the current
11 healthcare ecosystem for our next steps? In my
12 early years as a pharmacist, I benefitted from DUR
13 computer software to complement and even enhance
14 the capacity of my clinical knowledge as I had to
15 meet the demands of my dispensing role.

16 DUR has evolved from its initial goal in
17 1990 of reducing Medicaid fraud and can now compare
18 and analyze varying drug use criteria with both
19 pharmacy and medical claims to identify potential
20 drug therapy problems.

21 Similarly, designed technology-based logic
22 that interprets patterns of drug use in relation to

1 predetermined criteria in order to prevent or
2 minimize inappropriate prescribing can help address
3 this epidemic without adding significant burden to
4 the entire healthcare system.

5 Remember that some of these people started
6 out as patients whose goal was to manage their
7 pain, and they're now struggling to manage their
8 addiction because there was no manageable failsafe
9 for their healthcare provider.

10 As clinicians and as the public
11 organizations tasked with public safety, we should
12 think about the tools already available but
13 underleveraged that can alter the steps between
14 appropriately prescribed opioids and its future
15 illicit misuse. Thank you.

16 DR. THROCKMORTON: Thank you very much.

17 Lynda Martin.

18 MS. MARTIN: Hi. Good morning. I'm Lynda
19 Martin. I'm an RN. I'm the director of clinical
20 operations and also Premier, Inc's hospital
21 improvement innovation network, and we thank you
22 for the opportunity to represent Premier, Inc. here

1 today.

2 Premier is a membership organization with a
3 large national footprint across the nation. We
4 work with more than 3,750 hospitals, hundreds of
5 thousands of clinicians, and 130,000 other sites of
6 care across the country. Together with our
7 members, we transform healthcare from the inside
8 out by developing solutions to address the most
9 pressing needs of patients, providers, and
10 suppliers.

11 We have demonstrated time and again that we
12 can measurably improve patient outcomes while
13 safely reducing the cost of care on a large scale
14 through collaborative activities across our member
15 providers.

16 Today we want to encourage the FDA to
17 consider four things that could help change how
18 healthcare providers are educated and how they
19 treat patients using pain management and safe use
20 of opioids.

21 First, we feel that best practices currently
22 exist to train providers to effectively use

1 alternative pain management techniques. However,
2 they need to be further tested in real world
3 settings.

4 Second, we would like to encourage the FDA
5 to consider partnering with other organizations
6 such as Premier for use of technical and adaptive
7 approach and way of disseminating best practices
8 among providers and non-providers across the
9 country in care settings and supporting the
10 implementation of those practices on a large scale.

11 Third, we would like to encourage the FDA to
12 take advantage of existing data sources and utilize
13 additional registry platforms to monitor opioid use
14 and measure the impact of implementing best
15 practices.

16 Fourth but not least, we would like to
17 encourage the FDA to include a patient-centered
18 approach to training and education that involves
19 the patients as partners in their care in order to
20 promote mutual understanding and expectations of
21 the pain management treatment plan and to increase
22 patient compliance with self-management and to

1 decrease opioid misuse.

2 Our experience at Premier has shown that
3 this methodology is very effective in improving
4 care for patients regardless of the setting. As an
5 example, we have been monitoring the use of
6 naloxone reversal among acute inpatients with
7 opioids administered during their hospital stay.
8 We've also been monitoring opioid-related adverse
9 drug events per 10,000 patients with our current
10 data sources for one of the collaboratives we are
11 running on opioid safety.

12 We have found this to be an effective way to
13 identify organizations that are doing things well
14 as well as identifying those that have
15 opportunities for improvement. We subsequently
16 then work with them to provide education to
17 providers and non-providers, implement best
18 practices, measure to track progress, and then help
19 use these results to monitor and refine action
20 plans to close the gaps.

21 To date, we have seen improvement. However,
22 we still feel there is much more to be done. So

1 once again, on behalf of Premier, we thank you for
2 this opportunity and look forward to being a part
3 and being supportive of this important work. Thank
4 you.

5 DR. THROCKMORTON: Thank you very much.

6 Thomas Berger.

7 DR. BERGER: Good morning. Thank you. My
8 name is Tom Berger. I'm executive director of the
9 Veterans Health Council for Vietnam Veterans of
10 America.

11 The FDA, general public, and government
12 leaders are rightly concerned about our nation's
13 continuing opioid abuse epidemic, especially as it
14 has been related to the high rates of suicide in
15 our veterans' community, particularly among older
16 vets 50 to 65 years old. But we cannot allow abuse
17 concerns to restrict veterans' access to the
18 highest quality medications and the healthcare
19 needed to relieve their chronic pain. And I would
20 remind everyone that less than 40 percent of the
21 veterans' community seeks their healthcare or their
22 prescriptions through the VA, so it's all of us

1 that are involved here.

2 It's time for the FDA to take decisive
3 action to ensure that all opioids prescribed, both
4 immediate- and extended-release versions, contain
5 abuse-deterrent formulations. Taking such action
6 means denying approval of new products that do not
7 contain abuse-deterrent properties.

8 However, Vietnam Veterans of America also
9 believes that education of both physicians and
10 patients, as well as a better coordination among
11 PDMPs, are all common-sense actions that can take
12 place now, which could mitigate the public and
13 societal health risks associated with opioids.
14 Thank you very much.

15 DR. THROCKMORTON: Thank you.

16 Larry Twersky.

17 MR. TWERSKY: Hi. I'm Larry Twersky, CEO of
18 TimerCap. TimerCap is a cap that lets you know the
19 last time you took your medication.

20 We agree that there needs to be tools, that
21 the patients need tools to manage their medication.
22 It's been said and known that what gets measured

1 gets managed. Today, patients don't have the tools
2 they need to measure. Currently, all opioids come
3 in a cap that was developed in 1970 for
4 child-resistant packaging. That is what's
5 currently available to patients today.

6 When they're already impaired on opioids and
7 already cognitively disoriented, to try to get them
8 to take their medication correctly, they need
9 something like a timer. We have a timer that talks
10 to a smartphone or just a simple timer that lets
11 people know the last time they took their meds.

12 Patient safety and safety of people take two
13 forms. One, patient safety, you need to measure
14 the time in between the doses so you don't
15 accidentally overdose, monitor it so you don't get
16 behind the wheel, and measure it in the bottles
17 that they are dispensed in. We're already in every
18 CVS and Rite Aid. That helps the patient take
19 their medication better.

20 When I hear stuff like let's give people
21 naloxone right away, we missed a step of helping
22 people manage their own pain. Giving people that

1 plus a tracker form to manage what their pain level
2 is and what they're doing help patients manage
3 their medication.

4 We can't expect that the caregivers are
5 going to go in and, with one minute out of the
6 seven that they're going to spend, have the ability
7 to actually make a difference. Then we need to
8 take care of household safety which is we need to
9 detect unwanted openings, deter unwanted openings,
10 and dispose of unneeded medication.

11 Since the TimerCap resets every single time,
12 it's a detection tool to the exact minute when
13 people have been in your medication. It's a
14 deterrent because somebody could know that, and
15 then you need a disposal.

16 If it was something that was co-prescribed,
17 an anti-abuse prevention kit when opioids are
18 dispensed with such tools that help measure,
19 monitor, and manage medication and help dispose,
20 such as the doTerra or other tools, that a pharmacy
21 who already has the ability to schedule things such
22 as a 30-day recall could schedule a 30-day recall

1 to let people know to dispose of their medication.

2 We're advocating that the pharmacies do more
3 work, considering that you have 1.5 million
4 professionals that need to be trained, have a
5 transfer knowledge, and it's the only medication
6 that we have to change the behavior of the patient
7 where we've been telling them to take their
8 medication, finish their medication, complete their
9 medication, to not finish it, only take it when
10 needed. And we have to change the behavior and
11 give them tools because most people do not know
12 they're getting an opioid because it's called
13 something different.

14 So we're hoping that we can provide the
15 tools to the patient at the pharmacy as opposed to
16 spending money on knowledge transfer that may or
17 may not get to the patient. We need to provide
18 those tools to them. Thank you.

19 DR. THROCKMORTON: Thank you very much.

20 Andrew Rosenberg.

21 MR. ROSENBERG: Good morning, pleasure to be
22 here with you this morning. My name is Andrew

1 Rosenberg, and I'm here representing the CME
2 Coalition. It's an advocacy group representing
3 about three dozen CME stakeholders from across the
4 spectrum of education providers, supporters, and
5 physicians.

6 As you know, CME is critical to educating
7 prescribers about the risks inherent in opioid
8 medications and the success of the REMS program.
9 Under REMS programs, the FDA reviews and approves
10 programs developed by drug sponsors, and healthcare
11 professionals must then heed the program rules.

12 In order to ensure that healthcare
13 professionals understand the rules as well as the
14 roles in making sure that the rules are followed,
15 CME courses are essential.

16 There have been numerous studies done as to
17 the effectiveness of CME. Over the course of 39
18 systematic reviews published between 1977 and 2014,
19 the overall impact has been settled. CME courses
20 can more reliably change healthcare professionals'
21 knowledge and competence and their performance in
22 patient health outcomes.

1 CME courses accredited by the ACCME have
2 stringent criteria and standards that must be met.
3 In 2010, a prescriber education working group
4 stated that the stakeholders and the working group
5 recommend that the REMS prescriber training be
6 designed to exceed the goal of traditional CME
7 methods and instead aim to demonstrate optimized
8 practitioner performance and improved patient
9 outcomes.

10 As such, the ACCME has worked to streamline
11 and align CME's purpose with the ideas of the
12 working group and the needs of practicing
13 physicians.

14 Today the types of CMEs offered for REMS
15 include general information about the use of
16 opioids to aid in patient selection and counseling;
17 specific information about the individual drugs in
18 the class; and information on how to recognize the
19 potential for and evidence of addiction,
20 dependence, and tolerance.

21 CME as part of REMS is helpful to
22 practitioners because the FDA controls the needs

1 assessment and content requirements, and because it
2 encourages evidence-based debate on risk versus
3 benefit.

4 ACCME-accredited CME is especially helpful
5 because the scope of evaluation of effectiveness is
6 actually measured in one of three important ways:
7 change in competence, change in performance, or
8 change in patient outcomes. This helps to evaluate
9 how well physicians understand the REMS and the
10 effects of opioids on their patients.

11 Moving forward, we believe the FDA should
12 continue to rely on accredited CME as a vital tool
13 in prescriber education in the opioid space. The
14 strength of CME is that it can produce myriad
15 educational activities that are targeted to
16 physicians based on their professional practice
17 gaps, individualized needs, and stages of learning
18 and change. Added flexibility will allow
19 prescriber education to better address individual
20 prescriber's education and practice needs.

21 In addition to REMS, several government
22 agencies have also been helping to educate

1 physicians on the dangers and special care of the
2 patients who have been prescribed opioids need.
3 We're encouraged that the FDA sees efficacy CMS as
4 a valuable tool in combating the opioid epidemic.
5 Our members have developed hundreds of hours of
6 innovative and creative pain education programs and
7 have delivered them to hundreds of thousands of
8 physicians.

9 Finally, as an incentive for prescribers to
10 participate in opioid REMS, we recommend that the
11 FDA encourage CMS to include opioid REMS as an
12 improvement activity in the quality payment program
13 NIPS. Thank you very much.

14 DR. THROCKMORTON: Sorry, trying to type
15 that last bit down there. Thank you very much.

16 James Anderson.

17 DR. ANDERSON: Thank you. I am James
18 Anderson. I'm really glad to be here. I'm a PA,
19 physician assistant, and I'm a member of the
20 American Academy of PAs. I'm also the president of
21 the specialty organization within the AAPA called
22 Society of PAs in Addiction Medicine. I work in

1 opiate treatment. I work at an OTP in Seattle
2 called Evergreen Treatment Services.

3 One of the challenges I see is sometimes the
4 lack of taking advantage of all the resources that
5 are out there. I think the MDs and PAs and other
6 clinicians are a little overwhelmed by all the
7 guidelines available. So many of them are of such
8 high quality, but I think that sometimes the PAs
9 and MDs aren't still looking at them, and that's a
10 conundrum I think for this whole problem.

11 I'm on the Washington State Medical
12 Commission, and I'm surprised at when people come
13 to us and are in the middle of discipline, how many
14 of them have not ever actually accessed any of
15 these tools. It's like they don't know they exist.
16 I don't know what's lacking as far as reaching
17 them, but a lot of them just are not being reached,
18 and that's a problem.

19 There is also a great expansion of
20 resources. For example, I was on the Federation of
21 State Medical Boards group that revised the
22 guidelines recently, and I think they're an

1 excellent tool. But they're just one of many, and
2 sometimes they're just lost. I'm not sure how to
3 best address this, but it's a problem.

4 I do support expanding REMS to acute and
5 perioperative pain. One example of how this can be
6 done is in the state of Washington, the AMDG Pain
7 Guidelines done by a state group, the Association
8 of Medical Directors, and it started off as just a
9 guideline available to people. It focused on
10 long-acting and chronic pain, but now it's been
11 expanded to acute and perioperative. I think it's
12 a nice format and a nice role model for how that
13 could be done. I encourage everybody to take a
14 look at that, if you will.

15 I'm also very puzzled and concerned,
16 particularly because I work in opiate treatment,
17 with the correlation or is there a correlation
18 between decreased prescribing of opiate medications
19 while heroin use increases. I know it's difficult
20 to know, well, is it because of that; is it
21 happening for some other reason. But I do think we
22 as a profession need to get a better look at that

1 and get a handle on that because it's very
2 perplexing. It's hard to think that there's not a
3 connection there, but it's hard to measure as well.

4 Finally, let's say that one of the
5 challenges for my patients in opiate treatment
6 program, patients who mostly use heroin, is that
7 they cannot get their pain treated. They'll go to
8 have some teeth removed, and they'll be told you
9 don't need medication because you're on methadone,
10 sometimes just because of stigma, sometimes just
11 because of ignorance. The same thing will happen
12 for IND. They'll either get no medication or be
13 undermedicated.

14 My patients really bear the brunt of some of
15 the unintended consequences of the restriction of
16 opiates, so that's something I think about every
17 day. Thank you very much. I'm glad to be here.

18 DR. THROCKMORTON: Thank you very much.
19 Joseph Brence.

20 DR. BRENCE: Hello. My name is Joseph
21 Brence. I am a doctor of physical therapy and
22 educator, and I represent the interests of the

1 American Physical Therapy Association and its
2 95,000 physical therapists and physical therapy
3 assistants practicing across the U.S.

4 As we consider future training for opioid
5 analgesic prescribers, we need to consider the
6 recommendations outlined by the CDC. Within this,
7 they recommend if opioids are to be used, they
8 should be combined with nonpharmacological therapy
9 such as physical therapy.

10 After listening to many of the presenters
11 discuss education yesterday, I believe we are
12 moving in the right direction. That stated, I want
13 to ensure that physical therapists are recognized
14 as a profession and not simply an intervention and
15 that we aren't simply on a list with acupuncturists
16 and other potential alternative treatments. There
17 is a significant amount of evidence to support what
18 we do.

19 As we reflect on how to implement the CDC's
20 recommendations, we must first take a look at
21 current practice patterns for those who manage
22 pain. A recent study published in the Journal of

1 Spine analyzing data from 170 million primary care
2 visits for low back pain, from 1997 to 2010, found
3 that physical therapy referral occurred in only
4 10 percent of those visits as compared to an opioid
5 prescription, which occurred in 45 percent in the
6 last several years. Larger disparities in referral
7 rates were found in Medicaid and Medicare
8 beneficiaries. The stat is deeply troubling,
9 especially if we don't alter this trend.

10 As we pave a path forward, we must ensure
11 there are not only recommendations for education,
12 but there is a clear direct path for our patients
13 with pain to access a physical therapist.

14 At minimum, we need to ensure the
15 educational details that a physical therapy
16 referral occurs if an opioid prescription occurs.
17 Paper after paper shows that when a patient in pain
18 receives early access to a physical therapist,
19 there is significant reduction in overall cost,
20 reduction in care seeking for pain, and improved
21 functional outcomes. We cannot afford not to
22 recommend this.

1 For example, in 2010, we spent an estimated
2 \$635 billion in the management of pain, which is
3 more than cardiovascular disease, cancer, and
4 diabetes combined and twice the amount of money we
5 spent fighting a war in Afghanistan. In addition,
6 the estimated cost of managing a single patient
7 with chronic pain in 2015 was a little over
8 \$31,000. As everyone in this room knows, we cannot
9 continue down this expensive path. I think that
10 education is truly necessary.

11 In developing our educational strategy for
12 opioid prescribers, I would encourage we explain
13 the basic complexities of pain to not only
14 providers but also to patients.

15 For example, in 2014, Dr. Adriaan Louw found
16 that one educational session on pain from a
17 physical therapist reduced postsurgical costs by
18 45 percent and improved functional outcomes.

19 Because I'm out of time and in conclusion,
20 we are at a critical time for pain management.
21 Let's educate all parties involved to move forward
22 with the inclusion of physical therapies in any

1 education the legislation that is looking to
2 improve healthcare providers' ability to provide
3 pain management.

4 I truly believe yesterday we saw
5 stakeholders of major associations at that table.
6 I really think moving forward, you guys need a
7 physical therapist at the table as well. Thanks.

8 DR. THROCKMORTON: Thank you very much.

9 Shruti Kulkarni. Kulkarni. Apologies.

10 MS. KULKARNI: Good morning. I'm Shruti
11 Kulkarni. I'm outside counsel to the not-for-
12 profit Center for Lawful Access and Abuse
13 Deterrence, CLAAD. CLAAD's funders include
14 treatment centers, laboratories, and pharmaceutical
15 companies, and are disclosed on our website at
16 claad.org.

17 Our organization works to reduce
18 prescription drug fraud, diversion, misuse and
19 abuse, while also ensuring that individuals with
20 legitimate needs have lawful access to medications
21 that safely and effectively treat their health
22 conditions.

1 Thank you for the opportunity to offer
2 comments regarding training healthcare providers on
3 pain management and safe use of opioid analgesics.

4 Since 2010, our organization has taken an
5 active role in encouraging mandatory prescriber
6 education at a federal level for healthcare
7 practitioners who prescribe any controlled
8 prescription medications. We base this
9 recommendation on the following facts.

10 Under federal and state control substances
11 acts, the risks of abuse potential and related
12 duties are categorized by controlled substance
13 schedules, Schedule 2 versus Schedule 4, regardless
14 of drug class, for example, opioid analgesics
15 versus benzodiazepines.

16 Controlled substances by definition have a
17 higher potential of abuse than noncontrolled
18 medications, and therefore, practitioners who
19 prescribe controlled prescription medications to
20 patients have a higher duty of care. Prescribers
21 of controlled medications must take affirmative
22 steps to prevent diversion, misuse, abuse,

1 addiction, and overdose.

2 Through mandatory education, practitioners
3 can learn how to treat their patients' safety while
4 preventing adverse events. Mandatory education
5 should include greater detail on best practices for
6 prescribing controlled medication, including
7 nonpharmacologic, noncontrolled, and lower-schedule
8 treatments first; verifying through definitive
9 urine drug testing that patients are taking
10 prescribed medications and not illicit substances
11 or medications not prescribed to them; and
12 referring patients with inappropriate substance use
13 to a higher level of care, which may include
14 addiction treatment.

15 Finally, while some state legislatures have
16 taken proactive steps to prevent prescription drug
17 abuse by requiring mandatory education, many have
18 not. Prescriber education is needed on a national
19 level.

20 CLAAD recommends that mandatory prescriber
21 education be tied to the prescriber's controlled
22 substance registration and use the continuing

1 medical education infrastructure for course
2 content. Our full recommendation and legal
3 analysis of how the federal government should
4 proceed are set forth in our 2013 article "The Best
5 of Both Worlds: Applying Federal Commerce and
6 State Police Powers to Reduce Prescription Drug
7 Abuse."

8 Thank you for this opportunity. Please
9 contact CLAAD if we can be of service to you.

10 DR. THROCKMORTON: Thank you very much.

11 Our last speaker, Christopher Hulin.

12 MR. HULIN: Good morning. My name is Chris
13 Hulin. I'm a certified registered nurse
14 anesthetist and president of the Middle Tennessee
15 School of Anesthesia. I represent 50,000 student
16 CRNA members of the American Association of Nurse
17 Anesthetists.

18 As an anesthesia provider, educator, and
19 previous hospital administrator, I am passionate
20 about the opioid crisis because I have seen it hurt
21 so many. As anesthesia professionals, CRNAs
22 provide patient-centered acute and chronic pain

1 management services that offer comprehensive pain
2 management options to decrease or eliminate the
3 need for opioids.

4 In the perioperative period, an enhanced
5 recovery after-surgery protocol includes
6 multimodal, non-opioid medications, and when
7 appropriate, regional anesthesia to minimize or
8 completely eliminate the use of opioids during
9 surgery.

10 Chronic pain management incorporates
11 nonpharmacologic, multimodal pharmacologic, and
12 when appropriate, interventional approaches to
13 improve the patient's quality of life. When a
14 pharmacologic approach is used, the treatment is
15 tailored to the patient's level of pain,
16 functionality, and response.

17 The art and science of the pain management
18 continuum is evolving rapidly. Nurse anesthesia
19 education programs, the AANA, and state
20 associations play an active role in educating CRNAs
21 to reduce or when appropriate, eliminate the use of
22 opioids. Professional development opportunities

1 include educational webinars, online continuing
2 education, conferences, publications, and
3 fellowships in both acute and chronic pain
4 management for CRNAs.

5 A national education model should provide
6 recommendations developed by a collaborative
7 comprised of patients and all professionals to
8 provide pain management services. The education
9 recommendations offer a framework for integration
10 into each healthcare specialty, education for entry
11 into practice, and continued lifelong learning.

12 Prescribing data and other outcomes provide
13 metrics to improve education, recommendations,
14 clinical practice, and identify future research
15 opportunities.

16 Federal and non-federal partnerships are
17 crucial to address educating patients and providers
18 on this complex crisis. The AANA encourages and
19 participates in collaborative, multidisciplinary
20 dialogue to improve pain management and safe opioid
21 use, healthcare provider education models.
22 Collaborative, multidisciplinary clinical

1 education, research, and practice will have a
2 positive impact on the patient's safety and pain
3 experience.

4 With the demand for pain management services
5 increasing, additional healthcare professionals
6 with pain management expertise will be needed. It
7 is important to remove artificial, unnecessary
8 barriers at the practice, state, and federal level
9 for the interdisciplinary healthcare team that
10 includes CRNAs.

11 The ability for CRNAs and all healthcare
12 providers to care for patients to their full scope
13 of practice will increase the excellence and
14 availability of important pain management services
15 for all patients.

16 I ask that patients remain at the center of
17 this discussion. Patients need to be educated,
18 empowered, and engaged in their care to understand
19 their treatment options and that opioids may not
20 always be necessary to address their pain. Thank
21 you for your time and consideration.

22 DR. THROCKMORTON: Thank you very much.

1 If there are other people that didn't get a
2 chance to sign up that have not previously spoken,
3 you're welcome to make a comment, also, at this
4 time. Otherwise, we'll move on to our next
5 session.

6 (No response.)

7 DR. THROCKMORTON: Thank you. I'll thank
8 the panelists here, and then let's transition to
9 the people that are in the health system panel.

10 While you're coming up, I'm going to use my
11 chair's prerogative or whatever to hope that this
12 session and the sessions that we have the rest of
13 them morning are as lively as the ones we had
14 yesterday.

15 In particular, Wilson, I know you and I had
16 talked about this group and the important role that
17 the healthcare systems play. I hope they're able
18 to give us some really good information about the
19 impact of federal duplication on their efforts that
20 they're making and things like that as you guys
21 have your discussion.

22 DR. COMPTON: That's one of the questions

1 that was laid out.

2 DR. THROCKMORTON: Thanks very much.

3 Health System Panel

4 DR. COMPTON: Okay. I think we're live, and
5 the microphones seem to be working, so good
6 morning. I'm Wilson Compton, and I'm the deputy
7 director of the National Institute on Drug Abuse.
8 It's really a pleasure to be here and participate
9 with my colleagues from the FDA in this really
10 important endeavor to dig into the details of how
11 we might organize and structure training around
12 opioid prescribing.

13 Everyone agrees that this is a necessary
14 topic. The question is how to implement it. Do we
15 implement it at a local level? Do we implement it
16 at a systems level? How much should be
17 requirements? How much should be voluntary?
18 What's the role for potential federal rules and
19 regulations in this area?

20 Those are the questions that we're wrestling
21 with, and we're looking for the best advice from
22 our health systems panel to address these really

1 pressing topics.

2 I want to take a moment to thank the FDA for
3 organizing this meeting so effectively. I'm
4 particularly pleased to have a series of questions
5 that this panel will be wrestling with over the
6 next 64 minutes and 6 seconds, which have been
7 really elegantly stated, so that I think we'll have
8 a lively discussion about these issues. But I do
9 think the key question that I hope we'll keep in
10 mind -- there's a concept on the table.

11 Should the federal government mandate
12 training? One possibility is to implement this
13 through DEA registration procedures. That's at
14 least one vehicle. Should this be done through a
15 voluntary basis, or should the federal government
16 just stay out of it and continue to have the
17 developments on a voluntary basis with clinicians
18 and through state and local and systems level
19 efforts?

20 That is the key sort of uber question that
21 all of these panels are wrestling with, and so I
22 certainly hope to get opinions about those broad-

1 based questions from each one of you as we go
2 forward.

3 Let me take a moment just to introduce our
4 panelists, and they're sitting here in a different
5 order than I have here. First, we have David Craig
6 from the Moffitt Cancer Center and Research
7 Institute. We have Bernie Good from the Veterans
8 Administration. We have Colonel Trip Buckenmaeir
9 from the Uniformed Services University. We have
10 Larry Greenblatt from Duke University. We have
11 Beverly Cotton from the Indian Health Service, and
12 a repeat performance from Dr. Carol Havens --

13 DR. HAVENS: I didn't get a nametag so --

14 DR. COMPTON: Well, we already know who you
15 are because we learned about you yesterday.

16 DR. HAVENS: Can you read it? You can't
17 read those, either, so it's okay. It's all right.

18 DR. COMPTON: There's no particular order
19 for each one of you-all to answer these questions,
20 but if I don't hear from you, I will try to call on
21 each of you to make sure that we get your opinions
22 about both the broad questions as well as each of

1 the topics that we've been asked to address.

2 First off, I'd like each of you help us
3 understand the advantages and disadvantages of
4 implementing a required prescriber training
5 program. Within your organizations and within your
6 experience, what has worked? What are the lessons
7 that have been learned that can be applied if a
8 training program was implemented at a federal
9 level? Who'd like to start?

10 Go ahead.

11 DR. GREENBLATT: I'm leading a health system
12 effort at Duke around opioid safety, and we've been
13 working on this now since really -- it's been
14 four years and have offered CME and opportunities
15 to come and speak to groups of clinicians about
16 opioid safety and improving their prescribing
17 practices.

18 Really, there hasn't been a lot of interest.
19 It's been more us trying to invite ourselves to
20 meetings and the like and not a lot of uptake, and
21 folks demonstrating a lot of resistance.

22 Our medical board under requirements from

1 the North Carolina General Assembly recently
2 changed the requirement where everybody who has
3 prescribed any controlled substances in the last
4 three years will have a requirement upon their
5 renewal of their license in a 3-year cycle to
6 demonstrate that they've had 3 hours of CME around
7 safe opioid prescribing.

8 I can't tell you how many requests that I
9 get now, come and talk to us, we want to learn
10 about safe opioid prescribing. It has absolutely
11 changed the landscape. When people know that they
12 are required to do or they're not going to be able
13 to renew, all of a sudden, they're very interested.

14 I think that little bit has really changed
15 everything for us. Our requirement begins July 1
16 for people who might have their 3-year cycle due
17 then.

18 COL BUCKENMAIER: I represent the Department
19 of Defense, Uniformed Services University,
20 America's medical school, and this was mandated by
21 the previous administration that we will provide
22 prescriber training on opioids for every provider

1 in the DoD.

2 That has been ongoing for some time now. I
3 think we're about 60 percent of all providers.
4 Nobody's head's exploded. The system hasn't
5 collapsed, and everybody is doing just fine. In
6 fact, this training has been received well.

7 After 17 years of conflict and the
8 challenges that that has brought to our system,
9 this was long overdue. We've been working on it
10 since 2010. I'll refer you to the DoD's pain task
11 force effort, which actually preceded the IOM
12 report on pain.

13 There's a lot of products, and you can check
14 these products out, which you've paid for as a
15 taxpayer, that are involved in this, particularly
16 the joint pain educational program at dvcipm.org.

17 From my perspective, and of course, I'm in
18 the DoD, we have no problem mandating things. In
19 fact, that's when we're most comfortable.

20 (Laughter.)

21 COL BUCKENMAIER: I see no reason, as this
22 house is burning down around us, we would not go in

1 this direction. It's not like people aren't dying.
2 And so I think we need to get this education
3 started, figure out how best to do it, and we have
4 no time to lose. Thank you.

5 DR. GOOD: I've been prescribing opioids for
6 I think 33 years now, and over the years have done
7 talks to interns and residents and other physicians
8 in my region about safe practice of opioids. And I
9 thought pretty much there was nothing else I could
10 learn. But in the past couple of years, I've taken
11 a number of educational courses, some on my own and
12 some that were mandated, and I have to say that
13 every time I've done this, I've learned something.
14 I thought I knew everything, and there were
15 valuable things that I took away.

16 I took a course with the University of
17 Washington a couple of years ago, which was really
18 outstanding; did some work at the University of
19 Pittsburgh with patient-directed observations with
20 some difficult patients, and then did the mandatory
21 VA training. Then most recently, I did the
22 buprenorphine waiver training, and again, found

1 that there were many useful things that I learned.

2 So I support mandatory training for opioid
3 prescribing because I think we all stand to learn
4 something. And as Trip just says, the house is
5 burning down, and we need to make sure that our
6 providers are as skilled as possible.

7 I don't think that the training, though,
8 ends there. I think that there's only so much you
9 can do with mandatory training, and I think that it
10 really behooves physicians and clinicians who
11 prescribe opioids to be responsible prescribers and
12 to continue to seek education, educational
13 experiences.

14 I know that in VA, there are a tremendous
15 number of optional opportunities for learning, and
16 I can discuss some of those later, in addition to
17 the things that I presented yesterday.

18 DR. COMPTON: You raise an interesting
19 point, and we'll hear from everybody. But it seems
20 to me that with voluntary training or ad lib
21 training, we may reach the audiences that are in
22 some ways the least important because they're

1 already interested in the topic. For mandatory
2 training, that's a way to reach a much broader
3 group of clinicians.

4 But I also think you added an important
5 nuance to that that just taught me something. Even
6 for those that think a great deal about these
7 issues, are quite familiar with them, there are
8 additional things to learn every day.

9 You're an expert in this area, yet you found
10 great benefit from the trainings you experienced.
11 I think that's an important lesson for all of us,
12 and part of how the benefits of mandatory training
13 might extend beyond the obvious targets of
14 clinicians who have a real lack of any knowledge,
15 but also extend to those who are already pretty
16 familiar.

17 I was interrupting the broader discussion.

18 DR. HAVENS: Somebody has to take the
19 contrary view, so let that be me. I actually don't
20 support mandatory training and for a couple of
21 reasons.

22 First, let me backtrack and say not only do

1 I have the opportunity of having been involved with
2 the opioid initiative at Kaiser, but I've also been
3 part of the core faculty on opioid REMS for the
4 last four or five years. So I've had the
5 opportunity to do presentations around the country
6 on opioids.

7 California instituted mandatory training in
8 2001, 12 hours of CME for all physicians prior to
9 their second license renewal on either pain or end
10 of life, and there's absolutely zero evidence that
11 that has made any difference whatsoever.

12 Part of the challenge is the legislature,
13 who loves to practice medicine in California,
14 essentially just said you have to have 12 hours of
15 education on pain and/or end of life without any
16 further qualifications of that.

17 So it was a great boon to CME providers who
18 created lots of activities to provide 12 hours of
19 CME credit with very little standardization of what
20 the content was, or how it was presented, or what
21 the outcomes were, or whether they even needed to
22 measure outcomes.

1 So it's really led to a great number of CME
2 activities being offered in California with very
3 little benefit that we can see.

4 My experience has been that even without
5 mandating it, physicians are very interested in
6 this topic. Most of my education, at least through
7 our group, is with family docs because I am a
8 family physician. They find this to be an
9 incredibly challenging part of their practice, and
10 they really want to know how to do it better. So
11 they are eager to get information. They're eager
12 to get educated particularly on things that will
13 actually help them in their practice, that will
14 help them take care of their patients.

15 That's certainly not true for every
16 physician. And you're right, the people who need
17 it the most may be the least likely to come, but we
18 can at least reach a significant number of people
19 with voluntary education if it's designed well and
20 addresses their actual needs.

21 I think the problem with mandatory
22 training -- let me say, the good thing about

1 mandatory training is that means everybody gets it
2 and everybody gets a standardized curriculum if we
3 design it that way. The disadvantage of that is
4 that everybody gets the same education.

5 Speaking from my role in Kaiser, what our
6 orthopedic surgeons have asked for and need is
7 significantly different than what our pediatricians
8 have asked for and need. To create a one-size-
9 fits-all education for every prescriber in the
10 country, I think does a disservice by not meeting
11 the actual needs of those prescribers.

12 MS. COTTON: I am from Indian Health
13 Service. For those of you who are not familiar
14 with Indian Health Service, we are a federal agency
15 within the Department of Health and Human Services
16 and provide the federal healthcare for American
17 Indians and Alaska natives.

18 In 2014, we started encouraging prescribers
19 to take training on opioid prescribing and pain
20 management. With the former administration
21 requiring all federal prescribers to have that
22 training, we moved to requiring this mandatory

1 training, and that happened in 2016 even though we
2 were rolling out training prior to that.

3 When we started looking at our numbers of
4 prescribers and providers that had taken the
5 training, we were hovering around 40 percent. When
6 we issued the mandatory circular for all of our
7 providers to take that training, we set a very
8 aggressive goal to have our providers trained
9 within 6 months of issuing that memorandum back in
10 the summer of 2016. So they had until January of
11 this year to complete that training.

12 We saw those numbers skyrocket, of course.
13 Everyone got their training. We're about
14 96 percent of having all our federal prescribers
15 trained, and while we don't mandate that same
16 training for tribal or urban Indian healthcare
17 providers, they are able to take that training at
18 no cost. That training is provided through the
19 University of New Mexico.

20 And I understand that Dr. Joanne Katzman is
21 present. I was wondering if that was you. We've
22 never had the opportunity to meet.

1 As that training has rolled out, we have
2 seen that be successful in terms of increasing our
3 number of providers that have been trained. As we
4 get further into the discussion, we'll be able to
5 talk about what our early analysis of what those
6 impacts look like in terms of actual opioid
7 prescribing.

8 I think some of the challenges that we're
9 facing in terms of mandatory training in our
10 particular system is the turnover. We depend a lot
11 on locum tenens, and so making sure that those
12 folks have training when they might be there for a
13 very short period of time, so trying to stay on top
14 of that as well.

15 The training for us is 5 hours long, and
16 that is also required of locum tenens. So if they
17 have taken another training, does it meet the same
18 requirements that we are doing in terms of -- is
19 there standardization across training curriculums
20 or all points of interest that we've looked at?

21 But so far, that's where we're at. I think
22 the result that we can say is that providers have

1 said in their post-evaluation after taking training
2 is that they do feel like the training would impact
3 their prescribing habits. Like I said, when we get
4 further into the discussions this morning, we can
5 show what our early analysis looks like of our
6 prescribing data.

7 DR. COMPTON: Thanks very much. David?

8 DR. CRAIG: Thank you. I just wanted to
9 highlight something that Bernie was saying about
10 people prescribing opioids for a long period of
11 time. I work at a cancer hospital, and all of our
12 prescribers are oncologists, and they probably
13 would disagree that they need more training on
14 opioids, but I think that's not really true.

15 I work on another cancer pain guideline
16 workgroup, and we talk about this a lot, about how
17 to educate oncologists on how to manage opioids in
18 cancer patients. There's clearly something to be
19 gained by a program, but I don't like the mandatory
20 approach. I like Carol's approach, the carrot
21 rather than the stick approach, and incentivizing
22 them somehow to become better at what they do.

1 I think the cancer world, sometimes people
2 ignore a lot of the things that we discuss about
3 opioid risks. Although it's important in other
4 non-cancer worlds, it's also important in the world
5 that I live in, and especially end-of-life care,
6 it's extremely important there as well, which I
7 think people forget.

8 DR. COMPTON: To build on some of the
9 questions, the goal of training is not simply to
10 assure that people have had training but to change
11 clinician behavior as an intermediate step and then
12 to improve patient outcomes.

13 Certainly, Carol highlighted for us her lack
14 of evidence coming from her experience in
15 California. But are there experiences that any of
16 you-all have had where you can point to positive
17 outcomes from the requirements or voluntary systems
18 that you-all are a part of?

19 COL BUCKENMAEIR: I think we have plenty of
20 examples where there's mandatory training such as
21 ACLS or ATLS where at least we provide a common
22 standard foundation. The idea that somehow that

1 common standard is not necessarily meeting the
2 needs for everybody in the community, I don't doubt
3 that. As an anesthesiologist, I'm expected to be
4 able to perform in those roles as a leader, not
5 necessarily just having that basic understanding of
6 those attitudes.

7 I believe creating a foundation of
8 information, resources for these providers, and
9 then allowing either the states or the individual
10 medical specialties to decide what else they need
11 is appropriate. But to not mandate something
12 doesn't give this issue the proper attention like
13 we've given to ACLS, or to ATLS, or other things
14 that we mandate that it deserves.

15 Again, we are in the biggest epidemic this
16 country has ever experienced, and we're acting like
17 that's okay. It's like a jumbo jet crashing every
18 few weeks and nobody's noticing. And of course, if
19 that was the case, there would be all sorts of
20 regulation and challenges going down on the airline
21 industry. I think we need to respond appropriately
22 in the same way as healthcare providers.

1 DR. COMPTON: Actually, the overdose deaths
2 are about the equipment of two fully loaded 747s
3 crashing weekly.

4 DR. CRAIG: Damn. It's the coffee.

5 DR. COMPTON: That's my metaphor when I give
6 this talk.

7 DR. GREENBLATT: We had our opioid safety
8 committee meeting. We meet Monday mornings at
9 7:00. It's really popular.

10 (Laughter.)

11 DR. COMPTON: Those are surgeon's hours.

12 DR. GREENBLATT: That's when a lot of this
13 happens.

14 We have an individual who provides some data
15 back to us, which is what's extractable from our
16 electronic health record. We're Epic users at
17 Duke. And some of the things they could get at
18 were things like how often were people using our
19 patient education materials because it's a -- for
20 those of you who are Epic users, it's a smart
21 phrase, and we can actually record how often that's
22 used; how many urine drug screens have been

1 ordered; are people prescribing naloxone rescue
2 kits; really some of the things, the specific tasks
3 that we want clinicians to be deploying.

4 The numbers were really terrible. They were
5 quite disheartening, and we weren't seeing much
6 change. Then the individual who provided the data
7 was able to break it up into individual clinical
8 entities. And I know who are our highest
9 prescribers are. Not surprisingly, it's our spine
10 center, neurologists, cancer center, et cetera.

11 Looking at how often are those particular
12 clinical entities, were they ordering or doing
13 these various tasks, some of them who are in our
14 top five or so of prescribers, they weren't even
15 really doing any of this at all.

16 On the airplane, I read an article that a
17 colleague had sent me, which was -- he's a VA
18 researcher, and it was about the VA experience with
19 what they were doing around the opioid epidemic. I
20 was very impressed with this, seeing the dramatic
21 reductions in people getting opioids plus benzos,
22 or high-dose opioids, or what numbers got pain

1 agreements, et cetera, et cetera.

2 Tuesday morning, I came in, sat down next to
3 Bernie, and was complimenting him on it. I said,
4 "Gee, the VA is really impressive with all they've
5 done. I was really struck by how much more success
6 they've having than we're having." And Bernie
7 said, "Yeah, that's my work, and I wrote that
8 article."

9 I didn't realize that. But anyway, it was a
10 cool thing.

11 DR. GOOD: I appreciated that.

12 DR. GREENBLATT: It was a great moment for
13 me, too.

14 (Laughter.)

15 DR. GREENBLATT: It really was.

16 One thing I really realized is that it's one
17 thing to rely on people's good intentions and good
18 will to do the right thing -- and I have to tell
19 you, I mentioned this in comment yesterday. People
20 are really exhausted in healthcare. Literally,
21 there's burnout. There's depression.

22 I've had so many groups of providers say to

1 me, we are so damn busy. What are you going to
2 take away from us so that we can do the things that
3 you're asking us to do? We can't do any more. And
4 quite a few have said, if you make me do any of
5 that, I'm referring all my patients out.

6 It's not a warm welcome. It's not a hug and
7 a thank you. And I think when you have a more
8 top-down approach as the Chesters can manage to do
9 in their organizations -- they're both named
10 Chester. It's strange, isn't it?

11 DR. GOOD: And neither of us go by Chester.

12 COL BUCKENMAEIER: It's way too painful to
13 go through high school with Chester.

14 (Laughter.)

15 DR. GREENBLATT: But they both work in
16 organizations where if the leadership says it's
17 going to happen, it's going to happen. I work in
18 an academic health center. There is no true
19 leadership in an academic health center. It's lots
20 and lots of individual entities, each trying to
21 figure out how to publish, how to provide the best
22 care, how to make the most money. It's all these

1 kinds of things.

2 We do have leadership who has fully
3 endorsed, everything we're trying to do, but it's
4 not really a requirement. It doesn't have to
5 happen, and it's not happening.

6 I think our experience is probably much more
7 typical of what you're going to see in health
8 systems and communities because there isn't this
9 top-down approach. There isn't an integration into
10 the record where if somebody is writing a
11 particular drug, a reminder is going to come up to
12 say, why isn't this person on naloxone, or you
13 haven't ordered a urine drug screen in 6 months;
14 you need to do that today, or you're prescribing an
15 opioid and this person's already on a
16 benzodiazepine. Are you aware that these are
17 dangerous interactions?

18 That kind of a level that you can implement
19 if you have a closed system is much more effective
20 than trying to get people to do the right thing.
21 I'm a strong advocate for we need to not only
22 train, but we need to use some strategy that isn't

1 just providing information.

2 I completely agree with Carol. We don't
3 want hours of CME that leads to no change in
4 practice. That's a burden. We all feel burdened.
5 That's not going to get us where we need to be.

6 I don't know -- I don't have enough of an
7 education background to know what we need to do,
8 but maybe it's maybe 2 hours of CME and 2 hours of
9 having another partner in your practice audit your
10 behavior, and then giving that back to you. Let
11 them look at 15 charts and see are you ordering
12 drug screens appropriately, do patients have a pain
13 agreement, are you using the PDMP and documenting
14 that, or whatever it is.

15 Maybe that's not the right way to do it.
16 Maybe it's the academic detailing that the VA is
17 deploying, or to have somebody sit one-on-one with
18 problem prescribers.

19 We have to use a strategy that is going to
20 change practice, not a strategy that's going to
21 allow people to say I've got 80 percent of my
22 multiple choice questions right because I don't

1 care about that. I care about what we do with our
2 patients.

3 DR. COMPTON: Coming from Duke University,
4 you and your colleagues frequently ask us for
5 support for your interesting research ideas, and I
6 think what you've outlined in some ways is a
7 fascinating set of implementation science questions
8 in terms of how best to link some form of training
9 to actual prescriber behavior change as well as
10 important patient outcomes.

11 Those would be the kinds of questions that
12 me and my colleagues at NIH would be very
13 interested in helping you develop and supporting
14 some of those studies.

15 There were a couple of other comments around
16 this question, around how do we link it to outcomes
17 and is there evidence for that.

18 DR. GOOD: So there's an old saying, "the
19 absence of evidence is not evidence of absence." I
20 think with this issue of education, especially with
21 this opioid epidemic, it's going to be really
22 difficult to convincingly show that mandatory

1 education makes a difference. And it's because
2 there's so many other things that are happening.
3 I'm not discouraging doing research to do it. I
4 think that that's great.

5 I mentioned yesterday that we did have some
6 evidence that in providers that did get academic
7 detailing compared to those that did not, there was
8 a significant difference in prescribing in terms of
9 some of the safety metrics that we look at. We
10 have a couple of other small examples. But I can't
11 look you in the face and say that mandatory
12 training will absolutely make a difference.

13 I do think that you can tailor, so I agree
14 that just having a random requirement probably is
15 not the best way to do it, and it should be
16 tailored. If you're an anesthesiologist, it should
17 be different than if you're an orthopedic surgeon
18 or a family practitioner because the needs are very
19 different. So you could look to societies to help,
20 state organizations to help create those, or have
21 some national initiatives to do that.

22 I mentioned that I just recently took the

1 buprenorphine waiver training. I had to do
2 8 hours, not 2 hours or 4 hours, but 8 hours of
3 training so that I can prescribe buprenorphine,
4 which is a very safe drug relative to all the other
5 opioids. It's a safer drug, but I had to do 8
6 hours. But I can prescribe methadone for pain, and
7 I have, and it's an infinitely more dangerous drug
8 than buprenorphine. But I don't need any training
9 for that. I can just do it.

10 I think it's a pretty low bar to
11 say -- because every physician, every provider
12 needs to get CME anyway to maintain their license,
13 and to create some meaningful required training I
14 think is a pretty low bar, and I think we should
15 support it.

16 DR. COMPTON: Other comments around this
17 related issue?

18 (No response.)

19 DR. COMPTON: Okay. Well, let's move on to
20 our next topic bullet. What do you see as the role
21 for prescriber training within your organization in
22 the context of other activities related to both

1 pain management and then the broader opioid
2 epidemic?

3 I would encourage you to take those two
4 issues separately because while they're
5 interrelated, pain treatment and the opioid
6 epidemic, they're not one in the same at all.

7 How would this relate to your organization's
8 activities related to maximizing and improving pain
9 treatment, and then second, how does it relate to
10 the overall opioid crisis, which is the reason that
11 we're here today.

12 DR. GREENBLATT: I can comment. There's
13 been a lot of interest and request for individuals
14 to get CME about pain management, and I think pain
15 management is complicated and often misunderstood.
16 It's poorly taught in medical schools, although
17 that's starting to change. It's poorly taught in
18 residency, and there's lot of survey-type data and
19 analysis-type data on that.

20 Physicians don't feel well prepared for
21 managing pain in clinical practice, and that's
22 across many specialties. I think that's something

1 that really needs to happen.

2 I think a lot of the safe opioid prescribing
3 behaviors, frankly, they're not all that complex.
4 It's a checklist. If you give people a checklist
5 and say these are the things you need to do, it
6 doesn't get much more complicated than that.
7 People can do that.

8 I think there absolutely needs to be both.
9 There can be different approaches, and I think the
10 pain management piece is going to be the more
11 challenging. I think it makes sense to not have
12 one without the other. You really need both.

13 COL BUCKENMAEIR: From a DoD perspective, I
14 think we've been somewhat frustrated at the almost
15 complete and utter focus on the opioid problem to
16 the exclusion of the very difficult pain issues,
17 which is a national healthcare issue.

18 I liken it to treating cholera in the modern
19 era where the only thing you treat is cholera
20 patients and nobody ever bothers, like Snow did in
21 England, to remove the pump handle from the well
22 that was the source of that cholera. And that's

1 what's going on with pain.

2 So our focus in the DoD has been to try to
3 realign both our healthcare provider culture and
4 our patient culture away from this idea that pain
5 intensity is the only measure for pain, which if
6 that's your only measure, there's nothing better
7 than opioids to get your pain to zero.

8 Again, after 17 years of conflict, our
9 soldiers are telling us that if they had known,
10 when they started these opioids after their trauma,
11 what that was going to mean for their
12 rehabilitation and recovery, they would have
13 demanded other options from us from the very
14 beginning.

15 So we've very aggressively moving in the
16 pain space, recognizing the importance of the
17 activity that's going on in the addiction space,
18 but somewhat concerned that so much attention has
19 been placed on, I guess, the burning bush, and
20 nobody's really paying attention to what's feeding
21 those flames.

22 DR. COMPTON: What do you see as the most

1 promising approaches within your system to changing
2 that? What do you see as the alternatives that
3 you-all are implementing that you think make a lot
4 of sense in the pain area?

5 COL BUCKENMAEIR: Well, this is a culture
6 change, and so the most fundamental thing that
7 we've done is a product we call the Defense and
8 Veterans Pain Rating Scale. The feedback we got
9 from our 2010 review was that the 0 to 10 scale was
10 not very helpful in dealing with this
11 biopsychosocial issue.

12 So the DVPRS reframes the question in terms
13 of managing pain with function and both physical
14 and emotional function, and this allows other
15 modalities such as acupuncture, such as massage, to
16 actually compete with medications.

17 Now, understand, I'm an anesthesiologist.
18 I'm a retired military person. When you've just
19 had your legs blown off, nobody is yelling for stat
20 acupuncture. Got it.

21 Opioids have a very prominent and important
22 role in certain portions of this care. The problem

1 I think we had early in the war in 2003 is that was
2 our only solution, morphine. We had the morphine
3 hammer, and every patient was a nail, and we
4 pounded everybody with that tool.

5 It was effective. We could get everybody's
6 pain to zero, but they were essentially on the
7 couch watching I Love Lucy to the exclusion of the
8 rest of their lives. And when the kids came back
9 from school, they're still on the couch.

10 We asked ourselves, is that success, and the
11 answer was no. And that led to General Schumacher
12 as the former surgeon general, who is my immediate
13 boss right now, to form the Pain Task Force.

14 So I really think this is a cultural change
15 that we're asking of the public, and we need to
16 reeducate the public on having a different standard
17 for successful pain care in that getting their pain
18 to zero after a major operation, after a major
19 disease, may not necessarily be in their
20 self-interest.

21 But I don't think we've really said that to
22 them. I think we've said pills will get you where

1 you need to be and zero pain is the answer. That
2 really makes these other things that are more
3 passive, such as yoga, massage, acupuncture,
4 biofeedback, behavioral health modification, those
5 things can be a very important part of your
6 rehabilitation, hard to compete if the only thing
7 we're really measuring is pain intensity.

8 DR. COMPTON: Carol?

9 DR. HAVENS: I absolutely agree. I think in
10 some ways, we're really looking at two different
11 populations of patients, and one is those patients
12 who have been on opioids for a long time. Then
13 there's the future opioid users, the ones that
14 potentially have acute pain now and we want to try
15 to prevent them from becoming the chronic opioid
16 users.

17 That's a little bit easier group to deal
18 with because you can start the prevention right up
19 front. You can have the conversations with them
20 about being on opioids long term can lead to
21 adverse consequences down the line. We'll give you
22 opioids now to deal with your acute pain. Let's

1 talk about other opportunities moving forward. And
2 I absolutely agree. The goal is not absence of
3 pain. The goal is reduction of pain to make life
4 better.

5 So dealing with the future opioid users
6 requires a little bit different skill set than
7 dealing with the current opioid users because it's
8 a little bit harder for someone who's been taking
9 opioids on a daily basis for 10 years to say, okay,
10 now we're going to start over again, and we want to
11 talk about other options. And they're going, well,
12 why didn't we talk about this 10 years ago? Please
13 don't stop my drugs now.

14 I think it requires a multifactorial,
15 multi-interventional effort of educating our
16 providers, educating our patients, setting
17 realistic goals, talking about risks and benefits,
18 and making informed decisions. And I don't think
19 you can do that in the absence of other options.

20 Part of the discussion has to be what else
21 can we do besides opioids. Because you're right,
22 for years when all we had was opioids. When all we

1 had was a hammer, everything looked like a nail, so
2 that's what we did. Now we recognize that we have
3 to provide other options, and we have to talk about
4 what those other options are, and what the risks
5 and benefits of those are versus the use of
6 opioids.

7 DR. GOOD: I think it's a great question and
8 absolutely need to separate, even though they're
9 interrelated, the issue of treatment of chronic
10 pain, as well as acute pain, and how to prescribe
11 opioids.

12 I'll give a shout-out to the gentleman in
13 the comment period who was talking about physical
14 therapy. As I get older, I've had a number of
15 orthopedic-type surgeries, and I've become an even
16 greater fan of physical therapy. It was critical
17 to my getting better and getting well.

18 I think that things like physical therapy,
19 acupuncture, cognitive behavioral therapy, massage,
20 mindfulness, all these tools need to be available
21 for clinicians, and it behooves organizations like
22 VA, DoD, Kaiser and Blue Cross Blue Shield,

1 whatever it is, to make it easy for providers to
2 get their patients into these integrated pain
3 programs.

4 I mentioned yesterday the study that Aaron
5 Krebs did in the VA in Minnesota where they
6 compared using primarily an opioid-based treatment
7 regimen to a non-opioid treatment regimen for
8 chronic pain and how the outcomes after several
9 years were better for the non-opioid regimen.
10 However, I can assure you that it wasn't just usual
11 care with no opioids. It was intensive, having all
12 these tools available.

13 So if we're really serious about treating
14 pain -- and I'm not suggesting we never use opioids
15 for chronic pain. They clearly have a role. But
16 if we want to mitigate the risks and decrease the
17 number of patients that rely on opioids, we have to
18 give the physicians and the clinicians who see
19 these patients the tools that make it easy for them
20 to get the patients these alternative treatments
21 and other non-opioid pharmacologic therapies, too.

22 DR. COMPTON: Larry?

1 DR. GREENBLATT: I'd like to build a little
2 bit on what Carol said about thinking about these
3 two different populations, and I'm going to add a
4 third population, Carol.

5 DR. HAVENS: Oh, please.

6 DR. GREENBLATT: There's the population
7 who's not on opioids who might have a pain problem,
8 and we're trying to manage them without their
9 becoming long-term opioid users. There are the
10 long-term opioid users. And then a third group
11 that I think we need to keep in mind is there's
12 about -- of people on chronic opioid therapy, the
13 estimates in one systematic review are 8 to
14 12 percent of people on chronic opioid therapy
15 actually have opioid use disorder.

16 There are some people who have opioid use
17 disorder who never come into the healthcare system
18 because they're just buying it on the street,
19 getting it from friends or whatever they're doing.
20 I think that that population really needs to be
21 attended to as well. In many communities, there's
22 just not enough treatment.

1 I don't know what we need to do to get more
2 docs to sign on to do the buprenorphine or some
3 other treatments. Like Bernie, I'm a buprenorphine
4 provider. It's immensely gratifying. It's not
5 that hard. It requires some commitment on your
6 part. This is a tough population. That's why you
7 have 8 hours of training. It's not the drug; it's
8 the people.

9 Anyway, it's completely feasible, so let's
10 think about that population as well.

11 The comment I was going to make about what
12 do we need for individuals to be more effective in
13 pain management, I think pain management is
14 different from other things that docs learn to do.
15 You can teach doctors how to manage asthma or
16 hypertension or diabetes, and for the most part,
17 they can enact that. But I think pain management
18 often needs some ongoing mentoring.

19 It's tricky. Patients are all different.
20 Sometimes there's manipulation that happens on the
21 part of the patients. There's a huge affective
22 component on the part of the patients. We feel

1 that as well. A lot of us when we see our chronic
2 pain patients scheduled, we get like a knot in our
3 stomach. But having some ongoing mentoring like
4 the Project ECHO model or some other model, we do a
5 number of these things at Duke.

6 The physicians who have this available to
7 them find it immensely helpful. It's resource
8 intensive. You've got to have someone who knows
9 what they're doing to support. And then frankly, I
10 think you've got to find a way to not penalize the
11 physicians who are taking their time to do that.

12 If you're going to say take an hour out of
13 your day twice a month to talk about chronic pain
14 patients, you can't say, and we're going to take
15 that out of your paycheck, because that's how it
16 currently works. We're all paid on volumes, right?
17 So if you take an hour out, you're basically not
18 getting paid for that hour. That's not fair.

19 So there should be some way that people
20 doing the right way can at least not feel it in
21 their paycheck.

22 DR. COMPTON: I would bring up that the goal

1 of the prescriber training is both the clear goal
2 of how do we treat the patient right in front of
3 us, but there's a secondary prevention called
4 goal 2 in terms of keeping the broader population
5 at lower risk. We see so many, particularly of the
6 acute prescriptions, being diverted into other
7 populations for whom the prescriptions weren't
8 intended, that that's a clear goal of this
9 training.

10 How much do you see that as a target for the
11 training that you-all implement?

12 DR. HAVENS: Let me take a shot at that,
13 then. We started our project looking at the use of
14 chronic opioids and quickly realized that we had to
15 work further upstream. We have also included the
16 use of opioids for acute pain, both in the ER and
17 the primary care setting and the surgical setting,
18 to try to prevent the long-term downstream
19 problems.

20 So I think it's an important part, and I
21 think that, to a certain extent, the previous focus
22 of the REMS on the extended-release long-acting

1 really sort of disregarded that potential, the
2 issue of treating acute pain.

3 DR. COMPTON: To me personally, it means a
4 different role for physicians. Most of my training
5 and my colleagues' training was around how to deal
6 with the person right in front of us, and yet this
7 is much more of a population focus, which is a
8 little different perspective than many of us
9 routinely consider.

10 David?

11 DR. CRAIG: I'll just make a comment about
12 supplies and using it for acute pain. If you're
13 going to think about a training program, I think
14 one of the things that should be considered, which
15 I know people have been talking about a lot, is
16 takebacks and making things easier for patients to
17 return. Most of our patients die. They're young
18 patients. They're in their 40s. Just about every
19 day, somebody calls me and says, we have all these
20 drugs. What do I do with them?

21 Not only on the frontend, but also don't
22 forget about the backend is making it easier for

1 people who are really well-intentioned. If you've
2 ever been to a drug takeback, you'd just be
3 surprised on how much drugs. Even think about the
4 hospice populations, about how many millions of
5 people in a hospice are on opioids; every one of
6 them. Where do those opioids go? I don't know.

7 Anybody know?

8 So there's no real good mechanism for -- if
9 you're thinking about from a supply side, yes,
10 prescribing less is probably good for acute
11 situations. Don't forget about the backend,
12 patients who legitimately have medications and want
13 to get rid of them is extremely challenging. I get
14 this question at work almost every single day.
15 Unfortunately, our patients die, so what do we do
16 with those supplies? Don't forget about that.

17 DR. GREENBLATT: I want to make a couple
18 comments about that. In North Carolina, there's a
19 lot of effort around disposing of medications.
20 Every county, they have 100 counties, they all have
21 a fixed site where people can come and drop off,
22 and those medicines are incinerated. I think that

1 those public health efforts make a lot of sense.

2 This issue about excessive medications, I've
3 seen some survey data where they've asked people
4 who had extra medicines, what did you do with them.
5 The vast majority said, well, I just held on to
6 them. People aren't disposing of them, so that's a
7 concern.

8 There was a publication that came out. If
9 you're interested in trying to find it, it was in
10 the March 6th Annals of Surgery. I don't read the
11 Annals of Surgery; I'm an internist.

12 But it was a terrific, really simple study,
13 came out of Dartmouth, from the department of
14 general surgery there, where they simply asked
15 patients who had had a number of procedures -- I
16 think they targeted 5 procedures -- how many pain
17 pills did you end up needing after your
18 cholecystectomy, or radical mastectomy, or whatever
19 it was.

20 Then they provided this information back to
21 the clinicians who were doing these procedures and
22 said, well, gee, the people who have had the

1 procedure you're going to perform, they averaged
2 18 pain pills. The range was from 10 to 37.
3 Nobody took more than that. Therefore, we
4 recommend you prescribe this amount. And their
5 recommended amounts were a decrease of 53 percent
6 of what people had on average just by their best
7 estimate of what people might need.

8 They also did some brief training with the
9 patients where they said, if your pain is mild,
10 take some acetaminophen. If it's moderate, you
11 might take an ibuprofen or something like that.
12 And if it's more severe, go ahead and take your
13 opioid.

14 Then they went back and followed up with the
15 patients who got these new reduced quantities, and
16 under those reduced quantities, only 28 percent of
17 the pills were actually consumed. So they still
18 have 72 percent left over, and patients were quite
19 happy with their pain management.

20 I think programs like that where we actually
21 use some data to inform our prescribing
22 patterns -- I know in my institution, I think well-

1 intentioned surgeons were routinely prescribing way
2 more. In this role, everybody wants to tell me a
3 story about how they, their neighbor, their sister,
4 somebody got some huge bottle of oxycodone, took 7
5 pills, and had 110 left, or whatever.

6 That happens a lot, and I think physicians
7 don't want patients in pain. They also don't want
8 to have to go through the inconvenience of having
9 to get somebody a hard copy prescription,
10 particularly if you're in a center, whether it be a
11 rural center or an academic center, where some of
12 your patients are driving 100, 150 miles to come
13 and see you. To have somebody come up short on
14 their pain meds is a real problem.

15 Our state is looking at -- and it's almost
16 certainly going to pass -- limits on postsurgical
17 prescribing, no more than 7 days, and then for
18 acute pain, no more than 5 days. We're going to
19 try to meet with some of our legislators to try to
20 put some flexibility into that because I think that
21 that's potentially a huge problem. But we do need
22 to be thoughtful about the quantities and to use

1 real hard evidence to try to make these numbers
2 more concrete for clinicians. I thought that
3 that's something that could really be studied
4 broadly for any number of different indications.

5 DR. HAVENS: And in that study, even with
6 the lower numbers, almost nobody refilled them.

7 DR. GREENBLATT: Right. Virtually nobody
8 ran out.

9 DR. COMPTON: That reminds us of plate size.
10 If you have a big plate, you eat more. If you have
11 a small plate, you still don't quite finish what's
12 there, but it's a smaller amount.

13 DR. GREENBLATT: Even with the big plate,
14 people had huge quantities left over. They weren't
15 just consuming them because they had them. And the
16 point was that they now were in the cabinet, and
17 then potentially at risk for diversion.

18 DR. COMPTON: I was curious about the Indian
19 Health Service. In terms of your training, how
20 much do you focus on acute prescribing versus the
21 long-term management of pain in the long-term
22 opioid pain patients.

1 MS. COTTON: Most of our training is on the
2 long-term. There's not a huge focus -- and
3 Dr. Katzman can certainly correct me if I'm
4 misstating that piece on the acute portion.

5 I think with the CDC guidelines and those
6 being issued, now we're shifting that focus to make
7 sure that we have policy that's in place for our
8 health clinics, making sure that there's
9 directives, if you will, from the national
10 headquarters' standpoint that local facilities need
11 to look into their acute prescribing habits as
12 well. And there's been lots of feedback,
13 especially from surgeons, around how that would
14 work and what that would look like, and what are
15 the flexibilities and those things, in those
16 particular patient situations.

17 From our standpoint, we have set general
18 guidelines in place that say in most cases, 3 days,
19 and generally not -- or rarely over 7 days for
20 acute situations, but haven't set those in very
21 strict parameters so that there is some flexibility
22 for physicians to make those decisions for

1 individual patients.

2 DR. COMPTON: I would point out that we are
3 seeing the option of partial fills of prescription.
4 Pharmacies have done that for years when they
5 didn't have enough pills. They'd only give you as
6 many as they had, and you'd come back to get the
7 rest. But that new option for partial fills, which
8 was enabled by recent legislation, might provide
9 some new opportunities for a variation on this
10 theme that doesn't require patients to drive
11 300 miles for their new hard copy.

12 Carol, it looks like you have a thought
13 about that.

14 DR. HAVENS: Actually, as long as they get
15 it filled where they live rather than where they
16 get discharged, then they still --

17 DR. COMPTON: That's right.

18 DR. HAVENS: -- have to drive back to get
19 the rest of it filled. They're just back where
20 they were.

21 MS. COTTON: Which is a unique challenge for
22 Indian Health Service in terms of filling the

1 medication at the site where they receive their
2 care. If you live 150 miles, your option is to get
3 your medication filled.

4 DR. COMPTON: I think this is a good
5 transition to our next topic, which is to focus on
6 unintended consequences that may have occurred
7 because of either training or new practices or
8 requirements in your clinical settings.

9 Have you seen any unintended consequences of
10 your training, particularly negative consequences?
11 We've focused on the benefits already, but what
12 about negative consequences?

13 COL BUCKENMAEIR: I trained at the Uniformed
14 Services University that I'm working at right now,
15 and I received no formal education whatsoever in
16 pain. Pain was always a symptom of some other
17 disease process, and if we figured out how to use
18 that system and take care of the disease process,
19 then the pain would take care of itself.

20 I think the unintended consequence is the
21 relegation of this healthcare problem, this brain
22 disease, chronic pain, into a backwater symptom

1 that we can prescribe away. And the unintended
2 consequence is where we are right now.

3 I think we need to elevate, which is
4 happening -- the good news is, the newest specialty
5 in anesthesiology. I consider myself an acute pain
6 physician, and that's the newest subspecialty in
7 anesthesia. That's a preventative medicine space.

8 It has all the components of a disease
9 process in that it can be prevented. It can be
10 managed, and there are certain best practices for
11 dealing with those patients who develop a chronic
12 condition. I think we need to start acting that
13 way, both as professionals, but particularly in our
14 educational institutions.

15 I recognize there's no more room on the
16 curriculum, but we need to find room on the
17 curriculum for educating people in the science of
18 pain and how to manage it.

19 DR. COMPTON: Certainly, there is now a
20 classic study that documented the number of hours
21 in pain training among the U.S. medical schools
22 compared to Canadian, and then me and a number of

1 colleagues have compared that to the training hours
2 for veterinarian education. And it's pretty
3 shocking how little in four years of medical school
4 we get training around pain evaluation and
5 treatment.

6 It is estimated around 9 hours. It may have
7 changed since the 2011 publication, but I don't
8 think significantly.

9 COL BUCKENMAEIR: It's definitely changing
10 in our institution, rapidly.

11 DR. COMPTON: I think USUHS as the nation's
12 medical school may turn out to be a role model for
13 many of your colleagues in AAMC.

14 Other suggestions around unintended
15 consequences or benefits from the increased
16 training?

17 DR. CRAIG: I'll just make a comment on not
18 specifically training, but more maybe negative
19 media. Dr. Woodcock yesterday talked about cancer
20 patients in the '80s refusing to take their
21 medicine. Well, it's happening today, too, in
22 2017.

1 Patients watch the news. I read an
2 editorial in the local newspaper about this. I was
3 talking to a patient about why she needed to take
4 her medication, a young cancer patient in her 40s.
5 She subsequently died. And behind me on the TV was
6 another drug bust at an oxycodone pill mill in
7 Florida.

8 So she'd refused to be kind of carved from
9 that stone and said, "I'm a cancer patient, but I'm
10 a survivor. I want to walk away from that."

11 It depends on how you frame it. You have to
12 frame it in a positive way for patients so that
13 they don't feel afraid, that they feel encouraged,
14 that they realize it's an appropriate medical
15 treatment. Any training program must include those
16 elements, not forgetting those patients like that
17 where it's extremely necessary for them, I think,
18 for their quality of life, like those young cancer
19 patients that I care for.

20 DR. COMPTON: Certainly while we've carved
21 out cancer and end-of-life care, sort of an
22 exception to any of the proposed rules and

1 guidelines, there are many other medical conditions
2 that would fall into that category. The DoD
3 certainly has great experience in dealing with
4 non-cancer but really serious long-term,
5 life-threatening conditions, among others.

6 Other thoughts about unintended
7 consequences?

8 DR. GREENBLATT: In terms of unintended
9 consequences of the training, I don't really know
10 of any in my institution, but I would say in our
11 state, there's some new requirements for the
12 medical board to evaluate physicians, or PAs, who
13 are prescribing using certain patterns. Basically,
14 they took the top 1 percent. They're probably
15 going to go to the top 2 percent in terms of the
16 volume of patients receiving 100 milligrams of
17 morphine or the equivalent per day.

18 When the word went out that this was going
19 to happen, those who were prescribing these very
20 large amounts were either releasing patients to try
21 to get under whatever they perceived the threshold
22 to be or were arbitrarily cutting people back to

1 under 100. Oh, gee, I can't prescribe 150
2 milligrams or more. I'm going to give you 95 so
3 that I don't get scrutinized.

4 I think there were many, many complaints
5 back to the medical board about abandonment or
6 inappropriate prescribing, and I think we need to
7 be thoughtful about that.

8 I would say we haven't talked about
9 targeting yet, and I imagine we will. But you can
10 imagine if you require CME only for individuals who
11 have, as they do in my state, prescribed any
12 control substances within a certain amount of
13 time -- for us, it's three years -- what you might
14 find are people who are on the fence about it to
15 say, I'm not going to prescribe anymore because I
16 don't want to be bothered by the CME requirement.

17 So if somebody was already on the fence, do
18 I really want to make that part of my practice, or
19 do I just want to fragment that, send those
20 patients off, they'll say, well, forget it. I'm
21 just going to go off prescribing, so I no longer
22 will have to do that CME.

1 I wonder. That's a potential unintended
2 consequence. I don't think it's one that I've
3 personally seen, but I just worry. People are
4 anxious to -- this is a quote from one of my
5 colleagues -- "flee the pain space," he says. We
6 don't want people to feel the pain space. And I've
7 seen some data on our primary care physicians
8 within my system. The range of patients that they
9 manage with chronic opioids, many at zero; others,
10 it's 50 or 100. And the numbers of referrals to
11 the pain clinic also has a similar range, and you
12 can imagine the people who manage the fewest are
13 providing the most referrals.

14 I don't think it's good in a health system
15 that's already so fragmented to push further
16 fragmentation and to have somebody get their cancer
17 care with a cancer doctor and their pain from their
18 cancer managed by a pain specialist. I just don't
19 think that that's what's good for patients. It's
20 also not very cost efficient.

21 MS. COTTON: I think that we anticipated
22 seeing some of that, and in our early prescribing

1 data that we're looking at in our analysis, we
2 don't see those big shifts, interestingly enough.
3 But it is very early in terms of when we started
4 requiring mandatory training and looking at that
5 data, so we only have a year and a half of data to
6 look at since we --

7 DR. GREENBLATT: But you said everyone had
8 to be trained, not just prescribers.

9 MS. COTTON: True.

10 DR. GREENBLATT: So there's no incentive to
11 get out of it.

12 MS. COTTON: True.

13 DR. GREENBLATT: You could say I don't
14 prescribe anymore, but you're still doing your
15 training.

16 MS. COTTON: Right, right. Then for us,
17 just looking at pain management and the
18 fragmentation of -- and from a cultural standpoint,
19 really working on the integration of bringing back
20 cultural interventions and traditional medicine
21 practitioners, and pushing the system, I think, for
22 many native people, the issue of having the Western

1 medicine and traditional native medicine and the
2 separation, interestingly enough, pain management
3 has brought that back to an interesting point in
4 the conversation of making sure that we're not
5 separating that, going back to things that we've
6 known have worked for indigenous cultures.

7 In a spinoff of that is also
8 medication-assisted treatment. So when native
9 folks are practicing traditional medicine or
10 cultural interventions, the education that we're
11 going to treat a problem that started with medicine
12 with another medicine, and having that education
13 for the community as well as tribal leaders and
14 health system leaders has been a challenge that
15 we've seen to make sure that folks are properly
16 educated on what that looks like for folks that may
17 have an opioid-use disorder.

18 COL BUCKENMAEIR: This is a fascinating
19 conversation and perhaps -- I've only been without
20 an ID card for 21 days in my entire life, so
21 perhaps I'm institutionalized. But I'm sitting
22 here wondering about this disincentive.

1 The deaths that I've experienced in my
2 clinical practice have been from these deadly
3 medications. And so if somebody is put off by a
4 few hours of education, do I really want them
5 prescribing these drugs? So if this is a
6 disincentive for certain providers to get out of
7 this space, maybe they need to be out of this
8 space.

9 I understand what you're saying. I don't
10 think a pain specialist needs to see every pain
11 patient, and that's not what's happening in the DoD
12 or the VA. Primary care takes care of most of the
13 pain. Most of our products, the Joint Pain
14 Educational Program, the DVPRS, is directed towards
15 that community. But if there's a person in that
16 community who can't handle a few hours of training,
17 then they certainly shouldn't be handling a patient
18 on these deadly medications.

19 DR. GREENBLATT: Our pain clinic has a
20 9-month wait for next available.

21 DR. GOOD: At the VA, that would make
22 national news.

1 DR. GREENBLATT: That would be, right.

2 DR. COMPTON: I think this is a segue to
3 help us look at our last topic for this panel,
4 which is which specialty should be targeted? We've
5 heard a little bit of a variety from a couple of
6 examples of where this is targeting in some of your
7 locations, only those clinicians who have either a
8 state version of a registration to prescribe
9 controlled substances or some variation on that.

10 So targeting those who are obviously writing
11 the prescription versus a broad-based approach that
12 targets everybody, and then I think a little
13 variety of opinions about how much do we provide a
14 one-size-fits-all training versus how much can we
15 target it to different specialties and how
16 necessary is that.

17 Who should be targeted, and how should, and
18 a little bit of how often should we insist on
19 education?

20 DR. CRAIG: I'll start. I think our
21 colleges can be a target. I think that they would
22 probably disagree with that. I think that there's

1 a lot that they can learn, even simple concepts
2 about opioid prescribing. Generally, they don't
3 get a lot on opioids just in general.

4 I think that that's a lot of things that
5 could be done for them and if you make it in a
6 mandatory way. Don't forget about the oncologists
7 and their needs.

8 Just back on one point about unintended
9 consequences, I don't think the education would
10 have unintended consequences. I think news and
11 media has unintended consequences. And when you
12 have a referral -- just think about my cancer
13 center, we have a supportive medicine clinic now
14 that oncologists can refer to. We see significant
15 referrals for just simple stuff, oxycodone.

16 It's not the education. It's all the other
17 stuff. It's that the patients don't want to take
18 it. It's that they're sitting in the waiting room
19 to see you, and they're hearing all this crazy
20 stuff on the news. I think that that has much more
21 influence on -- just from where I sit in this
22 cancer center, I think that has a much more

1 negative and unintended consequence than any
2 educational program that you can design.

3 DR. GREENBLATT: I'm going to just offer my
4 opinion here. I don't really have any concrete
5 data to back this up. But I just see in my day-to-
6 day life, there's a huge diversity of what
7 physicians do. There are many physicians who
8 maintain a license who don't prescribe controlled
9 substances and really wouldn't be reasonably
10 expected to any time in the future. Maybe they're
11 engaged in research, or they're diagnostic
12 radiologists, or whatever it is. To me, it would
13 be burdensome to ask that everyone participate in
14 training.

15 I would favor targeted training towards
16 individuals who are likely to need it and make the
17 training something meaningful and viable and not
18 just a checkbox kind of thing. You did your 2 or
19 3 hours, or 4 hours, or 12 if you live in
20 California, but it didn't impact you.

21 Let's make it high quality. Let's focus on
22 the people who are going to benefit from it, or

1 their patients are going to benefit from it.

2 DR. HAVENS: I'd agree with the second half
3 of that comment, which is that I think it needs to
4 be targeted. The content used to be targeted
5 towards the attendees, towards the audience. I
6 think, however, everybody can benefit from
7 education on this. I've said I'm against
8 mandatory, but that doesn't mean I'm against
9 education.

10 I think everybody would benefit. I think
11 even those people who are not prescribing see
12 patients who are on opioids, and it would be good
13 for them to understand interactions with the drugs
14 that they might be prescribing. It's good for them
15 to understand the effect that opioids might be
16 having on their other diseases or other issues that
17 they might be dealing with.

18 So even if they're not prescribing, it would
19 be helpful if they understood some basic
20 information, some basic knowledge about opioids and
21 pain management.

22 The second thing I would say it's not just

1 prescribers. To be really effective in this, it
2 takes a village. In our practice, getting our
3 medical assistants and our nurses involved in this
4 has made a huge difference because they can help
5 reinforce the same messages that the physicians are
6 giving about realistic expectations and about
7 setting goals and about other options.

8 Since we're all disclosing here, I'm also
9 certified for bupre. I actually am certified in
10 addiction medicine and have been practicing mostly
11 addiction medicine for the last 20 years. And I'm
12 quite convinced that many of my patients -- and I
13 still see family medicine patients -- come to see
14 my medical assistant, not me. And I'm perfectly
15 okay with that, by the way. And having my medical
16 assistant be on the same page that I am with
17 management has made a huge difference.

18 I think that if we really want to make a
19 difference in patient care, we need to educate as
20 many people as possible. That includes as many
21 people as possible, and that includes everybody on
22 the team and the patients.

1 COL BUCKENMAEIR: I'd like to agree with
2 Carol.

3 DR. HAVENS: Thank you.

4 COL BUCKENMAEIR: I think this issue, if
5 it's just focused on prescribing, maybe that's the
6 confusion, and then you're allowing yourself to
7 pigeon hole just into prescribers. I don't think
8 that's what this training should be. I think a
9 component of the training should deal with
10 prescribing.

11 A much larger portion of this training needs
12 to deal with the national health crisis, which is
13 pain, and helping all of our providers, doctors,
14 nurses, and ancillary personnel, healthcare
15 personnel, learn how to deal with this issue
16 effectively.

17 So whether or not you prescribe doesn't
18 necessarily mean you're not in the pain space. As
19 a medical hobby, I'm an acupuncturist in Maryland.
20 I work with my wife -- actually, work for my
21 wife --

22 (Laughter.)

1 COL BUCKENMAEIR: -- like I have all my
2 life. It's her massage therapy business, and I do
3 her acupuncture; very effective together.

4 I specifically tell my patients, "I am not
5 acting as your primary care provider, and I will
6 not prescribe." But I'm still working very solidly
7 in the pain space. And while I've become a
8 painiac -- and I had no intention, the war did this
9 to me -- I think every provider who does anything
10 with patients is going to have to deal with pain.
11 It's a fundamental human experience.

12 So I think we need to use this opportunity
13 to provide that training. And I agree, it's not
14 enough just to teach ourselves. There needs to be
15 a program, if there's investment here, in educating
16 the public.

17 DR. GREENBLATT: What if someone's a
18 diagnostic pathologist? They spend their whole day
19 looking at slides. They're really good at it.
20 Maybe they do some research, but they really just
21 don't work with patients, don't manage pain --

22 COL BUCKENMAEIR: Is he in the family?

1 DR. GREENBLATT: Let's say -

2 (Laughter.)

3 COL BUCKENMAEIR: The reason -- you're
4 talking about -- the answer is when I say I'm an
5 MD, I don't get to qualify that. I'm a physician,
6 and so I take the whole jelly roll. And I'm asked
7 questions from my mother like I'm an oncologist,
8 like I'm a radiation therapist, and I'm asked
9 questions like this all the time.

10 So while I'm always qualifying that and
11 saying, look, I'm just a stupid anesthesiologist,
12 but I know who you need to talk to, I'm still
13 providing education as a physician, which as
14 physicians, that's our primary role, educating our
15 patients about their own health.

16 So I think we need to use this opportunity
17 since we've created this problem. We've met the
18 enemy. It's not the drugs. It's us. We did this.
19 And let's be very clear about that. If you're a
20 healthcare provider out there, you have just as
21 much culpability as I do. We did this, and so we
22 need to fix it. And that means all of us.

1 Whether or not you're a radiation oncologist
2 or a pathologist, you need to at least have some
3 basic information about what the medical doctrine
4 is on pain so that that message gets across to our
5 patients, so our patients aren't frustrated with
6 pain and their expectation is to leave with a
7 prescription for Percocet, and they leave with a
8 prescription for physical therapy and massage and
9 acupuncture, which the Asian countries have been
10 doing for forever.

11 So I respectfully think that, yeah,
12 everybody needs to have this.

13 DR. COMPTON: I do think we're clearly
14 hearing that because of the nature of the crisis,
15 both the pain and the consequences of that, we're
16 hearing an all-hands-on-deck message from at least
17 one of our panel members. But we have heard a
18 little bit of disagreement in terms of might there
19 be certain areas that really are less of a
20 priority.

21 DR. GREENBLATT: We don't like to be
22 regulated.

1 MS. COTTON: And as the sole nurse on the
2 panel -- like yay that I'm hearing that -- we don't
3 mandate that the education that we provide -- we
4 don't mandate that for nurses in our workforce.
5 But interestingly enough, when we look at the data,
6 tons of nurses have taken that training.

7 So that's really promising, and now that the
8 conversations are shifting about is there specific
9 training outside of what we're providing already,
10 that should be geared toward our nursing workforce
11 as well.

12 DR. COMPTON: Any sense of how frequent a
13 training might be needed? We're sort of dealing at
14 the edges of is it required, should it be required,
15 how would we implement it? How many hours are
16 sufficient, either at baseline or on an ongoing
17 basis for this?

18 Any thoughts about it? My head is swimming
19 a little bit of, well, it kind of depends on what
20 specialty and how many patients you see, and the
21 complexities of what your continuing education
22 ought to be generally.

1 COL BUCKENMAEIR: The DoD decided 2 hours
2 every three years, and no thought went into that.

3 (Laughter.)

4 DR. COMPTON: That's honest, a highly
5 empirical approach to 2 hours every 3 years.

6 COL BUCKENMAEIR: That's what the folks
7 thought they could stand.

8 DR. GREENBLATT: I think it's pretty clear
9 that there are changes that are happening in the
10 pain space, but that also that performance
11 deteriorates over time. So one time, absolutely
12 not. How often, I would think every 2 to 3 years
13 would be reasonable. Two hours seems awfully
14 short.

15 COL BUCKENMAEIR: I agree.

16 DR. COMPTON: Yesterday, there was at least
17 one person that discussed a 5-hour training. That
18 was more than I've heard other people suggest.

19 MS. COTTON: That's Indian Health Service.

20 DR. COMPTON: Carol, you look like you have
21 a thought.

22 DR. HAVENS: As I said yesterday, one

1 intervention is no intervention. So I think this
2 needs to be multiple interventions over time, but
3 I'm not sure that that translates to a 2 hours
4 every 3 years, or 5 hours every year, or anything
5 else.

6 I think there needs to be reinforcement,
7 frequent reinforcement. That can be in ways other
8 than classic CME activities. I think we can look
9 at options and alternatives. I don't know that we
10 can say how many hours and how frequently.

11 DR. GOOD: I agree. I don't think you can
12 say how many hours. But I do think that it would
13 be tremendous for health services researchers to
14 look at the type of intervention, and for mandatory
15 education to try, to find out what it is that works
16 best and might have a lasting impact on
17 prescribing.

18 I think it is a study-able question. I
19 don't think it's easily studied just based on
20 observational data. I think you would have to have
21 some thoughtful study where you would look at
22 different types of educational opportunities, and

1 maybe a one-size-fits-all approach versus a very
2 targeted approach. I don't know. I think there is
3 lots to be learned from that.

4 DR. COMPTON: Well, please join me in
5 thanking our panel for what's been I think a lively
6 and useful discussion.

7 (Applause.)

8 Questions and Answers

9 DR. COMPTON: We do have the opportunity for
10 questions from the audience at this point.

11 Dr. Harris?

12 DR. HARRIS: Good morning. Patrice Harris,
13 chair of the board. And in the spirit yesterday, I
14 don't think I have a question, but I have three
15 suggestions for going forward for this group since
16 we have thought leaders, of course, in this room
17 and folks that are thinking hard about this issue.

18 The first is I just agree with your last
19 point regarding who knows how many, and it will
20 depend. For that reason, I think -- and this
21 should come as no surprise to you, that I think
22 that speaks to a more local solution that can

1 assess and reassess, and have the nimbleness to
2 change when something isn't working. So I'll just
3 throw that out.

4 The other thing that you-all pointed out
5 today so well in this panel is how complicated this
6 is, how many factors, how many layers, and you even
7 started talking about segments, which I think we
8 don't hear a lot about, the folks that are naive at
9 this point versus folks that are chronic.

10 The other segment that I think is not often
11 discussed, particularly in these conversations, and
12 I'm guilty of this, we often have middle-class
13 conversations about these and other issues when we
14 get together.

15 So we say, and I'm including myself in this
16 group, we all agree that physical therapy is a
17 great alternative, evidence-based, but physical
18 therapy may require three visits, and there are
19 folks who can't get off from work. You did raise
20 the transportation issue.

21 So I just raise that as another segment that
22 we have to make sure that we watch our middle-class

1 conversations.

2 Finally, I want to say something about the
3 complexity of the conversation regarding pain, and
4 you've made that point, and the words that we use,
5 I'll just say "targeted," and this is not a
6 criticism; take this in the spirit that it's given.
7 But we do have to watch our language.

8 We shouldn't target folks. We should
9 support those folks who need that more support. I
10 think we should be really careful about that if we
11 want to bring folks in for behavior change. I'll
12 even say what's mild surgery, and you should have
13 mild pain after this surgery.

14 I will just give you a quick personal
15 example. In the span of three years, I had two
16 surgeries, one mild -- and this is even my
17 definition -- and one major. I had more pain with
18 the mild procedure than I did with the major
19 procedure.

20 So pain is complicated, biopsychosocial. We
21 can't really make assumptions regarding the type of
22 surgery or even the person. I just want to make

1 those points. Thank you.

2 DR. COMPTON: Thanks very much.

3 MR. TWERSKY: Larry Twersky. Question,
4 talking about mandatory education, and it seems
5 like it's a little bit flipped that we want to give
6 mandatory education to the providers in hopes that
7 it trickles down to the patient.

8 What about mandatory education for the
9 patients for 5 minutes local and that we build a
10 curriculum to support that 5-minute video before
11 somebody -- like Dr. Chester mentioned, I go on
12 Virgin Airlines. I love their 2-minute video on I
13 have to know how to put a seatbelt on, knowing that
14 I am less likely to die in that than like we just
15 talked about the plane crashes happening.

16 Giving patients the alternative to see a
17 video that is approved by the groups and maybe
18 individualized based on the specialties, and then
19 build an education that's mandatory around did you
20 have questions about that seems like a better way
21 to distribute.

22 Then by all means what I still believe is

1 patients need the tool to dispose medication right
2 after the time it's done and maybe even make it
3 illegal after a certain amount of days to keep it
4 so that they know that they have to get rid of it.
5 Because we're trying to treat third-party injuries
6 and not first party, which is what you're talking
7 to the patients about.

8 I'd love your guys' opinion about maybe
9 thinking about it in reverse. What do the patients
10 need to know, and then how do we deliver it to them
11 in an exceptional way every single time so that
12 they -- like you said, if they knew 10 years ago
13 that this was going to be the case, maybe they
14 would have made the three trips to the physical
15 therapist. Maybe they would have made a different
16 choice after that.

17 I want to ask that question to the group.

18 COL BUCKENMAEIR: The DoD along with the VA
19 actually created a video called "Understanding
20 Pain," which we shamelessly stole from the
21 Australians, with their permission, of course. We
22 understand in many of the VA institutions, many of

1 our institutions, that video just runs in various
2 clinics. It's spreading into civilian clinics.

3 So that's an example, again, on a whole host
4 of videos that you can find at our website
5 dvcipm.org. You already own this material.

6 I think it's an excellent suggestion, and
7 I'll just finish. I would have been far more
8 pleased to see a 30-second spot based on something
9 like that during the Super Bowl than the commercial
10 about my constipation because I have to take my
11 opioids. Those sorts of things need to be
12 addressed because right now the message is
13 completely controlled by the pharmaceutical
14 companies, and we're silent, and that's a problem.

15 DR. COMPTON: Over on that side next.

16 MR. BRENCE: Just to second his point, there
17 actually is some evidence regarding educating
18 patients. There was a 45 percent cost savings --

19 DR. COMPTON: Could you introduce yourself,
20 please?

21 MR. BRENCE: Oh, Joseph Brence, American
22 Physical Therapy Association. But there is good

1 evidence that is cost savings and improved outcomes
2 when patients do get an educational piece.

3 My question is more along the lines, I'm
4 hearing a divide up here. Do we educate
5 prescribers on opioid education or pain education?
6 I want to hear the consensus on if we're going to
7 mandate any type of education, is it pain
8 education, opioid education, or both?

9 I think that anybody here who also does pain
10 physiology research understands that over the past
11 15 years, we've learned more about pain than we
12 ever knew before. To Colonel Buckenmaeir's
13 point -- I butchered your name. Sorry.

14 COL BUCKENMAEIR: Close enough.

15 MR. BRENCE: Okay. We now know that it's
16 more than the tissues of our body. It's a
17 biopsychosocial experience, right? But we still
18 see our colleagues diagnosing arthritic pain or
19 kind of blaming the tissues of our body versus
20 understanding that complex experience.

21 Should the education be on pain, opioids,
22 both? I didn't really hear a consensus from the

1 group.

2 COL BUCKENMAEIR: Take a vote?

3 (Chorus of boths.)

4 DR. COMPTON: I think everyone said both. I
5 think there was consensus.

6 COL BUCKENMAEIR: I've been called far worse
7 before.

8 (Laughter.)

9 MS. CHRISTOPHER: I'm Myra Christopher, and
10 I hold the Foley Chair in Pain and Palliative Care
11 at the Center for Practical Bioethics. I want to
12 comment about your comment, Dr. Compton, about
13 end-of-life care and cancer pain being exempted as
14 we're developing policies and curriculum and so
15 forth.

16 I have spent 40 years of my life working on
17 end-of-life care. About 15 years ago, I became
18 completely convinced that those who live with
19 chronic pain on a daily basis have a greater burden
20 to bear than do those who live knowing that their
21 life will soon end. Those who are in the dying
22 trajectory know that relief will come and the end

1 is in sight.

2 I also am an ovarian cancer patient. I am
3 in remission, and I am very grateful to be in
4 remission and intend to be in remission for a very
5 long time.

6 These exemptions that I keep seeing pop up
7 are so offensive to me because it's all about
8 politics. It has nothing to do with the science of
9 pain or how we address this issue or the addiction
10 issue.

11 I really want to make a personal plea that
12 we're very mindful of the politics of all of this,
13 and as we can, we try to strip it out of this
14 discussion because I think it's very detrimental.

15 DR. COMPTON: Thank you for taking my bait
16 and being willing to address some of the issues
17 about how do we carve out different areas for
18 intervention and what are the actual appropriate
19 boundaries.

20 Any comments or thoughts with that really
21 interesting comment?

22 DR. GREENBLATT: I do think that a different

1 approach is appropriate for someone who's at end of
2 life than for someone who's not, but it doesn't
3 mean that those providers don't also need training.
4 For example, we put a lot of emphasis in our work
5 at Duke on risk assessment. Well, if somebody has
6 a high risk for becoming opioid dependent or
7 misusing opioids but they have stage 4 lung cancer,
8 I don't care. That person needs analgesia to
9 function and have a decent quality of life. They
10 should get it.

11 But there's plenty of cancer patients who
12 are going to survive long-term. The CDC guidelines
13 specifically exclude cancer patients. I think that
14 that's a mistake, and at the end-of-life care, we
15 need a different approach. But it isn't a free-
16 for-all is acceptable.

17 DR. COMPTON: Other comments? That was very
18 well stated. Over here?

19 MS. HARDESTY: Hi. Ilana Hardesty, Boston
20 University. This is probably mostly for the
21 non-government folks.

22 Yesterday, we talked a lot about how one

1 might incentivize if the education is kept
2 voluntary instead of mandatory. I'm wondering if
3 you-all have a sense, a position, on the role of
4 the malpractice insurers in terms of giving some of
5 those incentives.

6 DR. GREENBLATT: Like my 16-year-old getting
7 a break on driving insurance if he took driver's
8 ed? I'm not sure that that's a strong enough of a
9 driver. I think probably the difference in overall
10 risk for an individual who's had or not had opioid
11 safety training may not be big enough to drive it.

12 It'd be interesting to talk to somebody from
13 the insurance industry and see do they see any
14 difference and could they share some of that back
15 with the provider. And many of us don't even pay
16 our own malpractice anyway. It's covered by our
17 institution. More than half of doctors are
18 employed by large organizations, so it may not
19 work. Interesting idea.

20 DR. COMPTON: Others?

21 DR. KATZMAN: Hi there. Joanna Katzman.
22 Thank you so much for your discussion.

1 Just a couple comments. As you know in New
2 Mexico, we've had mandatory training since 2012,
3 and the Indian Health Service has had mandatory
4 training since January of 2015. No clinician with
5 prescription authority has been excluded, and I
6 agree with Myra Christopher and many on the panel
7 that this should continue.

8 I strongly believe that. Whether you're a
9 pathologist, a radiologist that does not prescribe
10 or see patients, you're a physician. You took that
11 primum non nocere oath when you graduated from
12 medical school, or you took the similar oath when
13 you graduated from nursing or dentistry school.

14 You might be a parent. You might be a
15 brother, a sister of a relative. There's very few
16 people in the audience that does not know somebody
17 who has either chronic pain or an opioid
18 substance-use disorder. We've had no pushback in
19 New Mexico or the Indian Health Service with having
20 everybody take the training.

21 Just another comment in terms of the hours
22 for the committee, Dr. Compton, is what we've seen

1 because we've been doing this for so long since
2 2012, is that we had 5 hours initially upfront.
3 The licensing boards, whether it's the New Mexico
4 Medical Board, the New Mexico Board of Nursing,
5 Dentistry, have now adopted their hours particular
6 to what their needs are.

7 After we had the initial 5 hours of what we
8 thought was just what they really needed to get
9 primarily emphasizing pain, which Trip Buckenmaeir
10 emphasized, pain management, non-pharmacology,
11 non-opioid pharmacology, screening for addiction,
12 and then a little bit about safe opioid
13 prescribing, which we all know is actually much
14 easier than all the other elements about pain
15 management -- but what you can do as the years go
16 on if you have a 2- or 3-hour mandatory training,
17 the next 2 or 3 years, you can divvy it up. You
18 can make the elements a little bit different.

19 If you're going to continue doing this, and
20 we need to, our country is burning down like you
21 guys have said with jumbo plane crashes twice a
22 week, but you can change the elements of the

1 training every two years so that you get the needed
2 parts as we're moving into different elements of
3 what we need to learn. Thank you.

4 MS. GAINER: Hi. I'm Kara Gainer. I'm with
5 the American Physical Therapy Association, and I'll
6 just be expanding a bit in my own words what my
7 colleague had said.

8 As discussions evolve --

9 DR. COMPTON: If you can help frame this as
10 a question a little bit.

11 MS. GAINER: Sure, yes. I'll just say one
12 quick statement. So as discussions evolve on
13 whether prescriber training should be mandatory or
14 voluntary, I would implore the government and other
15 stakeholders to also discuss in more depth what the
16 content of that training should be. Some of the
17 panelists did mention the importance of
18 alternatives to opioids and how barriers to access
19 must be lifted, but I have concerns that despite
20 this recognition, which I presume extends beyond
21 this room, the primary focus of pain management
22 education and prescriber training continues to be

1 on how to safely and competently use opioids in the
2 treatment of chronic pain.

3 I guess my question is to what extent within
4 each of your organizations are you providing that
5 education on alternatives to opioids. I imagine
6 you might be already, but how can we expand that
7 nationwide? I just would appreciate your thoughts.

8 COL BUCKENMAEIR: I just want to make one
9 comment. We don't train as alternatives to
10 opioids. Opioids are a vital component of what we
11 do in the DoD. We look at these as complementary
12 parts of a multimodal plan and training in our
13 providers on how to effectively use all of these
14 tools appropriately depending on the patient.

15 Sometimes opioids are going to be an
16 important part of that plan if you just had both
17 your legs blown off. Sometimes they won't if
18 you've just had a musculoskeletal injury.

19 As was pointed out earlier, language does
20 matter. The moment I say to one of my surgeons,
21 this is an alternative. They go, oh, then let me
22 do what I'm going to do, and then you can go do

1 that stuff that you call alternative.

2 The things that physical therapy and massage
3 and the rest is not alternative. It needs to be
4 front and center like it is in so many other
5 cultures. I think that's one of the challenges and
6 the reasons why the National Center for
7 Complementary and Integrative Health changed its
8 name to unburden itself from that word
9 "alternative." Thanks.

10 DR. COMPTON: Other comments?

11 DR. GREENBLATT: I'd like to make a comment.
12 One challenge to the idea of pointing to
13 alternative -- I'm sorry -- other primary means of
14 managing pain other than opioids is it tends to be
15 syndrome specific, and what works and what doesn't
16 work isn't the same. If you only have a few hours,
17 what works for a migraine, what works for back
18 pain, what works for arthritis, these things may be
19 vastly different.

20 If you're giving a CME, whether it be
21 online, face-to-face, or whatever, it's very hard
22 to include all of that. Certainly, you'd want to

1 address the idea that opioids shouldn't be your
2 first choice. Often, they're much further down the
3 list, but it's hard to get into the weeds.

4 In the stuff we've done, we try to avoid
5 that. Certainly, I do a lot of training with
6 medical students, residents, and we very often talk
7 about what are the eight things that are proven
8 effective for chronic low back pain. We should
9 really try to get through that list before we even
10 think about opioids for this person. That's a
11 better place to teach that kind of detail.

12 DR. COMPTON: I see that we're about out of
13 time. I want to give our panelists -- see if
14 there's any other burning concepts that we've
15 missed in the last hour and a half.

16 (No response.)

17 DR. COMPTON: If not, then I want to ask
18 everyone to join me in thanking our panelists for a
19 lively discussion.

20 (Applause.)

21 DR. COMPTON: If I read the schedule
22 correctly, we are on break for about 15 minutes.

1 We will see you at 5 to 11:00.

2 (Whereupon, at 10:37 a.m., a recess was
3 taken.)

4 Patients and Consumer Advocates

5 DR. EGGERS: As we make our way to our
6 seats, I'll get started. My name is Sara Eggers,
7 and I am in the Office of Program and Strategic
8 Analysis in the Office of Strategic Programs within
9 the Center for Drugs within CDER.

10 I want to thank you-all for coming. I have
11 learned a tremendous amount from our discussions so
12 far. I don't think day to day about opioids
13 necessarily. Why I think I'm here to help is
14 because I'm part of FDA's Patient-Focused Drug
15 Development initiative, which is an important
16 initiative that FDA has done for the past four-plus
17 years now to really do what I hope we're going to
18 do today through this session, which is a chance to
19 focus the dialogue on the people who have a real
20 stake in everything that is going on, the people
21 who deal with pain on a daily basis, the people who
22 need pain management on occasion, the people who

1 are at risk of opioid use disorders, and the people
2 who are suffering adverse events of opioids and
3 impact of opioid use disorders.

4 So getting the perspectives from our panel
5 members to really focus on the people involved, I
6 think that's what we're going to be doing in the
7 next session, hearing your perspectives from what
8 you've heard today and yesterday, from your
9 personal experiences, your experiences in your
10 organizations from what you hear from your
11 constituents.

12 I look forward to our discussion, which is
13 focused on training. I'll put out the disclaimer
14 for my panelists. Some of these questions, this is
15 the first time they've seen these questions, the
16 first one in particular. We are having a
17 discussion that builds on what we've heard
18 previously and tries to address what is really the
19 goal, what are we trying to get out of training. I
20 think that one will build very nicely on the panel
21 that just preceded us.

22 The second question, focusing more on

1 prescriber training required and what the likely
2 and potential effects of that may be on patients
3 and caregivers. And then as we have time, we can
4 move into other questions, looking, for example, at
5 what's the role of patient stakeholder groups and
6 patients themselves in addressing the educational
7 needs.

8 That's what we hope to cover in the next 73
9 minutes. We'll then have a Q&A session.

10 As we go through our introductions, we'll go
11 down the line in our introductions of your name and
12 your affiliation, I'm also going to give you a
13 chance to provide one burning question.

14 I'll ask you to keep it very brief and in
15 the form of a question, but what's the key question
16 that has been on your mind? It's on your mind
17 right as we start this. Even if we can't answer it
18 now, we might be able to answer it in the last
19 session, but what's still on your mind?

20 We'll start with Myra.

21 MS. CHRISTOPHER: First of all, I want to
22 say that I thought the last panel was just

1 fabulous, and I'm delighted to have an opportunity
2 to be here.

3 I said in the Q&A after the last session, I
4 am at the Center for Practical Bioethics. I hold
5 an endowed chair in pain and palliative care, and I
6 direct a national alliance called PAINS, which was
7 formed immediately following -- actually just
8 before the release of the IOM report "Relieving
9 Pain in America."

10 I had the opportunity to serve on that
11 committee, and I also have had the privilege of
12 serving on the NIH interagency pain research
13 coordinating committee, and in that capacity,
14 serving on the oversight committee for the
15 development of the National Pain Strategy report.

16 The burning question I have -- and it
17 actually came to me yesterday morning when we were
18 in the introductory phase of the meeting, that as
19 the -- I think there were six or seven goals of the
20 FDA's strategy that were articulated, and there was
21 no mention of improving chronic pain care among
22 those.

1 I think unless we begin to try to pull
2 together all the work that has been done over the
3 last six years that's culminated in the National
4 Pain Strategy report with all the work that is
5 being done, we have no chance of being successful
6 on either front.

7 So my question is, why is it that in this
8 context, it was only really until the last panel
9 that we heard anything about the relationship of
10 these two public health issues and the importance
11 of addressing them if not in an integrated way, at
12 least in tandem?

13 DR. EGGERS: Okay. Thank you. I'll go to
14 Maria.

15 DR. LOWE: Hello, everyone. My name is
16 Maria Lowe, and I'm here representing
17 PatientsLikeMe. We are an online patient-powered
18 research network that currently is home to a
19 community of over 500,000 patients, tracking their
20 experience with more than 2700 different disease
21 states. Our goal at PatientsLikeMe is to help
22 patients improve their lives through the collection

1 of new knowledge from shared real-world experiences
2 and outcomes.

3 My professional background is that I am a
4 pharmacist by training, but I work every day to
5 review patient experiences and help them translate
6 what's going on in their lives to structure data
7 that can be used for meaningful research.

8 I think what really occurs to me as my
9 burning question is a two-part question. What are
10 we doing to empower patients as partners throughout
11 this process alongside any required or mandatory
12 prescriber education? And what are we doing to
13 evaluate outcomes that matter to patients? And
14 building on what Myra just mentioned, we need to be
15 looking at overall impact on pain and care
16 management for these patients, and I haven't heard
17 much about that, either.

18 DR. EGGERS: Thank you. Penney?

19 MS. COWAN: Hi. My name is Penney Cowan.
20 I'm the founder and CEO of the American Chronic
21 Pain Association. I'm also on the board of the
22 International Alliance of Patient Organizations. I

1 serve as the secretary. I started the
2 International Pain Management Network. I'm on the
3 IPRCC. I was part of the National Pain Strategy,
4 co-chair of the public education and communication.

5 Essentially what the American Chronic Pain
6 Association does, and what I've been doing for
7 37 years, is reaching out and educating people
8 about a balanced approach to pain management,
9 really helping people become an active participant
10 rather than a passive patient in their care. It's
11 really important to hear the voice of the person.

12 One thing I remember hearing the first time
13 I went to a meeting at the International Alliance
14 of Patient Organizations, they said, "Nothing about
15 us without us," and that has stuck with me forever,
16 nothing about us without us. I love that statement
17 because it's very true.

18 I was thinking on the panel that was up here
19 before, there should have been a patient on that
20 panel. There should have been one on every panel,
21 I think, to have our voice in there, because if we
22 don't have it from the very beginning, then there's

1 a real issue.

2 I also was thinking back thinking about
3 this, and there was a declaration in Montreal back
4 in 2006, the International Association for the
5 Study of Pain, and it says, "Access to pain
6 management is a basic human right." One of the
7 comments was "a major deficit in knowledge of
8 healthcare providers regarding the mechanisms of
9 the management of pain."

10 I'm sitting here listening to all this today
11 and thinking, okay, so we're talking about
12 educating providers. We've been talking about it
13 for a long time. And my question is -- and I was
14 wondering, especially listening to the panel today,
15 so we do all this education, but how is it actually
16 put into practice? What does each one of those
17 individual providers do?

18 Do they actually take that time, talk to the
19 patient? Do they have any understanding of what's
20 going on with them, what it's really like to live
21 with pain? Do they understand what that is?

22 I think part of the problem, just to throw

1 this out, is the fact that they don't have the time
2 because they're not being reimbursed for that time
3 to give that kind of treatment and communication
4 that they need for their patients. So my question
5 is what do they do?

6 DR. EGGERS: What do they do?

7 MS. COWAN: What do they do with the
8 training?

9 DR. EGGERS: Then we have Teresa.

10 MS. CARR: Hi. I'm Teresa Carr. I'm a
11 senior editor with Consumer Reports. Specifically,
12 I work in our best buy drugs group. I'm in a
13 grant-funded position.

14 One of the things I do is I write about
15 medications and safety and the efficacy. For
16 example, the June cover story for Consumer Reports
17 is online now. It's on back pain, but it focuses a
18 lot on nondrug therapies and those approaches. We
19 try to bring that out while at the same time, of
20 course, reporting on opioids.

21 The other things that we do is we have a
22 public health component as part of our grant

1 funding. So for example, right now, we're working
2 with the VA in Minneapolis. We talked about Aaron
3 Krebs' research earlier. We're working with them
4 to develop some educational materials, and we've
5 been doing some focus group work with patients as
6 well as providers.

7 In terms of I think for me, the essential
8 question -- and I hope that gets addressed here, at
9 least by the end of the day, something that has
10 been thought about a lot -- is we've all agreed
11 upon there's a consensus that the opioid epidemic
12 is a huge, huge, huge problem. We know that
13 91 people dying a day is an enormous problem.

14 There's a lot of stakeholders at this point
15 working on it. I've talked to a lot of these
16 people, and I've heard over the last day and a half
17 about people that are working on it. A lot of
18 people are working on it.

19 From my perspective, the question I would
20 ask is, for the consumer, how can we bring some
21 consistency to what they are receiving in terms of
22 their care? Now, there's going to be variation in

1 care; there's going to be variation in consumer
2 needs. But there should be, I think, some
3 consistent messaging we all agree on regarding
4 opioid prescribing, and for people who are not
5 prescribers for people who are treating people who
6 taking opioids, that are at least -- so all of us
7 in the healthcare system have some very consistent
8 messaging. That's what I would hope that we would
9 achieve.

10 DR. EGGERS: Thank you, Teresa. And Jan?

11 MS. CHAMBERS: Hi. My name is Jan Chambers.
12 I'm the founder and president of the National
13 Fibromyalgia and Chronic Pain Association. We
14 focus on education, advocacy, research, and
15 support. I've served as a working group member on
16 the National Pain Strategy to develop that. I was
17 on the service and delivery working group, and then
18 I was also honored to work on the Federal Pain
19 Research Strategy, which is just now coming to a
20 finish, and then working there in the transition
21 from acute to chronic pain to basically develop a
22 blueprint for the research for the United States.

1 My concern, my alarm is up here after these
2 meetings and the recent events, and so my comments
3 are a little bit strong. I feel that
4 the -- especially the different agencies, the
5 federal agencies who are making policies and the
6 different service providers that they rely on or
7 are giving them recommendations are completely out
8 of touch with patients.

9 There have been no assessments, no national
10 assessments that have been discussed as a main tool
11 to measure how are people with chronic pain doing
12 and what do we do as they transition from acute to
13 chronic pain. We're only measuring the opioid
14 misuse and abuse.

15 My concern is that the policy is ignoring
16 and actually having an unintended consequence to
17 cause torture to millions of people, the fear of
18 pain, the experience of severe pain. And when I
19 talk about the disabling chronic pain, I'm not
20 talking about people with common chronic pain
21 ailments. I'm talking about people who can't get
22 out of bed, people who can't work, people who can't

1 help their families.

2 This kind of brain-seizing pain is the pain
3 that we need to focus on. This is what our
4 prescriber education needs to understand. This
5 often leads to suicidal ideation. We know from our
6 national surveys by our organization that 27
7 percent of patients when they don't have access to
8 pain relief, some kind of medication or treatment,
9 that 27 percent of them are considering suicide as
10 a way out. This is alarming.

11 So I'm really looking forward to the
12 discussion that we're going to have here, and I've
13 appreciated everybody's comments that we've had so
14 far. Thank you.

15 DR. EGGERS: Thanks, Jan. Greg?

16 MR. WILLIAMS: Hi. I'm Greg Williams. I'm
17 the co-founder and executive vice president of
18 Facing Addiction, a national nonprofit organization
19 that has brought together over 575 local, state,
20 and national groups from the prevention, treatment,
21 recovery, harm reduction, and research advocacy
22 space on addiction issues, broadly.

1 I'm also a person in long-term recovery.
2 For me, that means I haven't used alcohol or other
3 drugs in over 15 years, specifically have not
4 misused an opioid in over 15 years, and as a
5 result, my life has gotten a whole lot better.

6 I'm really privileged and happy to be here
7 with you-all on behalf of so many families of loss.
8 Many of our stakeholders are families of loss and
9 folks in recovery.

10 People are very concerned about the lack of
11 knowledge that they've received in doctor's offices
12 and in healthcare settings, in emergency
13 departments, around the intersection of addiction
14 and opioid pain management prescribing, meaning
15 that we know today -- the surgeon general released
16 the first ever surgeon general's report on alcohol,
17 drugs, and health just last November. And we know
18 today some of the very key risk factors of
19 addiction.

20 Broadly, we often talk about mis-prescribing
21 of opioid pain medication, but what we're not doing
22 is acknowledging there's a risk factor and a group,

1 a population like me, family history, family
2 history of mental health, early onset of use of
3 alcohol or marijuana, early use in adolescence, all
4 of these issues that we can predict who might
5 actually have and develop a problem with opioids
6 versus a population that might not have that same
7 risk factor.

8 That's the question that I'd love to talk
9 more about and raise today, is how prescriber
10 training can address the misinformation and the
11 lack of information from prescribers on addiction
12 issues.

13 DR. EGGERS: Thank you very much for your
14 questions. I think everyone in the room will
15 notice that these are people-focused questions that
16 are stemming from the people who live every day
17 with pain or the impacts of treatment.

18 Let's move and very much in this session be
19 solutions focused and address the first question.
20 It's really important to hear your perspectives
21 from your life experiences and from where you're
22 coming about what is the solution, what's the goal

1 of prescriber training on pain management and the
2 safe use of opioids.

3 I'll open it up to see if anyone wants to
4 start, and then we'll build on that. Penney raised
5 her hand first.

6 MS. COWAN: I think one of the biggest
7 problems -- and this is probably across
8 medicine -- is that providers are communicating on
9 one level, and patients are hearing on a different
10 level. When they're telling us instructions,
11 whatever, are we really hearing what they're having
12 to say?

13 I think part of it again is the time that
14 they have to talk, and they're not asking what is
15 the expectation of this treatment. I think if they
16 began to ask -- the goal of pain management is to
17 improve quality of life, reduce suffering, and
18 increase function. That's the goal of pain
19 management.

20 I don't know that they're asking
21 expectation. I've talked to, obviously in the last
22 37 years, lots and lots of people, and we've just

1 finished -- we were awarded the PCORI grant, and it
2 was all around people's expectation. They worked
3 with their primary care, and they just asked the
4 goal of pain management.

5 It was really interesting because what the
6 people said was one person wanted to go fishing
7 again. Another woman just wanted to walk up the
8 stairs to go to her studio to paint.

9 The problem is I think providers think that
10 we want our pain 100 percent gone when, in fact,
11 that may not be our goal at all. It's to have a
12 better quality of life. We hear all the time, "I
13 want my life back."

14 I think that in some sense, they're thinking
15 get to zero pain, and I think I've heard that
16 before, where, in fact, there's always going to be
17 some level of pain, no matter how good the
18 treatment is. But I also think that in that
19 training, if we don't do a balanced approach to
20 pain management, and if all we ever train them is
21 on how to prescribe opioids, then that's what
22 they're going to do.

1 So we need to have a more balanced approach
2 with an integrative, these are all the components
3 of pain management, and that is so very important.

4 I went through a pain program 38 years ago,
5 and it was the balanced approach. It was allowing
6 me to move from that patient back to a person
7 again. And I think in this training while we're
8 looking at prescribing opioids, if that's, again,
9 all we teach them, that's all they're going to do.

10 We need to begin to give them the whole
11 picture, but we also need to make sure that they
12 actually have the skills to communicate with their
13 patients and that the patients understand what
14 they're saying because we're not going to ask. Too
15 many of us don't ask questions. We just sit there
16 and shake our heads.

17 I think it's really important.
18 Communication is the key. That's why we've
19 developed a lot of graphical tools so the people
20 can communicate in that way, and it's really
21 important.

22 DR. EGGERS: Great. Penney, we think as we

1 get down to the final thing to talk about, the new
2 question I'm going to add is how can patient
3 stakeholders be partners. We'll bring that up
4 again.

5 Myra had wanted to build on what Penney was
6 saying.

7 MS. CHRISTOPHER: I do. I want to conjoin
8 my thoughts with yours, Penney.

9 I think the simple answer to the question
10 from my perspective, is to empower our healthcare
11 professionals to do that which called them to their
12 profession, that is, to address needless pain and
13 suffering and to help them shift from being
14 perceived as scapegoats or the cause of this
15 epidemic.

16 I hardly ever disagree with Trip about
17 anything because I'm kind of scared of him.

18 (Laughter.)

19 MS. CHRISTOPHER: But when you say, Trip, so
20 assertively, we caused this problem. Certainly,
21 healthcare professionals had a part in this, but
22 you are not the sole actors in this.

1 Why I wanted to speak next is that I wanted
2 to share some information that's not been published
3 yet. We're in the process of preparing it for
4 publication now, but recently with funding from the
5 American Academy of Family Physicians Foundation
6 and with assistance from their primary care
7 research network, we surveyed primary care
8 providers who treat chronic pain patients and the
9 patients they treat in nine sites all across the
10 country, all across the country.

11 What we learned from the providers who
12 participated is that they very much want to do this
13 and to do it well. But they feel strongly that
14 they are constrained from doing so by both external
15 and internal factors. The external factors that
16 surfaced over and over in these conversations and
17 surveys and interactions were that the healthcare
18 delivery system itself constrains them.

19 Dr. Greenblatt mentioned time, that if you
20 take someone out to do -- for them to go through
21 training and education, they are paid on volume.
22 So the systems constrain them from doing things

1 they know they need to do.

2 Lack of time for seeing patients, when we
3 see some business models in healthcare delivery
4 systems now saying you have 7 minutes to see a
5 patient, lack of time is a big deal, lack of access
6 to complementary therapies.

7 When I heard one of the panelists say we've
8 got to get people to these complementary therapies,
9 to alternative approaches, they don't have access
10 to acupuncture, behavioral health, physical
11 therapy, those things that we cluster and call
12 complementary therapies.

13 Then lastly, Penney, they pointed out very
14 strongly unrealistic and uninformed patient
15 expectations, but in addition, they talked about
16 that they have lost their self-confidence. They
17 are really very frustrated by how this whole opioid
18 epidemic has impaired their ability to care for
19 patients.

20 They don't feel that they have the control
21 they need to take care of their patients as they
22 think is best. They struggle with conflicting

1 ethical duties and obligations. They don't want to
2 see their patients suffer. They also don't want to
3 see their patients die of an overdose. They are
4 angry and feel that they have been stereotyped, as
5 have their patients, in very negative terms.

6 Then lastly, this is a whole population of
7 patients. Dr. Greenblatt was the first person
8 yesterday that mentioned burnout and the experience
9 that we are in this country losing very valuable
10 assets, that we see physicians retiring early,
11 physicians opting out of doing chronic pain
12 management. These people, these men and women
13 young and old, are living with compassion fatigue
14 and burnout, and we are idiots if we don't address
15 that issue.

16 DR. EGGERS: Great. So I heard a number of
17 things that I just want to make sure that I have
18 correct.

19 The goal of training is to increase the
20 healthcare provider's self-confidence, remove the
21 stereotypes. A goal of training can be to address
22 the burnout issues, a goal of the training program,

1 and to address all of the constraints that are
2 placed on healthcare providers.

3 MS. COWAN: Can I add one thing?

4 DR. EGGERS: Then we'll go to Maria. We'll
5 let Penney follow up, and then we'll go to Maria.

6 MS. COWAN: Just one quick thing, because I
7 think what I didn't say is that we really need to
8 put the patient in the center of care and make them
9 the center of everything.

10 MS. CHRISTOPHER: Absolutely.

11 MS. COWAN: I think that's never taught.
12 They really should be in the center when all these
13 things come out. So unless they are informed and
14 in the center, they can't make those informed
15 decisions to know what treatment is right. If they
16 don't have the time and they don't have the
17 reimbursement for that time, the provider, to
18 really have those communications --

19 MS. CHRISTOPHER: And they need to provide
20 their expertise in the development of the
21 curriculum.

22 MS. COWAN: And need to be able to

1 communicate what -- and I think the other thing is
2 the validation of their pain, that is real because
3 that's something -- people with pain are very
4 defensive, and so they pull back.

5 There's so many issues, and there's so many
6 complex ways of interacting with people with pain
7 that it's becoming -- but the patient should be
8 always be at the center of everything.

9 DR. EGGERS: Let's go with Maria.

10 DR. LOWE: I think that was an excellent
11 segue to what I wanted to add, which is I think we
12 really need to be focusing on how to partner with
13 patients and educate them to empower them alongside
14 this provider education. I think by educating
15 patients and empowering them with knowledge that
16 they need, they can help with some of these
17 time-constraint care situations. They can come
18 prepared and feel informed enough that they can
19 participate in their care decisions and also
20 evaluate if their provider is adhering to best
21 practices in talking about the kinds of things that
22 really need to be discussed in the setting of pain

1 management or opioid use.

2 I think that the more we consider patients
3 as integral parts of that process and empowering
4 them to do that, the better off we'll be. So I
5 think that was an excellent set up.

6 DR. EGGERS: We're going to hear from that
7 side of the table. I can't see your hand as much.
8 But we're going to come back after we hear these
9 and talk about what you think, how you
10 incorporate -- what are the ways that we can
11 incorporate these ideas of patients as partners and
12 to increase self-confidence inside the training.

13 First, let's go to Teresa.

14 MS. CARR: What I'm hearing are some
15 healthcare system issues, the 7-minute visit and a
16 lot of other things. But the most basic question
17 is what is the goal of training, and certainly
18 putting the patient at the center of that and
19 certainly the training should be centered on the
20 patient and the consumer in that moment. And I
21 think part of that training should be how to engage
22 the consumer in their own care.

1 At the most basic level, I think what we're
2 saying is we want to accomplish two things. We
3 want to put everybody that deals with patients who
4 might be prescribed opioids or are taking opioids
5 kind of on the same page. And it sounds so
6 simplistic, but that's not what we hear in the
7 field.

8 What I hear from readers is a wide variation
9 in the messages that they get. They get messages
10 in the press, including from us sometimes, because
11 an article may be 500 words long, and it's going to
12 be alarming, and you're trying to get somebody's
13 attention.

14 Very, very rarely do you ever see anything
15 that's telling people who have been opioids for
16 weeks, months, years and years and years -- we're
17 always saying this is bad, this is bad. And
18 nobody's talking to these people at all about what
19 the alternative to that might be or what that might
20 look like.

21 In fact, we know from talking to physicians
22 that they don't know how to handle those patients.

1 If you talk about you shouldn't be over a certain
2 level, threshold, then what next? What do you do
3 next?

4 At the very basic level, I think it should
5 put people on the same page regarding guidelines,
6 and there should be a very basic understanding of
7 pain management. You're not going to address all
8 these issues in one CME course, and hopefully, you
9 come back and catch these people at other times in
10 the course of their career. And depending on the
11 type of patients they treat and their specialty,
12 they may need more specialty education from their
13 own professional organization.

14 At the very, very most basic level, this is
15 what I think the education should do. We should be
16 putting everybody on the same page. There should
17 be some consistency at least in understanding.

18 There should be some consistency and some
19 understanding about pain management in general, and
20 there should be some consistency and understanding
21 about some techniques for engaging the patient or
22 the consumer, because these days, let's face it, in

1 our healthcare system, a patient is a consumer.
2 We're asking a tremendous amount of them. So there
3 should be some consistency in that.

4 We know from surveys of primary care
5 physicians, they often don't -- as you pointed out,
6 the confidence issue, they don't feel confident in
7 prescribing sometimes. They certainly don't
8 confident in recognizing a substance abuse disorder
9 or in managing it, should they uncover it in their
10 practice.

11 So you're not going to be able to teach
12 people all of those things, but you're going to be
13 able to give everybody these messages that they can
14 use.

15 That's what I think, just backing up. I
16 think those basic things are what we should
17 accomplish.

18 DR. EGGERS: Great. Greg or Jan?

19 MS. CHAMBERS: Thank you, Teresa.

20 I think that segues right into what I wanted
21 to comment on, and that is when we receive calls at
22 our office and when we're on our Facebook groups,

1 we hear a lot from people saying I don't know how
2 to find the right physician, or that physician hurt
3 me, or I don't know how to find the help that I
4 need. I strongly know, I feel and I know, that
5 people want to know the level of education or
6 services the different providers are offering.

7 When somebody has a pain and they look up
8 the narrow network that their insurance provider
9 has offered to them, they don't know how to
10 navigate that. They don't know how to ask the
11 questions and say that when I have this kind of
12 pain, I need this kind of a doctor. They don't
13 have that background to be able to delineate the
14 different services. And so they go to a
15 recommendation or they just blindly pick somebody.

16 When -- I'm hoping it's when -- when all of
17 the prescribers have the same information of a
18 basic education on how to prescribe opioids in
19 addition to the other integrative treatments that
20 we need, then they will know with a surety that if
21 they have to use opioids, that they are being
22 prescribed safely. Patients want to have safe

1 treatments. We do want to have pain relief. Pain
2 relief leads to more functionality. Pain relief
3 leads to more productivity.

4 Knowing that it's really hard to navigate
5 that system and we are consumers, as Teresa
6 commented, we're looking for that most effective
7 pain relief for our dollars. One of the most
8 important areas that we can look at is what do
9 consumers pay for out-of-pocket for the different
10 services that they don't have in their network
11 providers.

12 We've done surveys. We know what they are
13 paying for, and the insurance companies have a
14 chokehold on us because we cannot access those even
15 though people are using those very few dollars that
16 they have to go get the services that they need.

17 I'm answering your question, Sara, in two
18 ways, that we really do need to have that knowledge
19 to be able to look at a group of providers and be
20 able to know their baseline information of what
21 they're offering, what kind of services they're
22 offering so we can be more educated consumers.

1 DR. EGGERS: Thank you. I think I heard
2 from your comment that you then might support a
3 goal of training that reaches all types of
4 healthcare providers --

5 MS. CHAMBERS: Yes.

6 DR. EGGERS: -- following up on the last
7 conversation and the last panel discussion.

8 Greg?

9 MR. WILLIAMS: Thank you. Just to add to
10 the list that you mentioned earlier, I think risk
11 factors have to be mentioned. And I know it's
12 uncomfortable for healthcare professionals and
13 patients alike to hear the word "death," but the 91
14 deaths that we're talking about is grossly
15 underreported. Because if you add in heroin
16 deaths, which 85 percent relate to prescribing
17 opioids, and you add in alcohol, you get to 350
18 people who are going to die today from alcohol or
19 other opioid- or addiction-related issues.

20 That bucket, that population of people that
21 becomes substance-use dependent, largely, their
22 risk factors all look a lot the same, and their

1 early signs.

2 So I think that we need to get okay and
3 comfortable talking about these risk factors. And
4 not every other medication that a physician or a
5 prescriber prescribes can cause death, but they
6 need to get comfortable talking about this
7 particular issue.

8 I think about seatbelts and airbags in cars,
9 right? That was not very comfortable for car
10 manufacturers or for the industry as a whole to
11 have to employ that because you're implying to
12 customers, you could die once you get behind a
13 wheel because that's what a seatbelt and what an
14 airbag requires. And I think that we are at the
15 point where we cannot deny that truth, that fact,
16 that reality for people, given the gravity of this
17 and given how quickly and the percentage of people
18 who are prescribed.

19 We've talked about fear in patients around
20 this medication, and unfortunately, I think most of
21 our stakeholders and family loss groups and people
22 around the addiction and recovery conversation

1 would say, well, perhaps that's a healthy fear to
2 have.

3 MS. CHRISTOPHER: May I ask Greg a question?

4 DR. EGGERS: Sure.

5 MS. CHRISTOPHER: Greg, may I ask you a
6 question?

7 MR. WILLIAMS: Yes.

8 MS. CHRISTOPHER: I'm not at all afraid to
9 talk about death. I've spent most of my life
10 talking about death and chronic pain, so I hardly
11 ever get invited to cocktail parties anymore.

12 (Laughter.)

13 MR. WILLIAMS: People are very uncomfortable
14 talking about recovery.

15 MS. CHRISTOPHER: I'm really curious in that
16 we keep talking about the body count. I keep
17 thinking about -- I'm a kid of the '60s -- the
18 Vietnam War era. I've been asked to participate in
19 research studies to try to figure out how many
20 people are dying every day from suicide because of
21 untreated chronic pain.

22 I'm not interested in comparing deaths or

1 body counts. I think it's ridiculous. But I'm so,
2 I don't know, baffled by the fact that we have
3 80,000 deaths every year associated with alcohol
4 abuse, but we aren't going whacky about that
5 because this country runs on martinis. I just am
6 so curious about the politics of all of this, that
7 we ignore the 33,000 deaths associated with gun
8 violence every year as a public health issue.

9 So in your work, my question to you is, do
10 you give as much attention, time, and concern to
11 the alcohol issue as you do to the opioid, and how
12 would you think about those issues juxtaposed one
13 against the other?

14 DR. EGGERS: Before Greg answers, we'll
15 point out that you're touching upon issues are, of
16 course, much larger than we'll be able to discuss
17 today, so we won't get into too much of the
18 epidemiology. But, Greg, would you like to -- do
19 you have some --

20 MR. WILLIAMS: Absolutely. We see addiction
21 to alcohol and other drugs very closely linked, and
22 you're exactly right. The two leading causes of

1 death relating to substance use is correlated to
2 prescription opioids, and alcohol as the leader.
3 And often people want to talk about heroin and
4 other addiction issues. But I think what we need
5 to focus on in the healthcare system in the
6 conversation is that reported, between 50 and
7 80 percent of our ER visits are related to these
8 substances, and also, for primary care, and dental,
9 and all of those other issues.

10 Absolutely, we're just privileged to be at
11 this conversation talking about this issue, but
12 without a doubt, alcohol and other substance use is
13 a huge issue. So one of the projects that we're
14 working very heavily on is medical school education
15 and how much education on substance-use disorders
16 as a whole are physicians receiving across the
17 board.

18 MS. CHRISTOPHER: Good.

19 MS. COWAN: I wanted to comment. He talked
20 about the fear of taking the medication, and I
21 think there's another side of that for people with
22 pain is the fact that because of the pain -- and

1 say they need to go out and do something, it's the
2 fear of the pain itself that causes them to take
3 the extra one just in case.

4 So I think it's really important to
5 understand, again, it's that communication with
6 that person to really understand where their fear
7 is. Fear of the pain is the biggest controlling
8 factor of all. It's not even a pain. It's the
9 fear, because chronic pain is never consistent. We
10 have good days and bad days. There's the fear of
11 the drugs, but there's also the fear of the pain
12 itself, which really is the bigger motivator.

13 I was sitting in on a focus group not long
14 ago of people who are trying to taper off. They
15 would say they have to leave work because they
16 forgot their pills. They're so afraid that that
17 pill, the time is going to run out before they can
18 take their next pill. So there's a real fear
19 around the pain itself and their expectation of
20 this medication because that's all they were given.
21 Again, it's that balanced approach to pain
22 management and all those other things that we're

1 missing.

2 DR. EGGERS: Before we go to Jan, let me
3 just follow up. You guys are making my job easy
4 because what I was going to ask next is, as we move
5 into the discussion of the goals, to focus a little
6 bit on the opioid component of that and your
7 thoughts on the goals of that conversation about
8 the treatments, the use and management of the
9 opioids.

10 Penney, I think you started that off well to
11 say how -- I'm going to imply from what you're
12 saying is what is the role of a medication that you
13 can take to address something and how you use that
14 to control your fear of pain.

15 MS. COWAN: Right. I think sometimes it's
16 take as needed. Well, what does that mean? Do
17 they really understand that? So it's the job of
18 the provider but also the pharmacist to really have
19 that communication. And again, I think there's a
20 real breakdown in the communication. And again, it
21 goes back to the time that they have. There's no
22 reimbursement for that time, which I think is one

1 of the bigger problems.

2 I'd love to see the payers sitting here in
3 this room. I think that would be a great thing if
4 we could get the payers here because they're
5 really -- I think the wrong people are practicing
6 medicine, but anyway, yeah.

7 DR. EGGERS: Jan?

8 MS. CHAMBERS: As we think about policies
9 and we are sitting here talking about policy, we
10 have to look at CMS and the new changes that they
11 are putting into place, the hard stops, that when a
12 patient goes to have a prescription filled, they
13 will not be able to fill that beyond a certain MME.
14 So when we look at these consequences to the
15 patient, we aren't realizing that literally this
16 fear that Penney's mentioning is a major component,
17 a major driver of pain.

18 When you think about prisoners of war, or
19 you think about somebody who is being forced to do
20 something against their will, that's torture.
21 Literally torture is being legislated. And that's
22 a really strong term, but that's what's happening.

1 People are living with this fear.

2 We talked yesterday about the bottles and
3 why do people squirrel those away in their cabinets
4 after they've had surgery. It's because of that
5 fear of pain. I might need that in the future. I
6 might not be able to get it again. So they make
7 sure that they've got something because they're
8 living with that fear. And that fear drives us to
9 do a lot of things, including when people can't get
10 access to pain medications legally, they go to the
11 street.

12 I went to get my hair done one day, and I
13 was just commenting about where I was going to go
14 speak next. The woman said, "Oh, I'm so sorry to
15 hear that. If you don't have enough pain
16 medication, my husband has a lot of pain. I can
17 hook you up." And it was that fast, and it would
18 have been that easy.

19 I am clearly saying that we are driving
20 people out to illicit access because they don't
21 have options with the integrative treatments. I
22 know that if you ask any person who has to take a

1 pill, any kind of pill, if they didn't have to,
2 they would really rather not.

3 I don't care and patients don't care if it's
4 an opioid. They don't care if it's a massage.
5 They just want the pain relieved so that they can
6 get the function in their lives back and get the
7 quality of life to live again.

8 So I really think that we need to pay strong
9 attention to the unintended consequences of all
10 these policies that CMS, that the DEA, that the
11 FDA, that HHS in its varied forms is causing and
12 putting more and more fear into people.

13 DR. EGGERS: We'll let Maria, and then we'll
14 let Teresa go.

15 DR. LOWE: I agree. I want to echo and
16 underscore the point about these complementary and
17 non-opioid approaches to treating pain. I think
18 it's an integral part of these education programs,
19 but I don't think we can educate about them in a
20 vacuum without also simultaneously be trying to
21 tear down the walls that are putting up barriers to
22 patients accessing them.

1 I know we've heard that throughout the
2 conversation, but I think maybe one thing to
3 consider there and something that a group like
4 PatientsLikeMe can help offer is giving patients a
5 patient-facing mechanism for evaluating their
6 experience and their own outcomes with those
7 modalities to help start the conversation to
8 generate some evidence that can be used to further
9 their use and potentially tear down some of those
10 barriers.

11 DR. EGGERS: So another way that patient
12 stakeholders can partner with the community.
13 Teresa?

14 MS. CARR: Again, I wanted to acknowledge
15 all the really important points that have been
16 brought up here about problems with the system and
17 problems with access. Certainly in our own
18 surveys, we've shown that most recently, 90 percent
19 of people that had some of these nondrug therapies
20 would have had more of them for back pain if it had
21 been covered by their insurance, and they were
22 spending huge amounts out of pocket on this stuff.

1 Certainly, all of that's valid, but I think
2 what we're here today is to talk about training for
3 people who prescribe opioids and possibly for
4 people who aren't prescribers but who would be
5 dealing with patients.

6 Again, I'll bring this back to this very
7 most basic level of what we're trying accomplish.
8 And I just want to remind people that there's the
9 JAMA study that was cited earlier, that about
10 6 percent of people undergoing surgery, whether
11 it's minor or major, wind up taking opioids for
12 long term, 3 months. This is people that have
13 hernia surgery or people that have a hysterectomy;
14 regardless, about 6 percent wind up becoming
15 long-term opioid users.

16 Somebody is prescribing that opioid for
17 3 months after a day surgery. So 3 months later
18 that patient who was opioid naive going into
19 this -- and that's 2 and a half -- if you
20 extrapolate that, that's 2 and a half to 3 million
21 people in this country that wind up taking opioids.

22 It may have been that a doctor has always

1 prescribed 30 days' worth of opioids. That's just
2 how he or she learned to do it. I don't know, but
3 there's a huge, huge inconsistency in practice, and
4 it's killing people. For the person with the
5 underlying predisposition to get that first 30-day
6 prescription for a day surgery is almost
7 unconscionable, but it happens and it happens every
8 day.

9 There are big issues here. There are big
10 issues in terms of treating chronic pain, but some
11 of what education should be designed to do and it
12 shouldn't be -- we shouldn't be shortchanging
13 it -- is just to bring this very basic level of
14 understanding about opioid prescribing so that all
15 of us are on the same page.

16 DR. EGGERS: I would like to move in to a
17 few more points about the critical aspects of using
18 opioids for pain management as we move forward, and
19 then we're going to move on to the next topic. I
20 think Greg had something, and then we're going
21 to --

22 MR. WILLIAMS: Yes, just to jump in. I

1 absolutely with -- one of the core in some of the
2 data that our friends at NIDA and NIAAA have really
3 produced, I think there's a big conversation and a
4 big education opportunity here between the
5 difference between chronic pain and acute pain. A
6 lot of the stories that we have from families are
7 acute prescribing episodes from adolescence.

8 So that's a core issue that I think we need
9 to really focus on, the developing brain and what
10 opioids do for an adolescent population versus an
11 adult population because the frontal lobe isn't
12 developed until you're 25. And the risk factors
13 associated with the high school football player who
14 has a knee injury and gets prescribed opioids might
15 be very, very different than a prescription to a
16 35-year-old or a 40-year-old person with a
17 developed brain.

18 I think what we're seeing a lot of, that
19 transition from opioid as prescribed to opioid
20 misuse and overdose is young people in their 20s
21 and 30s who got prescribed during adolescence. And
22 I think that's a core issue in terms of really

1 training physicians around the adolescent onset of
2 substance-use disorders.

3 MS. CARR: Can I jump in just really quick
4 here to reinforce that?

5 DR. EGGERS: Yes.

6 MS. CARR: Paul Moore talked yesterday about
7 the dental. For a lot of young people going to get
8 their wisdom teeth out, it's the very first time
9 they've ever had an opioid, and there's no use in
10 them walking out with a 10-day prescription.

11 MR. WILLIAMS: It was a year or so, but I
12 walked into my oral surgeon's office, and I had
13 misused OxyContin as an adolescent. And he writes
14 down his prescription. He's like, "You're going to
15 hurt. It's four impacted wisdom teeth. It's going
16 to really, really hurt. Here's your prescription
17 for antibiotics, and here's your prescription for
18 Percocet. Is there anything I should know?"

19 I look at him, and I say, "Well, I'm an
20 opioid user." I said it in not nice words, and
21 this was an issue for me.

22 He looks and me, and he looks down at the

1 script, and he looks at me -- and this was 15 years
2 ago -- and he slowly slides it off the table and
3 crumples it up and throws it in the garbage can and
4 says, "Yes, Tylenol works well, too."

5 But I think it took me, as an 18-year-old
6 kid in recovery who nearly lost his life to
7 addiction to OxyContin, to be able to limit that
8 prescription. But that doesn't happen every day in
9 ERs and oral surgeons' office, so absolutely.

10 DR. EGGERS: Nice point. Penney, please.

11 MS. COWAN: I think there's another piece
12 that we haven't touched on as well, and that's the
13 safety of opioids. When they're prescribed, they
14 should probably be prescribed with naloxone as
15 accompanying it. We just did a survey of people,
16 and 60 percent of the people have heard of it.
17 Only 20 percent actually have access to it. And
18 they even know how to identify an opioid emergency,
19 but they have no way of actually doing anything
20 about it.

21 So I think that's really important to pull
22 that into it, that if they're prescribed an

1 opioid -- and it's not just for the person with
2 pain, but the whole family unit and around them
3 because public education is also missing in all of
4 this. And I know that's not part of it, but that's
5 where a big part of the problem is, is on the
6 public.

7 We have a 30-second video that we play in
8 movie theaters on safe storage, disposal, and not
9 sharing. It actually gets out to the whole public
10 and begins to understand that you don't take
11 something that doesn't belong to you. You store it
12 appropriately, because people that were there
13 aren't there anymore just because they misused it
14 and didn't understand it.

15 We actually did exit surveys, so we
16 understood what the impact of that was, and we got
17 an 80 percent recall on those videos. I think
18 something like that could really reach out to the
19 public in a way that's going to get out instead of
20 always in these meetings talking to the same
21 people. It's really important.

22 DR. EGGERS: Let's go to Myra, and then

1 we'll move on to our next topic.

2 MS. CHRISTOPHER: I hope we will talk about
3 public education and communication, but I wanted to
4 address the question you asked, Sara, about how to
5 engage people living with chronic pain in the work
6 that we're all focused on.

7 DR. EGGERS: And in the practical
8 constraints.

9 MS. CHRISTOPHER: In our PAINS project, we
10 have a group we call our citizen leaders, which is
11 made up of 50 people who live with chronic pain
12 and/or family caregivers of people living with
13 chronic pain. They meet with us on a monthly
14 basis. We have dinner with them, and then
15 they -- it's not a support group for them. It's a
16 support group for us. And then they advise us on
17 research, on education, and other activities that
18 we're engaged in, publications and so forth.

19 They are so eager to be involved even when
20 they know it won't help them necessarily, but to be
21 part of trying to help the population of patients
22 like them who struggle every day to live with this

1 problem.

2 They go with us to med schools and teach.
3 They participate at conferences. They participate
4 in developing research questions, data collection,
5 data analysis. There is a wealth of resource among
6 the 100 million Americans who live with chronic
7 pain and 30 million who live with high impact
8 chronic pain who want to be part of the solution.

9 DR. EGGERS: Is Bernie here? I'm hearing
10 this patient detailing component here coming up and
11 getting started, so to complement the academic
12 detailing.

13 I think what we're -- we'll come back
14 to -- one of the questions I had posed, not on the
15 screen, but how can we do this, and how can we
16 engage the patient stakeholders as partners in
17 this?

18 Penney, Maria, and Myra now have given some
19 ideas for that, but I do want to make sure that we
20 get to the question that is number 2 here and talk
21 about your thoughts on a required prescriber
22 training and how it may positively or negatively

1 impact patients and caregivers. And you're welcome
2 to also give your overall position.

3 I think this would be one that maybe you
4 prepared for in coming to this meeting, so I'm
5 going to go through, we'll start at the other end
6 and come back. And keep it brief and build on what
7 others have said. And if you agree with what
8 someone has said, then we'll move on.

9 MR. WILLIAMS: Thank you for having me. I
10 think at Facing Addiction, we would support a
11 federal requirement for prescriber education around
12 this. We feel like there is precedent between
13 HIPAA and OSHA and other kinds of required training
14 for physicians. We understand it's a burden to the
15 health community to have an additional training,
16 but we also understand this is the leading cause of
17 accidental death in America.

18 If this was happening with motor vehicles
19 and other things, we would also act with great
20 passion and quick, and we would burden the industry
21 in the name of the public good and saving lives.
22 That's where we would support.

1 As a person with a primary care doctor in
2 the family, I asked him before I came, and he said,
3 "Just make sure -- we pay a lot for our DEA
4 license. So make sure that if they do something,
5 that it is free and it counts as a CME credit."

6 That's from the primary care doctor, but he
7 wouldn't see an issue if it was online, if it was
8 free similar to the way that HIPAA is done for
9 physicians.

10 DR. EGGERS: Jan?

11 MS. CHAMBERS: I feel strongly that we
12 should have opioid training for all healthcare
13 providers, including the people in the office, so
14 that they understand that if they aren't
15 prescribing, that they still know how to work with
16 a person with pain who is using opioid medications.

17 We have to also look at that nexus of people
18 who have chronic pain disease as well as
19 substance-use disorder or addiction as a disease
20 because these aren't always treated by the same
21 methods, and we have to recognize that those people
22 need additional help. The opioid prescriber

1 education needs to look at the whole person and how
2 they are going to be included.

3 Eight hours, if that's what it takes,
4 5 hours, 8 hours, to me that's just a minimum or a
5 little bit of time to make sure that you're saving
6 somebody's life. And if it's a doctor who doesn't
7 want to prescribe those opioids, great, they didn't
8 really care about their patients and safe
9 prescribing anyway. Then let's go ahead and let
10 them go because I don't want to send people to a
11 prescriber who really doesn't care about them.

12 It is true that as we get into our habits,
13 we don't recognize the nuances and the changes that
14 we should be making in our practices. So continued
15 education is crucial to be able to be reminded of
16 the things we've forgotten as well as the new
17 information.

18 DR. EGGERS: I want to just clarify. You
19 mean required training that's -- when you say it
20 should be universal, it should be required?

21 MS. CHAMBERS: Yes.

22 DR. EGGERS: Teresa?

1 MS. CARR: Consumer Reports thinks that
2 required prescriber training -- or I would broaden
3 that as well. I would say healthcare professional
4 training should be required. I think it should be
5 required on a federal level. I understand the need
6 for -- I understand the differences for local
7 control, and I understand that different states
8 already have mandates. I'm hopeful that greater
9 minds than mine would be able to work out how that
10 would work.

11 But I still come back to the issue of
12 consistency and basic stuff. There's no way that
13 the CME is going to be able to address all these
14 complex issues dealing with pain, but just to get
15 some really very basic, consistent messaging for
16 the healthcare providers that they can then bring
17 to their patients.

18 There's also, absolutely -- this is what I
19 do every day -- the patient education component of
20 that. But what we're here today to talk about is
21 the healthcare system and the healthcare providers.
22 I think it would have a huge positive impact for

1 consumers because they would be able to
2 realistically expect some of that consistency in
3 their care.

4 It has the potential to improve their safety
5 greatly just by some of the low-hanging fruit stuff
6 we talked about, just for a prescription being
7 3 days instead of 7. I know that the guidelines
8 are being written that way, but they're not always
9 being implemented that way. This training helps
10 reinforce that.

11 In terms of safety and consistency for
12 consumers and in terms of doctors, we're talking
13 about confidence. We're talking about a
14 fairly -- I know there's so many demands on their
15 time, but it is not a large investment of time for
16 something that has become such a huge crisis. So I
17 can't imagine that that investment is not worth it
18 to them in terms of their peace of mind as well.

19 If there has to be a carrot in there, great,
20 but I think it should be required. Consumer
21 Reports thinks it should be.

22 DR. EGGERS: Thank you. Penney?

1 MS. COWAN: I agree with everything that has
2 been said so far. I think when they're developing
3 the training for the prescriber, I think unless
4 there's several patients at the table -- because
5 unless they really understand what it's like to
6 live with pain, what the expectations are, what is
7 it that that person actually needs to move from
8 patient to person, and not just prescribing
9 medication but all of pain management.

10 I can't impress upon enough that it's the
11 balanced approach. And there are some people who
12 may not need the opioid at all. It may be
13 something totally different, but they need a
14 combination of therapies and treatments.

15 Then my next thing, and it goes back to my
16 question initially, is if we give them that
17 training, how are they going to apply that to their
18 practice? That's my bigger concern. Are they
19 going to then approach this person with real
20 compassion and understanding? Are they going to
21 validate them? Are they going to take away their
22 defenses and say, okay, I get this? And that's how

1 we can work together. Because the person with pain
2 has got to be part of the treatment team, they've
3 got to be right at the center.

4 Again, I think it should be mandatory. I
5 think it would be great for the federal government
6 to do it. I don't know about the incentives. I
7 think that if they're really -- why did they get
8 into medicine in the first place? That's just sort
9 of -- but I also think it's important to reinforce
10 that training with the CMEs. I think that's
11 also -- because we tend to forget, and new things
12 are happening.

13 DR. EGGERS: Thank you, Penney. Maria?

14 DR. LOWE: Again, I'm going to echo some
15 comments that Penney just made. I think that
16 training is a great step, and making it mandatory
17 is one step in the right direction. We've had
18 numerous comments that have come up about it can't
19 just be prescribers. It has to be all healthcare
20 professionals, as some of my fellow panelists have
21 mentioned, or basically, anyone involved in the
22 care of that patient. You can't think about that

1 equation in that care of that patient without the
2 patient.

3 So I think while making provider education
4 or healthcare professional education mandatory is
5 great, it's one step. I think where we could
6 potentially get tripped up in causing potential
7 negativity towards these patients if we lose focus
8 on what we can do to bring them into the equation,
9 empowering them as partners, and ensuring that
10 we're giving them the right technology or
11 mechanisms to share their experiences and evaluate
12 the outcomes that matter to them.

13 DR. EGGERS: I just heard one practical
14 solution, since we were being solution focused, to
15 help engage patients is to bring them in in the
16 development of this. Myra?

17 MS. CHRISTOPHER: I would certainly say
18 ditto that. I think we all know that simple
19 solutions to complex problems hardly ever work. I
20 think as we imagine trying to address these two
21 public health issues, we have to think much more
22 broadly than we have been thinking in the last

1 couple of days. I know our focus has been on this
2 issue about education.

3 I'm actually kind of ambivalent about this
4 mandatory versus voluntary. We don't have any real
5 data that tell us that mandatory makes a lot of
6 difference, but then when I hear Joanna, I'm
7 compelled by that. Then when I hear Carol, I
8 think, no, we ought to go the voluntary route.

9 So I think we ought to think a lot more
10 about this, and it's probably some combination
11 thereof. When we're thinking about every provider
12 having some sort of basic education about both of
13 these issues, I think we can make an argument that
14 that ought to be mandatory for anyone who has a
15 healthcare professional license that is licensed by
16 the state, and I think the states do need to be
17 involved in this.

18 When we begin to think about really
19 targeting the needs of professionals, depending on
20 where they're working and what they're doing, I'm
21 not so interested in the number of hours that they
22 go to CME or how often, whether it's every year or

1 every other year. I'm really interested in
2 competency. Maybe some of them don't need to go to
3 any training. Maybe they do know already enough to
4 be practicing well. I would ask that we think
5 about that.

6 With regard to which agency, it appears to
7 me that this is a fait accompli. We're going to
8 have a mandate from the federal government, so we
9 ought to just maybe quit talking about this and
10 move on. But we've got a lot of federal agencies
11 who are vying for power and authority here and
12 people who have experience and things to bring to
13 the table.

14 So in the National Pain Strategy report,
15 what we encouraged was that we would see
16 collaboration among the FDA and CDC and AHRQ and
17 CMS and the surgeon general and others.

18 I have said a couple of times and to many of
19 you, I continue to be really frustrated about the
20 siloing of the federal agencies around this issue.
21 If we think it's a big issue, we ought to be
22 willing to break down the silos and begin working

1 together and try to maximize the resources, the
2 intellect, and the capacity we have to really
3 address this as quickly as possible.

4 DR. EGGERS: Thank you.

5 We have a few minutes. I think we'll go to
6 questions in 5 minutes and stay on the schedule.
7 We have a few more minutes to wrap up with final
8 thoughts, and we have heard some solutions.

9 We've heard Penney talk about the videos and
10 the training, and Maria talk about the role of data
11 and collecting data from patients and giving that
12 back to you patients and others, and Myra with the
13 patient details -- I forget how exactly you call
14 it, but bringing the patients into the
15 conversations and be peer helpers, and I think you
16 would probably say expand that to be developer
17 helpers, et cetera.

18 Other solutions or thoughts that you want to
19 put on the table as a concrete way that you think
20 we can address the issues that we've been talking
21 about? We'll go to Jan first, and then we'll go
22 with Penney.

1 MS. CHAMBERS: Prescription drug monitoring
2 programs have been wonderful, but they are very
3 alarming. They do not protect patient data.
4 There's voyeurism. They put people's lives and
5 their professions at jeopardy.

6 I know that the PDMPs need to be a part of
7 the opioid prescribing education, but I am strongly
8 saying that there need to be regulations around who
9 accesses that information. There need to be tight
10 controls over the path that's been in them. So
11 please pay attention to how those PDMPs are being
12 used wrongly and protect the patients.

13 The second part of what you're asking, Sara,
14 I think that we need to look at the people who need
15 high doses of opioids. I think that they may be a
16 different disease actually. Maybe they're a rare
17 disease and need to be looked at that way because
18 their bodies don't metabolize or their hormones are
19 different. But there are people who need very high
20 doses of opioids, and that's the only thing that
21 keeps them from committing suicide.

22 DR. EGGERS: Go to Penney.

1 MS. COWAN: We've been talking a lot about
2 the people who are practicing now, the prescribers,
3 but I think we haven't really touched on all of
4 those in the medical schools, the nursing schools,
5 the pharmacy schools. I think whatever effort we
6 put into this, we need to put double the effort
7 into the medical schools and get that education out
8 to them, so that when they go into practice,
9 they're already aware of these issues rather
10 than -- we've been talking about training in
11 medical schools for pain management for the last
12 20 years. And we keep talking and talking, but
13 it's the action.

14 It's time for action now. It was time for
15 action years ago, but today is the day that we need
16 to have action.

17 DR. EGGERS: We have Myra, then Greg, and
18 then Tom.

19 MS. CHRISTOPHER: Fifteen years ago, I was
20 in a conversation about this with regard to
21 education about palliative care and how we were
22 going to move better end-of-life care into

1 mainstream medicine. The AMA stepped forward and
2 developed a program called EPEC, and they've done a
3 wonderful job really with that CME program.

4 Unfortunately, when it was very first
5 released, there was absolutely no attention given
6 to the fact that we are a very culturally and
7 ethnically diverse population. There were 16
8 1-hour modules that were developed. There was not
9 a single person of color in any of the 16 modules,
10 nor was there any mention of the fact that your
11 patients may perceive this issue differently.

12 We know that chronic pain is an experience,
13 and it is very relevant the culture, the religious
14 background, ethnic background; as Ms. Cotton was
15 mentioning earlier with our Native American friends
16 and neighbors, that they perceive this issue very
17 differently.

18 So I just make a special appeal that as we
19 move forward to develop the curriculum for this
20 mandatory education, that in fact we give attention
21 to that really important factor.

22 DR. EGGERS: Thank you. Greg?

1 MR. WILLIAMS: Just one addition, I heard it
2 on the last panel, but I wanted to reiterate. I
3 think part of education needs to be disposal, and I
4 have long been baffled that our police stations
5 have answered the call because it doesn't make
6 sense to me as a person who's involved with the
7 healthcare system, you go and get your medicine
8 from the -- you get your prescription from the
9 doctor, then you go to the pharmacy. Then I have
10 to go into a criminal justice center to actually
11 return my medication like I'm a criminal. And it
12 doesn't make sense to families or individuals.

13 There's a lot of fear of disposing meds that
14 way. And I'm grateful for law enforcement for
15 acting first on this issue, but we are thrilled to
16 see some of the pharmacy companies and some of the
17 states who've started to put takeback boxes in
18 pharmacies because I think that's such a huge issue
19 moving forward.

20 Certainly, healthcare providers have to be
21 educated to tell their patients who are prescribed
22 this if they have medication that they're not

1 using, that it is a serious risk to their
2 household, their kids, their friends to have these
3 medications in the home if they're not using them
4 anymore. So that's a huge issue.

5 I just want to read a quote. Dr. Murthy,
6 our 19th surgeon general, wrote a letter to
7 2.3 million opioid prescribers last summer. And if
8 you missed it, there's a website, TurntheTide.org.
9 It just says, "Years from now, I want to look back
10 and know that in the face of a crisis that
11 threatened our nation, it was our profession that
12 stepped up and led the way. I know we can succeed
13 because healthcare is more than an occupation to
14 us. It's a calling rooted in empathy, science, and
15 service to humanity."

16 So I think we have to remember his legacy in
17 That letter that he wrote to those prescribers.

18 DR. EGGERS: Thank you.

19 Teresa, do you have anything?

20 MS. CARR: Oh, sure. I'm going to follow
21 that.

22 (Laughter.)

1 MS. CHRISTOPHER: Unfortunately, he got
2 fired.

3 MS. CARR: I read that quote as well, and I
4 thought it was wonderful.

5 The one thing I would say is I think it's
6 important to set expectations in terms of what
7 we're trying to accomplish. I know that's one of
8 the things we started this with, and maybe it's
9 someplace to land as we finish up.

10 It's not the solution to the opioid crisis.
11 It's not the solution to the very complex problem
12 of treating chronic pain. It's one part of a
13 multifactorial solution, and I think it's a very,
14 very important part.

15 To Myra's point, simple solutions to complex
16 problems rarely work, but that's not entirely true.
17 You have pilots that do a checklist before they fly
18 a plane, and that's been adopted in the surgery
19 theater as well. It doesn't tell you how to do the
20 surgery, and there are any number of things that
21 can go wrong. But it sets the stage so that
22 everybody is consistent. Everybody on the surgical

1 team is empowered to speak up.

2 If we can get that very basic level of
3 understanding of even what we're dealing with and
4 what the implications are, then you've made a huge,
5 huge step. You've set the stage for other
6 programs, other things, other educational things,
7 other training for physicians, all those things to
8 come in and work as well. But I just think you
9 need to start with that one place.

10 Questions and Answers

11 DR. EGGERS: Thank you.

12 I think we'll move into questions if people
13 have questions. I'll remind my FDA colleagues, you
14 can also come up to the mic and ask questions, too,
15 if you have additional questions.

16 We'll start here.

17 MR. BRENCE: Joseph Brence, American
18 Physical Therapy Association. I'm going to pose a
19 question that was posed to the last panel.

20 This gentleman over here had said, what if
21 we mandate a certain level of education for the
22 patient as well? So if we're going to prescribe or

1 we're going to recommend interventions, should we
2 be recommending some to the patient? I want to get
3 your perspective on the patients and consumers that
4 you guys represent.

5 If we were to give a 5-minute video, if we
6 were to recommend that something that ensures that
7 continuum of understanding occurs from the provider
8 to the patient, is that something that the
9 consumers and patients that you represent would be
10 willing to watch?

11 DR. EGGERS: We'll let Maria go first. We
12 got a yes. We'll let Maria go and then --

13 DR. LOWE: I would absolutely say yes, and I
14 think to add to that and to add on practical
15 solutions, I think maybe what we could be doing is
16 commending the FDA for their effort to revise the
17 provider blueprint and perhaps recommending a
18 companion patient blueprint be created as well.

19 I actually think each blueprint should be a
20 part of the other, so everyone knows what everyone
21 is learning. The more we can have a shared
22 understanding of that, the better those

1 conversations will be.

2 MS. CHRISTOPHER: When we were developing
3 the National Pain Strategy, Penney co-chaired the
4 committee on public education and communication,
5 and I was the liaison to that committee from the
6 oversight group. We originally felt that that
7 should be the very first part of the strategy
8 because until you have an understanding about the
9 severity of this, the solutions to this, at the
10 broad public level, you're going to be fighting
11 uphill the whole way.

12 I was very much in hopes when Dr. Vivek
13 Murthy did his Turn the Tide that the next thing we
14 would see was something like C. Everett Koop had
15 done around HIV/AIDS early on in that epidemic, and
16 unfortunately, he did get fired.

17 But I think that we need to seriously
18 understand that until there is an attitudinal shift
19 in the public about these issues, all of these
20 efforts won't take root. They're going to really
21 struggle.

22 DR. EGGERS: Penney?

1 MS. COWAN: I think that patient videos are
2 excellent. They're going to watch a video more
3 than they're going to read any kind of pamphlet.
4 But I think an important point is that we have to
5 really empower them, and not just look to medicine
6 to make us better, but what is that we need to do?
7 What are all those self-management skills? Because
8 pain is probably going to be -- there may always be
9 some level of pain.

10 So how are we going to manage that, and to
11 shift some of the responsibility on to the person
12 with pain? I mean, they're part of the treatment
13 team. So I think it's important for us to teach
14 them what it is they need to know, not just tell
15 me -- don't tell me to learn to live with it. You
16 have to teach me how, and I think that would be
17 part of it.

18 Five minutes probably isn't going to do it;
19 you'd need a whole bunch of them. It would be
20 something -- we have a lot of videos now that
21 people watch, but I think that one that would
22 really sort of compressed that if we worked with

1 the providers and did a joint video, I think that
2 would be really powerful, that we're all working
3 together.

4 DR. EGGERS: We'll go here with Fred.

5 MR. BRASON: I'm going to dovetail on the
6 comments that were just made, also, and follow up
7 with Myra's comments saying that it's a fait
8 accompli that they're going to be looking at
9 mandated education.

10 I don't totally agree with that, but on the
11 premise that that is so, I think we all agree that
12 best practice in pain management for the patient is
13 a lot of modalities. I don't agree with the word
14 "alternatives" because everything is melded
15 together. It's not one or the other. It can be
16 combined.

17 In looking at that, I'd ask the panel,
18 following Peter Lurie's way of doing things, a yes
19 or a no, without the payer's sources engaged in
20 this to allow those modalities to be evident, would
21 you each agree that in order to move this forward,
22 there has to be a yes, they need to be at the

1 table; yes, they need to be covering this;
2 otherwise, increase in education and saying these
3 modalities must be done is pointless.

4 MS. CARR: I would say that you don't have
5 to have the insurers all at the table saying yes,
6 they're going to cover it before we do the
7 education.

8 MR. BRASON: I understand that, but there
9 has to be, I think, that avenue of open door that
10 this is where we're headed. Because I know from
11 working with practitioners day in and day out on
12 this issue, the only way that we could enhance the
13 patient care was to offer in the community people
14 with patient support groups talking about the
15 different therapies, wellness, nutrition, exercise,
16 music therapy, meditation, all of that.

17 We had to do that externally, volunteering
18 in order to get that done. And the doctors would
19 freely refer their patients to use to do that. But
20 again, not every community has the wherewithal or
21 the means or the resources to do that.

22 I'm biased. Coming from an end-of-life care

1 and a home health background, and patient
2 compliance, I know being in those homes what we can
3 achieve as far as management of whatever the
4 disease, the issue, or the pain is, but that only
5 is a small segment of the population.

6 When we're talking about the number of
7 people that have pain issues, acute, chronic, or
8 otherwise, there has to be that element of
9 something else has to be covered besides the
10 prescription.

11 MS. CARR: I would say that there's been not
12 nearly enough research done on the cost
13 effectiveness of this stuff, and that research is
14 starting to be done more now. I think you will see
15 much, much coverage of these kind of things when
16 cost effectiveness becomes more clear.

17 But at the very basic level here, we're
18 trying to decide whether or not we should train
19 healthcare providers about opioids and pain, and I
20 think that's yes. And if part of that training
21 involves modalities that people don't always have
22 access to, that's going to pressure. That's going

1 to put more and more pressure, and that's how you
2 get there.

3 MS. CHRISTOPHER: But we had these
4 conversations with CDC, and as you know, in the
5 guidelines, they did suggest referring to
6 complementary therapies.

7 MR. BRASON: Right.

8 MS. CHRISTOPHER: There's a chicken and an
9 egg tension here, but you don't have to do this
10 stuff serially. We can be working on reimbursement
11 reform at the same time we're working on
12 educational initiatives.

13 MR. BRASON: Right, but my point is we
14 should be working on it.

15 DR. EGGERS: I think the point is -- I just
16 want to make sure we get to the other questions.

17 MS. COWAN: Just the fact that you talked
18 about the support groups for people and teaching
19 each other, that's what the ACPA has been doing for
20 37 years, those peer support groups. We teach all
21 of those. We have workbooks that we teach them out
22 of.

1 I think the important thing is you have to
2 have people who are actually willing to get
3 engaged, and that's the motivation. It gets very
4 complex, and part of it is referring the provider,
5 referring to these groups that then motivates the
6 person to actually get engaged.

7 MR. BRASON: We have practitioners saying
8 part of the treatment plan is you attend, yes.

9 MS. COWAN: That's right, and that would be
10 nice if they all did that.

11 DR. EGGERS: Thanks, Fred.

12 Over here.

13 MALE AUDIENCE MEMBER: Thank you. Just a
14 quick question. As representatives of patients and
15 patients' experience and their voice, if you had
16 the opportunity to tell the FDA what not to do in
17 the final product, if it was just handed to you,
18 what is that one thing that you would tell the FDA
19 not to do?

20 DR. EGGERS: Great question, but in the
21 interests of time because I imagine it could
22 probably another whole hour-and-a-half session.

1 (Laughter.)

2 DR. EGGERS: We'll just keep it very brief,
3 and we can elaborate the details in the final
4 session. So if anyone wants to answer the
5 question, go ahead.

6 DR. LOWE: I think I would recommend not
7 losing focus and don't over-focus on just the one
8 outcome of training providers. Let's look at
9 improving patient outcomes.

10 MS. COWAN: Include the patient in all the
11 conversations.

12 DR. EGGERS: So don't un-include -- don't
13 exclude.

14 MS. CHRISTOPHER: I would say don't focus on
15 opioid prescribing out of context of chronic pain
16 management.

17 MR. WILLIAMS: I would say out of context of
18 substance-use disorders. I think you have this
19 other chronic health problem that relates to opioid
20 prescribing, and substance-use disorders has to be
21 part of this education.

22 DR. EGGERS: We'll go to this.

1 DR. MILIO: Every year, a lot of trees are
2 cut down or every day because of all the
3 after-visit summaries and discharge summaries that
4 patients often get and are sort of tossed. They
5 include a list of medications, but often not how
6 patients should take them. There's not been any
7 discussion on how -- the last panel, it could have
8 been addressed, too -- how can we approach
9 educating patients, and where should this take
10 place on how to take their medications?

11 Just an example, I got called by a friend in
12 tears who had terminal cancer because she was sent
13 home with four different pain medications, three
14 different antiemetics, two bowel meds, and had no
15 clue how to coordinate their use. All she could
16 say was, "None of them are working. I have no idea
17 how to use them."

18 DR. EGGERS: So you're being very specific
19 about when to take it, how to take it, those types
20 of instructions, right?

21 DR. MILIO: Yes, because I think that's a
22 key point.

1 MS. COWAN: We've actually been working with
2 APA, the American Pharmacists Association, and we
3 have a graphical tool on how to exactly do that
4 because of all the calls from people that don't
5 know how to take the medications. So it's day or
6 night, with food or without food, things to avoid,
7 possible side effects.

8 Graphical tools, again, a picture is worth a
9 thousand words. That's a beginning, but we always
10 encourage people to really have that conversation
11 with their pharmacist. If they don't know, go back
12 and ask the pharmacist. They're trained to do
13 that. And the best resource is your pharmacist,
14 and actually go back and have that conversation
15 with them.

16 DR. EGGERS: Thanks, Penney. Our final
17 question?

18 DR. TERMAN: Greg Terman, University of
19 Washington and American Pain Society. I have a
20 question, but first an ad that Greg, allowed me to
21 make. Takeback programs are really important to
22 me. No matter what omniscient legislator tells me

1 how many pills to give to the average patient as
2 they leave the hospital for their lung transplant,
3 I'm likely to give some too many and some too few.
4 So takeback is really important. There's going to
5 be some that are going to be left over.

6 I just want to advertise -- I have no
7 conflicts of interest except for this interest in
8 takeback -- but in the last year, Walgreens has put
9 up 600 stores that have takeback containers.
10 They've collected 7.2 tons of medications, and
11 they're not just on DEA takeback. It's not just a
12 drug enforcement.

13 So I've changed my personal pharmacy because
14 of that, and if any other chains are doing the same
15 thing, I'd certainly be interested and advertise
16 them as well.

17 DR. EGGERS: Thank you.

18 DR. TERMAN: But assuming I can't get
19 everyone to takeback their unused medications, I'd
20 be interested in -- as you know, misuse, there have
21 been a number of studies that suggest that most
22 people who misuse medications is because of family

1 and friends giving them medications.

2 I'd be interested in your perspective as a
3 physician trying to teach my patients not to do
4 that, what is it about pain medicine that allows
5 people to think that they can give them to other
6 people?

7 If I see a kid with a sugar high, I don't
8 say, well, let me get my insulin and see if I can't
9 help them with that. What is it about pain
10 medicine that is seen so differently in our
11 society? I'd be interested.

12 DR. EGGERS: Does anyone want to quickly
13 give --

14 MS. CARR: I can say as somebody who reports
15 and writes about drugs when we do the drug surveys
16 and stuff every year, I kind of disagree. It's not
17 just pain meds, and people will tend to keep things
18 like antibiotics, for example, just in case so they
19 don't have to go back to the doc the next time
20 around. Or if somebody in the family gets the same
21 thing, they think they can just use the same drug
22 over and over again.

1 I think it's just a lack of understanding
2 about medications. And at a very, very basic level
3 what we find is that people often overestimate the
4 benefits and underestimate risk of medication. I
5 think we've been culturally trained to see them
6 that way.

7 MS. COWAN: I think it partly is we're a
8 compassionate society. We want to help people when
9 we see someone in pain. I'll never forget one of
10 the first meetings I went to at the FDA about REMS,
11 and there was a mother who got up and said that she
12 had a daughter who died from an overdose, but it
13 was because of the grandmother.

14 So the daughter was visiting the
15 grandmother, and the granddaughter was having some
16 pain issues, and the grandmother had gotten some
17 medicine for surgery and had some left over and
18 said, "Here, take this." No idea it was an opioid,
19 it would kill the granddaughter. The granddaughter
20 died.

21 I'm a grandmother. I can't imagine having
22 to live with something like that. So I think

1 people, that's where the public education is so
2 very critical, and we're not doing that. And we
3 better start doing it because if this grandmother,
4 if she had only known, she would never -- it's
5 unintentional. It's a mistake, and we're just
6 trying to help someone feel better.

7 That's human nature, and I think that's why
8 we do it.

9 MS. CHAMBERS: And, Dr. Terman, it goes
10 straight to that fear factor, that they have that
11 fear themselves or don't want to see other people
12 in that kind of pain, and so they are compassionate
13 and want to reduce that fear.

14 MR. WILLIAMS: I would just add, compassion,
15 I think, is one thing, but they work. They create
16 euphoria. Why do you invite somebody to a bar to
17 have a drink? It works. I think there's an
18 acknowledgement of the quick fix. I think
19 compassion is one emotion, but I think we are in a
20 quick fix culture, and this is one quick fix.

21 One thing for your patients, I think,
22 similar to public health education on guns, the

1 notion that we have to lock these medicines up
2 because -- look, teenagers have a lot of
3 information. Eight-year-olds have a lot of
4 information at their fingertips. I used to go on
5 rxlist.com when I was 14 years old. I knew exactly
6 what imprint codes would get me high, okay?

7 So I think we have to not be naive that
8 young people, especially who are the most at risk
9 for these medications, know a lot more about these
10 medications than some people. Our grandmothers and
11 our other folks know about these medications, so
12 locking them up is a really important thing that
13 people need to be educated about.

14 DR. EGGERS: I want to thank the panel for
15 excellent remarks and dialogue, and thanks for the
16 questions. We have an hour for lunch, is that
17 correct, Doug? So be back at 1:15, please.

18 (Applause.)

19 (Whereupon, at 12:19 p.m., a lunch recess
20 was taken.)

21

22

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

2 (1:19 p.m.)

3 DR. THROCKMORTON: All right. Second day,
4 thank you for coming back from lunch break. It is
5 a gorgeous day out there. I appreciate everybody
6 coming back.

7 This afternoon's panel, this first panel
8 we're holding is called the federal panel, and it
9 reflects the federal response to the opioid crisis.
10 The one that's going to help lead this is Chris
11 Jones, who's worked in many of the Feds.

12 Right, Chris? I think you have experience
13 across many of the -- currently the acting
14 associate deputy assistant secretary for science
15 and data policy of the assistant secretary for
16 planning at HHS, and there's going to be a series
17 of some presentations and a panel.

18 Chris, thanks for helping very much.

19 Federal Panel

20 DR. JONES: Thank you, Doug.

21 I think I will keep my comments certainly
22 brief for this portion and get started with the

1 presentations, but we do have a series of
2 presenters from various agencies within HHS who are
3 working on the opioids space. This gives you a bit
4 of flavor of what we're doing around education for
5 prescribers and prescriber training.

6 I believe our colleague from SAMHSA is going
7 to be the first up, and the slides are loaded up.

8 Mitra, if you want to come on up. Thank
9 you.

10 Presentation - Mitra Ahadpour

11 DR. AHADPOUR: Good afternoon. My name is
12 Mitra Ahadpour. I am the director of Division of
13 Pharmacologic Therapies at SAMHSA, and thank you
14 for allowing me to speak today. I'm aware that I
15 have 5 minutes, so I will talk very fast. So
16 hopefully you will understand what I'm saying with
17 my accent. When I talk very fast, it goes very
18 fast.

19 I just wanted to quickly go over what
20 happens on an average day in the United States. As
21 you see, more than 650,000 opioid prescriptions are
22 dispensed; 3,900 people initiate nonmedical use of

1 prescription opioids; 580 people initiated heroin
2 use; and 91 people die from an opioid-related
3 overdose.

4 I wanted to give you a brief overview of
5 some of our resources at SAMHSA. This is not
6 complete. I encourage you to go to our SAMHSA
7 website, and there is a lot of great resources for
8 the healthcare providers and for patients.

9 One of our programs that we are very proud
10 of is the Providers' Clinical Support System. This
11 is a collaborative agreement between many
12 professional organizations, and there is a PCSS-MAT
13 and PCSS-O. The MAT is for medication-assisted
14 treatment, and O is for opioid therapy.

15 As I love data, I'm going to give you some
16 data. These are just some of the highlights for
17 the PCSS-O on the number of webinars that they have
18 created. And what I wanted to highlight here
19 quickly is the mentors. There are free mentors
20 available. I think this is really important.

21 I've been sitting for the past day and a
22 half and hearing everyone's input on opioid

1 prescribing, safe opioid prescribing training
2 tools. I think the mentor piece is extremely
3 important for the clinicians.

4 They just released a pain curriculum, which
5 is 14 modules, and this really includes everything
6 from safe opioid prescribing, how to do the correct
7 communication, motivational interviewing, really
8 how to assess patients who both need an opioid pain
9 mediation but also have the comorbid mental
10 illness.

11 I think that's the piece we need to keep
12 going back to it. It's great to have a safe opioid
13 prescribing training for the clinicians, but let's
14 please keep in mind that we also need to include
15 the mental illness piece, the anxiety, the
16 depression, the PTSD.

17 The PCSS-MAT, these are some of the
18 highlights. Also, there is a mentor piece, free
19 mentorship both for PCSS-O and MAT for clinicians.

20 The opioid prescribing in the dental
21 setting, we have had courses that were both in the
22 PCSS-O but also through Boston University that we

1 have supported. The 2000 number for the completing
2 training is for the past about two years, and this
3 is really intended for the dentists.

4 If you're interested in the granular data, I
5 have it, of how many were general dentists, how
6 many were oral surgeons that have partaken in this
7 course. Because to our mind, the training should
8 be for all healthcare providers, for nurse
9 practitioners, nurses, physicians, dentists,
10 pharmacists, social workers, chiropractors.

11 I think any profession -- this is my
12 opinion. Any professional that touches a patient,
13 that has a connection with any patient, should be
14 aware about safe opioid prescribing and how to
15 assess the patient and about complementary
16 medicine.

17 I just wanted to give you that we have made
18 a MATx, which is an app that has wonderful
19 resources in it. It's on medication-assisted
20 treatment but also how to treat alcohol use
21 disorder and tobacco use disorder.

22 We went with Medscape and did a two-year

1 program of screening brief intervention, referral
2 to treatment, and we had close to 75,000 learners.

3 Thank you. I'm exactly on time.

4 (Applause.)

5 DR. JONES: Nice work. You'll get a reward
6 after that for staying on target.

7 Next is Major Debbie Dowell from CDC's
8 Division of Unintentional Injury Prevention.

9 Presentation - Deborah Dowell

10 MAJ DOWELL: Thanks, Chris.

11 Good afternoon, everyone, and I'll be
12 relatively brief. I just wanted to start making
13 some comments about the questions all of us have
14 been asked to address today and what we've heard so
15 far over the last day and a half.

16 I think I haven't heard much disagreement
17 with the fact that we have a problem; we have at
18 least a couple of problems, both with knowledge
19 about appropriate, effective, and safe management
20 of chronic pain in this country and also with
21 adverse events related to prescribing or opioid
22 analgesics.

1 I haven't heard much disagreement with the
2 idea that we need more education. Even if we don't
3 have randomized controlled trials showing that it
4 works, it's likely to have low risks, and we know
5 that there is a need out there.

6 I think the most prevalent concern we've
7 heard is the idea that prescribers, especially as
8 this was tied with the ability to prescribe opioids
9 through a DEA license or something, prescribers
10 might opt out and stop prescribing opioids. But I
11 think it's reassuring. We've heard from New Mexico
12 and some preliminary data from IHS that this hasn't
13 happened, as well as some data from Kaiser,
14 although that was not mandatory.

15 I also want to emphasize the opportunity for
16 potentially people to opt in in a different way
17 with education. We've also heard comments about
18 it's not so much the education, it's what people
19 hear in the media that scares them, and I think
20 education can be a way to emphasize messages such
21 as -- I'll just give you an example.

22 Most of you know the CDC put out guidelines

1 a little over a year ago on opioid prescribing for
2 chronic pain. I think a lot of people don't know
3 that the CDC guidelines advises against suddenly or
4 unilaterally stopping opioids in patients already
5 on high doses or doing it quickly or abandoning
6 patients. But you have to read the guideline to
7 find that out. You might not know that if you read
8 the news reports only.

9 Education gives us an opportunity to
10 emphasize those messages and get the important
11 information, if we can all agree on kind of a set
12 of basic information that's important to be
13 included education in an FDA blueprint or another
14 common understanding.

15 With that, I'm just going to spend a couple
16 minutes sharing with you some of the resources that
17 CDC has made available in the last year and is
18 still working on in order to support implementation
19 of the recommendations in the CDC guideline for
20 prescribing opioids for chronic pain.

21 In the last year, we've made more than 20
22 guideline-related educational tools available for

1 providers, including a checklist, fact sheet, and
2 guides. We had a speaker from Consumer Reports
3 this morning who mentioned the usefulness of a
4 checklist for airline pilots and in surgery. And I
5 just wanted to point out, we worked with Atul
6 Gawande, who wrote the Checklist Manifesto and has
7 been instrumental in getting checklists more widely
8 used in surgical practice. He and his team at
9 Ariadne Labs collaborated.

10 The page in back you see is a one-page
11 checklist that has all the key elements to think
12 about when you're considering or continuing opioid
13 prescribing for chronic pain, just on one page.

14 We also have a mobile app. It was released
15 a couple months ago.

16 We have made available free continuing
17 education credits on the guideline in partnership
18 with colleagues at the University of Washington.
19 It includes seven 1-hour webinars, which were
20 released between June and December of 2016, and
21 they're now available for download and free
22 continuing education credits on completion of a

1 short quiz at the end.

2 Just launched three weeks ago in April, we
3 are also offering free web-based continuing medical
4 education on the guideline featuring standalone
5 modules, interactive scenarios, resource links, and
6 knowledge checks.

7 Just in light of some of the discussion
8 we've had in terms of how do you incentivize, what
9 kind of uptake can you get with voluntary versus
10 mandatory training, we've had 2,500 page views of
11 this since we released the first module -- just the
12 first module is the only one available -- three
13 weeks ago, which we're pleased about. But when you
14 consider we're talking about over a million
15 prescribers, I think we've got more to go.

16 By the way, the previous slide I put up with
17 the webinars, had 44,000 page views, which again,
18 we're pleased about, but we're far from a majority
19 of opioid prescribers in the United States viewing
20 these.

21 We'll hear a little bit later from a
22 colleague at CMS, but I wanted to note that

1 colleagues at CMS have stated that they plan to
2 incentivize completion of these modules through
3 proposing as an improvement activity claiming CME
4 credit for these modules.

5 The first eight modules are listed here and
6 will become available on a rolling basis through
7 the rest of the year. And in addition to these, we
8 are going to be adding additional modules on acute
9 pain and other topics. You can see the ones we
10 have here add up to about 6 and a half hours, but
11 at this point, clinicians can pick and choose which
12 are most relevant or could do a subset of these.

13 Then with the additional content we plan to
14 release later, we might be able to think about
15 something if you do your initial continuing
16 education one year, and then two or three years
17 later, you can pick among the other modules that
18 are most relevant to your practice.

19 I just wanted to note Penney Cowan spoke
20 pretty eloquently earlier today about the need for
21 communication, and we did try to put an emphasis on
22 communication in these modules with one module

1 focusing exclusively on communication with
2 patients. The other modules have opportunities to
3 practice communication skills, including
4 motivational interviewing.

5 This is just information on where to find
6 CDC's training resources, and I will stop there and
7 continue the discussion later on. Thank you.

8 (Applause.)

9 DR. JONES: Thank you.

10 Next is Wilson Compton from National
11 Institute on Drug Abuse to talk about what NIDA and
12 NIH are doing in this space.

13 Presentation - Wilson Compton

14 DR. COMPTON: Thank you very much, Chris,
15 and good afternoon, everybody.

16 Part of the pleasure of working at the NIH
17 is that our job is to promote the development of
18 new knowledge, but if we do that in a vacuum and it
19 sits on a shelf, it's not very satisfying. So it's
20 essential that we collaborate, both with the
21 practice community and in order to reach the
22 practice community, through all of our federal

1 partners.

2 So the people at this table and many other
3 people in the room have been terrific partners in
4 both working with us to figure out, well, what are
5 the questions that we need to focus our research
6 enterprise on, and then in making sure that we
7 develop information that will reach the populations
8 that we hope to help solve their problems.

9 The broad theme for us at NIDA and for NIH I
10 think can be summed up with the title of this title
11 slide. Our goal is to science to make solutions to
12 the public health problems in our country, and of
13 course, in this case, we're talking about
14 educational issues related to clinicians and how we
15 can use this to drive towards solutions of the
16 opioid and pain crises in the United States.

17 Now, I just have a couple things I want to
18 highlight for you. First, I'll highlight for you a
19 series of meeting that the NIH will be undertaking
20 in June and July of this year. These are being
21 implemented out of the Office of the Director, so
22 Dr. Francis Collins is leading the effort to

1 develop three key targeted meetings that will
2 include hopefully, the development of
3 public/private partnerships where NIH provides much
4 of the work on the basic science, the process of
5 discovery, but we partner with the pharmaceutical
6 industry and with biotech and possibly even device
7 developers in order to see these things brought to
8 clinical practice. Because it's rare that we can
9 do this on our own, and it's only by working
10 together that we can bring these products out to
11 the public to make the difference that we hope they
12 will make.

13 Now, the three topics are addressing issues
14 that are of importance to the group here today.
15 First and foremost, we need better pain management.
16 The key obvious example is we use opioids for an
17 awful lot of pain treatment, and while we have
18 other approaches and we're all in favor of the
19 integrated approaches to pain treatment, wouldn't
20 it be nice if we had potent analgesics that didn't
21 have the same side effects as our current range of
22 the opioids?

1 There have been some breakthroughs recently.
2 I'm particularly excited about the biased mu opioid
3 agonist medications where it looks finally like
4 it's possible to have something that has a potent
5 opioid painkilling analgesic impact but doesn't
6 have the development of either sensitization or
7 tolerance -- that's part of your pathway to
8 addiction -- or respiratory depression, because it
9 turns out that those pathways can be decoupled.

10 Now, the question for the clinical studies
11 will be how much do these pathways completely
12 separate or is there relative separation. We, of
13 course, would like a complete separation for them
14 to maximize pain relief without addictive
15 potential. That remains to be proven, and that's
16 just one example of how we can develop safe and
17 effective non-addictive strategies.

18 I haven't even mentioned transcranial
19 magnetic stimulation and the like, but those are
20 some of the work that we hope to stimulate with
21 this meeting coming up.

22 The second broad theme, which isn't directly

1 related to the topic today, but could because I
2 think part of the implementation of training around
3 pain management is when is it appropriate to
4 implement naloxone distribution, naloxone
5 prescriptions and the like for pain patients.

6 Is it for every acute prescription that we
7 provide? Probably not, but is it for every
8 chronic, particularly high dose? The data would
9 suggest from some NIDA-funded research in the last
10 few years that that might make good sense.

11 The second meeting will be improving
12 overdose interventions and overdose reversal,
13 including such things as respiratory stimulation
14 systems.

15 Finally, the other key component of our
16 meetings and the third meeting will be focused on
17 improving opioid addiction treatment. This takes
18 two realms. We have on the one hand, we need to
19 improve our implementation of the strategies that
20 we know can be effective, but even in the best
21 hands, while I'm thrilled that we have methadone,
22 buprenorphine, and the long-acting naloxone to

1 treat opioid use disorders, they're not maximally
2 effective. They don't have the penicillin-size
3 effect size for middle ear infections, for example,
4 or something like that. And that's what we would
5 like. We'd like something that is easy for
6 patients to take, the patients want to take it, and
7 leads to better outcomes than the current
8 technologies.

9 So that's what we will be supporting in the
10 next month or two in this broad sphere to help
11 stimulate what we have as a broad portfolio in this
12 area.

13 Now, in terms of the educational areas, NIDA
14 is very pleased to add to the range of resources
15 that are available to clinicians. These are
16 broadly under our NIDA med website, and I highlight
17 for you a variety of materials.

18 In particular, I highlight for you our CME
19 courses that we did with Medscape. This was with
20 funding from OMDCP a couple of years ago. And we
21 were surprised that over 100,000 people took those
22 trainings. That was a new experience for us, to be

1 that popular in terms of people signing up, and it
2 spoke to us about the tremendous interest and need
3 that clinicians have, at least some of them, in
4 improving their prescribing practices.

5 Finally, more broadly across the NIH will be
6 the NIH Pain Consortium that are developing
7 specific pain assessment and treatment modules. I
8 encourage you to take a look at the website for the
9 Center of Excellence for Pain Education for modules
10 like Edna, who's a clinical case module to help
11 learn about assessment and treatment of low back
12 pain, and a handful of others. We will be rolling
13 out more and more of these to increase our range of
14 resources for those that want to improve assessment
15 and treatment of pain.

16 Thanks very much. I look forward to
17 discussion.

18 (Applause.)

19 DR. JONES: Thank you, Wilson.

20 Final presentation is Jeff Kelman from CMS
21 who will talk about what's happening in the
22 Medicare space.

1 Presentation - Jeffrey Kelman

2 DR. KELMAN: Thank you. I'd first like to
3 thank the FDA for inviting me to be on this panel.
4 It's always a nice event in my week. I'm always
5 also somewhat hesitant when I accept one of these
6 invitations because while you are all scientists,
7 I'm just a payer.

8 There was an administrator at CMS, about
9 10 years ago, who referred to us as "one big dumb
10 payer." Well, hopefully, we've gotten less dumb
11 since that point, and in fact, there are tools we
12 have at our disposal that can help us address the
13 opioid crisis, which is so risky for our
14 beneficiaries.

15 I'm going to talk about some of them and how
16 to impact the payment system to direct people to
17 better care. I want to discuss briefly within the
18 five minutes I have our utilization management
19 system for opioids, our point of sale step edits
20 for opioids, and our quality measurement for opioid
21 use.

22 In general, I'm going to be speaking about

1 the Part D drug benefit, which is only section of
2 areas we develop in, but it's a big section. We're
3 close to 30 percent of all written prescriptions in
4 the U.S. at this time.

5 The OMS was started in 2013 when we first
6 came to realize that we were using a lot of
7 narcotics in the Part D benefit. It's addressing
8 the most severe of the severe cases. It's a
9 retrospective review of those patients, of those
10 beneficiaries, who had more than 120 MED for more
11 than 90 consecutive days with more than three
12 prescribing physicians and more than three
13 pharmacies.

14 This is the fringe on the outside. We
15 require direct outreach, training, education, and
16 intervention, and follow-up if necessary to explain
17 and identify the needs of this population. We
18 excluded, by the way, cancer patients and patients
19 in a hospice. Over time, we've had a great
20 success. I was actually surprised by the effects
21 of this method, which goes to show payment actually
22 does count, and I can't resist giving some numbers.

1 In 2011, we had 31 million Part D enrollees
2 with 10 million enrollees on opioids, at least one
3 prescription during the year. That's 32 percent,
4 and that level stayed pretty much the same
5 throughout the program.

6 There were 29,404 beneficiaries who met the
7 criteria for outlier use as defined. In 2013,
8 there were 37 million enrollees, 31 percent using
9 opioids, and only 25,347 outliers.

10 In 2014, we had 40 million enrollees with,
11 again, 31 percent opioids and 21,838. In 2015, we
12 had 42 million enrollees with 15,651 outliers.
13 Last year in 2016, there are now 44 million Part D
14 enrollees with only 11,595 outliers.

15 In summary, we had a 60 percent reduction in
16 the absolute number of drug users in spite of
17 increasing population and a 70 percent reduction in
18 outliers, 60 percent of total enrollments. This is
19 more of a success than I expected, and it addresses
20 one coterie, but we hopefully have spillover
21 values.

22 The second program, which is starting this

1 year, is real-time point of sale edits. The OMS is
2 based on retrospective look after the damage is
3 done. The point of sale edit involves an edit
4 before the dispensing event is done, looking at
5 cumulative doses that trigger a certain level,
6 generally, 90 MEDs for a soft edit and 200 MEDs for
7 a hard edit.

8 A soft edit, by the way, means it's
9 reversible by the pharmacist at point of sale based
10 on discussion with a physician and a patient. A
11 hard edit means it requires an absolute planned
12 appeal before the drug can be dispensed. These are
13 all based on educational lines that we expect our
14 physicians and our pharmacists to follow.

15 Since we started it for the first time this
16 year, I can't give you any numbers as to success.

17 Lastly, we use a quality measurement of
18 opioids, which we've just developed with the
19 Pharmacy Quality Alliance.

20 Quality measurement is an interesting field.
21 If attached to a pay for performance system, it is
22 very effective at changing share, and it's

1 widespread and involves every opioid prescriber in
2 Part D and anybody else who downloads and utilizes
3 our quality measurement.

4 The opioid for high dose in persons without
5 cancer measure has three rates, and they're
6 basically an unpacking of our OMS system. The high
7 rates of simple daily dose more than 120 MED for 90
8 days, there is the proportion of individuals
9 receiving prescriptions from 4 or more pharmacies
10 and 4 or more prescribers, and the last one is the
11 combination where they have more than 120 MEDs for
12 90 days plus the 4 or more pharmacists and 4 or
13 more prescribers.

14 Because it's in a quality measurement system
15 which goes across all our plans, it's picked up by
16 everybody. Because it's in a pay-for-performance
17 system, everybody pays attention to it, and we have
18 great expectations going forward that this will
19 have a greater impact than our OMS system because
20 it's more broader based.

21 Thank you, and I'll take questions later.

22 (Applause.)

1 Panel Discussion

2 DR. JONES: Thank you to our presenters, and
3 I would ask FDA and DEA colleagues to come up and
4 join the panel. I think everybody has mics, so
5 hopefully, they're turned on.

6 We do have a few questions for discussion,
7 but I will probably go off script a little bit.
8 But I would like to start, based on the totality of
9 what folks have heard over the last couple days and
10 what you're doing within your own organizations and
11 what's happening across the federal government,
12 what do you think are the merits of a requirement
13 for prescriber education or alternatives for
14 voluntary or incentivizing?

15 What is, from your perspective, the best way
16 to approach ultimately accomplishing the goal of
17 reducing inappropriate prescribing, reducing
18 opioid-related harms?

19 I'll just turn it to the panel to address
20 that question. I know that some of you have
21 already spoken on some of this, but just thinking
22 from it collectively of what you've heard over the

1 last couple of days.

2 Debbie?

3 MAJ DOWELL: I can start. I think voluntary
4 is nice if it works. I'm a little bit skeptical of
5 our ability to reach the people we most need to
6 reach with the voluntary program. We've heard over
7 the last couple of days that the majority of
8 providers are now employed in organizations, and
9 we've heard a lot about a lot of great work in
10 education going on in health system, but there's
11 still a very large proportion of providers who are
12 in solo practice.

13 We also know that some of the states have
14 already required mandatory education but not all,
15 and states are going to have very variable amounts
16 of resources to come up with a prescriber training.

17 I think we've heard over the last couple of
18 days everybody acknowledges we have a problem and
19 that we don't have extensive proof that mandatory
20 education would work. It makes sense that it would
21 work. It's likely to be low risk.

22 My main concern about voluntary is that if

1 you incentivize, you're going to incentivize first
2 the prescribers that probably need this the least,
3 and we're not going to reach the prescribers who
4 really need this and other healthcare providers.

5 DR. AUTH: Doris Auth from the FDA. I would
6 just like to dovetail on what Deborah said. We
7 have a few voluntary prescriber education programs,
8 as I pointed out yesterday in my presentation.

9 In particular for the FDA extended-release
10 long-acting opioid REMS program, we haven't met our
11 training targets. You could say that we could have
12 done our targets differently. We could have come
13 up with different numbers. But we often wonder
14 when we look at the assessments and actual numbers,
15 are we really getting to the right providers? The
16 providers that are taking a voluntary training, how
17 are they different?

18 Our expectation is that maybe they are
19 providers that may not need to take the training.
20 They are the ones that are out there looking for
21 education and want to do the right thing. Maybe
22 those providers aren't really our target that are

1 taking the voluntary program.

2 DR. KELMAN: I actually always see a third
3 option. There's voluntary training, there's
4 mandatory training, and then there's incentivized
5 training. For us it's because we see this as a
6 payer. But in general, there are programs at CMS
7 that give incremental payment improvements for
8 following certain benchmarks.

9 That's not mandatory in the sense that the
10 prescriber is not out of the program if he doesn't
11 follow it, but it certainly enhances his interest
12 in actually finishing the option because he is
13 incentivized by higher payments. If we can cut
14 that, I've found it a more practical solution.

15 DR. COMPTON: Certainly from an NIH
16 perspective, this is not something that we're going
17 to have a direct opinion about. Our goal would be
18 to use research to help inform these discussions.
19 Where there is natural variation, that might lead
20 to natural experiments that could be exploited to
21 look at the impact of training models and
22 approaches to pit required education against

1 voluntary or incentivized education.

2 Certainly in listening to the discussion
3 yesterday and today, I'm impressed that an awful
4 lot of people don't get trained with a purely
5 voluntary -- the clinicians don't necessarily
6 recognize that they have a lack of knowledge or
7 lack of ability to do this prescribing. They think
8 it's easy, and they miss some of the nuances. I
9 think that may explain why we see such egregious
10 prescribing practices when we look at the medical
11 records.

12 DR. AHADPOUR: I think what would be
13 interesting is -- so for me, I know we keep talking
14 about physicians, but it's all health
15 professionals, physician assistants, nurse
16 practitioners, nurses, pharmacists, social workers,
17 chiropractors, physical therapists. To me, it is
18 all healthcare providers that we should keep in
19 mind.

20 I thought it would be interesting because we
21 have all these training modules that we've been
22 doing. Wouldn't it be interesting to look back and

1 have a survey, which we are considering right now
2 at SAMHSA, that after they complete their training,
3 go back to these healthcare providers six months
4 later, see has their behavior changed. How is the
5 patient affected? Has the quality of life of the
6 patient been affected? Has it become better?

7 Some of the questions to think about -- and
8 I do agree with Deborah that it is low risk to say
9 for right now, we don't have the randomized
10 controlled trials, we don't have all the data.

11 I love data myself, so I am biased towards
12 data, but right now because there is an opioid
13 crisis, we should not wait for the data, and maybe
14 we should make it mandatory. And there is so many
15 different options of incentivizing providers to
16 have this training. So to me, it makes sense.

17 DR. JONES: I have a question on the
18 mandatory side and the idea that people may opt in
19 if it's voluntary and those are the people maybe
20 we're not concerned about. But what do we know
21 about the people who are the outliers and whether
22 or not we think mandatory education would be

1 successful in changing their behavior?

2 We look at PDMP data, and we see that there
3 is a small number of prescribers prescribing large
4 volumes of opioids. Some of those are associated
5 with pain clinics, and certainly Florida and other
6 states have had issues with that. Mandatory might
7 check a box, but how do we work towards changing
8 their behavior when it's not necessarily a
9 knowledge deficit, and that might be contributing?

10 Just thoughts on approaches to address that
11 population, who really you would like to change
12 their behavior, but it may not be a knowledge
13 issue.

14 DR. AHADPOUR: One thing to think
15 about -- and I'm just throwing this out. I haven't
16 thought about this. One thing you could think
17 about is can we go back to these providers when we
18 do this 6-month or 3-month survey, but put a
19 mentoring piece to it, so they have a mentor after
20 they complete their training.

21 The mentor piece of it, there are several
22 different ideas of how you could have mentoring all

1 throughout the country that would be sustainable.
2 But maybe through that mentoring piece, we have
3 something to see are they changing their behavior,
4 maybe direct them to change their behavior.

5 MAJ DOWELL: I would definitely agree that
6 SAMHSA has PCSS-O and PCSS-MAT, which are great
7 mentoring programs. Project ECHO is another model
8 for how we might combine following up on some basic
9 education and possibly also get some feedback.

10 I think it's going to be a very large and
11 difficult workload to try to measure this across
12 the U.S. One thing you could do -- it's much
13 easier within health systems, and we've heard some
14 great examples yesterday and today about that.

15 CDC is also working on development of a
16 package of quality improvement metrics, and we
17 heard from CMS about quality measures. We don't
18 see it as tied to payment, but they're just
19 intended to be part of the quality improvement
20 process in healthcare systems, and we've been
21 vetting them with stakeholders on feasibility and
22 usability, and we'll be piloting those in a few

1 health systems. We've heard about some similar
2 work going on.

3 I think the challenge, again, is outside
4 those large health systems and making sure that
5 you're changing behavior among the solo docs. I
6 think one possibility for looking at that is having
7 states look at their PDMP data.

8 I also wanted to make the point -- I think
9 somebody else made this yesterday -- that there
10 probably is a small group of prescribers who are
11 not going to change no matter what we do, and I
12 think it's more fruitful to focus on the group that
13 has maybe learned prescribing and pain management
14 practices that we now know are outdated. I
15 actually think that that's a larger and certainly a
16 more changeable group than that core that are not
17 going to change no matter what you do, which is
18 probably a problem to be resolved not by education.

19 DR. KELMAN: It's very hard to get docs to
20 change their behavior, and I don't think it's
21 predominantly an education issue. I think it's a
22 culture of practice issue. If incentives can't do

1 it, then the only end result -- part of incentives
2 is also comparative information.

3 Sometimes it's very effective to send a
4 doctor a comparison to his similarly-situated peers
5 who may have a better prescribing behavior or any
6 activity. But in the end, if incentives don't work
7 and comparisons don't work and education doesn't
8 work, the only option is to remove the DEA license
9 to prescribe, because that will always work.

10 DR. COMPTON: Your question reminded me,
11 Chris, and Jeff just reminded me, that our goal is
12 not simply increasing the knowledge of clinicians.
13 Our goal is to change prescribing behavior, and
14 even that's not really our ultimate. Our goal is
15 to improve patient outcomes.

16 Keeping that as our target, I think is how
17 we ought to both measure and understand what role
18 does the education system provide, and can you
19 reach that culture change with incentivized
20 voluntary practices versus a mandatory education?
21 I think that's an important possibility.

22 I also think there might be some

1 technological approaches that might help. An awful
2 lot of prescriptions are now written on an
3 electronic basis. Well, if the normal numbers of
4 prescriptions aren't unlimited, maybe we could
5 nudge people towards smaller prescriptions with
6 automated prescriptions for 10 tablets. You could
7 always override it, but how come somebody always
8 writes for 120? Well, they do it out of habit. So
9 if we help shape that habit through the creative
10 use of technology, that might be a way to reach the
11 same goals.

12 DR. AUTH: The REMS assessments that we get
13 for the -- and we presented that in this last year
14 in our advisory committee. We do use surveys. We
15 ask the sponsors to conduct surveys of prescribers
16 who have taken the training and those who have not.
17 We try to make comparisons.

18 We are also trying to look at prescriber
19 behavior. That's exceedingly difficult, especially
20 in this population where there have been so many
21 different activities occurring. And we're also
22 trying to look at how can we get better at looking

1 at patient outcomes, and that's very, very -- at
2 least in the scope of the REMS assessments, it's
3 extremely challenging.

4 There's a lot of surveillance data out
5 there, and again, it's also lots of limitations
6 with that. But then also, what caused the change
7 in behavior, if there is a change in behavior? Was
8 it everything else that's happening? Was it the
9 educational program?

10 I think even patient outcomes is potentially
11 more difficult to study, but that's just my opinion
12 based on what we've seen in the REMS assessments.

13 DR. JONES: I have a question maybe for Jeff
14 to start. This is obviously focused on opioids and
15 certainly in the REMS context, it applies to a
16 particular group of opioids, and thinking about,
17 okay, we want to change behavior. We want to
18 improve patient outcomes. We want to improve
19 access to high quality pain care.

20 So in the context of mandating education or
21 scaling up education, what do you see as the other
22 critical elements to success? So thinking about

1 the CDC guideline says do other things than
2 prescribe opioids. That's the first recommendation
3 essentially. Do we have a system in place that
4 makes that possible?

5 So we're putting forward education to say
6 choose other options, but how do we build a system
7 and change reimbursement and payment, and work with
8 health systems to ensure that that is an option for
9 clinicians to actually have, if we're educating
10 them that that's what they should be doing?

11 DR. KELMAN: From my point of view, it goes
12 back to quality measurement and performance
13 measurement, and this is what it was invented for.
14 If you have a series of guidelines that
15 are -- measures start with best practice, they go
16 to guidelines, and then they go to quality
17 measurement. And establishing the measurement
18 through a consensus group is key. Getting it
19 adopted it is important. Getting it endorsed is
20 important. But none of this matters unless there
21 are payment incentives at the end is my general
22 impression.

1 I'm sorry to say that after the last
2 10 years, but just quality alone doesn't have
3 enough of an impact on cultural change. You need
4 incentives, and that's why pay-for-performance
5 systems were invented.

6 DR. JONES: Maybe a question for Wilson
7 thinking from the research perspective. In this
8 environment, it's often thought of mandatory CME, a
9 couple of hours, and that's what states have done.
10 It's some of the bills you've seen in Congress.

11 I think there is a growing evidence base for
12 how education can be provided. I worked with
13 Debbie when I was at CDC, she was in New York,
14 around academic detailing. Obviously, that's a
15 more intensive effort.

16 What's your take on how do we put programs
17 in place to create lasting behavior change, and
18 what does the science tell us, a 1- or 2-hour
19 course versus something more intense or some
20 stratified approach to where some individuals might
21 need a lighter approach and others a more in-depth
22 touch?

1 DR. COMPTON: To a certain extent, the
2 adoption of innovation has been studied in multiple
3 contexts, both healthcare and outside. So you
4 think about how simple of a behavior change are we
5 looking for. The simpler and easier to practice it
6 is, the more likely people are to take it up based
7 on educational efforts at least as the starting
8 point. But for most of the behaviors we're talking
9 about, they are a lot more complicated such as the
10 decisions that go into deciding how large a
11 prescription to write and how long to write it for.
12 That's ultimately what we're talking about here.

13 So a simple, single educational session is
14 unlikely to have the maximum impact on that. It
15 will have some impact around the edges, but I think
16 the education all by itself probably isn't going to
17 be enough. That's what the data would suggest.

18 How do we design a system that's more than
19 just do this online course for a couple hours? I
20 was really impressed by what we heard out of New
21 Mexico and others, that they're implementing in the
22 real world something a little more thorough and

1 more complete. And I'll be curious to learn does
2 that have the impact that it looks like it should
3 from a theoretical standpoint and from a knowledge
4 about education leading to change.

5 DR. JONES: Debbie, from the CDC's
6 perspective, obviously, over the last year, you
7 have put quite a lot of time and thought into
8 developing modules, developing different training
9 programs, conducting webinars. What was the
10 scientific process behind that and where you landed
11 and decided on certain things? What informed that?

12 MAJ DOWELL: The content of the modules?

13 DR. JONES: The content and then how you
14 were putting them into action.

15 MAJ DOWELL: A couple of different answers
16 to the two different questions, but the content of
17 the modules was mostly based on the CDC guideline
18 and the evidence that we had gathered and the
19 discussions with stakeholders we had gone through.
20 We have also vetted with additional stakeholders
21 from the perspective of how providers receive
22 education.

1 Then the evidence base for what kind of
2 education would work, I would say was less
3 developed, and so we just looked at what had been
4 done in the past, some of the work with Project
5 ECHO that has informed the University of Washington
6 and their tele-pain program. So we modeled the
7 webinar series on that.

8 I don't think there was a rich evidence base
9 to guide the educational method. You mentioned our
10 work previously on academic detailing, and I think
11 we actually got some promising results in terms of
12 both provider knowledge and behavior change. But
13 as you mentioned, that's a much more expensive,
14 much more resource-intensive effort that I don't
15 know is realistic to reach the entire United
16 States. But that's something we could think about
17 reaching, maybe areas of the country that have been
18 identified as having a bigger problem for that more
19 intensive educational effort.

20 DR. AHADPOUR: We did something close but
21 not about pain management. We did a campaign like
22 a couple of years ago at SAMHSA, and the idea

1 behind it was instead of waiting for the clinicians
2 or the patients to come to us that may have never
3 heard about SAMHSA, it's for us to go to them and
4 try to get the attention where they are.

5 We did several campaigns through Google to
6 see if they would click on our opioid overdose
7 prevention toolkit, and we actually got data,
8 because I love data. We looked at how many people
9 clicked on, were they on the SAMHSA website, did
10 they actually download it, did they actually read
11 it, and we took it a step further.

12 To me, it was exciting because what we did
13 was we looked at the digital footprint. So that's
14 something a little bit different. This is looking
15 a little bit at behavior. So they come to the
16 SAMHSA website, download it, but what do they do
17 afterwards?

18 Those are things to think about, just think
19 a little bit different, coming up with innovative
20 ways of looking at can we change behavior, and what
21 is that behavior change?

22 DR. JONES: Others on this topic?

1 (No response.)

2 DR. JONES: Going to the second question
3 that has been posed to the panel, we've talked a
4 little bit about this, but discussing the goals of
5 prescriber education and the desired impact that
6 these educational interventions should have, I know
7 that FDA's put a great deal of thought into
8 thinking how do we measure the impact of the REMS
9 program, and we probably heard some of that
10 already. But it might be interesting from Doris'
11 perspective to think about how has that shifted
12 over time as you-all have learned through this
13 process as the REMS was going.

14 Then just for others to weigh in on, what is
15 realistic for an educational intervention, and
16 where should we be setting those expectations?

17 DR. AUTH: How it's changed over time, I
18 think was brought to light last year at the
19 advisory committee. We had a few years of data, a
20 few years of experience, and I think what we really
21 learned was we need more information, we need it to
22 come in differently, we need to leave no stone

1 unturned as far as what we're evaluating.

2 I think with the help of our epidemiology
3 colleagues, we were getting better. I still think
4 we have a ways to go about where the best way to
5 measure the impact of these training programs.

6 The one item that we are asking the sponsors
7 to provide is medical examiner data from a few
8 different states. You may be aware that that's not
9 available throughout the country. We have to take
10 step back and think that we are not going to get
11 this global surveillance data, and it's going to be
12 hugely helpful, that we need to scale it back and
13 look at smaller pockets and see what's been
14 effective, how behavior has changed in those
15 pockets, and then maybe try to trace that back to
16 an educational program.

17 We're continuously evolving in how we're
18 evaluating the REMS program.

19 DR. COMPTON: I think one of the
20 difficulties is to measure how much the educational
21 program itself has the impact versus how much is
22 the publicity or the concept of drawing attention

1 to the issue of poor prescribing behavior in a
2 general sense is having the impact.

3 While we heard earlier that California
4 requiring extensive CME on the issue of pain and
5 prescribing didn't have a big impact in California,
6 I'd be curious whether there's evidence -- and I
7 don't know of any -- of whether simply drawing
8 attention to it by making these requirements at a
9 state or local level does have some salutary impact
10 in beginning to change the medical culture.

11 Because I don't know how much it's going to
12 be the direct training versus shifting of the herd
13 behavior, which ultimately may be the more
14 important goal and not easy to draw out the causal
15 pathways and really determine what the key
16 ingredients are.

17 That's why I certainly think an educational
18 program all by itself, probably not the way to go.
19 So how do we embed this in a larger set of
20 practices that link to poor treatment of pain on
21 the one hand and the overprescribing, overreliance
22 of opioids that's put us in this dreadful situation

1 with the opioid crisis?

2 DR. KELMAN: I'm impressed that there really
3 are three different kinds of prescribers, and they
4 probably have to be addressed in three different
5 kinds of ways. There's the doctor who is lack of
6 knowledge, who doesn't understand about the best
7 practices in opioid prescribing. There are a set
8 of doctors that may practice fine on their own but
9 aren't aware of the others who are writing
10 prescriptions for their patients, lack of
11 coordination. Then there are doctors who are
12 involved in pill mills and know exactly what
13 they're prescribing. It's a completely different
14 issue.

15 The training is different for all three of
16 them. The first group, actually educational
17 modules may work, the second group needs
18 educational modules about communication, and the
19 third group needs the Department of Justice, not an
20 educational module.

21 DR. COMPTON: We'll look down the table for
22 our colleague to help with that.

1 DR. JONES: Debbie, from your perspective,
2 since you have been rolling out the CDC guidelines
3 and I know there's plans to try to evaluate or get
4 a sense of impact, what was the thought process
5 that you guys put in place, and where did you land
6 on goals about what was realistic that you could
7 achieve with how you were implementing the
8 guideline dissemination?

9 MAJ DOWELL: We've thought about that in a
10 couple of different areas. One is just evaluating
11 the impact of the guideline itself, and we just
12 went through the recommendations in the entire
13 guideline and said what would we like to see in
14 terms of prescribing practices.

15 I would say some of the things we thought
16 were really important but really extremely
17 challenging to measure, other things we thought
18 were really important and easier to measure. For
19 example, better care of patients with chronic pain
20 has been one of the more challenging things to
21 figure out how to measure.

22 We are in the quality improvement metrics.

1 We are trying to look at that by looking at
2 referrals to nonpharmacologic therapies among
3 patients with chronic pain, whether or not they're
4 receiving opioids. Some of the things that might
5 be easier to measure, are people less often
6 prescribing 60 days of opioids after a minor
7 surgical procedure.

8 We were looking at both what do we think is
9 really important and what do we think is feasible,
10 and there's some overlap, some areas where it's
11 continuing to pose challenges.

12 DR. JONES: Mitra, from SAMHSA's
13 perspective, I know you covered a couple of
14 different things. What are the expectations around
15 the programmatic work that you do? What do you use
16 to measure impact? You have contractors or
17 grantees who are doing some of this for you, and
18 what's that process on engagement to say we're
19 making a good investment here in helping to change
20 behavior?

21 DR. AHADPOUR: We have the PCSS-O or
22 PCSS-MAT and Boston University. They all have

1 different programs, training programs that they
2 have put out for healthcare providers. We measure
3 the number of learners, how many healthcare
4 providers actually access our programs. That is
5 one way for us to look at.

6 We are taking it really a step forward. We
7 are looking at right now the proposal that we have
8 put forward is to go and look at these clinicians
9 three months down the line, six months down the
10 line. And it's wonderful to know how many people
11 have completed your program. That's great, like
12 expert for Medscape 75,000, that's wonderful.

13 I actually went and read everyone's
14 comments. They gave me the comments of the
15 healthcare providers. I would go and read each one
16 of them to see what the issues they were talking
17 about, what gaps they found in it, what do we need
18 to do differently.

19 That was helpful, but I really want to see
20 it three months down the line, six months down the
21 line and see have we changed their behavior. It's
22 wonderful for them to say, oh, we love your

1 training program. It was wonderful, but what is
2 happening in their practice? Is the dentist
3 changing their practice? Are they prescribing less
4 opioids? Are the patient outcomes improving?

5 In a way, we are seeing a change, and this
6 is not by randomized controlled trial. This is
7 just colleague speaking. Recently, I was with my
8 colleagues from dental school because I was in
9 dental school, before going to medical school, and
10 I was talking to them. They said they're
11 prescribing less opioids, and they were saying, we
12 don't know what's going on. Somehow there's all
13 this educational trainings on safe opioid
14 prescribing, and they said, we are doing less
15 because we found out regular Tylenol with a
16 nonsteroidal does the same thing, combination can
17 do the same thing as giving an opioid medication.

18 So their behaviors are changing. And it
19 would be nice to look at that impact with surveys.
20 I know it's not feasible to do it for the whole
21 nation, but if we can get a group of providers from
22 different specialties to look at it, it would be

1 interesting, and then change our training based on
2 what we find.

3 DR. JONES: I'll throw this out to the
4 group. Debbie raised this during her comments
5 around people opting out or unintended
6 consequences.

7 How are people measuring those types of
8 potential outcomes? Because we have seen
9 nationally opioid prescribing declining. I think
10 there's still questions among what population is it
11 declining. So as you're implementing programs, how
12 do you think about -- are we targeting the
13 populations of patients who we want to move away
14 from opioids or reduce their risk for opioids
15 versus those who are doing fine but are caught up
16 in efforts to broad-brush and constrain the supply?

17 DR. COMPTON: I don't know that we have much
18 data on the number of prescribers and whether
19 that's changing, or whether the practice patterns
20 are changing because of the either new requirements
21 or potential for new requirements. We're certainly
22 hearing anecdotes about that.

1 The data we've heard in the last day and a
2 half does not suggest that there's been a
3 widespread shift, but that is something that could
4 and should be tracked. I would think within
5 healthcare systems, they might be able to track
6 that fairly readily.

7 I would also think just simply tracking how
8 many people have their DEA registration, does that
9 shift over time? How many clinicians have their
10 registrations and do we see that dropping based on
11 these changes? That won't exactly work because you
12 could have a registration and not prescribe.

13 We also might be able to use commercial
14 databases like IMS and similar to track clinician
15 behavior. Those are at least some resources that
16 could be utilized to get at some of that question.
17 In some ways, it seems to be more of a theoretical
18 than a real concern at this point, but that's
19 certainly something to keep in mind.

20 Are we pushing people out of practice who
21 otherwise we would like to keep in practice? I
22 think that's important to consider, is maybe some

1 of those who are stopping writing prescriptions, we
2 don't writing the prescriptions to begin with. I
3 want to make sure you know what you're doing before
4 you write those prescriptions. We don't want
5 people just doing them without knowing how to do it
6 correctly and adequately, and we do see some really
7 egregious prescription practices.

8 DR. KELMAN: We can also look true outcomes,
9 opioid overdose deaths. If we found that
10 everything we did had no impact on overdose, it
11 wouldn't encourage us it was the right direction.
12 On the other hand, if you see a progressive
13 decrease in the overdoses in large databases, it
14 would encourage us that it's the correct outcome.

15 MR. COMPTON: It's getting a little more
16 complicated because of the importation of fentanyl
17 and so many people getting poisoned with illicit
18 opioids now, whether that's in -- they think
19 they're getting a pill from their friend or
20 neighbor but --

21 DR. KELMAN: It's a counterfeit?

22 DR. COMPTON: Yes.

1 DR. KELMAN: The problem is if all we're
2 dealing is switching from prescription opioids to
3 illegal fentanyl, I'm not sure we're not getting a
4 secondary outcome we don't want.

5 DR. COMPTON: Of course.

6 DR. AUTH: To the question you raised about
7 looking at number of prescribers and how that's
8 changed, at least for the extended-release, long-
9 acting opioids, before the program was approved, we
10 had some of our drug utilization folks do an
11 estimate. Again, these are prescribers who are
12 registered for C 2s and 3s that had written a
13 prescription for an extended-release and long-
14 acting in the previous 12 months.

15 When they looked at this in 2011, the
16 estimate was 320,000, and that's how we came up
17 with some of our training targets. We asked them
18 to go back and do that again last year before we
19 had the advisory committee. They used a slightly
20 different methodology, but the bottom line is that
21 it really hadn't changed.

22 Again, that's just maybe a small example

1 because we were focusing on the extended-release
2 and long-acting. So if we expected our program to
3 have any impact on who was prescribing those, it
4 really didn't.

5 DR. JONES: Maybe a wrap-up question; we
6 still have some time. The issue of state versus
7 federal and the idea of via REMS or via DEA
8 registration mandating education versus an approach
9 for supporting state efforts to mandate education,
10 or have some system in place to incentivize or
11 provide education, I would just be curious on
12 everybody's thoughts around what approach seems to
13 make the best sense, what are the pros and cons,
14 because there are obviously pros and cons on both
15 sides; and thinking about we are in a new
16 administration and thinking about states versus
17 federal issues and how do we accomplish the goals
18 that we all want to accomplish together.

19 We'll just go down the line. I'm going to
20 make DEA speak.

21 MR. ARNOLD: I was hoping I could get out of
22 here.

1 DR. JONES: We can start at the end.

2 MR. ARNOLD: That's fine. I'm good.

3 I travel around the country a lot,
4 particularly in the last two years, and I talk to a
5 lot of different medical professions, all kinds of
6 different medical professions about different
7 issues and different things. I talk to them about
8 PDMPs. I talk to them about training for
9 prescribing.

10 The one thing that seems to come up again
11 and again, and again, we wish there was one -- I
12 can't advocate this. This is my personal opinion.
13 I don't speak on behalf of the agency at this
14 point. But the one thing that keeps coming up all
15 the time, we wish there was one standard. We wish
16 there was a national standard, consistency,
17 particularly in regards to the PDMPs; any
18 information that's reported, who can access that
19 information, should that be mandatory accessing
20 that information; that kind of information that
21 would be provided on a national scale, we wish
22 there was one center.

1 Everybody thinks the DEA controls the PDMPs,
2 and we don't. Each individual state runs all
3 those, and the same with all the 50 different
4 states. There's 50 different states, and there's
5 50 different rules and regulations regarding
6 prescribing, dispensing, and accessing PDMPs.

7 In many ways, it might be better to have at
8 least -- if we could develop some sort of national
9 standard and be able to supply that on a national
10 level, people to access that information and
11 education and to further attack and address this
12 epidemic. That's neither here nor there, but those
13 are the few comments that I can add.

14 DR. AUTH: I'd also like to say that I'm not
15 really speaking -- this is not the FDA opinion.
16 But just from my experience in the past few years,
17 there were several that made a strong case for
18 keeping this at the local level and the states. We
19 know that several states have requirements already
20 in place. But if you're looking for making some
21 core program mandatory, I'm not really sure there's
22 any way to do that and get all the states to adopt

1 that. I'm not really sure where to go with that.

2 So then you're left with a federal solution,
3 and we hear that tying it to DEA registration would
4 take an act of Congress. I don't know that there's
5 support for that right now.

6 I don't know that there's a whole lot of
7 support for the FDA REMS, so I'm at a loss for
8 which way to vote here. And again, this is just my
9 opinion. I guess some of the frustration about
10 where we go next with this, we'll save that for the
11 next panel.

12 DR. KELMAN: We work a great deal with the
13 states. Medicaid is a combined state and federal
14 program, and I'm convinced that you have to do
15 both. If the states don't buy in, the program
16 won't work. They control the PDMPs, the state
17 board of health, board of pharmacy.

18 Programs should be led nationally or can be
19 led nationally, but you need local buy-in. If you
20 don't have local buy-in, the program is less likely
21 to succeed.

22 MR. COMPTON: I guess if we knew exactly

1 what educational standards to apply, like there was
2 a reasonable consensus, then of course, we'd want
3 the same standards to apply to everyone. There's
4 no reason to think the populations vary that much
5 in terms of their needs, but we don't have that
6 degree of consensus.

7 I do think there's tremendous opportunities
8 to take advantage of the variation across the
9 states to learn about best practices and potential
10 improvements. I'd love to say that 3 hours of
11 mandatory training linked with my DEA registration
12 would make sense, and while that has great appeal
13 because of the simplicity of the message it gives,
14 I don't know that those 3 hours would actually do
15 much to change clinician behavior.

16 I'd like some sense that whatever we put
17 into place will actually have the impact that we're
18 looking for. So at a minimum, be a starting point
19 where it was a partnership with medical
20 specialties, with other healthcare
21 specialties -- I'm sorry to be so medically
22 oriented; I'm wearing my physician hat much of the

1 time here -- with pharmacists, with nurses, with
2 others that play a key role.

3 That really I would see being the target, is
4 how do we make this a supportive approach and not
5 just this artificial, simple requirement that may
6 not have the impact that we'd like it to have.

7 MAJ DOWELL: I think we've certainly heard a
8 lot about the advantages of a local approach, and
9 some states have really taken and run with this
10 already. I wouldn't want to stop what they're
11 doing. I think it's probably ideal to have
12 something that if not designed at the local level,
13 at least is adopted for the local level, so it will
14 be more supportive and helpful to the providers
15 there in following their own laws.

16 As Doris mentioned, if we want to make sure
17 there's at least some basic education that everyone
18 gets, I'm not sure what the mechanism is if it's
19 left to the states. The advantage of a
20 federal -- I think there's disadvantages of a
21 federal program. It's hard to come up with a one
22 size fits all. It can't be as easily tailored.

1 But the advantages are it could just serve
2 as the very basics, and some of the other panels
3 have talked about what those basics might include,
4 appropriate treatment of pain, treatment of pain
5 without opioids, safe treatment with opioids. If
6 we could agree on a core of principles, we could at
7 least provide something to support providers in
8 states that aren't able to come up with that kind
9 of program itself.

10 I'll have to leave this to FDA and others,
11 but I'm wondering if there is a way we can come up
12 with a system. Some people have mentioned waivers,
13 letting states who are already doing this and have
14 already come up a program that meets the basic
15 criteria we've agreed on to waiver out but provide
16 something, or have continuing education providers,
17 or CDC or others provide something that's an option
18 to use when states are not in a position to develop
19 it themselves.

20 DR. AHADPOUR: I agree with everything that
21 has been said around the table. I wanted to give
22 you an example. I believe in collaboration, so

1 this is my opinion, not SAMHSA's opinion. I
2 believe in collaboration. I know SAMHSA believes
3 it, too, but just I wanted to give my opinion about
4 it.

5 I think it's important that there should be
6 a core, standard objectives that the core should
7 have. It could be about pain management. It would
8 be about how to treat adolescents, how to do
9 motivational interview, just the whole concept of
10 that.

11 For an example, let me give you something we
12 just really did. The Care Act was passed last
13 year, and in the Care Act, it says you need to have
14 24 hours of training for the nurse practitioners
15 and physician assistants to be able to be -- if
16 they're eligible in that state, to become data
17 waived to prescribe medication for opioid use
18 disorder.

19 What we did, we put a meeting together and
20 opened it up to the public. So patient advocates
21 could come to it; clinical experts from all the
22 professional organizations, they all came.

1 What we tried to do -- it wasn't perfect
2 because we were trying to do it as fast as
3 possible. Of course, if we had months and months,
4 it would have been like a perfect meeting, and
5 everything would have been perfect, but nothing
6 comes perfect when you try to rush it. And we
7 rushed it because we knew there was an opioid
8 crisis, so there isn't that much time to really
9 make a perfect meeting.

10 So when we brought everyone in, with the
11 clinical experts from their PCSS-MAT and O, we have
12 all these professional organizations. We reached
13 out to the physician assistants organizations, the
14 nurse practitioner organizations, nurses. We
15 brought everyone in, and we said, okay, this is
16 what we think should be some of the standards for
17 the training. What do you think?

18 We really did try to be stakeholder-centric.
19 We put this information together, sent it back to
20 the organizations, and they tweaked it. They
21 edited it. And I sent it back again to all the
22 organizations. I said, "Is this something that we

1 could reach a consensus? Do we agree with it?"

2 And there was agreement.

3 So we didn't say, okay, SAMHSA is going to
4 make this 24-hour training; we are doing it for
5 free. But there are other organizations that
6 wanted to make it themselves, and that's fine, too.
7 But we all try to follow the same objectives for
8 the training.

9 So that's something to think about if there
10 is going to be a mandatory training, try to be
11 collaborative in the effort and try to reach some
12 kind of a consensus. But I still believe that the
13 training should not just focus on opioids. It
14 should really focus on the whole person, talk about
15 comorbid mental illness. I think that's a big
16 factor, and having that mentorship piece I think is
17 really important.

18 DR. JONES: So as a good qualitative
19 interviewer might do, are there any things that I
20 did not ask that you think are relevant for the
21 conversation to move forward? I'm thinking
22 particularly about the next panel, which is next

1 steps in how we move forward. What have we not
2 raised here that would be important for people to
3 ponder on?

4 DR. COMPTON: I do think that there's one
5 other level of education that we're not completely
6 considering. This is primarily focused on current
7 prescribers, and yet to a current extent, I think
8 we are operating in a system where there was a lack
9 of preexisting education, where there needs to be
10 upstream educational efforts, whether that's
11 through medical schools, through dental schools,
12 through nursing schools, et cetera.

13 That we need to be paying attention to that
14 level of basic education, which has been sorely
15 lacking when it comes to pain issues, where at
16 least, especially in the medical community, pain
17 was mostly seen as a symptom.

18 We heard this earlier today. It was mostly
19 seen as a symptom. So if you just treat the
20 underlying condition, it will go away. Yet we've
21 learned enough about pain to realize it needs
22 attention on its own, and that's an

1 important -- that might really change the landscape
2 in the long run for continuing education.

3 In some cases, I think we're providing
4 primary education about these topics, and that
5 creates a complexity for designing the system in
6 that you've got clinicians who really don't know
7 what they're doing as opposed to those who just
8 need better coordination among the practice.

9 I loved your way of subdividing our
10 students.

11 DR. JONES: Other final thoughts?

12 MAJ DOWELL: Just to add to what Wilson has
13 suggested, in terms of thinking about continuing
14 education. Earlier panels have talked about should
15 this be one time; should it be repeated; if so, how
16 often, and other people have provided answers to
17 that. But we might want to think about providing
18 options -- once people have the baseline, providing
19 options for something that's well suited for their
20 profession, for their specialty, for what they need
21 to learn next.

22 One thing I just wanted to throw out there I

1 heard is being considered in Rhode Island is
2 they're requiring education on pain management and
3 opioid prescribing. They are allowing the 8-hour
4 training in buprenorphine to count for that. Now,
5 I don't think that is something we would want to do
6 for everybody, but for people who have the
7 basics -- there have also been questions about how
8 can we incentivize more, how can we expand
9 buprenorphine treatment.

10 So is that something we want to consider is
11 allowing that to count at least as an advanced
12 training once people already have the basics?

13 DR. JONES: All right. If there are no
14 other final comments, I'll thank the panel and
15 thank FDA for having us here to represent some of
16 the work that's happening across federal agencies.
17 Thank you.

18 (Applause.)

19 Questions and Answers

20 DR. JONES: That was not in my notes, but my
21 fault for not being here earlier.

22 Yes, we also have time for a Q&A. Go for

1 it.

2 DR. KAHN: Norman Kahn with the Conjoint
3 Committee on Continuing Education. For those of
4 you who are not aware, the audience is, we're the
5 26 organizations in medicine, nursing, pharmacy,
6 dentistry, physician assistants, and nurse
7 practitioners that formed a national coalition to
8 guide and provide this education. We take the
9 FDA's blueprint of educational partners. We've
10 trained over 200,000 completers, et cetera.

11 I have a very specific question probably for
12 Dr. Kelman. One of the things we talked about
13 yesterday was your issue of incentives. I'd just
14 like to clarify something I thought I heard you say
15 earlier, which has to do with how education in safe
16 opioid prescribing and management might qualify
17 under the merit-based incentive payment system as
18 either an improvement activity or a patient safety
19 or something like that.

20 Will that quality now, or is there something
21 we need to do to make that qualify?

22 DR. KELMAN: It's the kind of question I

1 never answer in public.

2 (Laughter.)

3 DR. KELMAN: Send me a note directly, and
4 I'll get you the answer.

5 DR. KAHN: Thanks.

6 DR. KELMAN: Thanks for the question.

7 DR. JONES: Sandy?

8 MS. MARKS: Hi. I'm Sandy Marks with the
9 American Medical Association. We've been working
10 with Dr. Kelman and CMS on Part D issues since
11 2005, and one of those issues was the
12 implementation of the opioid overutilization
13 monitoring system, which we have strongly
14 supported.

15 I think the numbers that he provided at the
16 beginning show dramatic, dramatic reductions in the
17 number of patients who are outliers in the Part D
18 system. If you define them as patients who are
19 receiving a high dose, high morphine equivalent
20 dose of opioids, plus getting prescriptions from at
21 least three different physicians, plus
22 getting -- you said three. I thought it was four.

1 DR. KELMAN: I said more than three.

2 MS. MARKS: Plus getting those prescriptions
3 dispensed from more than four or three pharmacies.
4 Those are truly outliers, and there has been a
5 70 percent reduction as a percentage of people who
6 are enrolled in Part D.

7 So providing physicians with data on what's
8 happening to their patients, I'm sure most of those
9 physicians who get contacted by their Part D plan
10 and told, did you know your patient Mrs. Whatever
11 was also getting opioids prescribed from these
12 three other physicians and was also getting them
13 dispensed from three other pharmacies besides the
14 prescription you wrote, most of them, I'm sure,
15 didn't know that. And clearly, there have been
16 changes in their behavior as a result of receiving
17 that feedback.

18 So I just want to strongly encourage all the
19 agencies to think about how you can provide data
20 back to physicians so that they know what's
21 happening with their patients. And I think that
22 will encourage of them to get additional training

1 because they'll see that they don't know as much as
2 they thought they did, and it will obviously lead
3 to some improvements in patient care.

4 DR. JONES: Over here?

5 DR. COMPTON: I'd like to add a caveat to
6 that, that when we identify patients that have
7 egregious prescribing practices, some of those
8 patients will be clearly drug seeking. So it's
9 easy for physicians to just have a knee-jerk
10 reaction and say, no, I'm not going to refill your
11 prescription because this isn't a pain issue here.
12 It's another kind of issue.

13 But in those situations, I think that's
14 where we need to equip our clinicians with the
15 appropriate techniques to deal with those kind of
16 patients, so that they aren't just simply saying,
17 no, I won't write you a prescription. Because we
18 could have reduced those numbers simply by saying,
19 no, I won't fill your prescriptions, but the
20 question is how many of those people were then
21 referred to some of the SAMHSA-funded programs or
22 elsewhere where they really need to be?

1 That's a key issue here, is how do we link
2 some of the patient behaviors that are clearly at
3 the very extreme tail end and represent my area of
4 practice and science, addiction, and do a better
5 job.

6 MS. MARKS: I don't think you would
7 have -- you wouldn't have these dramatic reductions
8 in the number of outliers who appear each year if
9 the individual physicians who had been called about
10 individual patients had simply stopped prescribing
11 to those patients. There's something else going
12 on.

13 It may be that some of those patients are
14 engaged in drug-seeking behaviors, but maybe their
15 physicians didn't know. So now they know they need
16 to learn how to more safety prescribe and recognize
17 those behaviors, right? So something is going on,
18 and I think providing physicians with that data can
19 really be helpful. And there's not enough of that
20 that happens.

21 DR. KELMAN: Lack of coordination is just as
22 dangerous as bad care and has to be resolved.

1 DR. AHADPOUR: Just very quickly, I'm sorry
2 to interrupt. I wanted to just emphasize what
3 Wilson said. I think it's really important that if
4 there are patients who are coming in into a
5 practice and you find out through the PDMP or you
6 get some kind of evaluation that they're getting
7 medications from different clinicians, I think it's
8 really important to take time with that patient,
9 not just have them out of your practice, or not
10 just decrease their opioids, but actually look at
11 and screening them to see if they have an opioid
12 use disorder.

13 If you don't feel comfortable, we have the
14 SAMHSA treatment locator that lists all the
15 clinicians, nurse practitioners, physician
16 assistants, and physicians who are qualified to
17 treat patients with substance-use disorder. So
18 please keep that in mind. Thank you.

19 DR. JONES: Yes, ma'am.

20 MS. KITLINSKI: First of all, I'm Linda
21 Kitlinski. I'm a REMS education consultant
22 currently independent, but previously served with

1 the ER/LA opioid REMS companies as the co-chair for
2 the REMS CE side of things. So I've been working
3 on this since 2009 now.

4 One comment and then one question for all of
5 you. First of all, in terms of a comment, kudos to
6 the FDA for having convened this meeting and gotten
7 not just the REMS side of things involved but all
8 of your organizations at the federal agency level
9 that are working on this from slightly different
10 perspectives, but certainly that have a shared
11 interest in resolving this dual public health
12 problem. So kudos on that.

13 One comment. Dr. Kahn here represents the
14 Conjoint Committee on Continuing Education, and as
15 he said, there is a wealth of experience already
16 among the accrediting bodies and the CE providers
17 who have been working in this space since 2012. So
18 as you go forward, please do reach out to them
19 because they are ready, willing, and able to do
20 this to help.

21 My question is, so we now have communication
22 as part of this meeting, and we have all expressed

1 an interest in collaboration, and that's important.
2 But I think that the final point of
3 coordination -- because this is a huge dual public
4 health issue, and we've got all these moving
5 pieces, and not to mention patients and the
6 political environment, right? So we really do have
7 to have a coordinated approach.

8 For my question to you guys is, we have
9 folks present from SAMHSA, from NIDA, DEA, FDA,
10 everyone. Would there be interest and willingness
11 to perhaps settle upon, as you were just saying, a
12 core group of concepts, whatever we want to call
13 them, right, without being overly prescriptive and
14 say, these basics about A, prescribing opioids,
15 pain medicine, and I think importantly, the basics
16 of addiction medicine because a lot of folks are
17 missing that -- can we arrive at some understanding
18 of what those might be, and then use an adaptive
19 learning type of approach that gets at here's the
20 basics for the knowledge transfer up front but then
21 builds on that to meet the learner's needs so that
22 they'll remain engaged in a continuing basis going

1 forward?

2 Because I think one of the other issues we
3 heard loud and clear, there's so much going on out
4 there in terms of education about responsible
5 opioids or safe-use of opioids, or this, that, and
6 the other thing, it's confusing for clinicians. If
7 they participate in one program but they don't get
8 to cover at least the basics of those three areas,
9 then we have some gaps.

10 That would just be my question to pose and
11 any discussion from the panel about willingness to
12 work together and actually coordinate efforts as
13 opposed to just being collaborative. Thank you.

14 DR. JONES: I'll take first stab at that. I
15 will say within the HHS family, we have pretty
16 strong coordination on efforts. In particular
17 after the CDC guidelines came out, there was a push
18 to think about how are we aligning our various
19 other educational components to what CDC is saying.
20 Similar with DoD and VA as well, they have new
21 guidelines that have come out.

22 I think within the federal family, there is

1 interest in doing that and making sure that there's
2 consistent messaging. We are in the midst of a
3 transition, and Dr. Price has raised opioids as one
4 of his top three priorities and is actually out
5 traveling states today talking about that. So we
6 are getting him up to speed on the work that's
7 happening within the department.

8 There previously was a group, and Sandy and
9 others from AMA and other groups were part of that,
10 where there was an internal/external working group
11 on opioids over the last 18 months. As we changed
12 administrations, that group disbanded, but there
13 are internal conversations around how we might
14 reengage in that space, one, to get feedback from
15 folks in the field who are doing this every day to
16 help inform where we go from a policy perspective;
17 but two, to also think about all the discrete
18 projects and collaborations that could come out of
19 that.

20 I think this is an idea that can be funneled
21 into those conversations. I appreciate you raising
22 it. I don't know if others have thoughts on it.

1 MR. TWERSKY: Hi. Larry Twersky, TimerCap.
2 I'm hearing there's a huge disparity of prescriber
3 knowledge about opioids that we're trying to
4 consolidate. Per Mitra's data, and I love your
5 data, by the end of today, the two days we've had,
6 1.3 million prescriptions of opioids have been
7 dispensed, and 7,800 people have used opioids for
8 nonmedical use per your slide.

9 With that happening, by the time you go
10 through change management, education of
11 prescribers, we're probably going to see a few
12 hundred thousand people die because it has to then
13 correlate to the patient.

14 What about making changes in to the patient
15 such as -- and I'm going to leave the chronic meds
16 alone for a second because that's already somebody
17 who has it. But for new meds, why not just raise
18 the fee after a certain rate so when doctors
19 prescribe over X number of pills, it just costs the
20 patient more on a certain fee? If that's the case,
21 then let them write something over and above it.

22 How do we make some changes where the

1 consumer is still involved for -- we had a friend
2 whose child of 14 had a wisdom tooth extracted, and
3 the doctor gave her 30 pills at the time. They
4 didn't need that. So number one, we've got to get
5 less opioids in practice, and so how do we provide
6 at the time of the payer, either A, more cost or
7 provide disposable bags, provide other tools for
8 the patients, but solving this quickly doesn't
9 sound like it's happening by what the conversation
10 is here.

11 I want to talk about what tools can be done
12 to help, that the patients at the last minute can
13 do it? Because I know if my co-pay went up to
14 \$100, if I had to get 30 pills and it was free for
15 10, whatever that number is for it, then that's
16 important.

17 For chronic people, maybe we should be
18 paying for the safes, and maybe we should be paying
19 for tools to lock them up so that people have it.
20 But we've got to stop this in one way, shape, or
21 form, and I'd love for you guys to talk about it in
22 that way, that what can also be done today, while

1 you're figuring out provider education because I
2 didn't hear anything about it. Thank you.

3 DR. KELMAN: Let me at least try to answer
4 that. A value-based insurance design is what
5 you're talking about. It's an interesting idea.
6 It can be effective, not always. But it tends to
7 subdivide effectiveness based on the income of the
8 patient. A poor patient is more sensitive than a
9 rich patient.

10 We prefer endeavoring to get the provider to
11 do the right prescription. In other words, if you
12 need more than seven days for a wisdom tooth, the
13 provider, in this case a dentist -- not to pick on
14 dentists; they actually do a very good job -- is
15 prescribing too much. And that's an education
16 system more than a value-based insurance design.

17 DR. AHADPOUR: I agree. I think it should
18 be a multipronged approach. There is no one single
19 solution, and I think this is a great time for us
20 to really think about the low-hanging fruits, look
21 at the prevention side, improving access to
22 treatment, the takeback program.

1 My son had his wisdom tooth extracted three
2 months ago, and the dentist gave him too many pills
3 of oxycodone. So when he came home -- I wasn't
4 there when he came home. He went with my husband.
5 So when I came back from work, I looked at it. I
6 said, "How many pills were there in here?" And he
7 said there were like 20 pills. I said, "So if
8 there were 20 pills in here, how come on the first
9 day 6 of them are gone?"

10 I actually took that bottle and put it in my
11 purse. I still have it in my purse.

12 (Laughter.)

13 DR. AHADPOUR: I wanted to do it to the
14 takeback.

15 (Laughter.)

16 DR. AHADPOUR: My son came back. He's like,
17 "Where are the pills? I need them." I was like,
18 "No, Brandon. You do not need the pills. You just
19 take a nonsteroidal and Tylenol."

20 So there is a lot of different ways, but we
21 really have to think of the multi-prong, innovative
22 approaches to do this.

1 MALE AUDIENCE MEMBER: We need the mothers
2 to be involved, apparently.

3 (Laughter.)

4 DR. KELMAN: Clearly, that's where the power
5 is.

6 (Crosstalk.)

7 DR. JONES: I'm sorry. Which purse was
8 that?

9 (Laughter.)

10 DR. JONES: I just want to also say that
11 this panel was asked to talk about certain things,
12 so it's not reflective of what HHS is doing broadly
13 on this issue, which is we just put out
14 \$485 million to states to focus on prevention and
15 treatment, and there are a number of other
16 activities that are comprehensively attempting to
17 address the issue.

18 MAJ DOWELL: I was going to say something
19 similar, that I appreciate and very much agree with
20 your sense of urgency, and there's so many other
21 things that we need to be and are doing. We've
22 been reminded multiple times by Doug today to focus

1 on education. But specifically in terms of a
2 co-pay, I'd have concerns about that because we
3 found that cash payments actually to be a potential
4 signal for diversion. That's not always the case,
5 but it sometimes is. In analyzing PDMP data, that
6 can actually be a cause for concern.

7 DR. JONES: I just want to note that we are
8 a little past time, so I think we'll take one more
9 question, and then I'm sure the panelists will be
10 willing to speak with folks after.

11 MR. SCHILLIGO: Great, thank you. Good
12 afternoon. Nick Schilligo with the American
13 Osteopathic Association. For the last two days,
14 we've heard about the various requirements that are
15 going around opioid-related education, mostly at
16 the state level, but there are instances where
17 individuals providers might have requirements
18 through their board certification process or being
19 a member of a professional association.

20 If the federal requirement would go into
21 effect, how do you see the agency in charge of that
22 working with professional associations, board

1 certifying entities, state medical boards, to make
2 sure that there's not a duplication of efforts,
3 both in what the education requirements are but the
4 reporting of that as well? Thank you.

5 DR. AUTH: I think by federal requirements,
6 you must mean REMS? Do you mean the FDA REMS
7 program?

8 MR. SCHILLIGO: If the result of something
9 like this meeting is that there will be a federal
10 requirement for opioid-based education and training
11 in order to prescribe opioids, how would that take
12 into account what's going on at the state level,
13 what different requirements are for different
14 providers to assure that they don't have to report
15 to various levels of government, creating a new
16 administrative burden for them, I guess?

17 DR. AUTH: I think that's some of the
18 challenges that I raised yesterday when I gave the
19 presentation about the REMS. We don't have the
20 answers right now. I would think that we would
21 have something in place if it were to be an FDA
22 REMS where we would consider allowances for certain

1 states. But again, if we're talking about a core
2 set of competencies, that's going to take a whole
3 lot of work, I think, to look through all the
4 different state requirements and deem something
5 okay that meets our criteria and others not.

6 That's a challenge that could take us some
7 time to sort out.

8 DR. JONES: All right. Now I will properly
9 close the panel, and thank the panelists.

10 (Applause.)

11 (Whereupon, at 2:55 p.m., a recess was
12 taken.)

13 Panel Summary

14 MS. GROSS: To start off with, we're going
15 to ask the panel moderators to provide around a
16 2-minute summary of what were the most important
17 points that came out of their panels. The first
18 panel was the patient and the professional affairs
19 panel, and that was Terry Toigo. If you could
20 summarize in a couple of minutes.

21 DR. TOIGO: We had five questions. Three of
22 them were related to required training. I think

1 there was general agreement that education was
2 important, but there were questions about how and
3 what. There were comments about if you want
4 meaningful patient impact, then the education needs
5 to be tailored to the practice, that clinicians
6 don't want people to just take a test and fill out
7 a box. We want to be more focused on outcomes.

8 There was agreement that core knowledge is
9 necessary but not sufficient, and comments about
10 solo and small independent, both medical and dental
11 practices are likely to find regulatory
12 requirements more burdensome and probably provide
13 pushback on required training.

14 In terms of the impact on members if a
15 required training program were implemented,
16 participants mentioned required certified training
17 requirements such as there are required training
18 programs such as certified child abuse education
19 requirements, but that training could be burdensome
20 on workflow.

21 If education is mandated, ensure that checks
22 are done through some type of electronic means;

1 don't believe there is evidence that if education
2 is mandated, that performance is improved.

3 Third question was related to which
4 organizations are best situated to track. Several
5 panel members stated that education should be
6 linked to DEA registration because they have a
7 tracking system in place. Everybody agreed that
8 DEA should not be in charge of the content of the
9 education.

10 Others stated that the decision to require
11 mandatory training should be done at the local or
12 state level since they know the landscape best.
13 State boards are a good place to start, but there
14 needs to be a coordinated effort.

15 There were comments on the heterogeneity of
16 state requirements, particularly because providers
17 are licensed in multiple states. Others felt that
18 it was impractical to do it at a state level.

19 On the required training, I don't think
20 there was a uniform opinion across all of the
21 groups. I think that's probably enough. I have
22 others, but that's good enough.

1 MS. GROSS: Thank you, Terry.

2 State panel was next, Peter Lurie.

3 DR. LURIE: Good afternoon. So our panel in
4 part addressed the question of whether or not any
5 voluntary or mandatory CME requirement is best
6 located at the state or the federal level.

7 I think we had a vigorous discussion. I
8 think that the grand conclusion was that people's
9 first instinct is to locate at things at more of a
10 state or local level. But I think most of the
11 panelists agreed that they probably would not be
12 opposed to some action at the federal level,
13 either. So there's your non-answer answer.

14 But I think perhaps more helpfully, we
15 identified a series of criteria that you might use
16 in trying to decide whether appropriate locus for
17 education ought to be at the state or federal
18 level. I'll go through about eight of those and
19 just discuss them briefly.

20 The first would be what is the severity of
21 the problem. To the extent that we consider this
22 either the inadequacy of pain treatment or the

1 addiction problem to be a severe one, I think most
2 people would agree that it weighs more in the
3 direction of federal involvement.

4 A second criteria was what about the
5 adequacy of current CME requirements, and there, I
6 think that the raw data that we have relate to, on
7 the one hand, the expanding numbers of programs
8 that are being offered; on the other hand, the
9 rather limited uptake so far of the REMS program
10 and the fact that only about half of the states
11 have required CME on either pain or on opioid
12 prescribing.

13 There will be a second one. To the extent
14 that we felt that the coverage was inadequate, that
15 would be in favor of more of a federal
16 intervention. To the extent that we were
17 comfortable with current degrees of coverage, that
18 would be in the favor of state or local approach.

19 A third criteria is just one of resources,
20 and typically, not always, the federal government
21 comes with, at least theoretically, the ability to
22 marshal greater resources. If that were a problem,

1 that would push in the direction of the federal.

2 If we feel that resources are appropriate at the
3 state level, obviously, that pushes in that
4 direction.

5 A fourth criteria was if we believe that the
6 education being offered at the state level was of
7 variable quality, and related are that there might
8 variability at the state level in terms of the
9 content, and we've heard that some states have
10 requirements for pain management; some have
11 requirements for opioids. And actually, they
12 historically have different routes.

13 Interestingly, most of the pain ones are the
14 older requirements, and as the pain concern turned
15 into a concomitant opioid addiction and abuse
16 concern, then you started seeing a second wave of
17 state CME requirements more recently in recognition
18 of that.

19 If we have concerns that this is too spotty
20 a coverage, that weighs in favor of federal. If
21 not, then things might be fine at the state level
22 as they currently are.

1 If we're concerned that certain prescribers
2 who ought to be targeted, like nurse practitioners,
3 dentists, PAs, in addition to physicians, if
4 they're not being touched upon at the state level
5 and we think they ought to be, that might militate
6 in favor of a federal solution and vice versa.

7 Let's see what else I have. Differences in
8 the epidemic might justify a state approach over a
9 federal one if one thought that the distribution of
10 patients, their ethnicity or other characteristics,
11 their socioeconomic status, was different enough
12 between states, then that might argue for a more
13 tailored state-based approach.

14 If one thought that the drugs of abuse were
15 different enough from state to state, then again,
16 that would favor a state-based approach. But I
17 think the question to us is not simply to be able
18 to point out differences, but they need to be
19 differences that are of a degree large enough to
20 merit a wholly different approach.

21 My last two points are on the adverse effect
22 side. One is we have to take into account the

1 relative burdens that might ensue from having a
2 federal approach versus a state one. It's not
3 obvious to me that one is inherently more
4 burdensome than another from the perspective of the
5 user, but that's at least something to think about.
6 Similarly, we have to think about any adverse
7 events that might result from a requirement for
8 state CME or federal CME.

9 Again, it's not obvious to me why it would
10 be different between the two, but we have to think
11 about the concern raised frequently at this meeting
12 about people opting out as a result of any
13 requirement at whatever level. That sums it up.

14 MS. GROSS: Thank you, Peter.

15 The next panel was health systems panel.
16 That was Wilson Compton.

17 DR. COMPTON. Thank you, Mary.

18 The health systems panel had a broad
19 representation of both federal groups, HMO, and I
20 guess private practice or broad academic practice
21 would be the other two key representatives.

22 There was not a consensus, or at least not

1 unanimous agreement, on whether a federal mandate
2 for training or a federal requirement was a good
3 idea. There were strong opinions on both sides and
4 well-reasoned arguments.

5 Some of the broad themes that I took note of
6 were -- and I would say these aren't fully
7 digested. These are just my notes on a piece of
8 paper.

9 (Laughter.)

10 DR. COMPTON: So if I've left something out,
11 I'll count on some of the members of the panel to
12 speak up and add something in.

13 I think one of the issues is the complexity
14 of trying to deal with a one-size-fits-all
15 approach, that because we're dealing with different
16 aspects, that pain is not a unified single entity,
17 so addressing it with a single unified set of CME
18 requirements seems a little extreme and certainly
19 won't fit.

20 Clinicians don't come in one size fits all,
21 either, so you have everything from people who are
22 already pain clinicians to hematologists that don't

1 see patients but look at slides all day. So how
2 would you design requirements that would address
3 the diversity of both the patient presentations as
4 well as the clinician issues?

5 On the other hand, mandates may give the
6 issue some prominence, and so that alone may be
7 worthwhile in changing the perception in all of
8 medicine and increasing the acceptability of both
9 pain and addiction treatment, which tend to be more
10 at the fringe of medical practice at current time.

11 I'd also say another broad theme that I
12 think cuts across all of these panels was medical
13 education is not going to be a panacea for the
14 opioid crisis, and we shouldn't expect it to be.
15 We need to be thinking about it as one piece in a
16 broad range of interventions, and it may not even
17 be the most powerful piece. But it is the one
18 we're talking about yesterday and today, and so
19 that's what we're sticking with.

20 One of the questions was how frequently
21 should we provide training, how often and how
22 frequently should they be targeted and should such

1 training occur. That seemed a little uncertain. I
2 certainly resonated to what we heard from New
3 Mexico about a baseline level of training, which I
4 would consider primary education. One would hope
5 that that would have occurred earlier in your
6 educational curriculum, but it hasn't for many
7 people. So how would we both provide some baseline
8 educational materials as well as follow up on an
9 ongoing basis?

10 It wasn't clear how frequently or how often.
11 There's some arbitrary limits that have been
12 established by certain groups that at least might
13 be a starting point, but this certainly opens us up
14 to the need to collect information about does that
15 produce the desired changes, because the desired
16 changes are not knowledge, but it's actual clinical
17 practice, and then patient outcomes are our goals.

18 Certainly, the nuances and complexities
19 suggest personalization and specificity in how we
20 implement whatever educational systems are
21 suggested.

22 Are there other key things from the health

1 systems panel? I'm not seeing any heads nodding,
2 and a couple of people are here. That seemed to
3 cover it.

4 MS. GROSS: Thank you, Wilson.

5 The next panel was the patient and consumer
6 advocates panel, and that was Sara Eggers.

7 DR. EGGERS: Thank you.

8 We had a fantastic panel this morning. It's
9 harder to summarize than it is to actually lead the
10 discussion, so I'll do my best.

11 We started our panel by asking the questions
12 instead of answering them, and it was how can we
13 improve chronic pain care; what are we doing to
14 empower patients; what are we doing to improve
15 outcomes for patients; how is education put into
16 practice; what do providers do with the information
17 and the learning that they get; how can we bring
18 consistency to care; how do we address the needs
19 for people in truly debilitating pain; and why
20 aren't we focusing on the risk factors of opioid
21 use disorders?

22 When we got those burning questions out, we

1 didn't get to address them all. I promised that
2 they could be saved for this panel, so that's why I
3 put them out right now. But then we got into what
4 the goals of treatment, any kind of provider
5 training, and we spilled a little bit into patient
6 training as well.

7 The goals are to validate patients' needs
8 and treat them with compassion. People living with
9 debilitating pain want their life back. How we put
10 patients at the center and partner with them to be
11 part of the care process, take a balance approach
12 to pain management? A goal would be to give
13 healthcare providers the skills they need to
14 communicate. It comes down to communication as
15 much as anything.

16 How can we increase the providers'
17 self-confidence and arm patients with the
18 information they need to help them partner in
19 decision-making? But also, how can we provide
20 consistent and basic information that everyone
21 needs about opioids?

22 How do we set patients and help them set

1 their own expectations about what they can get out
2 of their pain medications? The goal would be to
3 identify risk factors, including adolescents as one
4 subgroup, and I'm sure there were other
5 subpopulations we could have addressed.

6 The goal would be to recognize patients'
7 fear of pain, which is a driver for a lot of
8 behaviors that frustrate, that we've been talking
9 about today.

10 Focus on competency. Give people the tools
11 they need, both patients and providers. So
12 patients, give them the tools to manage the
13 medicines they have appropriately, use them
14 appropriately, and dispose of them appropriately.
15 Remember that education is not in a vacuum, as the
16 point was just made.

17 Then we focused on solutions, and the number
18 one, I think if I didn't say any other solutions,
19 it was to bring patients to the table when we are
20 thinking about the need for and the development of
21 training.

22 Engage patient stakeholders as partners for

1 creative and person-focused solutions, and we heard
2 a number of possible solutions in our panel. Give
3 people the tools they need. Understand and assess
4 how training is actually put into practice. And it
5 appeared to be general shared agreement, alignment,
6 that training should be required and required of
7 all healthcare providers, and if we can put it into
8 practice, of patients themselves, too.

9 I'll close by saying the panelists were all
10 very considerate of the constraints that it would
11 take to put this in practice in the current
12 healthcare system, and I thought that came out in
13 several of the remarks they made. With that, I
14 will end.

15 MS. GROSS: Thanks, Sara.

16 The last panel was the federal panel, and
17 unfortunately, Chris Jones was called back to the
18 department right afterwards. So we'd ask Wilson to
19 do a short summary.

20 DR. COMPTON: Well, since this is fresh in
21 everyone's mind because we just ended a few minutes
22 ago, I'm not going to review much about what the

1 panel other than to remind us that we heard from
2 multiple participants, whether that was SAMHSA,
3 CDC, the NIH, CMS. Those had formal presentations,
4 but we also on the panel had FDA and DEA.

5 I think that sets the stage for realizing
6 that clinician education is part of a broad range
7 of efforts to address the opioid crisis, whether
8 that relates towards inadequate assessment and
9 treatment of pain by so many people in our country
10 or the inadequate prevention and then treatment of
11 opioid problems, which are, of course, reflected in
12 the epidemic of overdose deaths that we've seen.

13 While there are multiple resources for
14 education, we need to think about these in terms of
15 the broad context of how we're intervening across
16 the two interrelated but separate areas of pain
17 assessment as well as what I would propose is the
18 opioid addiction set of issues.

19 That's what I wanted to highlight for us.

20 MS. GROSS: Thank you.

21 We're going to start the panel discussion
22 now. Dr. Throckmorton and Dr. Buckenmaeir are the

1 moderators, and I'm going to give each of them a
2 microphone. Also, once again, please remember to
3 identify yourselves when you talk for the
4 transcriber.

5 Large Panel Discussion

6 DR. THROCKMORTON: Thanks, Mary.

7 Before we get started, I just wanted to say
8 a couple of things. I tried to summarize, and you
9 heard me summarize yesterday afternoon, the things
10 that I heard. I'm not going to walk through in
11 detail because I think the summaries you just heard
12 capture a lot of the important points that we've
13 talked about in the last couple days.

14 A couple things I think that are worth
15 saluting the group, saluting the people that have
16 attended this, first, I get a sense of shared
17 responsibility. I think there's an acknowledgement
18 that we all own a part of this. Trip I think
19 quoted Pogo, "We have met the enemy, and it is us."

20 I think that's in a broad sense right; that
21 is, we all have aspects of this that we are -- all
22 things that we could be doing -- and I heard that

1 in these last couple days. I think that's a
2 terrific acknowledgement of the importance of this
3 and our shared responsibility.

4 I also like this meeting because it's given
5 us an opportunity to talk more than usually across
6 silos, and I hope, at least speaking for myself, it
7 helped me question some of my own assumptions.
8 I've heard things that have made me think about
9 some of the things that I had thought I understood
10 about the nature of the problem here and maybe some
11 of the solutions, and I hope that others in the
12 audience had a similar experience.

13 We are talking about one of several tools
14 that are being used in this space, and so I
15 understand that that made it challenging for the
16 participants. We were not talking about the
17 incentives and things that Jeff Kelman talked about
18 at CMS. That's a different tool to use. We were
19 not talking about enforcement actions that the DEA
20 takes, that the FDA can take, and things like that.
21 Those are different ways to get people to
22 straighten up and fly right.

1 Today, the focus was on education, and
2 whether that was an education of someone that
3 needed to know more than they did, or it was
4 education of someone about someone else's poor
5 behavior, or whether it was education of -- I guess
6 the third was the DEA. So it was a pill mill
7 thing, wasn't it? It would be educating to go and
8 take an enforcement action.

9 It was education that we were focused on,
10 and I think the conversation that we just heard
11 summarized captures what we heard the last couple
12 of days, a broad understanding of the importance of
13 education, the need to improve the current kinds of
14 education, and then I would say a vigorous back and
15 forth about whether or not something mandatory and
16 something federal is really necessary, and strong
17 voices on each side with a lot of good
18 conversation.

19 That leads me to the question I want to pose
20 to the group, and it's intentionally pointed to try
21 to stimulate a good conversation. We have other
22 things to talk about that are on the screen as

1 well, and let's just see where this takes us.

2 To boil down what we've been talking about
3 the last couple of days, I'm going to say there's a
4 first question that I'd ask -- I'll pick on people
5 if people don't offer -- should the federal system
6 do more, or should the focus be on doing what we're
7 doing better?

8 That's in a sense the first question we're
9 being asked. Are we doing the right stuff, we need
10 to do it better, or do we need to more? And more
11 in this case, in the educational sense, is
12 obviously mandatory prescriber education and those
13 kinds of things. To the extent you have other non-
14 education things you think we should prioritize
15 above any changes in education, we'd be interested
16 in that, too. But first and foremost, should we do
17 something new, or should we improve what we're
18 doing?

19 Who wants to answer?

20 DR. AHADPOUR: This is Mitra Ahadpour. For
21 the response to this question, I think we can
22 always do better. To my opinion, if we are having

1 an opioid crisis and -- we are talking right now,
2 about every 15 to 17 minutes, someone has died from
3 an overdose. I think that's a sobering fact.

4 I think there is more innovative approaches,
5 collaboration, and sometimes it does take a few
6 people to solve a problem. But in this situation,
7 I think collectively, we can do much better. It
8 really will take everyone in the community, not
9 just the federal programs or the states.

10 I am saying that we need as a community to
11 come together and work on the solutions.

12 DR. THROCKMORTON: You're not done. So
13 that's fine. Now I need to know what. So one
14 thing and how? It's easy to say we all need to
15 work together. I don't think anyone in this room
16 would disagree with that.

17 What one thing new should the federal
18 government do, and how should we do it?

19 DR. AHADPOUR: I have a lot to talk about,
20 but I'm going to keep it to one thing. So one
21 thing, which I've already mentioned before, and
22 this is a perspective from a physician who is a

1 primary care physician, I did not feel comfortable,
2 but I joined SAMHSA. I did not feel comfortable
3 when I took my 8-hour data waiver training to go
4 and see patients. And I didn't feel comfortable in
5 pain management because I didn't get the training
6 in medical school, and it was at University of
7 Maryland. My residency was at GW.

8 So I went and took a whole year of classes
9 on my own to become board certified in addiction
10 medicine. After that, I felt, hey, now I feel
11 comfortable seeing patients.

12 So I think the mentor piece is really
13 important, that everyone, all the clinicians will
14 not have a whole year while they're in private
15 practice to go and take all these trainings. We
16 need to come up with a short training but have that
17 mentor piece, and that free mentorship I think is
18 very important.

19 DR. THROCKMORTON: Great, thanks very much.
20 Myra?

21 MS. CHRISTOPHER: I think the answer is
22 clearly yes, and the one thing is to develop a

1 parallel plan focused on improving the treatment of
2 chronic pain. I think the way you do that is by
3 implementing the National Pain Strategy fully.

4 DR. THROCKMORTON: So implementing the
5 National Pain Strategy, that's the additional thing
6 that -- great, thank you very much.

7 That end, anybody down there?

8 MR. BRASON: What we're doing, we can do
9 better. I think that is the direction that we
10 should go. I am not for -- because I don't think
11 we can fit it in appropriately -- mandating a
12 certain segment of education. Education makes a
13 difference. Education brings change. Education
14 brings comfort for the practitioner to meet the
15 patient need.

16 Mandatory, I think would focus more on just
17 the prescribing of opioids because of all the
18 dynamics of pain management. We learned that if we
19 taught appropriately for best practice for pain
20 management, we got changes in opioid prescribing.
21 I don't believe that we will get best pain
22 management if we just direct it towards opioid

1 prescribing.

2 I think if we do what we do now better and
3 create a blanket of some of the standards that need
4 to be in there, then the states, then the
5 organizations, then SAMHSA, then the Federation of
6 State Medical Boards, everybody has the ability
7 then to appropriate that into what they're already
8 doing, and I think that will make it better.

9 DR. THROCKMORTON: Thank you very much.

10 MS. ROBIN: I'm Lisa Robin with the
11 Federation of State Medical Boards. One thing I
12 think that's really apparent to me after two days
13 of listening is I think that we certainly need to
14 do more research. And before implementing any sort
15 of mandatory education at any level, there needs to
16 be greater research out there to really know what
17 works, really know who should we educate, and
18 really put it in place something that can change
19 practice.

20 I agree with you. If it's just narrowly
21 focused on here's how to prescribe, I think you
22 miss the boat on really changing practice.

1 DR. GREENBLATT: Larry Greenblatt from Duke.
2 I'm going to pose that we consider moving towards a
3 system of accountability and measurement, where if
4 we're really going to focus on safe opioid
5 prescribing, perhaps there could be some system
6 where we actually collect data. Individual
7 prescribers who are prescribing opioids would need
8 to demonstrate whether they use their state PDMP at
9 least some percentage of the time, how many
10 patients have pain agreements, urine drug screens,
11 how many received appropriate and effective
12 education, and actually not just say yes, I took my
13 classes, and I got my multiple choice, but rather
14 here's the data from my EMR. I'm doing it.

15 DR. THROCKMORTON: So I'm hearing doing
16 better what we're doing now, is that --

17 DR. GREENBLATT: I'm talking about some
18 mandatory reporting of process measures to be able
19 to continue to prescribe opioids.

20 DR. TERMAN: I'm Greg Terman from the
21 University of Washington and the American Pain
22 Society. I continue to think that we need to have

1 some competence measure for people to be able to
2 prescribe controlled substances, and I think a test
3 of some sort to allow people to show competence and
4 getting their DEA registration is a first step.

5 Now, remember, what all these different
6 letters means, right, DEA, the Drug Enforcement
7 Agency, and FDA, Food and Drug Administration, does
8 that sound like good pain treatment to you,
9 necessarily? I'm not sure that that's going to
10 help pain treatment. That's a separate issue,
11 related, but if no one got prescribed opioids,
12 people would still get addicted. People would
13 still have pain. If everyone got prescribed
14 opioids, people would still get addicted, and they
15 would still have pain.

16 It's just a piece, so there will need to be
17 voluntary or mandatory state-based probably
18 education that is accompanying that prescriber
19 question. Because I'm not willing to take all of
20 the blame, Trip, for the problems that we're
21 having. Unless we can get heroin dealers to go
22 into the PDMP and say about their particular

1 clientele -- this is outside of medicine. There
2 are important medicine points here that we need to
3 do a better job educating on, but it's not all
4 about prescribing.

5 DR. THROCKMORTON: Just to clarify, you're
6 arguing for not a new mandatory federal activity in
7 terms of education but rather in terms of
8 competence testing, something we've not really
9 talked about very much the last couple days. I
10 just want to make sure I'm understanding.

11 DR. TERMAN: Right, and the tests could be
12 from Federation guidelines. It could be from the
13 new blueprint. It could be from Massachusetts
14 Medical School or the Pennsylvania Medical School,
15 but all published competencies that could be used
16 to build a test. But that's just part of the
17 issue.

18 COL BUCKENMAEIR: I would like to clarify
19 where my statement comes from our experience. So
20 we had to deal with this earlier because of the
21 pressure of the war. We went through the same
22 discussion, and these questions of evidence kept

1 coming up saying, well, why are we going to do
2 different?

3 One of the things that was stated, well,
4 there's never been a randomized controlled trial of
5 parachutes, and yet the paratroopers demand having
6 one of those every time they jump out of an
7 airplane. We felt we were in that situation.
8 Moreover, we did a top to bottom look at our system
9 comparing to your civilian systems. We met that
10 standard of care, and in many cases, exceeded it,
11 and yet we were snatching defeat from the jaws of
12 victory.

13 A less than 10 percent died of wounds rate,
14 and yet these soldiers were not returning back to
15 useful life, and in many cases, opioids were a
16 prime reason, particularly when suicides were
17 involved.

18 So the option for business as usual was no
19 longer an option, and the issue when I say
20 providers are responsible for this, I do think we
21 have significant culpability in what has gone down.
22 I absolutely agree with both you and Myra that

1 there's lots of other factors. This is an
2 extremely challenging problem, and that's why I
3 think we made the decision that some level of a
4 base foundational education was needed for every
5 provider in our system as a start but certainly not
6 the end. And I think we could manage this.

7 I also agree with Myra, which I often do,
8 that we should stop having this discussion of
9 whether or not we're going to do something. I
10 think our posterity will look at us very
11 unfavorably if the answer is we're doing just fine,
12 we need to do things better.

13 I think there are times when you have to be
14 aggressive, and the data will come along as we
15 launch on this. But I do think there needs to be
16 some sort of standard that the states can start
17 with, and then based on their localities will have
18 to adjust as they've already done in New Mexico and
19 other areas.

20 DR. THROCKMORTON: Others?

21 DR. KATZMAN: Hi. I'm Joanna Katzman here.
22 So I'd just like to say I agree with Trip, I agree

1 with Dr. Dowell immensely, and I agree with
2 Dr. Ahadpour.

3 What I think is definitely the country needs
4 mandated continuing medical education really
5 concentrating on pain and safe opioid prescribing.
6 I really believe that the opioid prescribing cannot
7 be delinked from pain at all, and that the emphasis
8 on pain really has to be the forefront. That's
9 been my realization over the past six, seven years.

10 I think that the federal government has done
11 an amazing job in terms of the NIDA trainings, the
12 CDC trainings. Everyone in the federal family is
13 doing a lot of work in terms of CME, but we're
14 realizing, and with FDA in the long-acting REMS, it
15 is not enough. That's why we're here.

16 So that's why I'm in support of mandated
17 continuing education for all clinicians with
18 prescriptive authority as well as voluntary
19 continuing medical education for those without
20 prescriptive authority.

21 Here's what I think. I think that the
22 federal government should get together -- the

1 federal agencies should get together or the FDA
2 should get together and figure out 2 or 3 hours of
3 a common core curriculum that they could deliver to
4 the states, and then the states that have met
5 already those requirements, like Dr. Dowell said,
6 should perhaps be considered to get a waiver. The
7 other states that are not doing that, this should
8 be their blueprint for having to perform the CME
9 that is required.

10 Many states that are doing CME right now, it
11 really needs to be looked at carefully, are just
12 for pain prescribers or just for folks that own a
13 pain practice and so on.

14 The other things are, in this education, you
15 can teach clinicians about how to use a PDMP. You
16 can teach clinicians how to talk to patients. You
17 can teach clinicians about how to actually address
18 a controlled substance agreement with your patient.
19 So this education is actually real world. It has a
20 lot to do with the patient advocacy group, and it
21 will address a lot of these issues. And I think
22 the next round of it can be the mentorship that

1 Dr. Ahadpour talked about, from SAMHSHA. Thank
2 you.

3 DR. THROCKMORTON: Thanks. Two real quick
4 questions in follow-up, if I could. One, do you
5 have a preference for how that mandatory education
6 should be done at the federal level, and then,
7 second, I don't know if you've had a chance to look
8 at the blueprint and how to identify those few
9 elements, given the complexity that we've heard of
10 trying to do not just training about the safe use
11 of opioids but also pain management, which I think
12 we all agree is important. That's a lot. How to
13 identify those common elements?

14 DR. KATZMAN: I've looked at the FDA
15 blueprint a little bit. I need to definitely look
16 at it a whole lot more, but I've done a lot of work
17 with Trip and Trip's shop at DVCPIM. I can tell
18 you that I could safely help you narrow it down to
19 2, 3 hours to get the common core curriculum to
20 what's necessary. Thank you.

21 DR. THROCKMORTON: Great, thank you.
22 Penney?

1 MS. COWAN: Penney Cowan, American Chronic
2 Pain Association. I think the answer to your two
3 questions is both. You need to do what you're
4 doing better, but you need to do more. I think
5 that's what really needs to be done.

6 DR. THROCKMORTON: I think doing better was
7 sort of an -- I heard strong consensus we needed to
8 do things better for different things, yes.

9 MS. COWAN: Right, but you need to go
10 beyond --

11 DR. THROCKMORTON: We need to do more, also,
12 is what we're hearing, yes.

13 MS. COWAN: But you also need to do more. I
14 think it needs to be both. I don't think it's
15 either/or.

16 We all got here because of our education,
17 correct? No one would be sitting here without it.
18 So education really is the key to everything, and I
19 think we need to educate providers, all healthcare
20 providers, around the aspects of pain and pain
21 management.

22 Myra said it, the National Pain Strategies,

1 I think you have that blueprint right there to
2 start with. Find some of the best experts in
3 education because the educators are the best ones,
4 and then make it mandated by the federal government
5 to do it. And make sure that you have the patient
6 voice in that. But I think it is through the
7 education that you're going to -- that's how we
8 learn. That's how you-all got here, like I said.
9 I think that's really what we need to do.

10 DR. THROCKMORTON: Do you have a view about
11 how that should be done?

12 MS. COWAN: I'm not sure who the best
13 educators are in this country. I think there's
14 probably --

15 DR. THROCKMORTON: No. I meant what fed
16 rules or tools should be used to do that.

17 MS. COWAN: I think there should be a voice
18 in each of those that were up here, the DEA, the
19 FDA, NIH. I think those three definitely would be
20 in there, SAMHSA. I don't know that it's for me to
21 say who the best ones are, but I think that there
22 should be an expert panel who decides who should be

1 in it. But if you don't have the educators in
2 there, you're still going to be spinning your
3 wheels.

4 DR. THROCKMORTON: Great, thank you.

5 DR. TERMAN: So the Center for Disease
6 Control and Prevention sounds like a really good
7 name for somebody that should help treat pain. It
8 may be hundreds of millions of people who have
9 chronic pain. It may only be 60 million people.
10 That's still a lot.

11 It was really heartwarming actually to see
12 CDC up here talking about motivational interviewing
13 that they're teaching and other behavioral health
14 strategies for taking care of pain. I think it's
15 great.

16 I wouldn't necessary agree that taking
17 Suboxone training is the same as pain education.
18 I've taken that, but it was wonderful to see the
19 various things that are coming out.

20 I'm afraid I don't necessarily agree with
21 Chris -- I'm sorry he's not here -- that there is
22 great communication between the different Health

1 and Human Services family. Every one of the people
2 had their own education.

3 I think it'd be a great opportunity for
4 someone to go and look -- and don't tell my bosses
5 at the University of Washington; I've actually done
6 all of those educations, including the states
7 ones -- and look and see what are the common
8 elements. Because I can tell you that some of the
9 federal ones disagree on certain points.

10 Anyway, CDC sounds like a place, and they
11 seem to be very interested in that.

12 DR. THROCKMORTON: Thanks. Next?

13 DR. GREENBLATT: Larry Greenblatt from Duke.
14 I think we have a very difficult task in that.
15 What we want to do is make whatever comes of this
16 feasible. It also has to be palatable to
17 practicing physicians, who we talked about earlier.
18 They're very, very busy. They're right now feeling
19 under a lot of strain, burnout, et cetera. But at
20 the same time, we don't want to introduce something
21 that is ineffective.

22 I think we need to figure out how do you get

1 a 2- to 3-hour, or whatever it's going to be,
2 5-hour training that actually improves practice.

3 I think patient outcomes would be the
4 ultimate thing to measure. That's very hard, and
5 there are all these other confounders. For
6 example, we learned from NIDA, that states that
7 have legalized medical marijuana have seen huge
8 drops in overdose deaths. That might be one
9 approach.

10 It's all about process measures, and those
11 are the things I was talking about earlier. It
12 seems to me you could even set up a natural
13 experiment here where if you had certain standards
14 that were set forth by the FDA or the CDC or some
15 other federal agency, and states were free to
16 implement whatever type of training that met those
17 standards, and maybe Montanan is going to do it
18 face to face, but let's say Missouri is going to do
19 it all online, and New York state is going to do it
20 with small groups of mentorship or whatever, then
21 you could look at who got the best change in
22 process measures, in outcomes of practice.

1 Then that could essentially become -- those
2 could be like the best practices. Because right
3 now, we know that a lot of CME, as it's currently
4 delivered, doesn't change practice. In fact, the
5 vast majority doesn't. People go, and they sit in
6 rooms. They listen. They take notes. If you give
7 them a test, they would do better on a test, but if
8 you look at what their patients got from them
9 before and after, it's the same. And 2 to 3 hours
10 of training that improves my knowledge but doesn't
11 improve my practice is wasted time.

12 DR. THROCKMORTON: Thank you.

13 DR. EGGERS: Sara Eggers from FDA. But I'm
14 going to put on my social science research hat and
15 say following up on Lisa and what you just said
16 about intervention research, I would say if there's
17 not a very strong foundation of formative research
18 into the individuals who are part of this system,
19 the individuals, the providers, the people living
20 with chronic pain, the people who have episodic
21 pain, the people at risk of substance-use
22 disorders, and the people who are suffering from

1 those, to understand their mental models, I'll call
2 it, of their situation and of what their needs are,
3 that formative research is as important, I believe,
4 as research on any interventions and learning
5 itself.

6 That could tell you a lot about what the
7 misperceptions are from our expert point of view,
8 as well as what they care about. If you do mental
9 models type research right, you can find out what
10 individuals care about, and it will go a long way
11 in being patient-focused as well as addressing
12 using good risk communication tools.

13 If that research is solid and there, then
14 great. If it's not, then that would be a way to
15 partner with patient stakeholders and others to do
16 that research.

17 DR. THROCKMORTON: Let me follow up just a
18 little bit. I'm reminded of what Peter asked about
19 yesterday. So I think we all recognize the
20 importance of research in the area. We're also in
21 the middle of a really profound healthcare crisis
22 here. So I want to make sure we don't research

1 something to death. I don't know to use -- to put
2 it bluntly.

3 How do you balance the need to understand
4 things better and the need to get something done
5 here? Because I think we all acknowledge the need
6 for the latter.

7 DR. EGGERS: That's a very fair question
8 from Doug because he stressed that to me earlier,
9 that you just can't come up with a solution.
10 Research is done all the -- there will continue to
11 be research with all the other interventions going
12 on, and so if you could prioritize the research
13 that's being done, I might suggest that the
14 formative research could be one of the research
15 priorities.

16 DR. THROCKMORTON: Excellent, thank you very
17 much.

18 MR. BRASON: Fred Brason, Project Lazarus.
19 Looking at the feasibility -- and you just
20 mentioned about being patient-centered, and that's
21 one of the first times that's been mentioned here
22 in the last 15, 20 minutes. It's more been

1 prescriber-centered.

2 We have to make sure that what we're talking
3 about is going to ultimately help the patient.

4 Keeping them safe and responsible, as pain free as
5 possible, and obviously, not having adverse events.

6 We don't know if mandatory education brings
7 that about. We do know that education brings it
8 about, but I also know that I have prescribers that
9 if a patient has to go to a refill, I immediately
10 refer them to pain management somewhere. That's
11 not feasible everywhere. I know in my county, that
12 means they have to go to another county.

13 So we have those kind of issues, and we're
14 trying to draw the prescriber into this from five
15 years ago. We now have that. They're happy to get
16 the guidelines. They're happy to get the
17 education. I think if we just say now you have to
18 do this, that changes that.

19 North Carolina just went to a mandated 3
20 hours over 3 years, but we're also at a place where
21 we've been in every community with every
22 prescriber. There is that more buy-in, so there

1 isn't a pushback with that. It's included with
2 their CME total, so it's not adding to, it's just
3 defining, in a way.

4 The feasibility is what is going to
5 implement into best practice and not stop practice.

6 DR. THROCKMORTON: I want to make sure I
7 understand, and this is something we actually
8 haven't talked about in the last couple days, but
9 it's been raised before; the notion that mandatory
10 education is less likely to be effective because
11 people, I'll say, resent being forced to do it or
12 something like that.

13 That's what you're talking about here, isn't
14 it?

15 MR. BRASON: Yes, yes.

16 DR. THROCKMORTON: When you say you know
17 non-mandatory education works, and you're not sure
18 whether mandatory education works, part of it is
19 grounded in that --

20 MR. BRASON: Yes.

21 DR. THROCKMORTON: -- the idea that people
22 made to do something would not learn as much or not

1 take --

2 MR. BRASON: Or not implement. All right.
3 Here's my canned stuff that I have to do. I did
4 it. I didn't like it. I'm not going to follow
5 through with it, or I'm just going to opt out and
6 just not even bother so that I don't have the issue
7 whatsoever.

8 DR. LURIE: I'm a researcher, so it's always
9 tempting to say more research is necessary. But
10 I'm with Trip on this. I think the amount of time
11 it will take to resolve these questions
12 satisfactorily is very, very long. In fact, it's
13 probably never. People have been researching CME
14 and its efficacy for probably two decades now.
15 We're left with a bunch of very hard-to-resolve
16 questions.

17 I don't know of any special reason to
18 believe that those uncertainties are any more
19 resolvable in the opioid pain area than they are
20 anywhere else. Given the limitedness of what is
21 being considered here, 3 hours of a physician's
22 time in the context of everything he or she has to

1 do in a year or two, it just seems so little.

2 To me, the evidence bar is maybe not what it
3 is for parachutes, but it's not very different than
4 that. It seems to me to make sense, and it seems
5 to me it's not a massive burden. It seems to me
6 that in the context of what we're dealing with
7 here, it's actually a very powerful message to the
8 prescribing community in general and to patients if
9 the community comes together and says, we feel so
10 strongly about this that we're going to mandate it.
11 There's a message there, too, quite independent of
12 the content.

13 Fred, as to your question about the idea
14 that the mandatory-ness itself might be somehow
15 disadvantageous, actually that I'd like to see some
16 research on because I doubt that strongly. I think
17 that it's a profound question in its way because it
18 goes to the appropriateness of federal imposition
19 of standards that go much beyond opioids, right?

20 So that I'd like to see researched, but I do
21 think that right now, there's no evidence for that
22 assertion.

1 MR. BRASON: I understand. There is not any
2 evidence. Let me clarify the difference in
3 mandatory. Within a state system with local
4 medical boards and so forth that are already
5 engaged with the prescribers within that state,
6 they have a camaraderie. They're part of that. So
7 when there's a consensus there that we need to
8 mandate so many hours of CME to do this, there's
9 more buy-in.

10 From the federal level suddenly saying, no,
11 you have to do this, that's a totally different
12 context from the local person saying, who are you
13 telling me when I've already got my medical board
14 here saying this?

15 So I think there's a difference in who's
16 saying who has to do what. So that if at the
17 federal level, whether it's the DEA, FDA, CDC, or
18 whomever saying that every prescriber in the nation
19 now has to do this, without the local state
20 authority support in initiating that, I think we
21 would lose in that context if it came to do that.

22 DR. THROCKMORTON: Thanks.

1 Peter, can I ask you a question because you
2 raised another point that I hadn't heard in the
3 last couple of days, the value of a federal action
4 as signaling. Another part of the forest here, we
5 up-scheduled hydrocodone a couple of years ago and
6 made it harder to prescribe. You couldn't call in
7 prescriptions and things.

8 One of the things people talked about that
9 action doing is sending a message, resetting
10 prescribers' expectations and understanding about
11 the use of, in this case, hydrocodone combination
12 products that were being used, 100 million
13 prescriptions a year or something like that.

14 It sent a signal. And what we saw was a
15 12 percent reduction in net prescribing for all
16 opioids, something like that, largely attributed to
17 I think what some things people have written to
18 that action.

19 Is that signaling thing, is that the one
20 example of the place where we could point to
21 evidence for a federal action, sending that kind of
22 signal and actually dramatically altering behavior?

1 Maybe that's not a good example. I don't know.

2 DR. LURIE: Well, I'm all for signaling. I
3 don't think that's the best example. I think what
4 happened there, based on the papers that we
5 published, is you got an immediate decrease in
6 hydrocodone, and that was the intervention. Stamp
7 out the refills, and the refills were stamped out.
8 It was almost like a surgical approach where you
9 said hydrocodone in refills, and that's where all
10 the reduction was.

11 There was some new prescribing that was done
12 as probably bit of a subterfuge. There was some
13 prescribing of other drugs to compensate. There
14 was some prescribing of larger prescriptions to
15 compensate. But fundamentally, that intervention
16 did just what it did.

17 DR. THROCKMORTON: So physicians'
18 perceptions weren't --

19 DR. LURIE: I don't think it was about that.
20 That doesn't mean that it didn't send a message,
21 and that doesn't mean that messages aren't
22 important. I think that they are. The surgeon

1 general wrote a letter to every physician in this
2 country. Do I think that people read it and that
3 educated them in some way? I do not.

4 Do I think it sent a message that the
5 surgeon general and the federal government care?
6 Yes, I do. Do I think it sent a message that this
7 problem is of a gravity that merited a once-in-a-
8 lifetime intervention because no surgeon general
9 has done that since Dr. Koop in the '80s? Yes, I
10 do.

11 So I think that you can send a message,
12 absolutely, by something like this, and I think
13 moreover, you can change -- to me, I look at
14 it -- I think all of us agree that education is a
15 small fraction of the solution here. I think all
16 of us agree it's important, but I think we also
17 agree modestly that it's not huge.

18 But you can change the social milieu
19 sometimes, and I think we can learn from tobacco in
20 that respect. I think that there are things that
21 have been done in tobacco that do not literally in
22 and of themselves have had an impact upon tobacco

1 consumption, but that together we have created a
2 social milieu in which the consumption of tobacco
3 is not as acceptable as it once was.

4 It's the accumulation of things. All these
5 things different actors do in different times and
6 different places add up to something, and suddenly,
7 we have a whole new generation of people to whom
8 tobacco smoking is unacceptable.

9 DR. THROCKMORTON: I'm seeing several heads
10 nodding vigorously.

11 DR. LURIE: I think something similar can be
12 done and that a requirement for education can be
13 some fraction of that.

14 DR. THROCKMORTON: Thank you.

15 Myra, I think you had a comment or --

16 MS. CHRISTOPHER: I just wanted to say one
17 thing. I think it's a false assumption to think
18 that it has to be the priority of the federal
19 government because I can attest to the fact that
20 this is a priority for the states. There is not
21 one state board, not one governor that this is not
22 a priority for them. And I would just, again,

1 believe that it will be more successful if we can
2 figure out how to work through with the state
3 boards of all the health professions.

4 DR. THROCKMORTON: Penney?

5 MS. COWAN: Penney Cowan, American Pain
6 Association. It's making me a little nervous
7 hearing about more research, more this. I think
8 what I just want to remind everyone is that there
9 are a lot of people out there living with pain that
10 want their lives back, and they want it back
11 yesterday. They don't want to be in pain anymore.

12 So I guess I'm imploring upon you to figure
13 this out quicker than keep talking about it. I
14 think I said before, we need action now, and I know
15 you have to do it and do it right. But we've been
16 talking about it for a long time, and I am really
17 concerned about all the people out there who are
18 now taking their lives because they are in pain and
19 they can't live with it anymore.

20 That's what I wanted to say, that we really
21 have to do something, and we can't just keep
22 talking.

1 DR. THROCKMORTON: Great, thanks. Myra?

2 MS. CHRISTOPHER: Peter, I agree with you.
3 In the IOM report, we talked about in sum, we said
4 we need a cultural transformation in the way pain
5 is perceived, judged, and treated. A cultural
6 transformation will require education of a lot of
7 different stakeholders, but it will not be
8 sufficient for a cultural shift, the kind you're
9 talking about. We know how long that took with
10 regard to tobacco, and we also know how much money
11 it took.

12 Now, the elephant in the room, I think, and
13 I've been absolutely stunned that the issue has not
14 been raised, is that via a populist movement, we
15 have a brand-new administration, and the House has
16 now passed healthcare reform that is dramatic and
17 from my perspective, draconian.

18 Regardless of which of the various models we
19 might latch on to or build out that we've heard
20 discussed in the last two days, we're talking about
21 big bucks. We are talking about hundreds of
22 millions of dollars.

1 So my question is to those of you in the
2 federal agencies -- and I don't mean this to sound
3 rude, but you're not the most popular people in
4 America these days.

5 Greg, when you were talking about the CDC, I
6 think there's a fair amount of animus against the
7 CDC because of the way the guidelines were
8 promulgated.

9 It seems to me that a question that has to
10 be answered is not only what are you going to do
11 but how in the world do you intend to pay for it,
12 and I want to know if there's any discussion in all
13 of this at this point.

14 DR. THROCKMORTON: Well, I'll answer
15 generally, and the general answer is it depends on
16 the tool used to accomplish it. If you're talking
17 about a federal decision to impose a federal
18 educational mandate or something, that's why I
19 asked the what question as my follow-up.

20 If you tell me you need a federal system, I
21 need to know which federal authority, which federal
22 path you would like to be used. Because depending

1 on which one you choose, then the budgetary
2 questions and all of those things have to be worked
3 out.

4 FDA has a certain set of authorities under
5 our REMS that the Congress has given us; takes you
6 down one path. DEA has another set of authorities.
7 CMS has other sets of authorities. State boards
8 have a fourth set. There are a series of
9 authorities that are out there. Depending on which
10 one you, Penney, say, you Myra, say we should do,
11 then it takes us down different paths as far as
12 where the money comes from and those things.

13 It's an incredibly important question, but
14 it starts with that discussion.

15 MS. CHRISTOPHER: And you're confident there
16 is money down this path?

17 DR. THROCKMORTON: I do not do money.

18 Jeff, actually Myra raises culture. I think
19 you were the first person to mention cultural
20 transformation in terms of what needed to happen
21 here. You talked about it when you talked about
22 incentives. You said if you really want to change

1 behavior, look to incentives, don't look at things
2 like education. I'm shorthanding.

3 Anything else you have to say about changing
4 culture? I'm hearing a lot of interest in doing
5 that around opioids.

6 DR. KELMAN: I think if you're serious about
7 this, you have to change culture. I'm always
8 impressed every time we look at the disparity in
9 healthcare in different communities. That's been
10 worked on at Dartmouth for many years, where you
11 have the same patients, different communities,
12 different forms of treatment. And I think we'll
13 find the same thing in opioid prescribing.

14 If we get a change in the culture around
15 opioid prescribing, the problem will go away. And
16 I think it's well beyond education and even beyond
17 incentives. I think it behooves us in the medical
18 profession to promote the cultural change, and if I
19 knew how to do it exactly, I would tell you.

20 DR. THROCKMORTON: Are there other things
21 you can point to beyond -- so we talked about the
22 three types of tools, enforcement, incentives, and

1 education. Are there other things that we should
2 be talking about without trying to pin you down to
3 the one thing?

4 DR. KELMAN: Those are very big tools to
5 use. If you could really have -- everybody were
6 educated, if everybody were incentivized, and
7 everybody had the appropriate enforcement, I don't
8 think we'd have a problem.

9 By the way, don't ask me where the money's
10 coming from, either. We don't answer questions
11 like that.

12 DR. THROCKMORTON: I'll just note that you
13 didn't include education in the two of the three
14 tools you mentioned there.

15 DR. KELMAN: Education as spoken.

16 DR. THROCKMORTON: I see. Others?

17 DR. AHADPOUR: This is Mitra Ahadpour. One
18 more thing I wanted to add is the culture change I
19 think is extremely important, and maybe we need to
20 look at it as a bigger picture and look at -- there
21 is social media that we haven't even tapped into.
22 This is a new generation, and we've noticed -- I

1 looked at some research on adolescents and how they
2 use social media, and how if the social media says
3 that such -- for an example, such an illicit drug
4 is acceptable, more adolescents go and use it.

5 My suggestion is that maybe we should look
6 at social media for the clinicians but also for the
7 consumers because the patients that are informed,
8 informed patients make better decisions, and then
9 they go to their practitioners. They can really
10 let the practitioners know. If the practitioner is
11 overprescribing an opioid medication, they can say,
12 no, I am not interested in this medication, or I am
13 interested in physical therapy, or I want to go to
14 a chiropractor.

15 I think the social media aspect shouldn't be
16 costly. It's something that it would be
17 interesting to use and gather data.

18 DR. THROCKMORTON: Great, thank you.

19 I'm going to transition. I wanted to ask
20 another question of the group just to make certain
21 that FDA knew where everybody is coming from. So
22 one of the other aspects we talked about was the

1 scope of the educational efforts. The REMS is
2 currently focused on prescribers, and there's been
3 a lot of discussion about whether or not to expand
4 that to other groups in the healthcare setting that
5 play an important role.

6 I heard lots of support for that. Does
7 anyone want to argue for the scope of the REMS
8 remaining focused on the prescribers, or is there a
9 consensus that a broader education for us would be
10 important? Whatever level of activity we do at the
11 federal level, it would be important for it to be
12 broader.

13 DR. GREENBLATT: I think realistically for
14 the kinds of things to happen that we're talking
15 about, you got to involve other members of the
16 healthcare team. It's no longer a solo sport.
17 It's a team sport.

18 I think that CMS is recognizing that in some
19 of their codes and things that they're willing to
20 pay for now, transitional care codes and the
21 chronic care codes, recognizing that other members
22 of the team -- collaborative care for depression is

1 now funded. That could be different members of an
2 office staff participating and play a role.

3 If you could reach out and train other
4 members and then maybe even fund those activities,
5 there's no reason it has to be the prescriber,
6 right? A nurse could do the education. Somebody
7 at the front desk could be looking at the PDMP for
8 me. Somebody else could be making sure that the
9 patient has a controlled substance agreement.
10 Whatever it is that we want to have happen, it can
11 be done broadly across the office.

12 What you'll get from a lot of providers is
13 they'll say, my staff is busy. They're just as
14 busy as I am. We're all maxed out. But if you had
15 some money behind it, then maybe individual offices
16 could actually pay for more hours or an additional
17 staff member, whatever, that could allow some of
18 these things to happen and get the focus off the
19 prescriber.

20 DR. THROCKMORTON: Thanks.

21 Yes? Identify yourself, please.

22 MS. BURNS: Hi. Anne Burns from the

1 American Pharmacists Association. We know from the
2 TIRF REMS, that it's very important to have
3 pharmacy included in the loop mainly from an
4 education back to prescribers if, for instance, the
5 prescriber isn't registered to inform the
6 prescriber that that needs to happen. We strongly
7 promote pharmacists and the role that they can play
8 in addressing opioid misuse. So we would be
9 supportive of pharmacists' inclusion.

10 DR. THROCKMORTON: Great, thanks.

11 Other have any -- yes, Trip.

12 COL BUCKENMAEIR: I just want to
13 mention -- we mentioned a culture change, which I
14 absolutely agree, and that we need to take some of
15 this burden off of the prescribers, that they're
16 not the only issue. I agree with that, also.

17 I think as we're discussing the lack of
18 resources, but we're going to try to resource to do
19 something, that patients have to be part of that
20 program. While training is directed at providers,
21 there needs to be an equal effort that's directed
22 at patients so that this cultural change isn't

1 being driven from the top -- I'm using an euphemism
2 now -- from the medical profession, but that we're
3 trying to get both sides of this coin with the
4 patient being the focus of this effort to meet
5 somewhere with this cultural change.

6 DR. COMPTON: Wilson Compton. I wanted to
7 echo what Trip just said in terms of the other key
8 participant that we haven't thought about are
9 patient behaviors or haven't thought about it as
10 much. I think I don't quite have a plan for how
11 your REMS program could be expanded to include
12 that, but that seems a natural extension to the
13 other potential clinicians that are involved,
14 including pharmacists, other healthcare staff, in a
15 collaborative care model as well as patient
16 behavior.

17 I would also suggest that just going back to
18 your last question in terms of something we might
19 do, that irrespective of whether there is a federal
20 mandate for training, there will be at state
21 levels. And something that we could provide as
22 federal agencies and a federal group are some

1 information about what are the best common
2 denominators for that training. We won't have the
3 final answer, but there are ways to bring together
4 experts that we can do like almost nobody else can.

5 DR. THROCKMORTON: I know, Lisa, your group
6 has done a lot of work in that area, haven't you?

7 MS. ROBIN: Right, and I think that states
8 would appreciate the resource. I really believe
9 that if we came up with some common things, that
10 they would appreciate the resource.

11 MS. CHRISTOPHER: I sound like one-note
12 Annie, but the National Pain Strategy report has a
13 whole section on public education and
14 communication. It's outlined. There's a strategy
15 outlined for how you do that, as there is for
16 education of healthcare professionals.

17 So I once again will appeal that we go back
18 to I think solid work that was done a couple of
19 years ago now and don't just start from scratch
20 once again.

21 DR. COMPTON: I like that we don't have to
22 reinvent the wheel.

1 DR. THROCKMORTON: Looking at the -- we have
2 about 5, 10 minutes left here. I'm looking at the
3 points that were identified for you-all to think
4 about. I'm looking for the things that people
5 might want to comment there.

6 We've talked about aspects of all of them at
7 one time or another here, ask everybody to look and
8 see if there are things there that you think are
9 missing or that we need to have some additional
10 comment on. Otherwise, I guess I'd invite folks in
11 the audience to make some comments, ask some
12 questions, put you guys on the spot.

13 MS. CHRISTOPHER: One more time, I'm going
14 to raise the issue about the importance of looking
15 at cultural and ethnic diversity as curricula are
16 developed.

17 DR. THROCKMORTON: Great, thanks.

18 DR. TERMAN: So if you do read the National
19 Pain Strategy, you'll see that one of the groups
20 that's not here that's going to be very important
21 for prescriber education, are the people that write
22 the tests that get people to actually be doctors or

1 nurse practitioners or dentists or whatever,
2 healthcare provider. They aren't here today, but
3 they are certainly in the broader picture and plan
4 for implementation of the National Pain Strategy.

5 I'm not sure -- again, it's a little
6 different if we're trying to help people prescribe
7 safer than if we're going to try and get people to
8 practice better pain medicine because prescribing
9 is just a small part of the pain medicine.

10 DR. THROCKMORTON: Great, thanks.

11 Why don't I invite anybody that has some
12 comments to make, why don't you just stand up and
13 make them hard.

14 DR. KAHN: I'm just going to add some
15 comments from the perspective of the Conjoint
16 Committee. Remember, we're your educational
17 implementers out here. So on July 7th, we're going
18 to have having a meeting, and I can just share with
19 you right now, there are two or three questions
20 that we're going to be addressing from what we've
21 learned today.

22 One of them is the question of how do we

1 know what we've done so far has been a good job?
2 Have we really done well? We've educated 208,000
3 completers. Are they the right ones? We don't
4 know that.

5 So we're going to be asking ourselves the
6 question of should we do more of what we've been
7 doing and just how valuable has it been. We're
8 going to be asking ourselves a question of what
9 else we can do, and I'm quite confident that I can
10 say that we're going to be looking at out of the
11 box. We've been so much in the box here today.
12 Every time we talk about education, we talk about a
13 3-hour course.

14 We got out of that box a little bit
15 yesterday, and we're going to be out of that box on
16 July 7th. We're going to be talking about adaptive
17 learning. I can guarantee it. We're going to be
18 talking about somebody getting five questions a
19 week for 3 months until they get them all right.
20 We're going to be talking about other ways of
21 personalizing it to what it is that the clinicians
22 really need.

1 Then the third thing I'm sure we're going to
2 be talking about is how do we integrate education
3 into practice. We can't separate education from
4 practice. That's again part of the box that we're
5 trapped in right now. We got to get out of that
6 box and look what Kaiser's done and what the
7 University of Washington has done and what the VA
8 has done, and how they integrate education with
9 clinical decision support and academic detailing
10 and mentoring, and all of these things, dashboards,
11 performance measures, all of those things that are
12 done.

13 The rest of what we're doing in clinical
14 practice through performance measures, through
15 clinical data registries, we have to explore how we
16 can do that in our educational efforts in meeting
17 this.

18 The final thing that I'll just say is we
19 need to focus on the right question, and there are
20 two questions that are hovering over us today. One
21 of them is how can we educate more people. I know
22 that you have to answer that question because you

1 have a law, but we also know that that isn't the
2 question.

3 The question is what you identified on July
4 12, 2012, which is how can we have an impact and
5 how can we prevent adverse outcomes that happen
6 from misuse of opioids? And that's a much broader
7 question than should we have mandatory or voluntary
8 education.

9 DR. THROCKMORTON: Great, thank you.

10 MS. WHITE: Hi. My name is Julie White.
11 I'm the director of CME at Boston University School
12 of Medicine. I'd just like to also compliment the
13 FDA. This has been a fascinating two days.

14 I also wanted to say, though, that as
15 someone who is in the trenches, that the education
16 we are doing is making a difference. It is
17 changing practice. We're seeing that. We are
18 seeing after four years that people are calling us
19 and saying, look, we're implementing system-based
20 changes. We need your help to come in and support
21 that with education.

22 You may not feel like you're making a

1 difference, but this is. This whole initiative is,
2 and I just want to thank you for that.

3 DR. THROCKMORTON: Thanks very much.

4 Anybody on the panel want to have last
5 words? Going once?

6 DR. LURIE: I'll take one. We've talked
7 about cultural change, and the first thing that
8 people say is it's just so difficult. It's so
9 impossible. It takes a sea-change. Every possible
10 interest group needs to be involved. We all need
11 to be involved.

12 I think what we forget is that actually
13 cultural change of a massive extent happened in
14 this very field in the last 15 years. Somebody
15 pulled it off. Now, it may not have been
16 especially favorable the way things have turned
17 out, but the fact is that 15 or 20 years ago, there
18 was a certain set of attitudes towards opioids and
19 towards pain treatment, and here we are 20 years
20 later with a completely different one.

21 So cultural change is possible. There's no
22 question, and it can be quick and widespread. The

1 question is if one concludes that there was adverse
2 cultural change, what can we learn from the way
3 that was pulled off in our own efforts to reverse
4 things?

5 Closing Remarks

6 DR. THROCKMORTON: Thank you, Peter.

7 I think we'll make that the last comment.
8 First, thanks to everyone. Please thank all of the
9 panelists and participants.

10 (Applause.)

11 DR. THROCKMORTON: Second thing, thank you
12 for your participation. As I said, I think this
13 has been a really fascinating meeting and made me
14 question some of the assumptions I think I brought
15 into the room the last couple of days.

16 Two small housekeeping things and then Peter
17 has a comment he wants to make. The blueprint is
18 out for comment. I would encourage people to give
19 us comment. We genuinely are interested in making
20 it better. Whether we have to do more, we need to
21 do better. We understand that.

22 The second thing is related. I'm interested

1 in resources to think about as we think about this
2 patient education. If there is a resource that
3 someone could point to for what that kind of an
4 outline might look like, I think we'd be interested
5 in knowing about that, too, as we digest what we've
6 heard the last couple of days and make the
7 decisions that we're going to have to make here in
8 the coming months.

9 Peter, does not have anything. So with
10 that, I wish everyone a safe trip, and thank you so
11 much for coming.

12 (Whereupon, at 4:30 p.m., the meeting was
13 adjourned.)

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