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

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FOOD AND DRUG ADMINISTRATION

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

Exploring the Path Forward – An FDA Workshop

Wednesday, May 10, 2017

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

Sheraton Silver Spring

8777 Georgia Avenue

Silver Spring, Maryland

C O N T E N T S

C O N T E N T S

P R O C E E D I N G S

(8:26 a.m.)

Opening Remarks

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

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

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

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

(Applause.)

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

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

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

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

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

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

Open Public Hearing

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. THROCKMORTON: Thank you very much.

Pat deCosta.

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

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

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

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

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

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

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

others or the misuse that is driving this epidemic.

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

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

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

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

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

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

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

DR. THROCKMORTON: Thank you very much.

Lynda Martin.

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

today.

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

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

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

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

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

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

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

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

decrease opioid misuse.

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

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

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

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

DR. THROCKMORTON: Thank you very much.

Thomas Berger.

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

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

that are involved here.

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

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

DR. THROCKMORTON: Thank you.

Larry Twersky.

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

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

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

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

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

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

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

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

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

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

to let people know to dispose of their medication.

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

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

DR. THROCKMORTON: Thank you very much.

Andrew Rosenberg.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

James Anderson.

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

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

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

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

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

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

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

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

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

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

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

DR. THROCKMORTON: Thank you very much.

Joseph Brence.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. THROCKMORTON: Thank you very much.

Shruti Kulkarni. Kulkarni. Apologies.

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

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

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

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

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

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

addiction, and overdose.

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

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

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

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

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

DR. THROCKMORTON: Thank you very much.

Our last speaker, Christopher Hulin.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. THROCKMORTON: Thank you very much.

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

(No response.)

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

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

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

DR. COMPTON: That's one of the questions

that was laid out.

DR. THROCKMORTON: Thanks very much.

Health System Panel

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

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

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

pressing topics.

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

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

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

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

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

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

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

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

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

the topics that we've been asked to address.

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

Go ahead.

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

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

Our medical board under requirements from

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

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

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

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

in the DoD.

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

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

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

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

(Laughter.)

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

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

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

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

that there were many useful things that I learned.

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

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

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

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

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

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

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

I was interrupting the broader discussion.

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

First, let me backtrack and say not only do

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. COMPTON: Thanks very much. David?

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

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

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

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

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

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

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

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

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

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

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

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

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

(Laughter.)

DR. COMPTON: Those are surgeon's hours.

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

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

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

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

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

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

agreements, et cetera, et cetera.

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

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

DR. GOOD: I appreciated that.

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

(Laughter.)

DR. GREENBLATT: It really was.

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

I've had so many groups of providers say to

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

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

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

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

(Laughter.)

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

kinds of things.

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

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

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

just providing information.

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

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

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

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

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

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

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

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

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

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

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

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

I mentioned that I just recently took the

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

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

DR. COMPTON: Other comments around this related issue?

(No response.)

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

pain management and then the broader opioid epidemic?

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

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

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

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

that really needs to happen.

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

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

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

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

what's going on with pain.

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

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

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

DR. COMPTON: What do you see as the most

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

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

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

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

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

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

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

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

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

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

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

DR. COMPTON: Carol?

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. COMPTON: Larry?

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

DR. HAVENS: Oh, please.

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

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

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

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

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

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

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

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

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

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

DR. COMPTON: I would bring up that the goal

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

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

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

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

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

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

David?

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

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

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

Anybody know?

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

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

those public health efforts make a lot of sense.

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. GREENBLATT: Right. Virtually nobody ran out.

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

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

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

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

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

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

individual patients.

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

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

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

DR. COMPTON: That's right.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Other thoughts about unintended consequences?

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

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

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

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

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

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

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

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

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

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

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

MS. COTTON: True.

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

MS. COTTON: True.

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

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

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

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

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

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

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

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

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

DR. GREENBLATT: That would be, right.

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

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

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

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

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

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

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

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

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

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

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

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

their patients are going to benefit from it.

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

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

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

The second thing I would say it's not just

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

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

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

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

DR. HAVENS: Thank you.

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

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

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

(Laughter.)

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

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

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

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

COL BUCKENMAEIR: Is he in the family?

DR. GREENBLATT: Let's say –

(Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

(Laughter.)

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

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

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

COL BUCKENMAEIR: I agree.

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

MS. COTTON: That's Indian Health Service.

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

DR. HAVENS: As I said yesterday, one

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

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

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

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

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

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

(Applause.)

Questions and Answers

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

Dr. Harris?

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

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

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

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

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

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

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

conversations.

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

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

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

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

those points. Thank you.

DR. COMPTON: Thanks very much.

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

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

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

Then by all means what I still believe is

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

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

I want to ask that question to the group.

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

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

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

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

DR. COMPTON: Over on that side next.

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

DR. COMPTON: Could you introduce yourself, please?

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

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

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

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

COL BUCKENMAEIR: Close enough.

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

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

group.

COL BUCKENMAEIR: Take a vote?

(Chorus of boths.)

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

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

(Laughter.)

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

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

is in sight.

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

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

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

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

Any comments or thoughts with that really interesting comment?

DR. GREENBLATT: I do think that a different

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

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

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

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

Yesterday, we talked a lot about how one

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

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

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

DR. COMPTON: Others?

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

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

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

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

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

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

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

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

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

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

As discussions evolve --

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

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

on how to safety and competently use opioids in the treatment of chronic pain.

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

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

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

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

that stuff that you call alternative.

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

DR. COMPTON: Other comments?

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

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

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

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

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

(No response.)

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

(Applause.)

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

We will see you at 5 to 11:00.

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

Patients and Consumer Advocates

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

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

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

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

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

The second question, focusing more on

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

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

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

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

We'll start with Myra.

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

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

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

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

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

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

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

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

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

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

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

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

DR. EGGERS: Thank you. Penney?

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

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

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

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

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

a real issue.

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

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

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

I think part of the problem, just to throw

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

DR. EGGERS: What do they do?

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

DR. EGGERS: Then we have Teresa.

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

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

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

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

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

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

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

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

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

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

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

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

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

help their families.

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

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

DR. EGGERS: Thanks, Jan. Greg?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Myra had wanted to build on what Penney was saying.

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

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

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

(Laughter.)

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

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

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

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

they know they need to do.

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

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

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

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

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

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

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

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

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

MS. COWAN: Can I add one thing?

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

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

MS. CHRISTOPHER: Absolutely.

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

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

MS. COWAN: And need to be able to

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

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

DR. EGGERS: Let's go with Maria.

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

management or opioid use.

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

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

First, let's go to Teresa.

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

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

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

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

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

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

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

At the very, very most basic level, this is what I think the education should do. We should be putting everybody on the same page. There should be some consistency at least in understanding. There should be some consistency and some understanding about pain management in general, and there should be some consistency and understanding about some techniques for engaging the patient or the consumer, because these days, let's face it, in

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

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

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

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

DR. EGGERS: Great. Greg or Jan?

MS. CHAMBERS: Thank you, Teresa.

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

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

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

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

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

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

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

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

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

MS. CHAMBERS: Yes.

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

Greg?

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

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

early signs.

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

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

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

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

MS. CHRISTOPHER: May I ask Greg a question?

DR. EGGERS: Sure.

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

MR. WILLIAMS: Yes.

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

(Laughter.)

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

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

I'm not interested in comparing deaths or

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

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

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

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

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

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

MS. CHRISTOPHER: Good.

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

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

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

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

missing.

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

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

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

of the bigger problems.

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

DR. EGGERS: Jan?

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

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

People are living with this fear.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

It may have been that a doctor has always

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

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

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

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

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

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

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

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

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

DR. EGGERS: Yes.

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

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

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

He looks and me, and he looks down at the

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

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

DR. EGGERS: Nice point. Penney, please.

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

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

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

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

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

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

we'll move on to our next topic.

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

DR. EGGERS: And in the practical constraints.

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

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

problem.

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

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

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

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

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

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

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

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

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

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

DR. EGGERS: Jan?

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

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

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

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

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

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

MS. CHAMBERS: Yes.

DR. EGGERS: Teresa?

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

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

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

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

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

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

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

DR. EGGERS: Thank you. Penney?

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

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

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

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

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

DR. EGGERS: Thank you, Penney. Maria?

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

equation in that care of that patient without the patient.

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

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

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

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

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

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

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

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

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

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

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

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

DR. EGGERS: Thank you.

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

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

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

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

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

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

DR. EGGERS: Go to Penney.

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

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

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

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

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

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

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

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

DR. EGGERS: Thank you. Greg?

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

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

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

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

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

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

DR. EGGERS: Thank you.

Teresa, do you have anything?

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

(Laughter.)

MS. CHRISTOPHER: Unfortunately, he got fired.

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

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

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

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

team is empowered to speak up.

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

Questions and Answers

DR. EGGERS: Thank you.

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

We'll start here.

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

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

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

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

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

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

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

conversations will be.

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

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

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

DR. EGGERS: Penney?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. BRASON: Right.

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

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

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

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

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

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

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

DR. EGGERS: Thanks, Fred.

Over here.

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

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

(Laughter.)

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

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

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

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

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

MR. WILLIAMS: I would say out of context of substance-use disorders. I think you have this other chronic health problem that relates to opioid prescribing, and substance-use disorders has to be part of this education.

DR. EGGERS: We'll go to this.

DR. MILIO: Every year, a lot of trees are cut down or every day because of all the after-visit summaries and discharge summaries that patients often get and are sort of tossed. They include a list of medications, but often not how patients should take them. There's not been any discussion on how -- the last panel, it could have been addressed, too -- how can we approach educating patients, and where should this take place on how to take their medications?

Just an example, I got called by a friend in tears who had terminal cancer because she was sent home with four different pain medications, three different antiemetics, two bowel meds, and had no clue how to coordinate their use. All she could say was, "None of them are working. I have no idea how to use them."

DR. EGGERS: So you're being very specific about when to take it, how to take it, those types of instructions, right?

DR. MILIO: Yes, because I think that's a key point.

MS. COWAN: We've actually been working with APA, the American Pharmacists Association, and we have a graphical tool on how to exactly do that because of all the calls from people that don't know how to take the medications. So it's day or night, with food or without food, things to avoid, possible side effects.

Graphical tools, again, a picture is worth a thousand words. That's a beginning, but we always encourage people to really have that conversation with their pharmacist. If they don't know, go back and ask the pharmacist. They're trained to do that. And the best resource is your pharmacist, and actually go back and have that conversation with them.

DR. EGGERS: Thanks, Penney. Our final question?

DR. TERMAN: Greg Terman, University of Washington and American Pain Society. I have a question, but first an ad that Greg, allowed me to make. Takeback programs are really important to me. No matter what omniscient legislator tells me

how many pills to give to the average patient as they leave the hospital for their lung transplant, I'm likely to give some too many and some too few. So takeback is really important. There's going to be some that are going to be left over.

I just want to advertise -- I have no conflicts of interest except for this interest in takeback -- but in the last year, Walgreens has put up 600 stores that have takeback containers. They've collected 7.2 tons of medications, and they're not just on DEA takeback. It's not just a drug enforcement.

So I've changed my personal pharmacy because of that, and if any other chains are doing the same thing, I'd certainly be interested and advertise them as well.

DR. EGGERS: Thank you.

DR. TERMAN: But assuming I can't get everyone to takeback their unused medications, I'd be interested in -- as you know, misuse, there have been a number of studies that suggest that most people who misuse medications is because of family

and friends giving them medications.

I'd be interested in your perspective as a physician trying to teach my patients not to do that, what is it about pain medicine that allows people to think that they can give them to other people?

If I see a kid with a sugar high, I don't say, well, let me get my insulin and see if I can't help them with that. What is it about pain medicine that is seen so differently in our society? I'd be interested.

DR. EGGERS: Does anyone want to quickly give --

MS. CARR: I can say as somebody who reports and writes about drugs when we do the drug surveys and stuff every year, I kind of disagree. It's not just pain meds, and people will tend to keep things like antibiotics, for example, just in case so they don't have to go back to the doc the next time around. Or if somebody in the family gets the same thing, they think they can just use the same drug over and over again.

I think it's just a lack of understanding about medications. And at a very, very basic level what we find is that people often overestimate the benefits and underestimate risk of medication. I think we've been culturally trained to see them that way.

MS. COWAN: I think it partly is we're a compassionate society. We want to help people when we see someone in pain. I'll never forget one of the first meetings I went to at the FDA about REMS, and there was a mother who got up and said that she had a daughter who died from an overdose, but it was because of the grandmother.

So the daughter was visiting the grandmother, and the granddaughter was having some pain issues, and the grandmother had gotten some medicine for surgery and had some left over and said, "Here, take this." No idea it was an opioid, it would kill the granddaughter. The granddaughter died.

I'm a grandmother. I can't imagine having to live with something like that. So I think

people, that's where the public education is so very critical, and we're not doing that. And we better start doing it because if this grandmother, if she had only known, she would never -- it's unintentional. It's a mistake, and we're just trying to help someone feel better.

That's human nature, and I think that's why we do it.

MS. CHAMBERS: And, Dr. Terman, it goes straight to that fear factor, that they have that fear themselves or don't want to see other people in that kind of pain, and so they are compassionate and want to reduce that fear.

MR. WILLIAMS: I would just add, compassion, I think, is one thing, but they work. They create euphoria. Why do you invite somebody to a bar to have a drink? It works. I think there's an acknowledgement of the quick fix. I think compassion is one emotion, but I think we are in a quick fix culture, and this is one quick fix.

One thing for your patients, I think, similar to public health education on guns, the

notion that we have to lock these medicines up because -- look, teenagers have a lot of information. Eight-year-olds have a lot of information at their fingertips. I used to go on rxlist.com when I was 14 years old. I knew exactly what imprint codes would get me high, okay?

So I think we have to not be naive that young people, especially who are the most at risk for these medications, know a lot more about these medications than some people. Our grandmothers and our other folks know about these medications, so locking them up is a really important thing that people need to be educated about.

DR. EGGERS: I want to thank the panel for excellent remarks and dialogue, and thanks for the questions. We have an hour for lunch, is that correct, Doug? So be back at 1:15, please.

(Applause.)

(Whereupon, at 12:19 p.m., a lunch recess was taken.)

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

(1:19 p.m.)

DR. THROCKMORTON: All right. Second day, thank you for coming back from lunch break. It is a gorgeous day out there. I appreciate everybody coming back.

This afternoon's panel, this first panel we're holding is called the federal panel, and it reflects the federal response to the opioid crisis. The one that's going to help lead this is Chris Jones, who's worked in many of the Feds.

Right, Chris? I think you have experience across many of the -- currently the acting associate deputy assistant secretary for science and data policy of the assistant secretary for planning at HHS, and there's going to be a series of some presentations and a panel.

Chris, thanks for helping very much.

Federal Panel

DR. JONES: Thank you, Doug.

I think I will keep my comments certainly brief for this portion and get started with the

presentations, but we do have a series of presenters from various agencies within HHS who are working on the opioids space. This gives you a bit of flavor of what we're doing around education for prescribers and prescriber training.

I believe our colleague from SAMHSA is going to be the first up, and the slides are loaded up.

Mitra, if you want to come on up. Thank you.

Presentation – Mitra Ahadpour

DR. AHADPOUR: Good afternoon. My name is Mitra Ahadpour. I am the director of Division of Pharmacologic Therapies at SAMHSA, and thank you for allowing me to speak today. I'm aware that I have 5 minutes, so I will talk very fast. So hopefully you will understand what I'm saying with my accent. When I talk very fast, it goes very fast.

I just wanted to quickly go over what happens on an average day in the United States. As you see, more than 650,000 opioid prescriptions are dispensed; 3,900 people initiate nonmedical use of

prescription opioids; 580 people initiated heroin use; and 91 people die from an opioid-related overdose.

I wanted to give you a brief overview of some of our resources at SAMHSA. This is not complete. I encourage you to go to our SAMHSA website, and there is a lot of great resources for the healthcare providers and for patients.

One of our programs that we are very proud of is the Providers' Clinical Support System. This is a collaborative agreement between many professional organizations, and there is a PCSS-MAT and PCSS-O. The MAT is for medication-assisted treatment, and O is for opioid therapy.

As I love data, I'm going to give you some data. These are just some of the highlights for the PCSS-O on the number of webinars that they have created. And what I wanted to highlight here quickly is the mentors. There are free mentors available. I think this is really important.

I've been sitting for the past day and a half and hearing everyone's input on opioid

prescribing, safe opioid prescribing training tools. I think the mentor piece is extremely important for the clinicians.

They just released a pain curriculum, which is 14 modules, and this really includes everything from safe opioid prescribing, how to do the correct communication, motivational interviewing, really how to assess patients who both need an opioid pain mediation but also have the comorbid mental illness.

I think that's the piece we need to keep going back to it. It's great to have a safe opioid prescribing training for the clinicians, but let's please keep in mind that we also need to include the mental illness piece, the anxiety, the depression, the PTSD.

The PCSS-MAT, these are some of the highlights. Also, there is a mentor piece, free mentorship both for PCSS-O and MAT for clinicians.

The opioid prescribing in the dental setting, we have had courses that were both in the PCSS-O but also through Boston University that we

have supported. The 2000 number for the completing training is for the past about two years, and this is really intended for the dentists.

If you're interested in the granular data, I have it, of how many were general dentists, how many were oral surgeons that have partaken in this course. Because to our mind, the training should be for all healthcare providers, for nurse practitioners, nurses, physicians, dentists, pharmacists, social workers, chiropractors.

I think any profession -- this is my opinion. Any professional that touches a patient, that has a connection with any patient, should be aware about safe opioid prescribing and how to assess the patient and about complementary medicine.

I just wanted to give you that we have made a MATx, which is an app that has wonderful resources in it. It's on medication-assisted treatment but also how to treat alcohol use disorder and tobacco use disorder.

We went with Medscape and did a two-year

program of screening brief intervention, referral to treatment, and we had close to 75,000 learners.

Thank you. I'm exactly on time.

(Applause.)

DR. JONES: Nice work. You'll get a reward after that for staying on target.

Next is Major Debbie Dowell from CDC's Division of Unintentional Injury Prevention.

Presentation – Deborah Dowell

MAJ DOWELL: Thanks, Chris.

Good afternoon, everyone, and I'll be relatively brief. I just wanted to start making some comments about the questions all of us have been asked to address today and what we've heard so far over the last day and a half.

I think I haven't heard much disagreement with the fact that we have a problem; we have at least a couple of problems, both with knowledge about appropriate, effective, and safe management of chronic pain in this country and also with adverse events related to prescribing or opioid analgesics.

I haven't heard much disagreement with the idea that we need more education. Even if we don't have randomized controlled trials showing that it works, it's likely to have low risks, and we know that there is a need out there.

I think the most prevalent concern we've heard is the idea that prescribers, especially as this was tied with the ability to prescribe opioids through a DEA license or something, prescribers might opt out and stop prescribing opioids. But I think it's reassuring. We've heard from New Mexico and some preliminary data from IHS that this hasn't happened, as well as some data from Kaiser, although that was not mandatory.

I also want to emphasize the opportunity for potentially people to opt in in a different way with education. We've also heard comments about it's not so much the education, it's what people hear in the media that scares them, and I think education can be a way to emphasize messages such as -- I'll just give you an example.

Most of you know the CDC put out guidelines

a little over a year ago on opioid prescribing for chronic pain. I think a lot of people don't know that the CDC guidelines advises against suddenly or unilaterally stopping opioids in patients already on high doses or doing it quickly or abandoning patients. But you have to read the guideline to find that out. You might not know that if you read the news reports only.

Education gives us an opportunity to emphasize those messages and get the important information, if we can all agree on kind of a set of basic information that's important to be included education in an FDA blueprint or another common understanding.

With that, I'm just going to spend a couple minutes sharing with you some of the resources that CDC has made available in the last year and is still working on in order to support implementation of the recommendations in the CDC guideline for prescribing opioids for chronic pain.

In the last year, we've made more than 20 guideline-related educational tools available for

providers, including a checklist, fact sheet, and guides. We had a speaker from Consumer Reports this morning who mentioned the usefulness of a checklist for airline pilots and in surgery. And I just wanted to point out, we worked with Atul Gawande, who wrote the Checklist Manifesto and has been instrumental in getting checklists more widely used in surgical practice. He and his team at Ariadne Labs collaborated.

The page in back you see is a one-page checklist that has all the key elements to think about when you're considering or continuing opioid prescribing for chronic pain, just on one page.

We also have a mobile app. It was released a couple months ago.

We have made available free continuing education credits on the guideline in partnership with colleagues at the University of Washington. It includes seven 1-hour webinars, which were released between June and December of 2016, and they're now available for download and free continuing education credits on completion of a

short quiz at the end.

Just launched three weeks ago in April, we are also offering free web-based continuing medical education on the guideline featuring standalone modules, interactive scenarios, resource links, and knowledge checks.

Just in light of some of the discussion we've had in terms of how do you incentivize, what kind of uptake can you get with voluntary versus mandatory training, we've had 2,500 page views of this since we released the first module -- just the first module is the only one available -- three weeks ago, which we're pleased about. But when you consider we're talking about over a million prescribers, I think we've got more to go.

By the way, the previous slide I put up with the webinars, had 44,000 page views, which again, we're pleased about, but we're far from a majority of opioid prescribers in the United States viewing these.

We'll hear a little bit later from a colleague at CMS, but I wanted to note that

colleagues at CMS have stated that they plan to incentivize completion of these modules through proposing as an improvement activity claiming CME credit for these modules.

The first eight modules are listed here and will become available on a rolling basis through the rest of the year. And in addition to these, we are going to be adding additional modules on acute pain and other topics. You can see the ones we have here add up to about 6 and a half hours, but at this point, clinicians can pick and choose which are most relevant or could do a subset of these.

Then with the additional content we plan to release later, we might be able to think about something if you do your initial continuing education one year, and then two or three years later, you can pick among the other modules that are most relevant to your practice.

I just wanted to note Penney Cowan spoke pretty eloquently earlier today about the need for communication, and we did try to put an emphasis on communication in these modules with one module

focusing exclusively on communication with patients. The other modules have opportunities to practice communication skills, including motivational interviewing.

This is just information on where to find CDC's training resources, and I will stop there and continue the discussion later on. Thank you.

(Applause.)

DR. JONES: Thank you.

Next is Wilson Compton from National Institute on Drug Abuse to talk about what NIDA and NIH are doing in this space.

Presentation – Wilson Compton

DR. COMPTON: Thank you very much, Chris, and good afternoon, everybody.

Part of the pleasure of working at the NIH is that our job is to promote the development of new knowledge, but if we do that in a vacuum and it sits on a shelf, it's not very satisfying. So it's essential that we collaborate, both with the practice community and in order to reach the practice community, through all of our federal

partners.

So the people at this table and many other people in the room have been terrific partners in both working with us to figure out, well, what are the questions that we need to focus our research enterprise on, and then in making sure that we develop information that will reach the populations that we hope to help solve their problems.

The broad theme for us at NIDA and for NIH I think can be summed up with the title of this title slide. Our goal is to science to make solutions to the public health problems in our country, and of course, in this case, we're talking about educational issues related to clinicians and how we can use this to drive towards solutions of the opioid and pain crises in the United States.

Now, I just have a couple things I want to highlight for you. First, I'll highlight for you a series of meeting that the NIH will be undertaking in June and July of this year. These are being implemented out of the Office of the Director, so Dr. Francis Collins is leading the effort to

develop three key targeted meetings that will include hopefully, the development of public/private partnerships where NIH provides much of the work on the basic science, the process of discovery, but we partner with the pharmaceutical industry and with biotech and possibly even device developers in order to see these things brought to clinical practice. Because it's rare that we can do this on our own, and it's only by working together that we can bring these products out to the public to make the difference that we hope they will make.

Now, the three topics are addressing issues that are of importance to the group here today. First and foremost, we need better pain management. The key obvious example is we use opioids for an awful lot of pain treatment, and while we have other approaches and we're all in favor of the integrated approaches to pain treatment, wouldn't it be nice if we had potent analgesics that didn't have the same side effects as our current range of the opioids?

There have been some breakthroughs recently. I'm particularly excited about the biased mu opioid agonist medications where it looks finally like it's possible to have something that has a potent opioid painkilling analgesic impact but doesn't have the development of either sensitization or tolerance -- that's part of your pathway to addiction -- or respiratory depression, because it turns out that those pathways can be decoupled.

Now, the question for the clinical studies will be how much do these pathways completely separate or is there relative separation. We, of course, would like a complete separation for them to maximize pain relief without addictive potential. That remains to be proven, and that's just one example of how we can develop safe and effective non-addictive strategies.

I haven't even mentioned transcranial magnetic stimulation and the like, but those are some of the work that we hope to stimulate with this meeting coming up.

The second broad theme, which isn't directly

related to the topic today, but could because I think part of the implementation of training around pain management is when is it appropriate to implement naloxone distribution, naloxone prescriptions and the like for pain patients.

Is it for every acute prescription that we provide? Probably not, but is it for every chronic, particularly high dose? The data would suggest from some NIDA-funded research in the last few years that that might make good sense.

The second meeting will be improving overdose interventions and overdose reversal, including such things as respiratory stimulation systems.

Finally, the other key component of our meetings and the third meeting will be focused on improving opioid addiction treatment. This takes two realms. We have on the one hand, we need to improve our implementation of the strategies that we know can be effective, but even in the best hands, while I'm thrilled that we have methadone, buprenorphine, and the long-acting naloxone to

treat opioid use disorders, they're not maximally effective. They don't have the penicillin-size effect size for middle ear infections, for example, or something like that. And that's what we would like. We'd like something that is easy for patients to take, the patients want to take it, and leads to better outcomes than the current technologies.

So that's what we will be supporting in the next month or two in this broad sphere to help stimulate what we have as a broad portfolio in this area.

Now, in terms of the educational areas, NIDA is very pleased to add to the range of resources that are available to clinicians. These are broadly under our NIDA med website, and I highlight for you a variety of materials.

In particular, I highlight for you our CME courses that we did with Medscape. This was with funding from OMDCP a couple of years ago. And we were surprised that over 100,000 people took those trainings. That was a new experience for us, to be

that popular in terms of people signing up, and it spoke to us about the tremendous interest and need that clinicians have, at least some of them, in improving their prescribing practices.

Finally, more broadly across the NIH will be the NIH Pain Consortium that are developing specific pain assessment and treatment modules. I encourage you to take a look at the website for the Center of Excellence for Pain Education for modules like Edna, who's a clinical case module to help learn about assessment and treatment of low back pain, and a handful of others. We will be rolling out more and more of these to increase our range of resources for those that want to improve assessment and treatment of pain.

Thanks very much. I look forward to discussion.

(Applause.)

DR. JONES: Thank you, Wilson.

Final presentation is Jeff Kelman from CMS who will talk about what's happening in the Medicare space.

Presentation – Jeffrey Kelman

DR. KELMAN: Thank you. I'd first like to thank the FDA for inviting me to be on this panel. It's always a nice event in my week. I'm always also somewhat hesitant when I accept one of these invitations because while you are all scientists, I'm just a payer.

There was an administrator at CMS, about 10 years ago, who referred to us as "one big dumb payer." Well, hopefully, we've gotten less dumb since that point, and in fact, there are tools we have at our disposal that can help us address the opioid crisis, which is so risky for our beneficiaries.

I'm going to talk about some of them and how to impact the payment system to direct people to better care. I want to discuss briefly within the five minutes I have our utilization management system for opioids, our point of sale step edits for opioids, and our quality measurement for opioid use.

In general, I'm going to be speaking about

the Part D drug benefit, which is only section of areas we develop in, but it's a big section. We're close to 30 percent of all written prescriptions in the U.S. at this time.

The OMS was started in 2013 when we first came to realize that we were using a lot of narcotics in the Part D benefit. It's addressing the most severe of the severe cases. It's a retrospective review of those patients, of those beneficiaries, who had more than 120 MED for more than 90 consecutive days with more than three prescribing physicians and more than three pharmacies.

This is the fringe on the outside. We require direct outreach, training, education, and intervention, and follow-up if necessary to explain and identify the needs of this population. We excluded, by the way, cancer patients and patients in a hospice. Over time, we've had a great success. I was actually surprised by the effects of this method, which goes to show payment actually does count, and I can't resist giving some numbers.

In 2011, we had 31 million Part D enrollees with 10 million enrollees on opioids, at least one prescription during the year. That's 32 percent, and that level stayed pretty much the same throughout the program.

There were 29,404 beneficiaries who met the criteria for outlier use as defined. In 2013, there were 37 million enrollees, 31 percent using opioids, and only 25,347 outliers.

In 2014, we had 40 million enrollees with, again, 31 percent opioids and 21,838. In 2015, we had 42 million enrollees with 15,651 outliers. Last year in 2016, there are now 44 million Part D enrollees with only 11,595 outliers.

In summary, we had a 60 percent reduction in the absolute number of drug users in spite of increasing population and a 70 percent reduction in outliers, 60 percent of total enrollments. This is more of a success than I expected, and it addresses one coterie, but we hopefully have spillover values.

The second program, which is starting this

year, is real-time point of sale edits. The OMS is based on retrospective look after the damage is done. The point of sale edit involves an edit before the dispensing event is done, looking at cumulative doses that trigger a certain level, generally, 90 MEDs for a soft edit and 200 MEDs for a hard edit.

A soft edit, by the way, means it's reversible by the pharmacist at point of sale based on discussion with a physician and a patient. A hard edit means it requires an absolute planned appeal before the drug can be dispensed. These are all based on educational lines that we expect our physicians and our pharmacists to follow.

Since we started it for the first time this year, I can't give you any numbers as to success.

Lastly, we use a quality measurement of opioids, which we've just developed with the Pharmacy Quality Alliance.

Quality measurement is an interesting field. If attached to a pay for performance system, it is very effective at changing share, and it's

widespread and involves every opioid prescriber in Part D and anybody else who downloads and utilizes our quality measurement.

The opioid for high dose in persons without cancer measure has three rates, and they're basically an unpacking of our OMS system. The high rates of simple daily dose more than 120 MED for 90 days, there is the proportion of individuals receiving prescriptions from 4 or more pharmacies and 4 or more prescribers, and the last one is the combination where they have more than 120 MEDs for 90 days plus the 4 or more pharmacists and 4 or more prescribers.

Because it's in a quality measurement system which goes across all our plans, it's picked up by everybody. Because it's in a pay-for-performance system, everybody pays attention to it, and we have great expectations going forward that this will have a greater impact than our OMS system because it's more broader based.

Thank you, and I'll take questions later.

(Applause.)

Panel Discussion

DR. JONES: Thank you to our presenters, and I would ask FDA and DEA colleagues to come up and join the panel. I think everybody has mics, so hopefully, they're turned on.

We do have a few questions for discussion, but I will probably go off script a little bit. But I would like to start, based on the totality of what folks have heard over the last couple days and what you're doing within your own organizations and what's happening across the federal government, what do you think are the merits of a requirement for prescriber education or alternatives for voluntary or incentivizing?

What is, from your perspective, the best way to approach ultimately accomplishing the goal of reducing inappropriate prescribing, reducing opioid-related harms?

I'll just turn it to the panel to address that question. I know that some of you have already spoken on some of this, but just thinking from it collectively of what you've heard over the

last couple of days.

Debbie?

MAJ DOWELL: I can start. I think voluntary is nice if it works. I'm a little bit skeptical of our ability to reach the people we most need to reach with the voluntary program. We've heard over the last couple of days that the majority of providers are now employed in organizations, and we've heard a lot about a lot of great work in education going on in health system, but there's still a very large proportion of providers who are in solo practice.

We also know that some of the states have already required mandatory education but not all, and states are going to have very variable amounts of resources to come up with a prescriber training.

I think we've heard over the last couple of days everybody acknowledges we have a problem and that we don't have extensive proof that mandatory education would work. It makes sense that it would work. It's likely to be low risk.

My main concern about voluntary is that if

you incentivize, you're going to incentivize first the prescribers that probably need this the least, and we're not going to reach the prescribers who really need this and other healthcare providers.

DR. AUTH: Doris Auth from the FDA. I would just like to dovetail on what Deborah said. We have a few voluntary prescriber education programs, as I pointed out yesterday in my presentation.

In particular for the FDA extended-release long-acting opioid REMS program, we haven't met our training targets. You could say that we could have done our targets differently. We could have come up with different numbers. But we often wonder when we look at the assessments and actual numbers, are we really getting to the right providers? The providers that are taking a voluntary training, how are they different?

Our expectation is that maybe they are providers that may not need to take the training. They are the ones that are out there looking for education and want to do the right thing. Maybe those providers aren't really our target that are

taking the voluntary program.

DR. KELMAN: I actually always see a third option. There's voluntary training, there's mandatory training, and then there's incentivized training. For us it's because we see this as a payer. But in general, there are programs at CMS that give incremental payment improvements for following certain benchmarks.

That's not mandatory in the sense that the prescriber is not out of the program if he doesn't follow it, but it certainly enhances his interest in actually finishing the option because he is incentivized by higher payments. If we can cut that, I've found it a more practical solution.

DR. COMPTON: Certainly from an NIH perspective, this is not something that we're going to have a direct opinion about. Our goal would be to use research to help inform these discussions. Where there is natural variation, that might lead to natural experiments that could be exploited to look at the impact of training models and approaches to pit required education against

voluntary or incentivized education.

Certainly in listening to the discussion yesterday and today, I'm impressed that an awful lot of people don't get trained with a purely voluntary -- the clinicians don't necessarily recognize that they have a lack of knowledge or lack of ability to do this prescribing. They think it's easy, and they miss some of the nuances. I think that may explain why we see such egregious prescribing practices when we look at the medical records.

DR. AHADPOUR: I think what would be interesting is -- so for me, I know we keep talking about physicians, but it's all health professionals, physician assistants, nurse practitioners, nurses, pharmacists, social workers, chiropractors, physical therapists. To me, it is all healthcare providers that we should keep in mind.

I thought it would be interesting because we have all these training modules that we've been doing. Wouldn't it be interesting to look back and

have a survey, which we are considering right now at SAMHSA, that after they complete their training, go back to these healthcare providers six months later, see has their behavior changed. How is the patient affected? Has the quality of life of the patient been affected? Has it become better?

Some of the questions to think about -- and I do agree with Deborah that it is low risk to say for right now, we don't have the randomized controlled trials, we don't have all the data.

I love data myself, so I am biased towards data, but right now because there is an opioid crisis, we should not wait for the data, and maybe we should make it mandatory. And there is so many different options of incentivizing providers to have this training. So to me, it makes sense.

DR. JONES: I have a question on the mandatory side and the idea that people may opt in if it's voluntary and those are the people maybe we're not concerned about. But what do we know about the people who are the outliers and whether or not we think mandatory education would be

successful in changing their behavior?

We look at PDMP data, and we see that there is a small number of prescribers prescribing large volumes of opioids. Some of those are associated with pain clinics, and certainly Florida and other states have had issues with that. Mandatory might check a box, but how do we work towards changing their behavior when it's not necessarily a knowledge deficit, and that might be contributing?

Just thoughts on approaches to address that population, who really you would like to change their behavior, but it may not be a knowledge issue.

DR. AHADPOUR: One thing to think about -- and I'm just throwing this out. I haven't thought about this. One thing you could think about is can we go back to these providers when we do this 6-month or 3-month survey, but put a mentoring piece to it, so they have a mentor after they complete their training.

The mentor piece of it, there are several different ideas of how you could have mentoring all

throughout the country that would be sustainable. But maybe through that mentoring piece, we have something to see are they changing their behavior, maybe direct them to change their behavior.

MAJ DOWELL: I would definitely agree that SAMHSA has PCSS-O and PCSS-MAT, which are great mentoring programs. Project ECHO is another model for how we might combine following up on some basic education and possibly also get some feedback.

I think it's going to be a very large and difficult workload to try to measure this across the U.S. One thing you could do -- it's much easier within health systems, and we've heard some great examples yesterday and today about that.

CDC is also working on development of a package of quality improvement metrics, and we heard from CMS about quality measures. We don't see it as tied to payment, but they're just intended to be part of the quality improvement process in healthcare systems, and we've been vetting them with stakeholders on feasibility and usability, and we'll be piloting those in a few

health systems. We've heard about some similar work going on.

I think the challenge, again, is outside those large health systems and making sure that you're changing behavior among the solo docs. I think one possibility for looking at that is having states look at their PDMP data.

I also wanted to make the point -- I think somebody else made this yesterday -- that there probably is a small group of prescribers who are not going to change no matter what we do, and I think it's more fruitful to focus on the group that has maybe learned prescribing and pain management practices that we now know are outdated. I actually think that that's a larger and certainly a more changeable group than that core that are not going to change no matter what you do, which is probably a problem to be resolved not by education.

DR. KELMAN: It's very hard to get docs to change their behavior, and I don't think it's predominantly an education issue. I think it's a culture of practice issue. If incentives can't do

it, then the only end result -- part of incentives is also comparative information.

Sometimes it's very effective to send a doctor a comparison to his similarly-situated peers who may have a better prescribing behavior or any activity. But in the end, if incentives don't work and comparisons don't work and education doesn't work, the only option is to remove the DEA license to prescribe, because that will always work.

DR. COMPTON: Your question reminded me, Chris, and Jeff just reminded me, that our goal is not simply increasing the knowledge of clinicians. Our goal is to change prescribing behavior, and even that's not really our ultimate. Our goal is to improve patient outcomes.

Keeping that as our target, I think is how we ought to both measure and understand what role does the education system provide, and can you reach that culture change with incentivized voluntary practices versus a mandatory education? I think that's an important possibility.

I also think there might be some

technological approaches that might help. An awful lot of prescriptions are now written on an electronic basis. Well, if the normal numbers of prescriptions aren't unlimited, maybe we could nudge people towards smaller prescriptions with automated prescriptions for 10 tablets. You could always override it, but how come somebody always writes for 120? Well, they do it out of habit. So if we help shape that habit through the creative use of technology, that might be a way to reach the same goals.

DR. AUTH: The REMS assessments that we get for the -- and we presented that in this last year in our advisory committee. We do use surveys. We ask the sponsors to conduct surveys of prescribers who have taken the training and those who have not. We try to make comparisons.

We are also trying to look at prescriber behavior. That's exceedingly difficult, especially in this population where there have been so many different activities occurring. And we're also trying to look at how can we get better at looking

at patient outcomes, and that's very, very -- at least in the scope of the REMS assessments, it's extremely challenging.

There's a lot of surveillance data out there, and again, it's also lots of limitations with that. But then also, what caused the change in behavior, if there is a change in behavior? Was it everything else that's happening? Was it the educational program?

I think even patient outcomes is potentially more difficult to study, but that's just my opinion based on what we've seen in the REMS assessments.

DR. JONES: I have a question maybe for Jeff to start. This is obviously focused on opioids and certainly in the REMS context, it applies to a particular group of opioids, and thinking about, okay, we want to change behavior. We want to improve patient outcomes. We want to improve access to high quality pain care.

So in the context of mandating education or scaling up education, what do you see as the other critical elements to success? So thinking about

the CDC guideline says do other things than prescribe opioids. That's the first recommendation essentially. Do we have a system in place that makes that possible?

So we're putting forward education to say choose other options, but how do we build a system and change reimbursement and payment, and work with health systems to ensure that that is an option for clinicians to actually have, if we're educating them that that's what they should be doing?

DR. KELMAN: From my point of view, it goes back to quality measurement and performance measurement, and this is what it was invented for. If you have a series of guidelines that are -- measures start with best practice, they go to guidelines, and then they go to quality measurement. And establishing the measurement through a consensus group is key. Getting it adopted it is important. Getting it endorsed is important. But none of this matters unless there are payment incentives at the end is my general impression.

I'm sorry to say that after the last 10 years, but just quality alone doesn't have enough of an impact on cultural change. You need incentives, and that's why pay-for-performance systems were invented.

DR. JONES: Maybe a question for Wilson thinking from the research perspective. In this environment, it's often thought of mandatory CME, a couple of hours, and that's what states have done. It's some of the bills you've seen in Congress.

I think there is a growing evidence base for how education can be provided. I worked with Debbie when I was at CDC, she was in New York, around academic detailing. Obviously, that's a more intensive effort.

What's your take on how do we put programs in place to create lasting behavior change, and what does the science tell us, a 1- or 2-hour course versus something more intense or some stratified approach to where some individuals might need a lighter approach and others a more in-depth touch?

DR. COMPTON: To a certain extent, the adoption of innovation has been studied in multiple contexts, both healthcare and outside. So you think about how simple of a behavior change are we looking for. The simpler and easier to practice it is, the more likely people are to take it up based on educational efforts at least as the starting point. But for most of the behaviors we're talking about, they are a lot more complicated such as the decisions that go into deciding how large a prescription to write and how long to write it for. That's ultimately what we're talking about here.

So a simple, single educational session is unlikely to have the maximum impact on that. It will have some impact around the edges, but I think the education all by itself probably isn't going to be enough. That's what the data would suggest.

How do we design a system that's more than just do this online course for a couple hours? I was really impressed by what we heard out of New Mexico and others, that they're implementing in the real world something a little more thorough and

more complete. And I'll be curious to learn does that have the impact that it looks like it should from a theoretical standpoint and from a knowledge about education leading to change.

DR. JONES: Debbie, from the CDC's perspective, obviously, over the last year, you have put quite a lot of time and thought into developing modules, developing different training programs, conducting webinars. What was the scientific process behind that and where you landed and decided on certain things? What informed that?

MAJ DOWELL: The content of the modules?

DR. JONES: The content and then how you were putting them into action.

MAJ DOWELL: A couple of different answers to the two different questions, but the content of the modules was mostly based on the CDC guideline and the evidence that we had gathered and the discussions with stakeholders we had gone through. We have also vetted with additional stakeholders from the perspective of how providers receive education.

Then the evidence base for what kind of education would work, I would say was less developed, and so we just looked at what had been done in the past, some of the work with Project ECHO that has informed the University of Washington and their tele-pain program. So we modeled the webinar series on that.

I don't think there was a rich evidence base to guide the educational method. You mentioned our work previously on academic detailing, and I think we actually got some promising results in terms of both provider knowledge and behavior change. But as you mentioned, that's a much more expensive, much more resource-intensive effort that I don't know is realistic to reach the entire United States. But that's something we could think about reaching, maybe areas of the country that have been identified as having a bigger problem for that more intensive educational effort.

DR. AHADPOUR: We did something close but not about pain management. We did a campaign like a couple of years ago at SAMHSA, and the idea

behind it was instead of waiting for the clinicians or the patients to come to us that may have never heard about SAMHSA, it's for us to go to them and try to get the attention where they are.

We did several campaigns through Google to see if they would click on our opioid overdose prevention toolkit, and we actually got data, because I love data. We looked at how many people clicked on, were they on the SAMHSA website, did they actually download it, did they actually read it, and we took it a step further.

To me, it was exciting because what we did was we looked at the digital footprint. So that's something a little bit different. This is looking a little bit at behavior. So they come to the SAMHSA website, download it, but what do they do afterwards?

Those are things to think about, just think a little bit different, coming up with innovative ways of looking at can we change behavior, and what is that behavior change?

DR. JONES: Others on this topic?

(No response.)

DR. JONES: Going to the second question that has been posed to the panel, we've talked a little bit about this, but discussing the goals of prescriber education and the desired impact that these educational interventions should have, I know that FDA's put a great deal of thought into thinking how do we measure the impact of the REMS program, and we probably heard some of that already. But it might be interesting from Doris' perspective to think about how has that shifted over time as you-all have learned through this process as the REMS was going.

Then just for others to weigh in on, what is realistic for an educational intervention, and where should we be setting those expectations?

DR. AUTH: How it's changed over time, I think was brought to light last year at the advisory committee. We had a few years of data, a few years of experience, and I think what we really learned was we need more information, we need it to come in differently, we need to leave no stone

unturned as far as what we're evaluating.

I think with the help of our epidemiology colleagues, we were getting better. I still think we have a ways to go about where the best way to measure the impact of these training programs.

The one item that we are asking the sponsors to provide is medical examiner data from a few different states. You may be aware that that's not available throughout the country. We have to take step back and think that we are not going to get this global surveillance data, and it's going to be hugely helpful, that we need to scale it back and look at smaller pockets and see what's been effective, how behavior has changed in those pockets, and then maybe try to trace that back to an educational program.

We're continuously evolving in how we're evaluating the REMS program.

DR. COMPTON: I think one of the difficulties is to measure how much the educational program itself has the impact versus how much is the publicity or the concept of drawing attention

to the issue of poor prescribing behavior in a general sense is having the impact.

While we heard earlier that California requiring extensive CME on the issue of pain and prescribing didn't have a big impact in California, I'd be curious whether there's evidence -- and I don't know of any -- of whether simply drawing attention to it by making these requirements at a state or local level does have some salutary impact in beginning to change the medical culture.

Because I don't know how much it's going to be the direct training versus shifting of the herd behavior, which ultimately may be the more important goal and not easy to draw out the causal pathways and really determine what the key ingredients are.

That's why I certainly think an educational program all by itself, probably not the way to go. So how do we embed this in a larger set of practices that link to poor treatment of pain on the one hand and the overprescribing, overreliance of opioids that's put us in this dreadful situation

with the opioid crisis?

DR. KELMAN: I'm impressed that there really are three different kinds of prescribers, and they probably have to be addressed in three different kinds of ways. There's the doctor who is lack of knowledge, who doesn't understand about the best practices in opioid prescribing. There are a set of doctors that may practice fine on their own but aren't aware of the others who are writing prescriptions for their patients, lack of coordination. Then there are doctors who are involved in pill mills and know exactly what they're prescribing. It's a completely different issue.

The training is different for all three of them. The first group, actually educational modules may work, the second group needs educational modules about communication, and the third group needs the Department of Justice, not an educational module.

DR. COMPTON: We'll look down the table for our colleague to help with that.

DR. JONES: Debbie, from your perspective, since you have been rolling out the CDC guidelines and I know there's plans to try to evaluate or get a sense of impact, what was the thought process that you guys put in place, and where did you land on goals about what was realistic that you could achieve with how you were implementing the guideline dissemination?

MAJ DOWELL: We've thought about that in a couple of different areas. One is just evaluating the impact of the guideline itself, and we just went through the recommendations in the entire guideline and said what would we like to see in terms of prescribing practices.

I would say some of the things we thought were really important but really extremely challenging to measure, other things we thought were really important and easier to measure. For example, better care of patients with chronic pain has been one of the more challenging things to figure out how to measure.

We are in the quality improvement metrics.

We are trying to look at that by looking at referrals to nonpharmacologic therapies among patients with chronic pain, whether or not they're receiving opioids. Some of the things that might be easier to measure, are people less often prescribing 60 days of opioids after a minor surgical procedure.

We were looking at both what do we think is really important and what do we think is feasible, and there's some overlap, some areas where it's continuing to pose challenges.

DR. JONES: Mitra, from SAMHSA's perspective, I know you covered a couple of different things. What are the expectations around the programmatic work that you do? What do you use to measure impact? You have contractors or grantees who are doing some of this for you, and what's that process on engagement to say we're making a good investment here in helping to change behavior?

DR. AHADPOUR: We have the PCSS-O or PCSS-MAT and Boston University. They all have

different programs, training programs that they have put out for healthcare providers. We measure the number of learners, how many healthcare providers actually access our programs. That is one way for us to look at.

We are taking it really a step forward. We are looking at right now the proposal that we have put forward is to go and look at these clinicians three months down the line, six months down the line. And it's wonderful to know how many people have completed your program. That's great, like expert for Medscape 75,000, that's wonderful.

I actually went and read everyone's comments. They gave me the comments of the healthcare providers. I would go and read each one of them to see what the issues they were talking about, what gaps they found in it, what do we need to do differently.

That was helpful, but I really want to see it three months down the line, six months down the line and see have we changed their behavior. It's wonderful for them to say, oh, we love your

training program. It was wonderful, but what is happening in their practice? Is the dentist changing their practice? Are they prescribing less opioids? Are the patient outcomes improving?

In a way, we are seeing a change, and this is not by randomized controlled trial. This is just colleague speaking. Recently, I was with my colleagues from dental school because I was in dental school, before going to medical school, and I was talking to them. They said they're prescribing less opioids, and they were saying, we don't know what's going on. Somehow there's all this educational trainings on safe opioid prescribing, and they said, we are doing less because we found out regular Tylenol with a nonsteroidal does the same thing, combination can do the same thing as giving an opioid medication.

So their behaviors are changing. And it would be nice to look at that impact with surveys. I know it's not feasible to do it for the whole nation, but if we can get a group of providers from different specialties to look at it, it would be

interesting, and then change our training based on what we find.

DR. JONES: I'll throw this out to the group. Debbie raised this during her comments around people opting out or unintended consequences.

How are people measuring those types of potential outcomes? Because we have seen nationally opioid prescribing declining. I think there's still questions among what population is it declining. So as you're implementing programs, how do you think about -- are we targeting the populations of patients who we want to move away from opioids or reduce their risk for opioids versus those who are doing fine but are caught up in efforts to broad-brush and constrain the supply?

DR. COMPTON: I don't know that we have much data on the number of prescribers and whether that's changing, or whether the practice patterns are changing because of the either new requirements or potential for new requirements. We're certainly hearing anecdotes about that.

The data we've heard in the last day and a half does not suggest that there's been a widespread shift, but that is something that could and should be tracked. I would think within healthcare systems, they might be able to track that fairly readily.

I would also think just simply tracking how many people have their DEA registration, does that shift over time? How many clinicians have their registrations and do we see that dropping based on these changes? That won't exactly work because you could have a registration and not prescribe.

We also might be able to use commercial databases like IMS and similar to track clinician behavior. Those are at least some resources that could be utilized to get at some of that question. In some ways, it seems to be more of a theoretical than a real concern at this point, but that's certainly something to keep in mind.

Are we pushing people out of practice who otherwise we would like to keep in practice? I think that's important to consider, is maybe some

of those who are stopping writing prescriptions, we don't writing the prescriptions to begin with. I want to make sure you know what you're doing before you write those prescriptions. We don't want people just doing them without knowing how to do it correctly and adequately, and we do see some really egregious prescription practices.

DR. KELMAN: We can also look true outcomes, opioid overdose deaths. If we found that everything we did had no impact on overdose, it wouldn't encourage us it was the right direction. On the other hand, if you see a progressive decrease in the overdoses in large databases, it would encourage us that it's the correct outcome.

MR. COMPTON: It's getting a little more complicated because of the importation of fentanyl and so many people getting poisoned with illicit opioids now, whether that's in -- they think they're getting a pill from their friend or neighbor but --

DR. KELMAN: It's a counterfeit?

DR. COMPTON: Yes.

DR. KELMAN: The problem is if all we're dealing is switching from prescription opioids to illegal fentanyl, I'm not sure we're not getting a secondary outcome we don't want.

DR. COMPTON: Of course.

DR. AUTH: To the question you raised about looking at number of prescribers and how that's changed, at least for the extended-release, long-acting opioids, before the program was approved, we had some of our drug utilization folks do an estimate. Again, these are prescribers who are registered for C 2s and 3s that had written a prescription for an extended-release and long-acting in the previous 12 months.

When they looked at this in 2011, the estimate was 320,000, and that's how we came up with some of our training targets. We asked them to go back and do that again last year before we had the advisory committee. They used a slightly different methodology, but the bottom line is that it really hadn't changed.

Again, that's just maybe a small example

because we were focusing on the extended-release and long-acting. So if we expected our program to have any impact on who was prescribing those, it really didn't.

DR. JONES: Maybe a wrap-up question; we still have some time. The issue of state versus federal and the idea of via REMS or via DEA registration mandating education versus an approach for supporting state efforts to mandate education, or have some system in place to incentivize or provide education, I would just be curious on everybody's thoughts around what approach seems to make the best sense, what are the pros and cons, because there are obviously pros and cons on both sides; and thinking about we are in a new administration and thinking about states versus federal issues and how do we accomplish the goals that we all want to accomplish together.

We'll just go down the line. I'm going to make DEA speak.

MR. ARNOLD: I was hoping I could get out of here.

DR. JONES: We can start at the end.

MR. ARNOLD: That's fine. I'm good.

I travel around the country a lot, particularly in the last two years, and I talk to a lot of different medical professions, all kinds of different medical professions about different issues and different things. I talk to them about PDMPs. I talk to them about training for prescribing.

The one thing that seems to come up again and again, and again, we wish there was one -- I can't advocate this. This is my personal opinion. I don't speak on behalf of the agency at this point. But the one thing that keeps coming up all the time, we wish there was one standard. We wish there was a national standard, consistency, particularly in regards to the PDMPs; any information that's reported, who can access that information, should that be mandatory accessing that information; that kind of information that would be provided on a national scale, we wish there was one center.

Everybody thinks the DEA controls the PDMPs, and we don't. Each individual state runs all those, and the same with all the 50 different states. There's 50 different states, and there's 50 different rules and regulations regarding prescribing, dispensing, and accessing PDMPs.

In many ways, it might be better to have at least -- if we could develop some sort of national standard and be able to supply that on a national level, people to access that information and education and to further attack and address this epidemic. That's neither here nor there, but those are the few comments that I can add.

DR. AUTH: I'd also like to say that I'm not really speaking -- this is not the FDA opinion. But just from my experience in the past few years, there were several that made a strong case for keeping this at the local level and the states. We know that several states have requirements already in place. But if you're looking for making some core program mandatory, I'm not really sure there's any way to do that and get all the states to adopt

that. I'm not really sure where to go with that.

So then you're left with a federal solution, and we hear that tying it to DEA registration would take an act of Congress. I don't know that there's support for that right now.

I don't know that there's a whole lot of support for the FDA REMS, so I'm at a loss for which way to vote here. And again, this is just my opinion. I guess some of the frustration about where we go next with this, we'll save that for the next panel.

DR. KELMAN: We work a great deal with the states. Medicaid is a combined state and federal program, and I'm convinced that you have to do both. If the states don't buy in, the program won't work. They control the PDMPs, the state board of health, board of pharmacy.

Programs should be led nationally or can be led nationally, but you need local buy-in. If you don't have local buy-in, the program is less likely to succeed.

MR. COMPTON: I guess if we knew exactly

what educational standards to apply, like there was a reasonable consensus, then of course, we'd want the same standards to apply to everyone. There's no reason to think the populations vary that much in terms of their needs, but we don't have that degree of consensus.

I do think there's tremendous opportunities to take advantage of the variation across the states to learn about best practices and potential improvements. I'd love to say that 3 hours of mandatory training linked with my DEA registration would make sense, and while that has great appeal because of the simplicity of the message it gives, I don't know that those 3 hours would actually do much to change clinician behavior.

I'd like some sense that whatever we put into place will actually have the impact that we're looking for. So at a minimum, be a starting point where it was a partnership with medical specialties, with other healthcare specialties -- I'm sorry to be so medically oriented; I'm wearing my physician hat much of the

time here -- with pharmacists, with nurses, with others that play a key role.

That really I would see being the target, is how do we make this a supportive approach and not just this artificial, simple requirement that may not have the impact that we'd like it to have.

MAJ DOWELL: I think we've certainly heard a lot about the advantages of a local approach, and some states have really taken and run with this already. I wouldn't want to stop what they're doing. I think it's probably ideal to have something that if not designed at the local level, at least is adopted for the local level, so it will be more supportive and helpful to the providers there in following their own laws.

As Doris mentioned, if we want to make sure there's at least some basic education that everyone gets, I'm not sure what the mechanism is if it's left to the states. The advantage of a federal -- I think there's disadvantages of a federal program. It's hard to come up with a one size fits all. It can't be as easily tailored.

But the advantages are it could just serve as the very basics, and some of the other panels have talked about what those basics might include, appropriate treatment of pain, treatment of pain without opioids, safe treatment with opioids. If we could agree on a core of principles, we could at least provide something to support providers in states that aren't able to come up with that kind of program itself.

I'll have to leave this to FDA and others, but I'm wondering if there is a way we can come up with a system. Some people have mentioned waivers, letting states who are already doing this and have already come up a program that meets the basic criteria we've agreed on to waiver out but provide something, or have continuing education providers, or CDC or others provide something that's an option to use when states are not in a position to develop it themselves.

DR. AHADPOUR: I agree with everything that has been said around the table. I wanted to give you an example. I believe in collaboration, so

this is my opinion, not SAMHSA's opinion. I believe in collaboration. I know SAMHSA believes it, too, but just I wanted to give my opinion about it.

I think it's important that there should be a core, standard objectives that the core should have. It could be about pain management. It would be about how to treat adolescents, how to do motivational interview, just the whole concept of that.

For an example, let me give you something we just really did. The Care Act was passed last year, and in the Care Act, it says you need to have 24 hours of training for the nurse practitioners and physician assistants to be able to be -- if they're eligible in that state, to become data waivered to prescribe medication for opioid use disorder.

What we did, we put a meeting together and opened it up to the public. So patient advocates could come to it; clinical experts from all the professional organizations, they all came.

What we tried to do -- it wasn't perfect because we were trying to do it as fast as possible. Of course, if we had months and months, it would have been like a perfect meeting, and everything would have been perfect, but nothing comes perfect when you try to rush it. And we rushed it because we knew there was an opioid crisis, so there isn't that much time to really make a perfect meeting.

So when we brought everyone in, with the clinical experts from their PCSS-MAT and O, we have all these professional organizations. We reached out to the physician assistants organizations, the nurse practitioner organizations, nurses. We brought everyone in, and we said, okay, this is what we think should be some of the standards for the training. What do you think?

We really did try to be stakeholder-centric. We put this information together, sent it back to the organizations, and they tweaked it. They edited it. And I sent it back again to all the organizations. I said, "Is this something that we

could reach a consensus? Do we agree with it?" And there was agreement.

So we didn't say, okay, SAMHSA is going to make this 24-hour training; we are doing it for free. But there are other organizations that wanted to make it themselves, and that's fine, too. But we all try to follow the same objectives for the training.

So that's something to think about if there is going to be a mandatory training, try to be collaborative in the effort and try to reach some kind of a consensus. But I still believe that the training should not just focus on opioids. It should really focus on the whole person, talk about comorbid mental illness. I think that's a big factor, and having that mentorship piece I think is really important.

DR. JONES: So as a good qualitative interviewer might do, are there any things that I did not ask that you think are relevant for the conversation to move forward? I'm thinking particularly about the next panel, which is next

steps in how we move forward. What have we not raised here that would be important for people to ponder on?

DR. COMPTON: I do think that there's one other level of education that we're not completely considering. This is primarily focused on current prescribers, and yet to a current extent, I think we are operating in a system where there was a lack of preexisting education, where there needs to be upstream educational efforts, whether that's through medical schools, through dental schools, through nursing schools, et cetera.

That we need to be paying attention to that level of basic education, which has been sorely lacking when it comes to pain issues, where at least, especially in the medical community, pain was mostly seen as a symptom.

We heard this earlier today. It was mostly seen as a symptom. So if you just treat the underlying condition, it will go away. Yet we've learned enough about pain to realize it needs attention on its own, and that's an

important -- that might really change the landscape in the long run for continuing education.

In some cases, I think we're providing primary education about these topics, and that creates a complexity for designing the system in that you've got clinicians who really don't know what they're doing as opposed to those who just need better coordination among the practice.

I loved your way of subdividing our students.

DR. JONES: Other final thoughts?

MAJ DOWELL: Just to add to what Wilson has suggested, in terms of thinking about continuing education. Earlier panels have talked about should this be one time; should it be repeated; if so, how often, and other people have provided answers to that. But we might want to think about providing options -- once people have the baseline, providing options for something that's well suited for their profession, for their specialty, for what they need to learn next.

One thing I just wanted to throw out there I

heard is being considered in Rhode Island is they're requiring education on pain management and opioid prescribing. They are allowing the 8-hour training in buprenorphine to count for that. Now, I don't think that is something we would want to do for everybody, but for people who have the basics -- there have also been questions about how can we incentivize more, how can we expand buprenorphine treatment.

So is that something we want to consider is allowing that to count at least as an advanced training once people already have the basics?

DR. JONES: All right. If there are no other final comments, I'll thank the panel and thank FDA for having us here to represent some of the work that's happening across federal agencies. Thank you.

(Applause.)

Questions and Answers

DR. JONES: That was not in my notes, but my fault for not being here earlier.

Yes, we also have time for a Q&A. Go for

it.

DR. KAHN: Norman Kahn with the Conjoint Committee on Continuing Education. For those of you who are not aware, the audience is, we're the 26 organizations in medicine, nursing, pharmacy, dentistry, physician assistants, and nurse practitioners that formed a national coalition to guide and provide this education. We take the FDA's blueprint of educational partners. We've trained over 200,000 completers, et cetera.

I have a very specific question probably for Dr. Kelman. One of the things we talked about yesterday was your issue of incentives. I'd just like to clarify something I thought I heard you say earlier, which has to do with how education in safe opioid prescribing and management might qualify under the merit-based incentive payment system as either an improvement activity or a patient safety or something like that.

Will that quality now, or is there something we need to do to make that qualify?

DR. KELMAN: It's the kind of question I

never answer in public.

(Laughter.)

DR. KELMAN: Send me a note directly, and I'll get you the answer.

DR. KAHN: Thanks.

DR. KELMAN: Thanks for the question.

DR. JONES: Sandy?

MS. MARKS: Hi. I'm Sandy Marks with the American Medical Association. We've been working with Dr. Kelman and CMS on Part D issues since 2005, and one of those issues was the implementation of the opioid overutilization monitoring system, which we have strongly supported.

I think the numbers that he provided at the beginning show dramatic, dramatic reductions in the number of patients who are outliers in the Part D system. If you define them as patients who are receiving a high dose, high morphine equivalent dose of opioids, plus getting prescriptions from at least three different physicians, plus getting -- you said three. I thought it was four.

DR. KELMAN: I said more than three.

MS. MARKS: Plus getting those prescriptions dispensed from more than four or three pharmacies. Those are truly outliers, and there has been a 70 percent reduction as a percentage of people who are enrolled in Part D.

So providing physicians with data on what's happening to their patients, I'm sure most of those physicians who get contacted by their Part D plan and told, did you know your patient Mrs. Whatever was also getting opioids prescribed from these three other physicians and was also getting them dispensed from three other pharmacies besides the prescription you wrote, most of them, I'm sure, didn't know that. And clearly, there have been changes in their behavior as a result of receiving that feedback.

So I just want to strongly encourage all the agencies to think about how you can provide data back to physicians so that they know what's happening with their patients. And I think that will encourage of them to get additional training

because they'll see that they don't know as much as they thought they did, and it will obviously lead to some improvements in patient care.

DR. JONES: Over here?

DR. COMPTON: I'd like to add a caveat to that, that when we identify patients that have egregious prescribing practices, some of those patients will be clearly drug seeking. So it's easy for physicians to just have a knee-jerk reaction and say, no, I'm not going to refill your prescription because this isn't a pain issue here. It's another kind of issue.

But in those situations, I think that's where we need to equip our clinicians with the appropriate techniques to deal with those kind of patients, so that they aren't just simply saying, no, I won't write you a prescription. Because we could have reduced those numbers simply by saying, no, I won't fill your prescriptions, but the question is how many of those people were then referred to some of the SAMHSA-funded programs or elsewhere where they really need to be?

That's a key issue here, is how do we link some of the patient behaviors that are clearly at the very extreme tail end and represent my area of practice and science, addiction, and do a better job.

MS. MARKS: I don't think you would have -- you wouldn't have these dramatic reductions in the number of outliers who appear each year if the individual physicians who had been called about individual patients had simply stopped prescribing to those patients. There's something else going on.

It may be that some of those patients are engaged in drug-seeking behaviors, but maybe their physicians didn't know. So now they know they need to learn how to more safety prescribe and recognize those behaviors, right? So something is going on, and I think providing physicians with that data can really be helpful. And there's not enough of that that happens.

DR. KELMAN: Lack of coordination is just as dangerous as bad care and has to be resolved.

DR. AHADPOUR: Just very quickly, I'm sorry to interrupt. I wanted to just emphasize what Wilson said. I think it's really important that if there are patients who are coming in into a practice and you find out through the PDMP or you get some kind of evaluation that they're getting medications from different clinicians, I think it's really important to take time with that patient, not just have them out of your practice, or not just decrease their opioids, but actually look at and screening them to see if they have an opioid use disorder.

If you don't feel comfortable, we have the SAMHSA treatment locator that lists all the clinicians, nurse practitioners, physician assistants, and physicians who are qualified to treat patients with substance-use disorder. So please keep that in mind. Thank you.

DR. JONES: Yes, ma'am.

MS. KITLINSKI: First of all, I'm Linda Kitlinski. I'm a REMS education consultant currently independent, but previously served with

the ER/LA opioid REMS companies as the co-chair for the REMS CE side of things. So I've been working on this since 2009 now.

One comment and then one question for all of you. First of all, in terms of a comment, kudos to the FDA for having convened this meeting and gotten not just the REMS side of things involved but all of your organizations at the federal agency level that are working on this from slightly different perspectives, but certainly that have a shared interest in resolving this dual public health problem. So kudos on that.

One comment. Dr. Kahn here represents the Conjoint Committee on Continuing Education, and as he said, there is a wealth of experience already among the accrediting bodies and the CE providers who have been working in this space since 2012. So as you go forward, please do reach out to them because they are ready, willing, and able to do this to help.

My question is, so we now have communication as part of this meeting, and we have all expressed

an interest in collaboration, and that's important. But I think that the final point of coordination -- because this is a huge dual public health issue, and we've got all these moving pieces, and not to mention patients and the political environment, right? So we really do have to have a coordinated approach.

For my question to you guys is, we have folks present from SAMHSA, from NIDA, DEA, FDA, everyone. Would there be interest and willingness to perhaps settle upon, as you were just saying, a core group of concepts, whatever we want to call them, right, without being overly prescriptive and say, these basics about A, prescribing opioids, pain medicine, and I think importantly, the basics of addiction medicine because a lot of folks are missing that -- can we arrive at some understanding of what those might be, and then use an adaptive learning type of approach that gets at here's the basics for the knowledge transfer up front but then builds on that to meet the learner's needs so that they'll remain engaged in a continuing basis going

forward?

Because I think one of the other issues we heard loud and clear, there's so much going on out there in terms of education about responsible opioids or safe-use of opioids, or this, that, and the other thing, it's confusing for clinicians. If they participate in one program but they don't get to cover at least the basics of those three areas, then we have some gaps.

That would just be my question to pose and any discussion from the panel about willingness to work together and actually coordinate efforts as opposed to just being collaborative. Thank you.

DR. JONES: I'll take first stab at that. I will say within the HHS family, we have pretty strong coordination on efforts. In particular after the CDC guidelines came out, there was a push to think about how are we aligning our various other educational components to what CDC is saying. Similar with DoD and VA as well, they have new guidelines that have come out.

I think within the federal family, there is

interest in doing that and making sure that there's consistent messaging. We are in the midst of a transition, and Dr. Price has raised opioids as one of his top three priorities and is actually out traveling states today talking about that. So we are getting him up to speed on the work that's happening within the department.

There previously was a group, and Sandy and others from AMA and other groups were part of that, where there was an internal/external working group on opioids over the last 18 months. As we changed administrations, that group disbanded, but there are internal conversations around how we might reengage in that space, one, to get feedback from folks in the field who are doing this every day to help inform where we go from a policy perspective; but two, to also think about all the discrete projects and collaborations that could come out of that.

I think this is an idea that can be funneled into those conversations. I appreciate you raising it. I don't know if others have thoughts on it.

MR. TWERSKY: Hi. Larry Twersky, TimerCap. I'm hearing there's a huge disparity of prescriber knowledge about opioids that we're trying to consolidate. Per Mitra's data, and I love your data, by the end of today, the two days we've had, 1.3 million prescriptions of opioids have been dispensed, and 7,800 people have used opioids for nonmedical use per your slide.

With that happening, by the time you go through change management, education of prescribers, we're probably going to see a few hundred thousand people die because it has to then correlate to the patient.

What about making changes in to the patient such as -- and I'm going to leave the chronic meds alone for a second because that's already somebody who has it. But for new meds, why not just raise the fee after a certain rate so when doctors prescribe over X number of pills, it just costs the patient more on a certain fee? If that's the case, then let them write something over and above it.

How do we make some changes where the

consumer is still involved for -- we had a friend whose child of 14 had a wisdom tooth extracted, and the doctor gave her 30 pills at the time. They didn't need that. So number one, we've got to get less opioids in practice, and so how do we provide at the time of the payer, either A, more cost or provide disposable bags, provide other tools for the patients, but solving this quickly doesn't sound like it's happening by what the conversation is here.

I want to talk about what tools can be done to help, that the patients at the last minute can do it? Because I know if my co-pay went up to $100, if I had to get 30 pills and it was free for 10, whatever that number is for it, then that's important.

For chronic people, maybe we should be paying for the safes, and maybe we should be paying for tools to lock them up so that people have it. But we've got to stop this in one way, shape, or form, and I'd love for you guys to talk about it in that way, that what can also be done today, while

you're figuring out provider education because I didn't hear anything about it. Thank you.

DR. KELMAN: Let me at least try to answer that. A value-based insurance design is what you're talking about. It's an interesting idea. It can be effective, not always. But it tends to subdivide effectiveness based on the income of the patient. A poor patient is more sensitive than a rich patient.

We prefer endeavoring to get the provider to do the right prescription. In other words, if you need more than seven days for a wisdom tooth, the provider, in this case a dentist -- not to pick on dentists; they actually do a very good job -- is prescribing too much. And that's an education system more than a value-based insurance design.

DR. AHADPOUR: I agree. I think it should be a multipronged approach. There is no one single solution, and I think this is a great time for us to really think about the low-hanging fruits, look at the prevention side, improving access to treatment, the takeback program.

My son had his wisdom tooth extracted three months ago, and the dentist gave him too many pills of oxycodone. So when he came home -- I wasn't there when he came home. He went with my husband. So when I came back from work, I looked at it. I said, "How many pills were there in here?" And he said there were like 20 pills. I said, "So if there were 20 pills in here, how come on the first day 6 of them are gone?"

I actually took that bottle and put it in my purse. I still have it in my purse.

(Laughter.)

DR. AHADPOUR: I wanted to do it to the takeback.

(Laughter.)

DR. AHADPOUR: My son came back. He's like, "Where are the pills? I need them." I was like, "No, Brandon. You do not need the pills. You just take a nonsteroidal and Tylenol."

So there is a lot of different ways, but we really have to think of the multi-prong, innovative approaches to do this.

MALE AUDIENCE MEMBER: We need the mothers to be involved, apparently.

(Laughter.)

DR. KELMAN: Clearly, that's where the power is.

(Crosstalk.)

DR. JONES: I'm sorry. Which purse was that?

(Laughter.)

DR. JONES: I just want to also say that this panel was asked to talk about certain things, so it's not reflective of what HHS is doing broadly on this issue, which is we just put out $485 million to states to focus on prevention and treatment, and there are a number of other activities that are comprehensively attempting to address the issue.

MAJ DOWELL: I was going to say something similar, that I appreciate and very much agree with your sense of urgency, and there's so many other things that we need to be and are doing. We've been reminded multiple times by Doug today to focus

on education. But specifically in terms of a co-pay, I'd have concerns about that because we found that cash payments actually to be a potential signal for diversion. That's not always the case, but it sometimes is. In analyzing PDMP data, that can actually be a cause for concern.

DR. JONES: I just want to note that we are a little past time, so I think we'll take one more question, and then I'm sure the panelists will be willing to speak with folks after.

MR. SCHILLIGO: Great, thank you. Good afternoon. Nick Schilligo with the American Osteopathic Association. For the last two days, we've heard about the various requirements that are going around opioid-related education, mostly at the state level, but there are instances where individuals providers might have requirements through their board certification process or being a member of a professional association.

If the federal requirement would go into effect, how do you see the agency in charge of that working with professional associations, board

certifying entities, state medical boards, to make sure that there's not a duplication of efforts, both in what the education requirements are but the reporting of that as well? Thank you.

DR. AUTH: I think by federal requirements, you must mean REMS? Do you mean the FDA REMS program?

MR. SCHILLIGO: If the result of something like this meeting is that there will be a federal requirement for opioid-based education and training in order to prescribe opioids, how would that take into account what's going on at the state level, what different requirements are for different providers to assure that they don't have to report to various levels of government, creating a new administrative burden for them, I guess?

DR. AUTH: I think that's some of the challenges that I raised yesterday when I gave the presentation about the REMS. We don't have the answers right now. I would think that we would have something in place if it were to be an FDA REMS where we would consider allowances for certain

states. But again, if we're talking about a core set of competencies, that's going to take a whole lot of work, I think, to look through all the different state requirements and deem something okay that meets our criteria and others not.

That's a challenge that could take us some time to sort out.

DR. JONES: All right. Now I will properly close the panel, and thank the panelists.

(Applause.)

(Whereupon, at 2:55 p.m., a recess was taken.)

Panel Summary

MS. GROSS: To start off with, we're going to ask the panel moderators to provide around a 2-minute summary of what were the most important points that came out of their panels. The first panel was the patient and the professional affairs panel, and that was Terry Toigo. If you could summarize in a couple of minutes.

DR. TOIGO: We had five questions. Three of them were related to required training. I think

there was general agreement that education was important, but there were questions about how and what. There were comments about if you want meaningful patient impact, then the education needs to be tailored to the practice, that clinicians don't want people to just take a test and fill out a box. We want to be more focused on outcomes.

There was agreement that core knowledge is necessary but not sufficient, and comments about solo and small independent, both medical and dental practices are likely to find regulatory requirements more burdensome and probably provide pushback on required training.

In terms of the impact on members if a required training program were implemented, participants mentioned required certified training requirements such as there are required training programs such as certified child abuse education requirements, but that training could be burdensome on workflow.

If education in mandated, ensure that checks are done through some type of electronic means;

don't believe there is evidence that if education is mandated, that performance is improved.

Third question was related to which organizations are best situated to track. Several panel members stated that education should be linked to DEA registration because they have a tracking system in place. Everybody agreed that DEA should not be in charge of the content of the education.

Others stated that the decision to require mandatory training should be done at the local or state level since they know the landscape best. State boards are a good place to start, but there needs to be a coordinated effort.

There were comments on the heterogeneity of state requirements, particularly because providers are licensed in multiple states. Others felt that it was impractical to do it at a state level.

On the required training, I don't think there was a uniform opinion across all of the groups. I think that's probably enough. I have others, but that's good enough.

MS. GROSS: Thank you, Terry.

State panel was next, Peter Lurie.

DR. LURIE: Good afternoon. So our panel in part addressed the question of whether or not any voluntary or mandatory CME requirement is best located at the state or the federal level.

I think we had a vigorous discussion. I think that the grand conclusion was that people's first instinct is to locate at things at more of a state or local level. But I think most of the panelists agreed that they probably would not be opposed to some action at the federal level, either. So there's your non-answer answer.

But I think perhaps more helpfully, we identified a series of criteria that you might use in trying to decide whether appropriate locus for education ought to be at the state or federal level. I'll go through about eight of those and just discuss them briefly.

The first would be what is the severity of the problem. To the extent that we consider this either the inadequacy of pain treatment or the

addiction problem to be a severe one, I think most people would agree that it weighs more in the direction of federal involvement.

A second criteria was what about the adequacy of current CME requirements, and there, I think that the raw data that we have relate to, on the one hand, the expanding numbers of programs that are being offered; on the other hand, the rather limited uptake so far of the REMS program and the fact that only about half of the states have required CME on either pain or on opioid prescribing.

There will be a second one. To the extent that we felt that the coverage was inadequate, that would be in favor of more of a federal intervention. To the extent that we were comfortable with current degrees of coverage, that would be in the favor of state or local approach.

A third criteria is just one of resources, and typically, not always, the federal government comes with, at least theoretically, the ability to marshal greater resources. If that were a problem,

that would push in the direction of the federal. If we feel that resources are appropriate at the state level, obviously, that pushes in that direction.

A fourth criteria was if we believe that the education being offered at the state level was of variable quality, and related are that there might variability at the state level in terms of the content, and we've heard that some states have requirements for pain management; some have requirements for opioids. And actually, they historically have different routes.

Interestingly, most of the pain ones are the older requirements, and as the pain concern turned into a concomitant opioid addiction and abuse concern, then you started seeing a second wave of state CME requirements more recently in recognition of that.

If we have concerns that this is too spotty a coverage, that weighs in favor of federal. If not, then things might be fine at the state level as they currently are.

If we're concerned that certain prescribers who ought to be targeted, like nurse practitioners, dentists, PAs, in addition to physicians, if they're not being touched upon at the state level and we think they ought to be, that might militate in favor of a federal solution and vice versa.

Let's see what else I have. Differences in the epidemic might justify a state approach over a federal one if one thought that the distribution of patients, their ethnicity or other characteristics, their socioeconomic status, was different enough between states, then that might argue for a more tailored state-based approach.

If one thought that the drugs of abuse were different enough from state to state, then again, that would favor a state-based approach. But I think the question to us is not simply to be able to point out differences, but they need to be differences that are of a degree large enough to merit a wholly different approach.

My last two points are on the adverse effect side. One is we have to take into account the

relative burdens that might ensue from having a federal approach versus a state one. It's not obvious to me that one is inherently more burdensome than another from the perspective of the user, but that's at least something to think about. Similarly, we have to think about any adverse events that might result from a requirement for state CME or federal CME.

Again, it's not obvious to me why it would be different between the two, but we have to think about the concern raised frequently at this meeting about people opting out as a result of any requirement at whatever level. That sums it up.

MS. GROSS: Thank you, Peter.

The next panel was health systems panel. That was Wilson Compton.

DR. COMPTON. Thank you, Mary.

The health systems panel had a broad representation of both federal groups, HMO, and I guess private practice or broad academic practice would be the other two key representatives.

There was not a consensus, or at least not

unanimous agreement, on whether a federal mandate for training or a federal requirement was a good idea. There were strong opinions on both sides and well-reasoned arguments.

Some of the broad themes that I took note of were -- and I would say these aren't fully digested. These are just my notes on a piece of paper.

(Laughter.)

DR. COMPTON: So if I've left something out, I'll count on some of the members of the panel to speak up and add something in.

I think one of the issues is the complexity of trying to deal with a one-size-fits-all approach, that because we're dealing with different aspects, that pain is not a unified single entity, so addressing it with a single unified set of CME requirements seems a little extreme and certainly won't fit.

Clinicians don't come in one size fits all, either, so you have everything from people who are already pain clinicians to hematologists that don't

see patients but look at slides all day. So how would you design requirements that would address the diversity of both the patient presentations as well as the clinician issues?

On the other hand, mandates may give the issue some prominence, and so that alone may be worthwhile in changing the perception in all of medicine and increasing the acceptability of both pain and addiction treatment, which tend to be more at the fringe of medical practice at current time.

I'd also say another broad theme that I think cuts across all of these panels was medical education is not going to be a panacea for the opioid crisis, and we shouldn't expect it to be. We need to be thinking about it as one piece in a broad range of interventions, and it may not even be the most powerful piece. But it is the one we're talking about yesterday and today, and so that's what we're sticking with.

One of the questions was how frequently should we provide training, how often and how frequently should they be targeted and should such

training occur. That seemed a little uncertain. I certainly resonated to what we heard from New Mexico about a baseline level of training, which I would consider primary education. One would hope that that would have occurred earlier in your educational curriculum, but it hasn't for many people. So how would we both provide some baseline educational materials as well as follow up on an ongoing basis?

It wasn't clear how frequently or how often. There's some arbitrary limits that have been established by certain groups that at least might be a starting point, but this certainly opens us up to the need to collect information about does that produce the desired changes, because the desired changes are not knowledge, but it's actual clinical practice, and then patient outcomes are our goals.

Certainly, the nuances and complexities suggest personalization and specificity in how we implement whatever educational systems are suggested.

Are there other key things from the health

systems panel? I'm not seeing any heads nodding, and a couple of people are here. That seemed to cover it.

MS. GROSS: Thank you, Wilson.

The next panel was the patient and consumer advocates panel, and that was Sara Eggers.

DR. EGGERS: Thank you.

We had a fantastic panel this morning. It's harder to summarize than it is to actually lead the discussion, so I'll do my best.

We started our panel by asking the questions instead of answering them, and it was how can we improve chronic pain care; what are we doing to empower patients; what are we doing to improve outcomes for patients; how is education put into practice; what do providers do with the information and the learning that they get; how can we bring consistency to care; how do we address the needs for people in truly debilitating pain; and why aren't we focusing on the risk factors of opioid use disorders?

When we got those burning questions out, we

didn't get to address them all. I promised that they could be saved for this panel, so that's why I put them out right now. But then we got into what the goals of treatment, any kind of provider training, and we spilled a little bit into patient training as well.

The goals are to validate patients' needs and treat them with compassion. People living with debilitating pain want their life back. How we put patients at the center and partner with them to be part of the care process, take a balance approach to pain management? A goal would be to give healthcare providers the skills they need to communicate. It comes down to communication as much as anything.

How can we increase the providers' self-confidence and arm patients with the information they need to help them partner in decision-making? But also, how can we provide consistent and basic information that everyone needs about opioids?

How do we set patients and help them set

their own expectations about what they can get out of their pain medications? The goal would be to identify risk factors, including adolescents as one subgroup, and I'm sure there were other subpopulations we could have addressed.

The goal would be to recognize patients' fear of pain, which is a driver for a lot of behaviors that frustrate, that we've been talking about today.

Focus on competency. Give people the tools they need, both patients and providers. So patients, give them the tools to manage the medicines they have appropriately, use them appropriately, and dispose of them appropriately. Remember that education is not in a vacuum, as the point was just made.

Then we focused on solutions, and the number one, I think if I didn't say any other solutions, it was to bring patients to the table when we are thinking about the need for and the development of training.

Engage patient stakeholders as partners for

creative and person-focused solutions, and we heard a number of possible solutions in our panel. Give people the tools they need. Understand and assess how training is actually put into practice. And it appeared to be general shared agreement, alignment, that training should be required and required of all healthcare providers, and if we can put it into practice, of patients themselves, too.

I'll close by saying the panelists were all very considerate of the constraints that it would take to put this in practice in the current healthcare system, and I thought that came out in several of the remarks they made. With that, I will end.

MS. GROSS: Thanks, Sara.

The last panel was the federal panel, and unfortunately, Chris Jones was called back to the department right afterwards. So we'd ask Wilson to do a short summary.

DR. COMPTON: Well, since this is fresh in everyone's mind because we just ended a few minutes ago, I'm not going to review much about what the

panel other than to remind us that we heard from multiple participants, whether that was SAMHSA, CDC, the NIH, CMS. Those had formal presentations, but we also on the panel had FDA and DEA.

I think that sets the stage for realizing that clinician education is part of a broad range of efforts to address the opioid crisis, whether that relates towards inadequate assessment and treatment of pain by so many people in our country or the inadequate prevention and then treatment of opioid problems, which are, of course, reflected in the epidemic of overdose deaths that we've seen.

While there are multiple resources for education, we need to think about these in terms of the broad context of how we're intervening across the two interrelated but separate areas of pain assessment as well as what I would propose is the opioid addiction set of issues.

That's what I wanted to highlight for us.

MS. GROSS: Thank you.

We're going to start the panel discussion now. Dr. Throckmorton and Dr. Buckenmaeir are the

moderators, and I'm going to give each of them a microphone. Also, once again, please remember to identify yourselves when you talk for the transcriber.

Large Panel Discussion

DR. THROCKMORTON: Thanks, Mary.

Before we get started, I just wanted to say a couple of things. I tried to summarize, and you heard me summarize yesterday afternoon, the things that I heard. I'm not going to walk through in detail because I think the summaries you just heard capture a lot of the important points that we've talked about in the last couple days.

A couple things I think that are worth saluting the group, saluting the people that have attended this, first, I get a sense of shared responsibility. I think there's an acknowledgement that we all own a part of this. Trip I think quoted Pogo, "We have met the enemy, and it is us."

I think that's in a broad sense right; that is, we all have aspects of this that we are -- all things that we could be doing -- and I heard that

in these last couple days. I think that's a terrific acknowledgement of the importance of this and our shared responsibility.

I also like this meeting because it's given us an opportunity to talk more than usually across silos, and I hope, at least speaking for myself, it helped me question some of my own assumptions. I've heard things that have made me think about some of the things that I had thought I understood about the nature of the problem here and maybe some of the solutions, and I hope that others in the audience had a similar experience.

We are talking about one of several tools that are being used in this space, and so I understand that that made it challenging for the participants. We were not talking about the incentives and things that Jeff Kelman talked about at CMS. That's a different tool to use. We were not talking about enforcement actions that the DEA takes, that the FDA can take, and things like that. Those are different ways to get people to straighten up and fly right.

Today, the focus was on education, and whether that was an education of someone that needed to know more than they did, or it was education of someone about someone else's poor behavior, or whether it was education of -- I guess the third was the DEA. So it was a pill mill thing, wasn't it? It would be educating to go and take an enforcement action.

It was education that we were focused on, and I think the conversation that we just heard summarized captures what we heard the last couple of days, a broad understanding of the importance of education, the need to improve the current kinds of education, and then I would say a vigorous back and forth about whether or not something mandatory and something federal is really necessary, and strong voices on each side with a lot of good conversation.

That leads me to the question I want to pose to the group, and it's intentionally pointed to try to stimulate a good conversation. We have other things to talk about that are on the screen as

well, and let's just see where this takes us.

To boil down what we've been talking about the last couple of days, I'm going to say there's a first question that I'd ask -- I'll pick on people if people don't offer -- should the federal system do more, or should the focus be on doing what we're doing better?

That's in a sense the first question we're being asked. Are we doing the right stuff, we need to do it better, or do we need to more? And more in this case, in the educational sense, is obviously mandatory prescriber education and those kinds of things. To the extent you have other non-education things you think we should prioritize above any changes in education, we'd be interested in that, too. But first and foremost, should we do something new, or should we improve what we're doing?

Who wants to answer?

DR. AHADPOUR: This is Mitra Ahadpour. For the response to this question, I think we can always do better. To my opinion, if we are having

an opioid crisis and -- we are talking right now, about every 15 to 17 minutes, someone has died from an overdose. I think that's a sobering fact.

I think there is more innovative approaches, collaboration, and sometimes it does take a few people to solve a problem. But in this situation, I think collectively, we can do much better. It really will take everyone in the community, not just the federal programs or the states.

I am saying that we need as a community to come together and work on the solutions.

DR. THROCKMORTON: You're not done. So that's fine. Now I need to know what. So one thing and how? It's easy to say we all need to work together. I don't think anyone in this room would disagree with that.

What one thing new should the federal government do, and how should we do it?

DR. AHADPOUR: I have a lot to talk about, but I'm going to keep it to one thing. So one thing, which I've already mentioned before, and this is a perspective from a physician who is a

primary care physician, I did not feel comfortable, but I joined SAMHSA. I did not feel comfortable when I took my 8-hour data waiver training to go and see patients. And I didn't feel comfortable in pain management because I didn't get the training in medical school, and it was at University of Maryland. My residency was at GW.

So I went and took a whole year of classes on my own to become board certified in addiction medicine. After that, I felt, hey, now I feel comfortable seeing patients.

So I think the mentor piece is really important, that everyone, all the clinicians will not have a whole year while they're in private practice to go and take all these trainings. We need to come up with a short training but have that mentor piece, and that free mentorship I think is very important.

DR. THROCKMORTON: Great, thanks very much. Myra?

MS. CHRISTOPHER: I think the answer is clearly yes, and the one thing is to develop a

parallel plan focused on improving the treatment of chronic pain. I think the way you do that is by implementing the National Pain Strategy fully.

DR. THROCKMORTON: So implementing the National Pain Strategy, that's the additional thing that -- great, thank you very much.

That end, anybody down there?

MR. BRASON: What we're doing, we can do better. I think that is the direction that we should go. I am not for -- because I don't think we can fit it in appropriately -- mandating a certain segment of education. Education makes a difference. Education brings change. Education brings comfort for the practitioner to meet the patient need.

Mandatory, I think would focus more on just the prescribing of opioids because of all the dynamics of pain management. We learned that if we taught appropriately for best practice for pain management, we got changes in opioid prescribing. I don't believe that we will get best pain management if we just direct it towards opioid

prescribing.

I think if we do what we do now better and create a blanket of some of the standards that need to be in there, then the states, then the organizations, then SAMHSA, then the Federation of State Medical Boards, everybody has the ability then to appropriate that into what they're already doing, and I think that will make it better.

DR. THROCKMORTON: Thank you very much.

MS. ROBIN: I'm Lisa Robin with the Federation of State Medical Boards. One thing I think that's really apparent to me after two days of listening is I think that we certainly need to do more research. And before implementing any sort of mandatory education at any level, there needs to be greater research out there to really know what works, really know who should we educate, and really put it in place something that can change practice.

I agree with you. If it's just narrowly focused on here's how to prescribe, I think you miss the boat on really changing practice.

DR. GREENBLATT: Larry Greenblatt from Duke. I'm going to pose that we consider moving towards a system of accountability and measurement, where if we're really going to focus on safe opioid prescribing, perhaps there could be some system where we actually collect data. Individual prescribers who are prescribing opioids would need to demonstrate whether they use their state PDMP at least some percentage of the time, how many patients have pain agreements, urine drug screens, how many received appropriate and effective education, and actually not just say yes, I took my classes, and I got my multiple choice, but rather here's the data from my EMR. I'm doing it.

DR. THROCKMORTON: So I'm hearing doing better what we're doing now, is that --

DR. GREENBLATT: I'm talking about some mandatory reporting of process measures to be able to continue to prescribe opioids.

DR. TERMAN: I'm Greg Terman from the University of Washington and the American Pain Society. I continue to think that we need to have

some competence measure for people to be able to prescribe controlled substances, and I think a test of some sort to allow people to show competence and getting their DEA registration is a first step.

Now, remember, what all these different letters means, right, DEA, the Drug Enforcement Agency, and FDA, Food and Drug Administration, does that sound like good pain treatment to you, necessarily? I'm not sure that that's going to help pain treatment. That's a separate issue, related, but if no one got prescribed opioids, people would still get addicted. People would still have pain. If everyone got prescribed opioids, people would still get addicted, and they would still have pain.

It's just a piece, so there will need to be voluntary or mandatory state-based probably education that is accompanying that prescriber question. Because I'm not willing to take all of the blame, Trip, for the problems that we're having. Unless we can get heroin dealers to go into the PDMP and say about their particular

clientele -- this is outside of medicine. There are important medicine points here that we need to do a better job educating on, but it's not all about prescribing.

DR. THROCKMORTON: Just to clarify, you're arguing for not a new mandatory federal activity in terms of education but rather in terms of competence testing, something we've not really talked about very much the last couple days. I just want to make sure I'm understanding.

DR. TERMAN: Right, and the tests could be from Federation guidelines. It could be from the new blueprint. It could be from Massachusetts Medical School or the Pennsylvania Medical School, but all published competencies that could be used to build a test. But that's just part of the issue.

COL BUCKENMAEIR: I would like to clarify where my statement comes from our experience. So we had to deal with this earlier because of the pressure of the war. We went through the same discussion, and these questions of evidence kept

coming up saying, well, why are we going to do different?

One of the things that was stated, well, there's never been a randomized controlled trial of parachutes, and yet the paratroopers demand having one of those every time they jump out of an airplane. We felt we were in that situation. Moreover, we did a top to bottom look at our system comparing to your civilian systems. We met that standard of care, and in many cases, exceeded it, and yet we were snatching defeat from the jaws of victory.

A less than 10 percent died of wounds rate, and yet these soldiers were not returning back to useful life, and in many cases, opioids were a prime reason, particularly when suicides were involved.

So the option for business as usual was no longer an option, and the issue when I say providers are responsible for this, I do think we have significant culpability in what has gone down. I absolutely agree with both you and Myra that

there's lots of other factors. This is an extremely challenging problem, and that's why I think we made the decision that some level of a base foundational education was needed for every provider in our system as a start but certainly not the end. And I think we could manage this.

I also agree with Myra, which I often do, that we should stop having this discussion of whether or not we're going to do something. I think our posterity will look at us very unfavorably if the answer is we're doing just fine, we need to do things better.

I think there are times when you have to be aggressive, and the data will come along as we launch on this. But I do think there needs to be some sort of standard that the states can start with, and then based on their localities will have to adjust as they've already done in New Mexico and other areas.

DR. THROCKMORTON: Others?

DR. KATZMAN: Hi. I'm Joanna Katzman here. So I'd just like to say I agree with Trip, I agree

with Dr. Dowell immensely, and I agree with Dr. Ahadpour.

What I think is definitely the country needs mandated continuing medical education really concentrating on pain and safe opioid prescribing. I really believe that the opioid prescribing cannot be delinked from pain at all, and that the emphasis on pain really has to be the forefront. That's been my realization over the past six, seven years.

I think that the federal government has done an amazing job in terms of the NIDA trainings, the CDC trainings. Everyone in the federal family is doing a lot of work in terms of CME, but we're realizing, and with FDA in the long-acting REMS, it is not enough. That's why we're here.

So that's why I'm in support of mandated continuing education for all clinicians with prescriptive authority as well as voluntary continuing medical education for those without prescriptive authority.

Here's what I think. I think that the federal government should get together -- the

federal agencies should get together or the FDA should get together and figure out 2 or 3 hours of a common core curriculum that they could deliver to the states, and then the states that have met already those requirements, like Dr. Dowell said, should perhaps be considered to get a waiver. The other states that are not doing that, this should be their blueprint for having to perform the CME that is required.

Many states that are doing CME right now, it really needs to be looked at carefully, are just for pain prescribers or just for folks that own a pain practice and so on.

The other things are, in this education, you can teach clinicians about how to use a PDMP. You can teach clinicians how to talk to patients. You can teach clinicians about how to actually address a controlled substance agreement with your patient. So this education is actually real world. It has a lot to do with the patient advocacy group, and it will address a lot of these issues. And I think the next round of it can be the mentorship that

Dr. Ahadpour talked about, from SAMHSHA. Thank you.

DR. THROCKMORTON: Thanks. Two real quick questions in follow-up, if I could. One, do you have a preference for how that mandatory education should be done at the federal level, and then, second, I don't know if you've had a chance to look at the blueprint and how to identify those few elements, given the complexity that we've heard of trying to do not just training about the safe use of opioids but also pain management, which I think we all agree is important. That's a lot. How to identify those common elements?

DR. KATZMAN: I've looked at the FDA blueprint a little bit. I need to definitely look at it a whole lot more, but I've done a lot of work with Trip and Trip's shop at DVCPIM. I can tell you that I could safely help you narrow it down to 2, 3 hours to get the common core curriculum to what's necessary. Thank you.

DR. THROCKMORTON: Great, thank you. Penney?

MS. COWAN: Penney Cowan, American Chronic Pain Association. I think the answer to your two questions is both. You need to do what you're doing better, but you need to do more. I think that's what really needs to be done.

DR. THROCKMORTON: I think doing better was sort of an -- I heard strong consensus we needed to do things better for different things, yes.

MS. COWAN: Right, but you need to go beyond --

DR. THROCKMORTON: We need to do more, also, is what we're hearing, yes.

MS. COWAN: But you also need to do more. I think it needs to be both. I don't think it's either/or.

We all got here because of our education, correct? No one would be sitting here without it. So education really is the key to everything, and I think we need to educate providers, all healthcare providers, around the aspects of pain and pain management.

Myra said it, the National Pain Strategies,

I think you have that blueprint right there to start with. Find some of the best experts in education because the educators are the best ones, and then make it mandated by the federal government to do it. And make sure that you have the patient voice in that. But I think it is through the education that you're going to -- that's how we learn. That's how you-all got here, like I said. I think that's really what we need to do.

DR. THROCKMORTON: Do you have a view about how that should be done?

MS. COWAN: I'm not sure who the best educators are in this country. I think there's probably --

DR. THROCKMORTON: No. I meant what fed rules or tools should be used to do that.

MS. COWAN: I think there should be a voice in each of those that were up here, the DEA, the FDA, NIH. I think those three definitely would be in there, SAMHSA. I don't know that it's for me to say who the best ones are, but I think that there should be an expert panel who decides who should be

in it. But if you don't have the educators in there, you're still going to be spinning your wheels.

DR. THROCKMORTON: Great, thank you.

DR. TERMAN: So the Center for Disease Control and Prevention sounds like a really good name for somebody that should help treat pain. It may be hundreds of millions of people who have chronic pain. It may only be 60 million people. That's still a lot.

It was really heartwarming actually to see CDC up here talking about motivational interviewing that they're teaching and other behavioral health strategies for taking care of pain. I think it's great.

I wouldn't necessary agree that taking Suboxone training is the same as pain education. I've taken that, but it was wonderful to see the various things that are coming out.

I'm afraid I don't necessarily agree with Chris -- I'm sorry he's not here -- that there is great communication between the different Health

and Human Services family. Every one of the people had their own education.

I think it'd be a great opportunity for someone to go and look -- and don't tell my bosses at the University of Washington; I've actually done all of those educations, including the states ones -- and look and see what are the common elements. Because I can tell you that some of the federal ones disagree on certain points.

Anyway, CDC sounds like a place, and they seem to be very interested in that.

DR. THROCKMORTON: Thanks. Next?

DR. GREENBLATT: Larry Greenblatt from Duke. I think we have a very difficult task in that. What we want to do is make whatever comes of this feasible. It also has to be palatable to practicing physicians, who we talked about earlier. They're very, very busy. They're right now feeling under a lot of strain, burnout, et cetera. But at the same time, we don't want to introduce something that is ineffective.

I think we need to figure out how do you get

a 2- to 3-hour, or whatever it's going to be, 5-hour training that actually improves practice.

I think patient outcomes would be the ultimate thing to measure. That's very hard, and there are all these other confounders. For example, we learned from NIDA, that states that have legalized medical marijuana have seen huge drops in overdose deaths. That might be one approach.

It's all about process measures, and those are the things I was talking about earlier. It seems to me you could even set up a natural experiment here where if you had certain standards that were set forth by the FDA or the CDC or some other federal agency, and states were free to implement whatever type of training that met those standards, and maybe Montanan is going to do it face to face, but let's say Missouri is going to do it all online, and New York state is going to do it with small groups of mentorship or whatever, then you could look at who got the best change in process measures, in outcomes of practice.

Then that could essentially become -- those could be like the best practices. Because right now, we know that a lot of CME, as it's currently delivered, doesn't change practice. In fact, the vast majority doesn't. People go, and they sit in rooms. They listen. They take notes. If you give them a test, they would do better on a test, but if you look at what their patients got from them before and after, it's the same. And 2 to 3 hours of training that improves my knowledge but doesn't improve my practice is wasted time.

DR. THROCKMORTON: Thank you.

DR. EGGERS: Sara Eggers from FDA. But I'm going to put on my social science research hat and say following up on Lisa and what you just said about intervention research, I would say if there's not a very strong foundation of formative research into the individuals who are part of this system, the individuals, the providers, the people living with chronic pain, the people who have episodic pain, the people at risk of substance-use disorders, and the people who are suffering from

those, to understand their mental models, I'll call it, of their situation and of what their needs are, that formative research is as important, I believe, as research on any interventions and learning itself.

That could tell you a lot about what the misperceptions are from our expert point of view, as well as what they care about. If you do mental models type research right, you can find out what individuals care about, and it will go a long way in being patient-focused as well as addressing using good risk communication tools.

If that research is solid and there, then great. If it's not, then that would be a way to partner with patient stakeholders and others to do that research.

DR. THROCKMORTON: Let me follow up just a little bit. I'm reminded of what Peter asked about yesterday. So I think we all recognize the importance of research in the area. We're also in the middle of a really profound healthcare crisis here. So I want to make sure we don't research

something to death. I don't know to use -- to put it bluntly.

How do you balance the need to understand things better and the need to get something done here? Because I think we all acknowledge the need for the latter.

DR. EGGERS: That's a very fair question from Doug because he stressed that to me earlier, that you just can't come up with a solution. Research is done all the -- there will continue to be research with all the other interventions going on, and so if you could prioritize the research that's being done, I might suggest that the formative research could be one of the research priorities.

DR. THROCKMORTON: Excellent, thank you very much.

MR. BRASON: Fred Brason, Project Lazarus. Looking at the feasibility -- and you just mentioned about being patient-centered, and that's one of the first times that's been mentioned here in the last 15, 20 minutes. It's more been

prescriber-centered.

We have to make sure that what we're talking about is going to ultimately help the patient. Keeping them safe and responsible, as pain free as possible, and obviously, not having adverse events.

We don't know if mandatory education brings that about. We do know that education brings it about, but I also know that I have prescribers that if a patient has to go to a refill, I immediately refer them to pain management somewhere. That's not feasible everywhere. I know in my county, that means they have to go to another county.

So we have those kind of issues, and we're trying to draw the prescriber into this from five years ago. We now have that. They're happy to get the guidelines. They're happy to get the education. I think if we just say now you have to do this, that changes that.

North Carolina just went to a mandated 3 hours over 3 years, but we're also at a place where we've been in every community with every prescriber. There is that more buy-in, so there

isn't a pushback with that. It's included with their CME total, so it's not adding to, it's just defining, in a way.

The feasibility is what is going to implement into best practice and not stop practice.

DR. THROCKMORTON: I want to make sure I understand, and this is something we actually haven't talked about in the last couple days, but it's been raised before; the notion that mandatory education is less likely to be effective because people, I'll say, resent being forced to do it or something like that.

That's what you're talking about here, isn't it?

MR. BRASON: Yes, yes.

DR. THROCKMORTON: When you say you know non-mandatory education works, and you're not sure whether mandatory education works, part of it is grounded in that --

MR. BRASON: Yes.

DR. THROCKMORTON: -- the idea that people made to do something would not learn as much or not

take --

MR. BRASON: Or not implement. All right. Here's my canned stuff that I have to do. I did it. I didn't like it. I'm not going to follow through with it, or I'm just going to opt out and just not even bother so that I don't have the issue whatsoever.

DR. LURIE: I'm a researcher, so it's always tempting to say more research is necessary. But I'm with Trip on this. I think the amount of time it will take to resolve these questions satisfactorily is very, very long. In fact, it's probably never. People have been researching CME and its efficacy for probably two decades now. We're left with a bunch of very hard-to-resolve questions.

I don't know of any special reason to believe that those uncertainties are any more resolvable in the opioid pain area than they are anywhere else. Given the limitedness of what is being considered here, 3 hours of a physician's time in the context of everything he or she has to

do in a year or two, it just seems so little.

To me, the evidence bar is maybe not what it is for parachutes, but it's not very different than that. It seems to me to make sense, and it seems to me it's not a massive burden. It seems to me that in the context of what we're dealing with here, it's actually a very powerful message to the prescribing community in general and to patients if the community comes together and says, we feel so strongly about this that we're going to mandate it. There's a message there, too, quite independent of the content.

Fred, as to your question about the idea that the mandatory-ness itself might be somehow disadvantageous, actually that I'd like to see some research on because I doubt that strongly. I think that it's a profound question in its way because it goes to the appropriateness of federal imposition of standards that go much beyond opioids, right?

So that I'd like to see researched, but I do think that right now, there's no evidence for that assertion.

MR. BRASON: I understand. There is not any evidence. Let me clarify the difference in mandatory. Within a state system with local medical boards and so forth that are already engaged with the prescribers within that state, they have a camaraderie. They're part of that. So when there's a consensus there that we need to mandate so many hours of CME to do this, there's more buy-in.

From the federal level suddenly saying, no, you have to do this, that's a totally different context from the local person saying, who are you telling me when I've already got my medical board here saying this?

So I think there's a difference in who's saying who has to do what. So that if at the federal level, whether it's the DEA, FDA, CDC, or whomever saying that every prescriber in the nation now has to do this, without the local state authority support in initiating that, I think we would lose in that context if it came to do that.

DR. THROCKMORTON: Thanks.

Peter, can I ask you a question because you raised another point that I hadn't heard in the last couple of days, the value of a federal action as signaling. Another part of the forest here, we up-scheduled hydrocodone a couple of years ago and made it harder to prescribe. You couldn't call in prescriptions and things.

One of the things people talked about that action doing is sending a message, resetting prescribers' expectations and understanding about the use of, in this case, hydrocodone combination products that were being used, 100 million prescriptions a year or something like that.

It sent a signal. And what we saw was a 12 percent reduction in net prescribing for all opioids, something like that, largely attributed to I think what some things people have written to that action.

Is that signaling thing, is that the one example of the place where we could point to evidence for a federal action, sending that kind of signal and actually dramatically altering behavior?

Maybe that's not a good example. I don't know.

DR. LURIE: Well, I'm all for signaling. I don't think that's the best example. I think what happened there, based on the papers that we published, is you got an immediate decrease in hydrocodone, and that was the intervention. Stamp out the refills, and the refills were stamped out. It was almost like a surgical approach where you said hydrocodone in refills, and that's where all the reduction was.

There was some new prescribing that was done as probably bit of a subterfuge. There was some prescribing of other drugs to compensate. There was some prescribing of larger prescriptions to compensate. But fundamentally, that intervention did just what it did.

DR. THROCKMORTON: So physicians' perceptions weren't --

DR. LURIE: I don't think it was about that. That doesn't mean that it didn't send a message, and that doesn't mean that messages aren't important. I think that they are. The surgeon

general wrote a letter to every physician in this country. Do I think that people read it and that educated them in some way? I do not.

Do I think it sent a message that the surgeon general and the federal government care? Yes, I do. Do I think it sent a message that this problem is of a gravity that merited a once-in-a-lifetime intervention because no surgeon general has done that since Dr. Koop in the '80s? Yes, I do.

So I think that you can send a message, absolutely, by something like this, and I think moreover, you can change -- to me, I look at it -- I think all of us agree that education is a small fraction of the solution here. I think all of us agree it's important, but I think we also agree modestly that it's not huge.

But you can change the social milieu sometimes, and I think we can learn from tobacco in that respect. I think that there are things that have been done in tobacco that do not literally in and of themselves have had an impact upon tobacco

consumption, but that together we have created a social milieu in which the consumption of tobacco is not as acceptable as it once was.

It's the accumulation of things. All these things different actors do in different times and different places add up to something, and suddenly, we have a whole new generation of people to whom tobacco smoking is unacceptable.

DR. THROCKMORTON: I'm seeing several heads nodding vigorously.

DR. LURIE: I think something similar can be done and that a requirement for education can be some fraction of that.

DR. THROCKMORTON: Thank you.

Myra, I think you had a comment or --

MS. CHRISTOPHER: I just wanted to say one thing. I think it's a false assumption to think that it has to be the priority of the federal government because I can attest to the fact that this is a priority for the states. There is not one state board, not one governor that this is not a priority for them. And I would just, again,

believe that it will be more successful if we can figure out how to work through with the state boards of all the health professions.

DR. THROCKMORTON: Penney?

MS. COWAN: Penney Cowan, American Pain Association. It's making me a little nervous hearing about more research, more this. I think what I just want to remind everyone is that there are a lot of people out there living with pain that want their lives back, and they want it back yesterday. They don't want to be in pain anymore.

So I guess I'm imploring upon you to figure this out quicker than keep talking about it. I think I said before, we need action now, and I know you have to do it and do it right. But we've been talking about it for a long time, and I am really concerned about all the people out there who are now taking their lives because they are in pain and they can't live with it anymore.

That's what I wanted to say, that we really have to do something, and we can't just keep talking.

DR. THROCKMORTON: Great, thanks. Myra?

MS. CHRISTOPHER: Peter, I agree with you. In the IOM report, we talked about in sum, we said we need a cultural transformation in the way pain is perceived, judged, and treated. A cultural transformation will require education of a lot of different stakeholders, but it will not be sufficient for a cultural shift, the kind you're talking about. We know how long that took with regard to tobacco, and we also know how much money it took.

Now, the elephant in the room, I think, and I've been absolutely stunned that the issue has not been raised, is that via a populist movement, we have a brand-new administration, and the House has now passed healthcare reform that is dramatic and from my perspective, draconian.

Regardless of which of the various models we might latch on to or build out that we've heard discussed in the last two days, we're talking about big bucks. We are talking about hundreds of millions of dollars.

So my question is to those of you in the federal agencies -- and I don't mean this to sound rude, but you're not the most popular people in America these days.

Greg, when you were talking about the CDC, I think there's a fair amount of animus against the CDC because of the way the guidelines were promulgated.

It seems to me that a question that has to be answered is not only what are you going to do but how in the world do you intend to pay for it, and I want to know if there's any discussion in all of this at this point.

DR. THROCKMORTON: Well, I'll answer generally, and the general answer is it depends on the tool used to accomplish it. If you're talking about a federal decision to impose a federal educational mandate or something, that's why I asked the what question as my follow-up.

If you tell me you need a federal system, I need to know which federal authority, which federal path you would like to be used. Because depending

on which one you choose, then the budgetary questions and all of those things have to be worked out.

FDA has a certain set of authorities under our REMS that the Congress has given us; takes you down one path. DEA has another set of authorities. CMS has other sets of authorities. State boards have a fourth set. There are a series of authorities that are out there. Depending on which one you, Penney, say, you Myra, say we should do, then it takes us down different paths as far as where the money comes from and those things.

It's an incredibly important question, but it starts with that discussion.

MS. CHRISTOPHER: And you're confident there is money down this path?

DR. THROCKMORTON: I do not do money.

Jeff, actually Myra raises culture. I think you were the first person to mention cultural transformation in terms of what needed to happen here. You talked about it when you talked about incentives. You said if you really want to change

behavior, look to incentives, don't look at things like education. I'm shorthanding.

Anything else you have to say about changing culture? I'm hearing a lot of interest in doing that around opioids.

DR. KELMAN: I think if you're serious about this, you have to change culture. I'm always impressed every time we look at the disparity in healthcare in different communities. That's been worked on at Dartmouth for many years, where you have the same patients, different communities, different forms of treatment. And I think we'll find the same thing in opioid prescribing.

If we get a change in the culture around opioid prescribing, the problem will go away. And I think it's well beyond education and even beyond incentives. I think it behooves us in the medical profession to promote the cultural change, and if I knew how to do it exactly, I would tell you.

DR. THROCKMORTON: Are there other things you can point to beyond -- so we talked about the three types of tools, enforcement, incentives, and

education. Are there other things that we should be talking about without trying to pin you down to the one thing?

DR. KELMAN: Those are very big tools to use. If you could really have -- everybody were educated, if everybody were incentivized, and everybody had the appropriate enforcement, I don't think we'd have a problem.

By the way, don't ask me where the money's coming from, either. We don't answer questions like that.

DR. THROCKMORTON: I'll just note that you didn't include education in the two of the three tools you mentioned there.

DR. KELMAN: Education as spoken.

DR. THROCKMORTON: I see. Others?

DR. AHADPOUR: This is Mitra Ahadpour. One more thing I wanted to add is the culture change I think is extremely important, and maybe we need to look at it as a bigger picture and look at -- there is social media that we haven't even tapped into. This is a new generation, and we've noticed -- I

looked at some research on adolescents and how they use social media, and how if the social media says that such -- for an example, such an illicit drug is acceptable, more adolescents go and use it.

My suggestion is that maybe we should look at social media for the clinicians but also for the consumers because the patients that are informed, informed patients make better decisions, and then they go to their practitioners. They can really let the practitioners know. If the practitioner is overprescribing an opioid medication, they can say, no, I am not interested in this medication, or I am interested in physical therapy, or I want to go to a chiropractor.

I think the social media aspect shouldn't be costly. It's something that it would be interesting to use and gather data.

DR. THROCKMORTON: Great, thank you.

I'm going to transition. I wanted to ask another question of the group just to make certain that FDA knew where everybody is coming from. So one of the other aspects we talked about was the

scope of the educational efforts. The REMS is currently focused on prescribers, and there's been a lot of discussion about whether or not to expand that to other groups in the healthcare setting that play an important role.

I heard lots of support for that. Does anyone want to argue for the scope of the REMS remaining focused on the prescribers, or is there a consensus that a broader education for us would be important? Whatever level of activity we do at the federal level, it would be important for it to be broader.

DR. GREENBLATT: I think realistically for the kinds of things to happen that we're talking about, you got to involve other members of the healthcare team. It's no longer a solo sport. It's a team sport.

I think that CMS is recognizing that in some of their codes and things that they're willing to pay for now, transitional care codes and the chronic care codes, recognizing that other members of the team -- collaborative care for depression is

now funded. That could be different members of an office staff participating and play a role.

If you could reach out and train other members and then maybe even fund those activities, there's no reason it has to be the prescriber, right? A nurse could do the education. Somebody at the front desk could be looking at the PDMP for me. Somebody else could be making sure that the patient has a controlled substance agreement. Whatever it is that we want to have happen, it can be done broadly across the office.

What you'll get from a lot of providers is they'll say, my staff is busy. They're just as busy as I am. We're all maxed out. But if you had some money behind it, then maybe individual offices could actually pay for more hours or an additional staff member, whatever, that could allow some of these things to happen and get the focus off the prescriber.

DR. THROCKMORTON: Thanks.

Yes? Identify yourself, please.

MS. BURNS: Hi. Anne Burns from the

American Pharmacists Association. We know from the TIRF REMS, that it's very important to have pharmacy included in the loop mainly from an education back to prescribers if, for instance, the prescriber isn't registered to inform the prescriber that that needs to happen. We strongly promote pharmacists and the role that they can play in addressing opioid misuse. So we would be supportive of pharmacists' inclusion.

DR. THROCKMORTON: Great, thanks.

Other have any -- yes, Trip.

COL BUCKENMAEIR: I just want to mention -- we mentioned a culture change, which I absolutely agree, and that we need to take some of this burden off of the prescribers, that they're not the only issue. I agree with that, also.

I think as we're discussing the lack of resources, but we're going to try to resource to do something, that patients have to be part of that program. While training is directed at providers, there needs to be an equal effort that's directed at patients so that this cultural change isn't

being driven from the top -- I'm using an euphemism now -- from the medical profession, but that we're trying to get both sides of this coin with the patient being the focus of this effort to meet somewhere with this cultural change.

DR. COMPTON: Wilson Compton. I wanted to echo what Trip just said in terms of the other key participant that we haven't thought about are patient behaviors or haven't thought about it as much. I think I don't quite have a plan for how your REMS program could be expanded to include that, but that seems a natural extension to the other potential clinicians that are involved, including pharmacists, other healthcare staff, in a collaborative care model as well as patient behavior.

I would also suggest that just going back to your last question in terms of something we might do, that irrespective of whether there is a federal mandate for training, there will be at state levels. And something that we could provide as federal agencies and a federal group are some

information about what are the best common denominators for that training. We won't have the final answer, but there are ways to bring together experts that we can do like almost nobody else can.

DR. THROCKMORTON: I know, Lisa, your group has done a lot of work in that area, haven't you?

MS. ROBIN: Right, and I think that states would appreciate the resource. I really believe that if we came up with some common things, that they would appreciate the resource.

MS. CHRISTOPHER: I sound like one-note Annie, but the National Pain Strategy report has a whole section on public education and communication. It's outlined. There's a strategy outlined for how you do that, as there is for education of healthcare professionals.

So I once again will appeal that we go back to I think solid work that was done a couple of years ago now and don't just start from scratch once again.

DR. COMPTON: I like that we don't have to reinvent the wheel.

DR. THROCKMORTON: Looking at the -- we have about 5, 10 minutes left here. I'm looking at the points that were identified for you-all to think about. I'm looking for the things that people might want to comment there.

We've talked about aspects of all of them at one time or another here, ask everybody to look and see if there are things there that you think are missing or that we need to have some additional comment on. Otherwise, I guess I'd invite folks in the audience to make some comments, ask some questions, put you guys on the spot.

MS. CHRISTOPHER: One more time, I'm going to raise the issue about the importance of looking at cultural and ethnic diversity as curricula are developed.

DR. THROCKMORTON: Great, thanks.

DR. TERMAN: So if you do read the National Pain Strategy, you'll see that one of the groups that's not here that's going to be very important for prescriber education, are the people that write the tests that get people to actually be doctors or

nurse practitioners or dentists or whatever, healthcare provider. They aren't here today, but they are certainly in the broader picture and plan for implementation of the National Pain Strategy.

I'm not sure -- again, it's a little different if we're trying to help people prescribe safer than if we're going to try and get people to practice better pain medicine because prescribing is just a small part of the pain medicine.

DR. THROCKMORTON: Great, thanks.

Why don't I invite anybody that has some comments to make, why don't you just stand up and make them hard.

DR. KAHN: I'm just going to add some comments from the perspective of the Conjoint Committee. Remember, we're your educational implementers out here. So on July 7th, we're going to have having a meeting, and I can just share with you right now, there are two or three questions that we're going to be addressing from what we've learned today.

One of them is the question of how do we

know what we've done so far has been a good job? Have we really done well? We've educated 208,000 completers. Are they the right ones? We don't know that.

So we're going to be asking ourselves the question of should we do more of what we've been doing and just how valuable has it been. We're going to be asking ourselves a question of what else we can do, and I'm quite confident that I can say that we're going to be looking at out of the box. We've been so much in the box here today. Every time we talk about education, we talk about a 3-hour course.

We got out of that box a little bit yesterday, and we're going to be out of that box on July 7th. We're going to be talking about adaptive learning. I can guarantee it. We're going to be talking about somebody getting five questions a week for 3 months until they get them all right. We're going to be talking about other ways of personalizing it to what it is that the clinicians really need.

Then the third thing I'm sure we're going to be talking about is how do we integrate education into practice. We can't separate education from practice. That's again part of the box that we're trapped in right now. We got to get out of that box and look what Kaiser's done and what the University of Washington has done and what the VA has done, and how they integrate education with clinical decision support and academic detailing and mentoring, and all of these things, dashboards, performance measures, all of those things that are done.

The rest of what we're doing in clinical practice through performance measures, through clinical data registries, we have to explore how we can do that in our educational efforts in meeting this.

The final thing that I'll just say is we need to focus on the right question, and there are two questions that are hovering over us today. One of them is how can we educate more people. I know that you have to answer that question because you

have a law, but we also know that that isn't the question.

The question is what you identified on July 12, 2012, which is how can we have an impact and how can we prevent adverse outcomes that happen from misuse of opioids? And that's a much broader question than should we have mandatory or voluntary education.

DR. THROCKMORTON: Great, thank you.

MS. WHITE: Hi. My name is Julie White. I'm the director of CME at Boston University School of Medicine. I'd just like to also compliment the FDA. This has been a fascinating two days.

I also wanted to say, though, that as someone who is in the trenches, that the education we are doing is making a difference. It is changing practice. We're seeing that. We are seeing after four years that people are calling us and saying, look, we're implementing system-based changes. We need your help to come in and support that with education.

You may not feel like you're making a

difference, but this is. This whole initiative is, and I just want to thank you for that.

DR. THROCKMORTON: Thanks very much.

Anybody on the panel want to have last words? Going once?

DR. LURIE: I'll take one. We've talked about cultural change, and the first thing that people say is it's just so difficult. It's so impossible. It takes a sea-change. Every possible interest group needs to be involved. We all need to be involved.

I think what we forget is that actually cultural change of a massive extent happened in this very field in the last 15 years. Somebody pulled it off. Now, it may not have been especially favorable the way things have turned out, but the fact is that 15 or 20 years ago, there was a certain set of attitudes towards opioids and towards pain treatment, and here we are 20 years later with a completely different one.

So cultural change is possible. There's no question, and it can be quick and widespread. The

question is if one concludes that there was adverse cultural change, what can we learn from the way that was pulled off in our own efforts to reverse things?

Closing Remarks

DR. THROCKMORTON: Thank you, Peter.

I think we'll make that the last comment. First, thanks to everyone. Please thank all of the panelists and participants.

(Applause.)

DR. THROCKMORTON: Second thing, thank you for your participation. As I said, I think this has been a really fascinating meeting and made me question some of the assumptions I think I brought into the room the last couple of days.

Two small housekeeping things and then Peter has a comment he wants to make. The blueprint is out for comment. I would encourage people to give us comment. We genuinely are interested in making it better. Whether we have to do more, we need to do better. We understand that.

The second thing is related. I'm interested

in resources to think about as we think about this patient education. If there is a resource that someone could point to for what that kind of an outline might look like, I think we'd be interested in knowing about that, too, as we digest what we've heard the last couple of days and make the decisions that we're going to have to make here in the coming months.

Peter, does not have anything. So with that, I wish everyone a safe trip, and thank you so much for coming.

(Whereupon, at 4:30 p.m., the meeting was adjourned.)

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