FOOD AND DRUG ADMINISTRATION (FDA)

CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

IMPACT OF APPROVED DRUG LABELING ON CHRONIC OPIOID THERAPY

PART 15 PUBLIC HEARING

Friday, February 8, 2013

Bethesda Marriott

5151 Pooks Hill Road

Bethesda, Maryland 20814

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16 Epidemiology, CDER, FDA

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18 Douglas Throckmorton, MD, Deputy Center Director, CDER,

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

2 Opening Remarks

3 DR. THROCKMORTON: Good morning, everyone.

4 Something seems to have thinned the ranks just a little

5 bit. I can't imagine what that might have been. I hope

6 people are safe, whether they're here or headed home.

7 Welcome to the second day of this meeting.

8 Again, yesterday we heard some very valuable things.

9 I'm looking forward to the comments that we'll have

10 today. And there will be a little bit of shuffling.

11 People have, of necessity, had to leave early and

12 things and so we'll be needing to give us just a little

13 extra time to make sure we have the names right. And

14 I'll apologize in advance for any glitches that occur

15 there.

16 Mary, we can start right in with the first

17 panel if you'd like. And I have Mr. Capolongo, William

18 Schmidt, David Bagnall, okay. And then after that I've

19 got write in people. So maybe you could -- so P.

20 Jackson and then Avi Israel, Judy Rummler, okay. And

21 Lexi Reed Holtum. Okay. Great, thank you. Mr.

22 Capolongo, good morning. Whenever you're ready sir,

1 and take your time.
2 MR. CAPOLONGO: Here we go. And do I get a
3 clicker? I think there was a clicker. There we are.
4 All right, thank you. Good morning from the members of
5 the Arachnoiditis Society for Awareness and Prevention.
6 What do the words mysterious, illusive and
7 taboo have to do with today's hearing? The rapidly
8 expanding segment of society that I represent suffers
9 from a horrific and painful disease of the spinal cord
10 that is mostly iatrogenically caused. It's called
11 adhesive arachnoiditis. Ask yourselves if you've ever
12 heard of it, and be honest.
13 Sadly, this mysterious condition remains
14 elusive to many in the medical community, despite the
15 multitude that contract the disease every year. Even
16 some here today who propose new limitations and
17 regulations on long-term opioid therapy for non-
18 cancerous pain have bravely admitted their ignorance on
19 the topic, the various members of this and other
20 patient advocacy groups.
21 Adhesive arachnoiditis is a severe
22 inflammatory response to a subdural insult, either

1 chemical, surgical, microbial or trauma causing the
2 internal nerve root structures to permanently swell and
3 adhere onto the inner walls of the spinal cord, the
4 arachnoid membrane, as it progressively restricts the
5 CSF flow.
6 The resulting injury is permanent, producing
7 progressive neuropathic pain at levels beyond your
8 imaginative comprehension. It is often described as
9 the pain of terminal cancer, without the release and
10 comfort of death.
11 Grossly misdiagnosed for various reasons,
12 including the fear of reprisal, arachnoiditis sufferers
13 must often endure humiliating circumstances as they
14 fight for an honest diagnosis and lifelong treatments.
15 Most if not all lose everything that they've
16 ever worked for: their livelihoods, their marriages,
17 enduring friendships, their dreams, but mostly their
18 sense of self respect as they deliberately are
19 misinformed and unfortunately tagged with other
20 trashcan diagnoses as they desperately seek relief from
21 their relentless agony.
22 Thus, over time, they are often and sadly

1 rejected, considered expendable casualties, collateral
2 taboo, by the same medical industry that created them.
3 Depending on the level and progression of the
4 disease, symptoms span a wide gamut from severe sensory
5 disturbance, chronic intractable neuropathic pain, the
6 permanent paralysis along with other severe physical
7 disorders, and disabilities too appalling to describe
8 here.
9 We honestly believe that this horrible and
10 shamefully misdiagnosed malady, one that is neither
11 cancerous nor non-cancerous, is unique and cannot be
12 pigeonholed into either of the two categories proposed
13 in PROP's petition, which is currently under review by
14 the distinguished members of the committee.
15 In a recent letter from PROP to our director,
16 Dr. Kolodny admits that the model for his petition was
17 flawed, since it failed to consider incurable, non-
18 cancerous disorders, such as arachnoiditis. We
19 couldn't agree more. Therefore we wish to propose that
20 a third category be created for these incurable, non-
21 cancerous conditions, one that would recognize, first
22 recognize the severity of the modality and then it

1 exempts sufferers from any restrictive policies that
2 would limit their access to opioid consumption, since
3 there's no other treatment.
4 Stimulators have proven to be ineffective
5 over the long-term. Intrathecal pumps, surgical
6 repairs and other popular invasive therapies, such as
7 epidural steroid injections, which are, by the way, not
8 indicated or approved by the FDA, nor recommended by
9 the manufacturers due to the reports of serious adverse
10 events, including the development of arachnoiditis,
11 have proven to be disastrous when implemented by
12 furthering the progression of the disease.
13 In fact, Dr. Antonio Aldrete of the
14 Department of Anesthesiology at the University of
15 Alabama Birmingham, and Director of the Arachnoiditis
16 Foundation, was recently quoted on ABC news that as
17 many as 10 to 15 percent of all epidural steroid
18 injections are intrathecally placed, which is
19 specifically contraindicated by the FDA, grossly
20 underreported, and the number one primary suspect as
21 the cause for developing arachnoiditis according to
22 your own agency. These patients will no doubt develop

1 chemical meningitis, which precedes arachnoiditis,
2 requiring opioids for the remainder of their lives.
3 So to us it's crystal clear why opioid
4 prescriptions have nearly tripled since 1991. The
5 explosive growth in invasive procedures by the
6 exploiting medical industry to treat back pain is well-
7 documented. According to Dr. Martin Makary of Johns
8 Hopkins in his bestselling new book Unaccountable, over
9 30 percent of medical procedures and surgeries,
10 nationwide, are completely unnecessary.
11 Additionally, nearly 64 percent of all
12 epidural steroid injections, a known cause of a
13 neurological damage such as arachnoiditis, are also
14 unnecessary, exposing patients to needless risks,
15 according to Dr. Laxmaiah Manchikanti, Director of the
16 American Society of Interventional Pain Physicians, 64
17 percent.
18 With 9.5 million steroid injections given
19 every year, in the last three years, that's millions of
20 people, yes people, that were needlessly exposed to
21 serious harm and the potential need for lifelong opioid
22 use. Take a look at that graph. The graphical

1 correlation is quite interesting, isn't it?
2 Recently our patient community was made
3 aware, by the CDC, that 57 percent of patients that
4 received tainted epidural steroid injection therapy to
5 treat their back pain have now contracted
6 arachnoiditis; that data just came to us last week.
7 Fifty-seven percent during the fungal meningitis
8 outbreak are contracting arachnoiditis. They're not
9 contracting fungal meningitis, they're contracting
10 arachnoiditis.
11 And we have been alerted by these very same
12 patients, and their families, that they are now being
13 coerced, against their will, to have additional
14 injections before they would qualify for opioid
15 medications to treat their condition. This is simply
16 unacceptable, and wrong. It should not be tolerated
17 but investigated.
18 In closing, we wish to thank the FDA for
19 allowing us to present our perspective on this
20 extremely complex issue. We understand and sympathize
21 with those who have lost family and friends as a result
22 of their horrible addiction. No one wishes to be an

1 addict, and we appreciate your efforts to first
2 identify and then limit opioid exposure to disqualify
3 candidates. However, please keep in mind that the need
4 for opioid consumption is not always by choice, nor
5 addiction. Thank you.
6 DR. THROCKMORTON: Thank you, sir. Mr.
7 Schmidt?
8 DR. SCHMIDT: There we go. Thank you very
9 much for the opportunity to come and address you today.
10 If we could bring up the first slide, I think I have
11 control of it beyond this. My name is Bill Schmidt.
12 I'm the president of my own consulting company. I come
13 here as an independent industry consultant. I'm a
14 neuropharmacologist by training.
15 And in the 40 years that I've been working in
16 this area, in academic and in industry-related
17 research, I've been the vice president of clinical
18 development for five companies. In the last seven
19 years, as an independent consultant, I have supported
20 more than a hundred companies in North America, South
21 America, Europe, Middle East, and Asia in development
22 of analgesic drugs.

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1 I've helped to support five products that are
2 FDA approved that include narcotic-related analgesics,
3 drugs to treat narcotic dependency, drugs to treat
4 alcoholism, and drugs to treat the side effects of
5 opioid analgesics, and I've helped to support many
6 other companies in developing novel analgesic products.
7 When I submitted my summary to the FDA, I had
8 eight different ideas that I wanted to discuss. Because
9 of the limits in time, I think I'll have time to
10 discuss only six or seven of them. The first is that
11 not all patients respond to opioid drugs in the same
12 way.
13 This is from a study that I helped to support
14 more than 10 years ago, that was a postoperative pain
15 study. Patients underwent total abdominal
16 hysterectomy, or colon cancer surgery. In their
17 immediate postoperative care, they had patient-
18 controlled analgesia. They had the ability to control
19 the amount of morphine or morphine-like drugs that were
20 administered for pain control.
21 The median across all of the study groups was
22 about 70 milligrams of morphine equivalent over five

1 days. That's not too surprising for postoperative pain
2 relief. But when we look at the individual variation,
3 I looked at every single patient record, and none of
4 these patients were narcotic dependent at the time they
5 came in. Yet some patients used as little as one
6 single 10 milligram dose of morphine over the five
7 days, other patients, at the extreme, used 272
8 milligrams of morphine to control their own pain.
9 What we've learned in the 15 years since the
10 new opioid receptor was cloned is there is only one
11 gene product that controls the new opioid receptor,
12 whether that's in the brain, in the gut or anywhere
13 else in the body, but there are many spliced variants
14 that have been identified.
15 Dr. Gavril Pasternak at Memorial Sloan-
16 Kettering has been one of the most progressive
17 investigators in this area. He's identified more than
18 20 splice variants. And depending upon how the opioid
19 receptor is put together, this governs whether you are
20 able to respond to morphine or fentanyl or other opioid
21 drugs.
22 And in his investigations, he's found that

1 with deletion of certain parts of the receptor, or
2 splice variance in other ways, you can vary by as much
3 20-fold the responsiveness as an analgesic to morphine
4 or to fentanyl or vice versa.
5 To put this into context with real patients,
6 it's not surprising that patients with cancer pain, and
7 with non-cancer pain, require quite varied amounts of
8 narcotic analgesics to control their pain.
9 This was a study that was published in 2007
10 that looked at variance in the new opioid receptor,
11 here that is expressed as OPRM1, and catechol-O-methyl
12 transferase. There is variation in the COMT gene as
13 well.
14 What these investigators found was that with
15 certain variants of the opioid receptor and the COMT
16 gene, cancer patients required 80 milligrams of
17 morphine or morphine equivalent drugs per day to
18 control their pain. Other patients required 147
19 milligrams of morphine equivalent doses. In other
20 respects these patients were identical.
21 Some patients don't respond well to opioid
22 analgesics at all. I'd like to talk and think about a

1 patient who died more than 10 years ago, Cathy Hainer.
2 She was a correspondent for USA Today, and over the
3 course of several months she chronicled her history of
4 cancer pain, breast cancer pain, through front page
5 stories in the newspaper.
6 It was the same week that she posted her
7 final report that I started a program for treating the
8 symptoms that she found most distressing. She found
9 that the constipation caused by opioid analgesics was
10 so intensely painful that she chose to stop using
11 opioid analgesics all together and die in severe pain.
12 Patients like that I keep in mind every single day when
13 I'm working on developing new classes of analgesic
14 drugs.
15 Outside of the area of cancer pain, patients
16 with non-cancer pain have great variations in their
17 levels of pain and in their requirements for different
18 types of drug treatments. This is a study that was
19 published in 2009 in support of the approval of
20 duloxetine, or Cymbalta, for treating osteoarthritis
21 pain. Duloxetine now has that approved indication in
22 the label.

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1 I did not participate in this study but I use
2 this to illustrate the fact that patients who came into
3 this trial had, on the average, pain scores of 6.2 on a
4 zero to 10 scale, meeting moderate to severe pain,
5 despite the fact that nearly 60 percent of the patients
6 were using maximally tolerated doses of non-steroidal
7 anti-inflammatory drugs at the time they joined the
8 trial.
9 The trial was designed so that they can
10 continue taking NSAID drugs in addition to duloxetine.
11 Duloxetine did separate from placebo in this trial. It
12 was, I believe, used as one of the registration studies
13 in support of duloxetine.
14 What's important though is not just that the
15 average pain was 6, but in studies that I've designed
16 we typically have, as inclusion criteria, a range of 4
17 to 8 on a zero to 10 scale, meaning that many patients
18 who come into osteoarthritis studies have severe pain.
19 Some of them are able to tolerate NSAIDs,
20 some cannot. Some are able to tolerate opioids, some
21 cannot. But clearly they need to have long-term
22 support of their osteoarthritis pain, especially if

1 they are not candidates for joint replacement.
2 I think the statement at the top of this
3 slide is perhaps one of the least controversial over
4 all the statements that we've heard in the last day or
5 so. Cancer pain patients may need opioid therapy for
6 the rest of their life. Pain often increases with
7 progression of disease. But the labels that we have on
8 all analgesic products today do not distinguish between
9 cancer pain and non-cancer pain.
10 This is the kind of label that was approved
11 only last month, and it does not talk about cancer pain
12 in its indication or usage. In the label it does talk
13 about open-label studies of cancer pain patients where
14 totally daily dose was between 20 milligrams to 640
15 milligrams per day, and the average total daily dose
16 was 105 milligrams per day. So putting limits on
17 opioid doses may put a substantial burden on cancer
18 pain patients who may not be able to achieve adequate
19 levels of pain control.
20 The industry has responded in some respects.
21 Over the last four years the FDA has approved four
22 abuse deterrent, or crush resistant, opioid products

1 that include both immediate release and controlled
2 release analgesic products. We've heard yesterday that
3 among the controlled release analgesic products, that
4 the abuse of these compounds has been substantially
5 lower than the original compounds. This is one step
6 forward; it's not the only way that we can improve upon
7 the therapy of chronic pain with opioids or non-opiate
8 analgesics.
9 We need to have better training for
10 physicians in medical schools, residency programs and
11 postgraduate programs. In the IOM report that was
12 published a couple of years ago, it stated that in many
13 medical schools physicians receive only about two hours
14 of training in treating pain. Yet among primary care
15 physicians, about a third of their patients come in
16 with a pain-related complaint.
17 Some states' medical examiners have now
18 required physicians to take additional postgraduate
19 training. The State of Oregon, more than 10 years ago,
20 required six hours of face-to-face training in pain
21 control or end of life care, in addition to one hour of
22 online training.

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1 I can't tell you whether that has changed the
2 practice of pain medicine in Oregon, but I think, from
3 my perspective, working with the Eastern Pain
4 Association, with other pain associations that I'm a
5 member of, I think that that is one step in the right
6 direction. It's beyond, however, the mandate of the
7 FDA.
8 We might want to consider, as a possibility,
9 requiring at least biannual medical education, such as
10 attendance in pain conferences or CME credits for
11 physicians or other prescribers to maintain their
12 Schedule II prescribing privileges.
13 Or we may consider that, instead of
14 prescribing two weeks of opioid analgesics for acute
15 postoperative pain, such as dental extraction
16 procedures, maybe we should provide fewer doses
17 initially and require a consultation before the
18 patients receive refills.
19 Maybe we need better training of providers so
20 that they establish contracts with patients who require
21 long-term opioid therapy, and they consider switching
22 to alternate therapies, they treat side effects and

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1 they continue the use when it's not appropriate.
2 The FDA can, of course, restrict the types
3 and the doses of opioids that are available, but
4 perhaps, instead of restricting these all together, we
5 might want to create a class of physicians who are
6 qualified to use these higher doses for a longer period
7 of time, by virtue of their specialty training and
8 licensure.
9 Or we might require that with patients who
10 receive new analgesic prescriptions, where there is an
11 abuse-resistant product available, that the older non-
12 abuse-resistant products are withdrawn from the market,
13 and we favor the use of abuse-resistant formulations.
14 DR. THROCKMORTON: I'd ask you to come to the
15 end of your comments please. Thanks.
16 DR. SCHMIDT: And my last comment is the last
17 point on this slide, which is that we currently have
18 better regulations on the dispensing of pseudoephedrine
19 than we have for any opioid analgesic. And I would
20 encourage additional measures to take a look at ways
21 that we can prevent doctor shopping or pharmacy
22 shopping among patients who have chronic pain to

1 prevent the abuse of these drugs. Thank you.

2 DR. THROCKMORTON: Thank you. And Mr.

3 Bagnall?

4 DR. BAGNALL: Thank you. I'm speaking today

5 on behalf of the American Academy of Physical Medicine

6 and Rehabilitation, which is the national association

7 representing more than 8,000 physical medicine and

8 rehabilitation physicians known as physiatrists. The

9 AAPM&R is the only national physician specialty

10 organization committed exclusively to serving the needs

11 of people with a wide range of disabilities and chronic

12 conditions, including pain.

13 Physiatrists treat adults and children with

14 acute and chronic pain, musculoskeletal and neurologic

15 and rheumatologic disorders, persons who have

16 experienced catastrophic events resulting in

17 paraplegia, quadriplegia, traumatic brain injury,

18 spinal cord injury, limb amputations or any other

19 disease process that results in impairment or

20 disability.

21 The nature of our specialty implies that our

22 patients have pursued appropriate acute and sub-acute

1 care, but continue to carry pathophysiology that
2 prevents them from functioning normally. Specifically
3 patients with chronic pain who present to physiatrists
4 have almost always demonstrated an objective
5 pathological lesion, and have failed a number of
6 interventions. Additionally, these patients have
7 suffered a loss of function associated with diffuse
8 psychosocial problems.
9 Physiatrists are committed to effectively
10 managing the complex clinical, functional and
11 psychosocial issues associated with chronic pain
12 management. Our goal is always the restoration of
13 function by minimizing pain. It is our philosophy to
14 first treat a patient's functional status and design a
15 means of obtaining functional goals rather than
16 approaching the patient's symptomatology.
17 This comes about through a process of shared
18 decision making between the patient and his or her
19 physiatrist. From the beginning of care, a physiatrist
20 educates his or her patient to understand that a
21 patient must first bear responsibility for their
22 situation, and must understand the pathological

1 process, potential treatment options, including risks,
2 benefits and alternatives, and most importantly
3 understand that the goal is to restore function not
4 eliminate pain.
5 The AAPM&R and its members share the concerns
6 with many in this country about how to balance the use
7 of potentially high-risk narcotics to maximize our
8 patients' functional capacity, with the effect that the
9 misuse of these medications has on individual patients,
10 their families, and our society.
11 We believe that physician education,
12 including the recently FDA mandated risk evaluation and
13 mitigation strategies for the safe use of opiate
14 analgesics, continues to be the most effective means of
15 decreasing the risk of morbidity associated with the
16 use of opiate analgesics.
17 However, we are also concerned that well-
18 meaning regulatory intervention will invariably lead to
19 unintended consequences that will unfairly affect some
20 of Medicare and Medicaid's most vulnerable
21 beneficiaries, individuals already struggling with
22 chronic disability.

1 The three areas of greatest concern to our
2 specialty, on behalf of our patients, are the arbitrary
3 determination of mild, moderate and severe pain,
4 limiting the use of opiates to 90 days, and codifying a
5 maximum daily morphine equivalent dosage. The use of
6 such subjective terms as mild, moderate or severe is
7 problematic because it is arbitrary.
8 The language allows significant
9 interpretation, and therefore can and will be used by
10 patients and physicians to gain access to what they
11 perceive as being appropriate treatment, but will also
12 lead to unnecessary suffering through under treatment.
13 Physicians tend to agree that there is
14 variability in pain intensity over the continuum of
15 chronic nonmalignant pain. Pain may be moderate during
16 periods of rest, but frequently become severe when a
17 patient is physically active.
18 Patients are frequently treated with an
19 opiate in anticipation of physical activity, thereby
20 maximizing function by minimizing the impact of pain.
21 This is most appropriately accomplished by using
22 regularly scheduled sustained release opiates.

1 Likewise, opiates provided for longer than 90
2 days are effective for carefully selected patients. To
3 assume that a patient with chronic nonmalignant pain
4 will spontaneously achieve relief of their symptoms in
5 90 days denies currently accepted pathophysiology and
6 clinical experience.
7 It is our position that in appropriate cases
8 the use of sustained release opiates in nonmalignant
9 chronic pain has the potential of maximizing function
10 and quality of life, decreasing the risk of a
11 depression, anxiety and deconditioning commonly
12 observed in these patients.
13 In addition, in carefully selected patients,
14 the prolonged use of sustained release opiates may
15 reduce the risk of abuse and addiction over short-
16 acting opiates when used for nonmalignant chronic pain.
17 Our third concern regards establishing a
18 maximum daily morphine equivalent. Universal
19 population conversion tables utilized to determine
20 equivalent morphine doses in patients treated with non-
21 morphine opiates differ widely and are based on
22 heterogeneous groups of patients, including those of

1 various ages and with a variety of medical
2 comorbidities.
3 Significant clinical experience supports
4 patient variances in the analgesic effect of opiates
5 and opioids, and pharmacokinetic differences are
6 clearly proven to exist among patients. Therefore an
7 arbitrary cap on daily dose based on morphine
8 equivalents for nonmalignant chronic pain would not
9 serve treatment needs across the spectrum of patients.
10 In fact recent literature suggests a nonlinear opiate
11 variability, calling into question the accuracy of
12 morphine equivalent conversion paradigms.
13 Just as important, such a cap could provide a
14 false sense of security for those clinicians using
15 doses lower than 100 milligram morphine equivalents.
16 Serious adverse events, including respiratory
17 depression, cognitive impairment, addiction and sudden
18 death have been demonstrated in opiate doses below 100
19 milligram equivalents.
20 I appreciate the opportunity to comment
21 on the use of opiates in the treatment of chronic pain.
22 Our academy strongly supports the national search for

1 meaningful solutions to reduce opiate-related harm and
2 ensure public safety. Our focus should never waiver
3 from improving the education of clinicians, not only on
4 opiate prescribing, but also with an assessment and
5 treatment of pain that incorporates patients in a
6 shared decision making process that results in clearly
7 defined functional goals and improvement of quality of
8 life. Thank you. FDA Questions
9 DR. THROCKMORTON: Thank you. I'd asked if
10 any of the panelists have questions, and maybe I'll
11 just begin with one for Mr. Capolongo. You said that
12 57 percent of the individuals that had developed fungal
13 meningitis had developed arachnoiditis.
14 MR. CAPOLONGO: No, that's not what I said.
15 DR. THROCKMORTON: It wasn't? Okay, thank
16 you. Please clarify.
17 MR. CAPOLONGO: The CDC has notified us that,
18 as of last week, 57 percent of those that were given
19 the tainted steroid, not everyone -- you know 13,000
20 injections were given with the tainted steroid. Only
21 650 cases of fungal meningitis has been confirmed.
22 DR. THROCKMORTON: How about the other

1 thousands?

2 MR. CAPOLONGO: They're coming down with

3 arachnoiditis. And we say 57 percent are coming down

4 with arachnoiditis; these injections were intrathecally

5 placed, which is contraindicated.

6 DR. THROCKMORTON: So again, let me -- I'm

7 trying to make sure I understand. So 57 percent of the

8 --

9 MR. CAPOLONGO: Fifty-seven percent --

10 DR. THROCKMORTON: Of what number of --

11 MR. CAPOLONGO: -- of people that were

12 injected are coming down with arachnoiditis. That's

13 the only statement we got from the CDC. To dissect

14 that at this point, I don't know exactly what it means,

15 but they're claiming that besides the fungal

16 meningitis, they are having patients being confirmed

17 with significant arachnoiditis, adhesive arachnoiditis,

18 clinically significant.

19 So what does that tell you? It tells you

20 that somehow these were inadvertently placed epidural

21 steroid injections. The number one cause of

22 arachnoiditis, and the number one need for increased

1 opiate dependency. If you look at the chart, you can
2 see that they're running parallel. The correlation is
3 indisputable.
4 DR. THROCKMORTON: Thank you. Do other
5 people have questions for the -- Bob?
6 DR. RAPPAPORT: Also for Mr. Capolongo. You
7 said that the patients were being coerced to have
8 additional injections before receiving appropriate
9 opioid therapy. Who was coercing them?
10 MR. CAPOLONGO: We have a tremendously large
11 group of individuals in our organization, of families
12 that have just come into it that had loved ones
13 injected with the tainted steroids. Our Facebook page
14 is just flying wildly with reports of people that are
15 contracting arachnoiditis, but their doctors are
16 demanding that they go in for another series of steroid
17 injections in order to be eligible for opiate
18 treatment. This is just -- this has to end.
19 DR. RAPPAPORT: Do you have any information
20 as to why the doctors are requiring the additional
21 injections?
22 MR. CAPOLONGO: We've actually got in touch

1 with OSHA, and we also got in touch with Workers'
2 Compensation, and we're trying to find out who has the
3 authority to mandate certain medical treatments before
4 other treatments. Usually it should be the doctor, but
5 see the doctors are saying, well now we're being
6 mandated, this is the way our protocol has to work out.
7 Everyone's passing the buck, but the poor patient is
8 suffering in the meantime.
9 DR. THROCKMORTON: I had a question for Mr.
10 Bagnall also then. You said something about nonlinear
11 morphine variability in your comments related to why
12 the dose limitation or something wasn't appropriate.
13 Could you just clarify what you meant by that?
14 DR. BAGNALL: Well just the difference
15 between -- and Dr. Schmidt talked about this to a large
16 degree. There's a variability in pharmacokinetics, not
17 only among patients but also among morphine equivalent
18 analgesics, and so that there is not a linear
19 correlation between those two. And the concern that we
20 have is that if there is a 100 morphine equivalent
21 limitation, how will it be managed among different
22 types of medications and among different patients.

1 DR. THROCKMORTON: Let's move on to the next
2 group then. Is it Bridget?
3 UNIDENTIFIED FEMALE SPEAKER: Pete, Pete
4 Jackson.
5 DR. THROCKMORTON: Pete Jackson. Mr.
6 Jackson, good morning.
7 MR. JACKSON: Good morning. I'm Pete Jackson
8 with Advocates for the Reform of Prescription Opioids
9 and I've been given the honor of reading a statement on
10 behalf of Sarah Bowker of Buffalo, New York who could
11 not be here today.
12 Before I proceed with Sarah's statement I
13 just wanted to offer two quick observations based on
14 some comments we've heard here. First we've heard from
15 groups representing individuals with various pain
16 conditions, and also from many commercial enterprises
17 representing products or services designed to reduce
18 the risk of harm from prescription opioids. Neither of
19 these perspectives diminishes the need to correct
20 opioid labeling, which is not evidence-based.
21 The other comment I just wanted to make in
22 response to something Mr. Schmidt said here this

1 morning, and just to clarify that the PROP labeling
2 changes do not apply to cancer patients. So if that's
3 not obvious.
4 And now with Sarah's statement.
5 "Good morning. I know a thing or two about
6 chronic pain. Luckily, I am still alive to tell my own
7 story. Many times you hear from a third party who lost
8 a loved one to the opiate pain killer circus ring that
9 exists today. I, too, almost lost my life after an
10 addiction to hydrocodone.
11 "I am a 36-year-old wife, mother, and have
12 over 10 years of law enforcement service. I am not an
13 experimental teenager. I never had a history of drug
14 abuse, but now I am 16 months sober from a long battle
15 with a cocktail of prescriptions including hydrocodone.
16 "In 2008, I was diagnosed with rheumatoid
17 arthritis. The birth of my daughter brought on a
18 painful flare up unparalleled to anything I have ever
19 experienced. The aftereffect of my pregnancy sent me
20 into a tailspin of rheumatoid arthritic pain. My
21 rheumatologist prescribed hydrocodone for a short
22 period.

1 "It worked, for a short period. I very
2 quickly developed a tolerance. When I consulted with
3 my doctor about the hydrocodone feeling less effective,
4 he referred me to a pain specialist. Anyone in pain
5 enough will profess the same feeling about pain
6 killers, they just want the pain to stop.
7 "It is with this feeling that I saw the pain
8 specialist. The first thing they did was increase my
9 hydrocodone. They didn't even ask if I was comfortable
10 with that increase. They didn't ask what I did for
11 work, if I cared for children, if I drove a car, and I
12 was in pain so I didn't care. I was miserable.
13 "However, they did not tell me anything about
14 the possibility of addiction, emotional changes, or
15 suicidal behavior. Nor did they have any care for
16 interactions I may have had with my other medications.
17 No one ever mumbled a sentence to the like of, this is
18 a very strong, powerful drug; you'll need to be very
19 careful and watch for changes in behavior.
20 "This especially enrages me to this day.
21 Before they gave me the hydrocodone, I provided them
22 with a list of other medications to include Prozac,

1 Wellbutrin, Lyrica, Cymbalta, prednisone, clonazepam,
2 methotrexate and a DMARD to treat my rheumatoid
3 arthritis.
4 "After I developed a tolerance, and was
5 obviously addicted to the hydrocodone, I visited the
6 specialist again. By then I was in a fog. I was
7 taking more hydrocodone than prescribed, and it still
8 wasn't helping my pain. I was more concerned with the
9 amount of Tylenol I was ingesting in fear of liver
10 toxicity.
11 "The specialist smirked, then she told me
12 about Norco. The same amount of hydrocodone with less
13 Tylenol, 325 milligrams instead of 500 milligrams per
14 tablet. The script was written. I began to spiral
15 downward. I was not showing up to work. I couldn't
16 take care of my child. Everything I could do was
17 prefixed with a pill, just in case.
18 "I returned to my pain specialist, this time
19 obviously taking way too much hydrocodone, and still
20 not getting relief. Red flag. This time they gave me
21 the Norco and added, alternately, Dilaudid, oxycodone
22 and MS Contin. They explained that I should take the

1 second pain killer for breakthrough pain when it was
2 really bad.
3 "At this point, I literally couldn't finish a
4 sentence. Words would not come out of my mouth. I was
5 losing my memory. Emotionally, I felt nothing. I had
6 become severely depressed. I convinced myself that my
7 husband and two-year-old daughter were better off
8 without the burden of my being.
9 "For a long consecutive period of time, I
10 swallowed more pills at bedtime than I could hold in my
11 hand, and figured if I didn't wake up in the morning,
12 oh well, no loss. I didn't know at the time that long-
13 term use of opioids can cause hyperalgesia, a high
14 sensitivity to pain that aggravates an already painful
15 condition.
16 "During this time, I was taking 8 to 10 Norco
17 pills a day, on top of everything else. I had no
18 explanation of why I had not died yet. One day,
19 Wednesday, after lying to my husband, and myself and
20 everyone else, for two years about the amount of Norco
21 I was taking, I walked downstairs in tears and put my
22 head in my husband's lap. I had hit bottom and fessed

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1 up.

2 "By Friday, I was in withdrawal, tremoring,

3 night sweats, vomiting, and having hallucinations. I

4 called my pain specialist to ask for help but they

5 insisted they couldn't do a thing for me unless I came

6 into the office. I explained that I was hallucinating,

7 unable to drive, et cetera, and I asked them one more

8 simple question. If I try to detox at home, will I

9 die? They said they could not give me any information

10 over the phone.

11 "I was devastated. These drugs would be the

12 means to the end of my life. I wanted to die. But

13 with the support of an amazing husband and the love of

14 a two-year-old daughter, I made it, on my own.

15 "One month later, I watched the news and saw

16 a story about another local boy, Michael, 20 years old

17 with everything to offer, who put a shotgun to his head

18 and took his own life. He was also addicted to

19 hydrocodone and could not get the help he needed

20 either.

21 "Always plenty of hydrocodone, never any help

22 for the disaster it creates in its wake. Why did I

1 survive and not Michael? It is an existential question
2 that I cannot answer, but I know for sure that having
3 been given a second chance at life means that I will
4 tell my story as many as I have to in order to save
5 lives.
6 "Pain is subjective, but hydrocodone is a
7 slippery slope. I was given Lortab after my C-section
8 when they cut open my abdominal wall, took out my
9 organs, a baby, and then put me back together and
10 stitched me up. How is it that the same medication is
11 written for a toothache, bursitis, frozen shoulder, and
12 ankle sprain?
13 "Why is this medication being prescribed for
14 long-term use? I understand there are some who need
15 the drug, cancer patients, veterans with their limbs
16 blown off, accident victims, but a continuous supply of
17 hydrocodone for chronic, unexplained pain that isn't
18 getting better?
19 "I still struggle with chronic pain, and
20 maybe I will for the rest of my life, but at least I am
21 still alive. It scares me when I hear about other
22 chronic pain patients take the defensive accusatory

1 stance about taking their pills away. It is such a
2 transparent statement of addiction. They don't even
3 know what they are saying because these drugs, they
4 cause so much confusion, lethargy, memory loss, and a
5 depressed mental state.
6 "As you continue to research into this
7 matter, think of my daughter, Ava, who nearly lost her
8 mother because she was so heavily drugged, unable to
9 conceive the repercussions of her child having to
10 forever deal with the fact that her mother committed
11 suicide or died of an overdose. Act for the people who
12 don't even know their lives are dangerously close to an
13 end.
14 "The power of hydrocodone needs to be
15 reserved for severe, immobilizing pain. Further, it
16 should never be prescribed for long-term pain
17 management. Thank you for hearing my story." Sarah
18 Bowker.
19 DR. THROCKMORTON: Thank you. Mr. Israel?
20 MR. ISRAEL: Good morning. I am going to
21 read a statement from Tish Westrup regarding her
22 daughter, Cassandra; as you can see on the screen, a

1 beautiful girl who died way too young.

2 "Cassandra Lewis was born on November 4th of

3 1987 in San Clemente, California. She grew up in

4 Irvine, California with her mother and a grandmother.

5 She had wonderful friends that lasted from kindergarten

6 through college. She played soccer, ran cross country,

7 was a cheerleader. After finishing high school, she

8 went on to graduate from a fashion institute of design

9 and merchandising in Los Angeles.

10 "Cassandra was introduced to opioids in high

11 school, like so many other teenagers. It was fairly

12 innocent at the time; what began as a normal teenager

13 and just turned into a most difficult battle of her

14 life. Cassandra was addicted by the time she turned

15 21. The next two years were the toughest she would

16 ever face. One drug led to another. After several

17 attempts to quit on her own, she finally reached out

18 for help and Cassandra went to rehab and stayed sober

19 for six months. She was ready to move on with a happy

20 and healthy life.

21 "On February 17 of 1911 (sic), Cassandra met

22 with a friend from her group for young people with

1 addiction. They spoke after the meeting and discussed
2 getting high the last time. One more time. They met
3 in a local restaurant after she got off work. They
4 used in a parking lot.
5 "Cassandra drove home, and went into bed.
6 And on the morning of February 18, 2011, her mother
7 went into her room to wake her up but Cassandra never
8 woke up. She had passed away in the middle of the
9 night."
10 The last couple of days over here, or at
11 least a day and this morning, I've been listening to
12 all kinds of conversation, stats, slides, and I think
13 that this whole citizen petition has been hijacked,
14 turned around, and made up to look like we are trying
15 to keep people from getting their medication. That is
16 so far from the truth.
17 The whole object over here is to keep people
18 from dying. We keep forgetting about that. Nobody's
19 trying to keep anybody from getting medication. If you
20 are that bad that you need that medication, you should
21 have it. But at the same time we all know that opioids
22 are very addictive. And this is what happened to these

1 young kids.
2 There's so much of it on the street. There
3 are so many doctors who are not trained and will give
4 it to you for a pulled tooth, for a twisted toe.
5 They'll give it to you for anything. I like that old
6 saying, what my doctor used to say. You know, and
7 somebody made a remark yesterday, what is moderate
8 pain?
9 Well I can tell you what moderate pain is.
10 Moderate pain is take two aspirin and call me in the
11 morning. That is moderate pain. Severe pain is for
12 somebody who is really at the end of the rope, somebody
13 who there's nothing else that work for, and nobody's
14 trying to hold that away from them. No one.
15 What you have to keep in mind is this.
16 There's kids who try things at high school, or there's
17 kids like Michael, my son, who followed doctors
18 directions. None of them got up that morning and said
19 I want to be an addict. None of them wants to be an
20 addict. None of them wanted to die.
21 I feel bad; I mean my heart breaks, not for
22 me, not for Tish Westrup, or Cheryl Placek, or any of

1 the parents, my heart aches for the kids. These kids
2 never got to live a full life. These kids never got to
3 do things that you and I all did. And instead, they're
4 buried somewhere and here we are debating whether or
5 not we're going to restrict this, or do that, we're
6 going to look at slide, and to me, and I don't want to
7 sound harsh, my God, we all forgot that it's about
8 saving life.
9 It's saving lives; that's what you've got to
10 keep in mind. And especially young life, but the way
11 we're going, there will be no next generation and then
12 what are we going to do? Thank you.
13 DR. THROCKMORTON: Thank you. Ms. Rummler?
14 MS. RUMMLER: Good morning. Thank you for
15 allowing me to present today. My name is Judy Rummler.
16 I am the mother of Steve Rummler and I am president of
17 the Steve Rummler Hope Foundation.
18 My husband, Bill, and I established the Steve
19 Rummler Hope Foundation in July of 2011. The mission
20 of the foundation is to heighten awareness of the
21 dilemma of chronic pain and the disease of addiction,
22 and to improve the associated care process.

1 Our son, Steve, suffered with chronic pain
2 for 15 years. In 2005, he was prescribed opioids for
3 his pain. He was given chronic opioid therapy. His
4 well- intentioned and highly regarded primary care
5 doctor believed that this medication would help Steve.
6 This doctor believed that these medications would be
7 safe and effective for long-term use.
8 We have come to believe that the current
9 approved labeling on these medications, along with the
10 aggressive marketing of pharmaceutical companies, has
11 led physicians and the patients and the public to
12 underestimate the risks of these drugs.
13 Steve became addicted to his prescribed
14 opioid medications. In the spring of 2011, he received
15 28 days of in-patient addiction treatment at Hazelden
16 in Minnesota. After his treatment he told us that his
17 pain was better. Not only had these drugs caused him
18 to develop the disease of addiction, they had also
19 increased his pain. He had hyperalgesia.
20 Steve relapsed shortly after, and on July
21 1st, 2011 Bill and I received the phone call that every
22 parent dreads more than anything in the world, our son

1 Steve had died. He had died of an accidental drug
2 overdose. We miss him terribly and our lives will
3 never be the same. However, we have learned that we
4 are not alone in this.
5 Nearly 15,000 people die every year of
6 overdoses involving prescription pain killers. This
7 epidemic has left thousands of others, like ourselves
8 here on this panel, who are grieving, who have pain,
9 and who are feeling guilt ridden because of what
10 happened to our families, which have been devastated.
11 This is a slide that was prepared for me by
12 Dr. Charles Reznikoff, who is an addiction doctor and
13 an internal medicine doctor at Hennepin County Medical
14 Center in Minneapolis. He serves on the medical
15 advisory committee for the Steve Rummler Hope
16 Foundation, and is a signer of the PROP petition.
17 This slide shows that in addition to overdose
18 deaths, there is a much larger problem. For every one
19 overdose death in the United States, nine people enter
20 opioid addiction treatment, 35 people visit emergency
21 rooms related to opioid incidents, 161 are addicted to
22 or abuse opioids, and 461 admit to using opioids

1 inappropriately.
2 This is a graph that's been displayed several
3 times during this hearing, but I think it's an
4 extremely important graph. It illustrates the
5 correlation between the sales of opioid pain relievers
6 and pain reliever overdose deaths and admissions to
7 addiction treatment. The top line, the dotted line,
8 shows the opioid pain reliever sales over a 10-year
9 period and how these have quadrupled. Correlating
10 directly are overdose deaths and admissions for
11 addiction treatment.
12 These maps show state admissions for
13 addiction treatment over a 10-year period. In 1999,
14 the rate of admissions into addiction treatment was --
15 illustrated by white and yellow colors on the map. The
16 highest rate was 50 admissions per 100,000 population,
17 in 1999.
18 By the year 2009 the map has become dark red,
19 and the rate of admission has significantly increased
20 so that the maximum rate was 379 per 100,000
21 population. So addiction rates of admission have
22 increased substantially and have become a huge problem.

1 Another slide from Dr. Reznikoff showing that
2 17 percent of all prescriptions filled in America are
3 for an opioid. And the most filled prescription in
4 America is Vicodin, a hydrocodone combination product.
5 Twenty percent of the recipients of these scripts
6 misuse them.
7 I don't mean to pick on Purdue Pharma, but
8 this is a chart of the 200 top drugs in the U.S. market
9 by sales in the year 2010. It shows that number 15 on
10 this list is OxyContin, and that Purdue made $3.08
11 billion selling their drug in this year.
12 The interesting thing about this chart is
13 that the top 14, the drugs all listed above OxyContin,
14 are drugs that are indicated for chronic conditions,
15 like diabetes, hypertension.
16 And somehow we have -- the effective
17 marketing of Purdue for their drug for long-term
18 chronic pain has enabled them to become number 15 on
19 this list. And as I said, it's not just Purdue Pharma.
20 Number 15, $3,000 in sales.
21 Now I strongly believe, as Avi has just said,
22 that we need to treat pain in this country and that

1 there are people who need opioid therapy. Obviously
2 it's clear that for acute pain opioids are very
3 important and need to be prescribed, as well as for end
4 of life and palliative care.
5 And I am sure there are many instances where
6 it's essential for these patients to have it, and we
7 are not trying to stop that. We understand and we feel
8 very strongly that these need to be made available.
9 We're not trying to limit access. However, in this
10 country we have somehow come to believe that the
11 treatment of pain is an expectation.
12 We have patients who now go to the doctor
13 believing that they are going to get their opioid
14 readily because they have pain. We're asked
15 immediately when we go to the doctor, what is our level
16 of pain. You think about it, you're going to find some
17 pain someplace, and I believe that this is something
18 that is a result of the marketing for these opioids
19 that the Joint Commission was convinced to mandate
20 aggressive assessment for pain.
21 And as a result, we now expect that we're
22 going to receive pain treatment, whereas pain is

1 something that is telling us something. When our body
2 has pain, there's a reason, and we need to try to
3 understand that rather than just look for a pill.
4 Addiction is a huge result of this epidemic
5 and our son Steve did not want to be an addict. He
6 tried very hard to fight the disease of addiction.
7 There's a misconception in this country today about
8 addiction. There's a stigma associated with it, which
9 makes it very difficult for people to speak up about it
10 and try to do something about it.
11 Addiction is a chronic brain disorder. It's
12 not a social problem, or a moral problem, or a criminal
13 problem, it's a brain problem, and we need to treat it
14 like a disease. It's a disease like cancer and we need
15 to treat it like one. This information's from the
16 American Society of Addiction Medicine.
17 So the current labeling has led to the
18 overprescribing of opioids and, in my opinion, has led
19 to the overtreatment of pain with opioids. We need to
20 find alternative ways to treat pain wherever possible.
21 So this has led to an overdose death epidemic,
22 increased opioid addiction, expectations of pain-free

1 living, and huge profits for big pharma.
2 So we recommend the specific actions listed
3 in the PROP petition. We would like to see the FDA
4 strike the term moderate from the indication for non-
5 cancer pain. To have the FDA add a maximum daily dose
6 equivalent to 100 milligrams of morphine for non-cancer
7 pain, and to add a maximum duration of 90 days for
8 continuous daily use for non-cancer pain. Thank you.
9 DR. THROCKMORTON: Thank you. Ms. Holtum?
10 MS. HOLTUM: Good morning. Thank you for
11 allowing my testimony to be heard today and my name is
12 Lexi Reed Holtum. Steve Rummler was my fianc He was
13 the kind of man that you wanted to be the father of
14 your child.
15 I am vice president of the Steve Rummler Hope
16 Foundation, and I'm here today in support of the PROP
17 petition, and to implore you to please change the
18 labeling on opioid drugs. I was here last May. Some
19 of you heard my story already. I was here a couple
20 weeks ago for the scheduling. Some of you heard the
21 story then.
22 And I want to let you know I understand your

1 job is difficult. I understand that change is hard. It
2 takes courage. It takes telling the truth. It takes
3 focus and not being distracted by false lies around
4 what will impact society with this change.
5 I'm going a little bit away from what I had
6 prepared to say today because of all of the testimonies
7 I've heard and things I've learned here today. And I
8 want to say, I am not a doctor. I am not a judge. I
9 am not a lawyer. I'm not a government official. I am
10 an American citizen who is deeply disturbed by the lack
11 of change happening at the FDA.
12 Again, I have tremendous respect for the
13 difficult job you do. But, I cannot understand why we
14 are not changing, why you aren't changing the labeling
15 on these drugs. I am clear, as a non-medical person,
16 that off-label prescribing is possible.
17 Not only is it possible, it's done. And so I
18 don't understand why we are spending time discussing
19 the difficulty that pain patients are going to have in
20 getting the appropriate treatment that they need.
21 Again, we are for the pain patient getting
22 help. We want -- Steve suffered with pain. I lived

1 with him. I did not -- I intended to marry him. I did
2 not want to see him suffer. I wanted him to get help.
3 The problem is that Steve's doctor thought he was doing
4 something that was safe for Steve, right?
5 So when his doctor, when I or Steve or any of
6 the other number of pain patients in this country go to
7 their doctor, knowing that is a person who is educated,
8 has taken an oath to provide the best possible, safest
9 care that they can for that patient.
10 If these doctors are unaware, because of the
11 current labeling, and because of the relentless
12 education that big pharma has done around the safety of
13 these drugs, if they are unaware, how can they possibly
14 help their patients?
15 So I see that changing the labeling would
16 only have the impact of helping doctors to be aware of
17 the dangers of the drugs, of the opioid drugs. And
18 that is what it would cause. And that the patients
19 that need opioids, they'd be allowed to get it.
20 It can be prescribed off-label, as I know to
21 be true of many drugs currently being used. They're
22 off-label but they're still prescribed. So help me

1 understand what the problem is with that. I don't see
2 it.
3 This is Steve and my daughter Isabella. This
4 picture was taken the summer before Steve overdosed and
5 died, as a direct result of the labeling of opioid
6 pills. That little girl in that picture, after Steve
7 died I held her for weeks as she cried in my arms and
8 said, Mommy, why didn't he just listen to us. Why
9 didn't he stop taking the pills? Now you tell me how
10 you explain to a nine-year-old that he wanted to and
11 could not.
12 This was a note we found after Steve's death,
13 where he wrote of his pain pills, "At first, it was a
14 lifeline. Now it is a noose around my neck." That is
15 where that brilliant, successful, making over six
16 figures, a person who paid taxes, voted, took care of
17 his family and friends; this is what he wrote about it.
18 When he started down this journey, it was not to get
19 high. It was to relieve his suffering from his chronic
20 pain.
21 This is Steve at his high school graduation.
22 He graduated with honors. He played sports. This is

1 the two of us. It's not like I just met Steve. We
2 were each other's first true loves in high school and
3 college. This is back in 1987. I know this man. He
4 was not a drug seeking person, going to the doctor to
5 get high.
6 Steve ran marathons. He ran this one in
7 under four hours. This is us after we became engaged.
8 This is again my daughter. This is in Judy's backyard
9 in Minnesota. His death, and the pain that has been
10 caused from that, and the cost that has been caused
11 from that, impacts hundreds of people. And we aren't
12 the only family. I just simply cannot understand it.
13 And in seeking to find answers to my
14 questions, why, how did we get here? How did our great
15 country get to a place where one person every 19
16 minutes dies from a prescription drug, from an opioid
17 drug that is the same as heroin? It's illegal. Heroin
18 is illegal and yet we are prescribing it as the top
19 medicine prescribed in our country today. I don't
20 understand.
21 In trying to find answers to my questions, I
22 have sought out experts, because as I've said, I'm not

1 a doctor. I'm a simple, ordinary, average American who
2 does not understand.
3 One of the experts that I sought out is Dr.
4 Miles Belgrade. Dr. Belgrade is Medical Director of
5 Fairview Pain Management Center at the University of
6 Minnesota, or I'm sorry, at the University of Minnesota
7 Medical Center, in Minneapolis, Minnesota.
8 Under the direction of Dr. Belgrade,
9 Fairview's Pain Management Center has twice been
10 awarded the Clinical Center of Excellence Award given
11 by the American Pain Society. Dr. Belgrade is also a
12 member of the Steve Rummler Hope Foundation's medical
13 advisory committee, and Dr. Belgrade signed the PROP
14 petition.
15 This is a direct quote from him, in my
16 seeking to find answers for myself. Dr. Belgrade said,
17 "One often quoted study, that was actually a letter to
18 the editor in the New England Journal of Medicine," so
19 this wasn't a study, this was a letter.
20 "One often quoted study, that was actually a
21 letter to the editor in the New England Journal of
22 Medicine from the early 1980s, by Porter and Jick, who

1 reviewed some 11,000 hospital charts, and could only
2 identify four out of those 11,000 who became addicted
3 to their opioids that were used for managing pain.
4 This flawed and poorly documented study
5 became the justification for prescribing opioid
6 analgesics without worry about addiction. It is simply
7 untrue that these drugs are safe. There is, to my
8 knowledge, no scientific evidence backing up long-term
9 use of opioid prescription medicine for non-cancer
10 pain."
11 I would love it if you find some evidence, if
12 somebody would please email it to me, because I really
13 want to hold onto somewhere there's justification for
14 this massive epidemic that is killing people every 19
15 minutes in our country. Thank you so much for your
16 time. Please do the right thing. FDA Questions
17 DR. THROCKMORTON: Thank you. Do members of
18 the panel have questions for anyone that's made
19 comments in the last -- panel? Thank you very much. I
20 think we're going to take a break now. We're a little
21 ahead of schedule. Why don't we say that we'll be back
22 at 10:20? Thank you.

1 (Break)

2 DR. THROCKMORTON: If people could start
3 finding their seats please, that would be terrific.
4 Marianne Cloeren, Jamie Threadgill, Kevin Nicholson and
5 Jack Henningfield are the next people I have on my
6 list. Followed by David Egilman, Miro Pavelka, Jane
7 Ballantyne. Ms. Cloeren, if you're -- okay. You can
8 get started whenever it's convenient. Thanks.

9 DR. CLOEREN: Hi, I'm Dr. Marianne Cloeren.
10 I'm an internal medicine and occupational medicine
11 doctor, and I'm here on behalf of the American College
12 of Occupational and Environmental Medicine. ACOEM was
13 founded in 1916. It's the nation's largest medical
14 society dedicated to promoting the health of workers
15 and preventing unnecessary disability. We represent
16 about 4,500 physicians and other healthcare
17 professionals.

18 ACOEM has developed practice guidelines,
19 starting in 1997. The latest addition was published in
20 2010 and it has excellent compliance with Institute of
21 Medicines criteria for evidence-based guidelines with
22 review of thousands of scientific articles, and 2,500

1 evidence-based recommendations, including
2 recommendations on chronic pain management and use of
3 opioids. The panels that wrote the guidelines, and
4 editorial panel, are multi-disciplinary.
5 Based on the latest addition of ACOEM
6 occupational medicine practice guidelines, the routine
7 use of opioids for chronic, non-malignant pain is not
8 recommended. And I wanted to point out that the
9 guidelines are available for free at that website, if
10 you wanted to take a look at the research upon which
11 it's based and the reasoning and the evidence strength,
12 et cetera.
13 While we are very fond of our guidelines, and
14 think they're the best in the world, there are also a
15 whole bunch of other very good guidelines as well.
16 There's a comparison of the pain management guidelines
17 available at the website that's right here.
18 I want to point out that they have in common
19 with ACOEM guidelines the following recommendations,
20 that before treating people with opioids, that they are
21 screened for appropriateness, risk for addiction, that
22 other treatments are used first, that opioids are only

1 used in conjunction with other treatments, including
2 physical activity, psychological treatment, you know
3 other medications if they're indicated.
4 And most importantly, you know we think,
5 probably coming from our perspective as preventative
6 medicine doctors dealing with people who work, that
7 they should only be continued if there's evidence that
8 they're improving function.
9 And what we frequently see is that doctors
10 will write, yes, function is improving, but if you more
11 carefully, what you see is that over time a lot of
12 patients that are on chronic opioids are actually
13 becoming socially withdrawn, doing less and less in
14 their life activities, including work.
15 And so we strongly recommend that there be
16 objective measurements of function used when
17 prescribing opioids, and that they be discontinued if
18 they're not improving function. And this actually is
19 in common with other treatment guidelines as well, not
20 just ours. And then, of course, monitoring urine drug
21 screening and referring to the prescription drug
22 monitoring programs, when they're available.

1 So fine, we have lots of guidelines. Are
2 doctors following the guidelines? In a study done in
3 2011 by the Workers' Compensation Research Institute,
4 and this was looking at practices in 17 states, they
5 found that in only four percent cases with long-term
6 opioids were psychological evaluations performed. And
7 that only seven percent of the long-term opioid using -
8 - you know the cases involving long-term opioid use,
9 that drug screening was performed in only seven
10 percent. So you know there are guidelines available,
11 but there's pretty good evidence that doctors are not
12 routinely following the guidelines.
13 What about function? Is there evidence that
14 chronic use of opioids for non-cancer pain improves
15 function? In one study of about 2,000 Workers' Comp
16 claimants, it was found that six percent were receiving
17 opioids at a year, and the study found that the daily
18 dose increased significantly over the year.
19 So people were going back and getting more
20 opioids, presumably because their pain was not
21 controlled. This study found that only a small percent
22 improved significantly in pain, and even less improved

1 in function; 16 percent had a 30 percent or greater
2 improvement in function.
3 What about mortality? I mean, you've seen
4 this many times. I don't know if you saw this study
5 yet, but there was one study looking at opioid-related
6 death in patients on opioids for non-malignant pain.
7 And in about 600,000 people prescribed opioids, there
8 were about 500 opioid-related deaths. And there was a
9 very strong correlation between the dose and the risk
10 of death.
11 So do guidelines make a difference when they
12 are followed? This is a study looking at Washington
13 State's guidelines, which were not ACOEM guidelines,
14 they're different guidelines. But not only did they
15 put into place these guidelines, which required the
16 involvement of specially trained specialists at a
17 certain dose of opioids, they also made it easier for
18 doctors to follow the guidelines.
19 They put into place systems for helping
20 people access psychological care, et cetera, and good
21 education for the doctors. But what they found was
22 that the dose did go down, that the yearly trend in

1 prescribing opioids that is went down, and that deaths
2 went down as well, opioid-related deaths went down as
3 well.
4 So our recommendations are, in addition to
5 whatever you decide related to the labeling, that there
6 be requirements for doctors to follow guidelines, and
7 whatever controls need to be put into place so that
8 it's easier for doctors to follow guidelines.
9 And these guidelines should include using
10 screening tools to make sure that opioids are
11 appropriate for the patient; that there's documentation
12 that other treatments have been used and didn't work;
13 and that also that opioids would be one part of the
14 treatment plan, not the only treatment, especially
15 behavioral therapy, cognitive behavioral therapy and
16 comparable kinds of mental health treatment; that
17 opioids be discontinued if there's not any improvement
18 in objective measurements of function; that patient
19 contracts be used; that urine drug screening be used.
20 And again there's a connection, a link to the
21 guidelines.
22 A lot of the focus is on safety and risk of

1 overdose, and diversion, et cetera, and that's very
2 important. We'd also like the panel to consider the
3 impact on productivity and the financial impact to
4 employers, to the country of unnecessary disability.
5 The recommendations that are followed should be
6 evidence-based.
7 ACOEM has also been involved in developing
8 some model legislation for state workers compensation
9 commissions, or for state legislatures to consider,
10 related to Workers' Compensation related opioid
11 prescribing, and we'd be happy to share our ideas with
12 you related to that.
13 Just one final thought is that we need to
14 make it easier for doctors to do the right thing.
15 Right now it's very, very easy for doctors to just
16 write prescriptions for more and more and more and
17 more. It's not so easy for them to do the right things.
18 It's not so easy for them to follow the guidelines.
19 There may not be mechanisms for
20 reimbursement, for spending the time doing behavioral
21 counseling, access to behavioral counseling, access to
22 the kind of physical therapy that helps people get

1 better.

2 And one other thing, since you haven't cut me

3 off yet. Informed decision making. We notice that the

4 current patient education documents really start at the

5 point that the decision has already been made to

6 prescribe opioids. We would recommend that there be

7 patient education documents that address whether or not

8 opioids are appropriate. And then also whether it's

9 appropriate to stop opioids when they're not working.

10 Doctors really would benefit from having those kind of

11 tools as well for informed decision making. Thank you.

12 DR. THROCKMORTON: Thank you. Mr. (sic)

13 Threadgill. I think we have an audio.

14 DR. THREADGILL: My name is Jaime Threadgill,

15 and as a veteran pharmacist of 30 years I have some

16 insights on opioids being used for chronic pain.

17 Practicing in Chattanooga, Tennessee, off the I-75,

18 I've seen the effects of the Florida to Kentucky Oxy

19 Express. I've also witnessed firsthand the effects of

20 oxycodone on a community.

21 Tennessee has implemented many of the CDC

22 recommends to help address the epidemic of opioid

1 overdoses and deaths. However, with Tennessee being a
2 border state to Georgia, Arkansas and Missouri, that
3 have no active prescription monitoring programs, PMPs,
4 and Alabama that restricts its database to Alabama
5 pharmacists only, it does create a situation where
6 patients can easily access these border states to do
7 doctor shopping and pharmacy shopping.
8 After Tennessee began using its PMP database,
9 it quickly noticed that roughly 20 percent of its
10 providers were prescribing slightly more than 80
11 percent of the opioids used by Tennesseans.
12 Another of the CDC recommendations was for
13 states to enact laws to prevent doctor shopping and
14 pill mills. As mentioned, Tennessee being a border
15 state, and many of our largest population centers with
16 Memphis next to Arkansas, Chattanooga near Georgia and
17 Alabama and the Tri-Cities near Virginia, they have
18 easy access to states that do not share information
19 with Tennessee, or who do not have the restricted pain
20 clinic registrations, or similar law enforcement.
21 Another recommendation was to have insurance
22 limit the number of doses a patient may receive under

1 insurance. For example, TennCare, or the Tennessee
2 Medicaid program, limits oxycodone to 90 tablets per
3 month. However, pharmacies are allowed to bill the
4 first 90 tablets to TennCare and have the patient pay
5 cash for the remainder prescribed.
6 Here's an example of preprinted pain clinic
7 prescriptions that the majority of our local pain
8 clinic patients receive. Two strengths of oxycodone
9 IR, both for 180 tablets, one to be used every 4 hours,
10 the other to be used every 2 hours as needed for
11 breakthrough pain. TennCare patients would end up with
12 three bottles of oxycodone, 90 in the first bottle,
13 that TennCare would pay 100 percent of.
14 Generally what we see, and the pattern that
15 we noticed, is patients receiving that first free
16 bottle, going out to the parking lot and returning with
17 the cash to pay for the remainder of the order. Our
18 local sheriff's department speculates they may be
19 availing themselves of the value of, the street value
20 of the oxycodone at $1.00 per milligram.
21 So recommended improve access to treatment
22 centers, Tennessee has noticed a seven-fold increase in

1 admissions to treatment abuse centers from 2000 to
2 2010. The capacity of our treatment centers has not
3 been able to keep up with the demand, resulting in long
4 waiting periods to enter programs in most metropolitan
5 centers in Tennessee.
6 Some of the most serious side effects of the
7 increase in opioid use for chronic pain has resulted in
8 the increase in neonatal abstinence syndrome, with up
9 to 50 percent of the neonates admitted to NICUs in East
10 Tennessee now. And having four times more likely a
11 visit to an ER, and 12 times more likely to be admitted
12 as an inpatient for opioid users, is causing a huge
13 increase in Medicaid spend here in Tennessee yearly.
14 Conclusion, Tennessee has really paid the
15 price for the policy changes of the '80s and '90s
16 toward use of opioids for chronic pain. It's time to
17 look at policy changes in light of new information on
18 rates of addiction and risk of overdose death. And the
19 experiment with the states providing policy has failed.
20 A more national approach is required, with a national
21 PMP and provider accountability.
22 DR. THROCKMORTON: Mr. Nicholson?

1 MR. NICHOLSON: Thank you. Good morning.
2 I'm Kevin Nicholson, and I'm speaking today on behalf
3 of the National Association of Chain Drug Stores.
4 NACDS represents traditional drug stores, supermarkets
5 and mass merchants with pharmacies. Our members
6 operate more than 41,000 pharmacies, and employ more
7 than 3.8 million employees, including 132,000
8 pharmacists.
9 Our members fill over 2.7 billion
10 prescriptions annually, which is more than 72 percent
11 of annual prescriptions in the U.S. NACDS and our
12 member pharmacies are proud to be the most accessible
13 healthcare providers to Americans.
14 We are deeply concerned about the nation's
15 prescription drug abuse problem, and have committed to
16 work with FDA and other federal and state bodies to rid
17 this scourge. We thank FDA, and specifically this
18 panel, for the opportunity to speak with you today
19 about the use of opioid medications in the treatment of
20 chronic pain.
21 We urge FDA to exercise caution as you
22 consider potential labeling changes for opioid

1 medications. A level of pain that one individual
2 considers to be moderate could be perceived as severe
3 by someone else. Changes to prescription labeling for
4 opioid pain medications that are not supported by sound
5 clinical and scientific evidence could lead to
6 prescribers having to prescribe off-label.
7 Prescribing off-label could affect
8 prescriber's professional liability and their
9 willingness to treat conditions requiring pain
10 management. Moreover, patients' health insurance may
11 not cover medical treatment and prescription
12 medications that are considered off-label.
13 We have similar concerns about proposals to
14 impose a maximum daily dose for opioid drugs. Since
15 individuals experience pain differently, we fear that
16 an objective daily maximum dose would merely be an
17 arbitrary standard. In addition, it would lead to the
18 sickest patients having to suffer the most.
19 It is common for patients to develop
20 tolerance to opioid pain medications, thus requiring
21 higher daily doses of these medications. The risk of
22 overdose should be controlled by good prescribing

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1 practices and patient monitoring. And only opioid
2 tolerant patients should receive higher doses of opioid
3 medications.
4 It would be unconscionable to prohibit a
5 healthcare provider from treating a patient's pain by
6 imposing an arbitrary maximum daily dose. Adopting an
7 arbitrary limitation assures the ineffective treatment
8 of many patients, or assumes that the limitation will
9 be ignored by healthcare providers whenever necessary
10 to properly treat pain.
11 Just as we cannot support a maximum daily
12 dose for opioid medications, we cannot support limits
13 on the duration of use of opioid medications. Such a
14 limit would also be arbitrary. Unless suitable pain
15 treatment alternatives to opioid medications are found,
16 imposing a maximum time limit would deprive patients
17 who benefit from such therapy, thus leading to
18 ineffective treatment of many patients, or again an
19 expectation that healthcare providers will ignore the
20 limitation.
21 We believe that policy solutions should focus
22 on striking a necessary balance to curb the abuse of

1 prescription medications, while also ensuring access
2 for legitimate patients.
3 As we have talked about, as NACDS has
4 mentioned before, we support the FDA REMS program for
5 long-acting and extended lease opioid products. An
6 essential component of this REMS is an education
7 program for prescribers, so these medications can be
8 prescribed and used safely.
9 NACDS agrees that prescribers should be
10 properly educated about the risks and benefits of
11 prescription drugs, especially those that have elevated
12 abuse potential. It is critical that all prescribers
13 understand the nature of addiction and abuse before
14 issuing prescriptions for these medications.
15 NACDS and other industry stakeholders have
16 worked closely with FDA, over the past few years, to
17 design and implement a REMS for the transmucosal
18 fentanyl products. We are appreciative of this
19 collaborative effort spearheaded by FDA. If this REMS
20 is successful, we are hopeful that it could serve as a
21 model for future REMS.
22 As we pursue solutions to the problem of

1 prescription drug abuse, it is critical that we do not
2 place undue burdens on the legitimate patients. As FDA
3 has recognized through the REMS program, the risk of
4 medications must be mitigated relative to their
5 benefits. However, we cannot mitigate risks to the
6 point that legitimate patients cannot receive their
7 medications. We believe FDA has struck a proper
8 balance with the REMS.
9 NACDS members are committed to the health and
10 welfare of our patients as well as all Americans,
11 including ensuring that they do not fall victim to
12 prescription drug abuse. The prescription drug abuse
13 problem can be successfully curbed, however we urge FDA
14 not to recommend unworkable provisions, such as poorly
15 conceived labeling changes and arbitrary limits on
16 opioid pain medications.
17 Combatting prescription drug abuse must take
18 a holistic approach. All stakeholders must work
19 proactively to tackle and resolve this problem, and we
20 all must work at the federal, state and local levels.
21 Thank you.
22 DR. THROCKMORTON: Thank you. And Mr.

1 Henningfield?
2 DR. HENNINGFIELD: Thank you. Good morning.
3 I'm Jack Henningfield, Vice President for Research,
4 Health Policy and Abuse Liability at Pinney Associates,
5 and Professor Adjunct of Behavioral Biology at the
6 Johns Hopkins University School of Medicine.
7 I prepared these comments with input from Dr.
8 Sidney Schnoll and Karen Gerlach. Dr. Schnoll is a
9 world-recognized expert in pain management and
10 addiction medicine. Dr. Gerlach is an epidemiologist
11 and public health leader, formerly with CDC, NCI and
12 the Robert Wood Johnson Foundation.
13 We care about families suffering from abuse
14 of opioids and other drugs, and about families and
15 individuals suffering from pain. Pinney Associates
16 helps pharmaceutical companies develop and market drugs
17 to minimize the risks of abuse and overdose. I am
18 neither representing nor speaking on behalf of any
19 client today. My travel and so forth is paid at the
20 expense of Pinney Associates.
21 Our main message is to caution FDA about the
22 adverse public health effects from regulatory actions

1 that hinder patient care without actually addressing
2 opioid abuse and opioid overdose. We need to help both
3 populations. We feel that the petition would help
4 neither. We commend FDA for holding hearings to find
5 solutions that will help and not hurt.
6 There are several points on which we think
7 most agree, and these can serve as a foundation for
8 moving forward. First, opioid medications are vital
9 for the treatment of pain, many types of pain. Second,
10 effective and safe patient care requires responsiveness
11 to the individual needs of each patient.
12 Third, most prescription opioid abuse does
13 not occur among those who have been prescribed these
14 drugs, and will not. Fourth, most overdose deaths
15 involve multiple drugs, including alcohol. Fifth,
16 proposals to improve care and reduce abuse should be
17 evidence-based.
18 These points underlie our concerns about the
19 labeling recommendations under consideration. We do
20 have a science base for effective action. This
21 includes strategies to identify patients at elevated
22 risk of abuse and how to manage their pain. It

1 includes strategies to minimize overdose risks. It
2 includes prescription monitoring programs and the
3 development of abuse deterrent opioids.
4 We should also heed the recommendations of
5 the 2011 Institute of Medicine Report on pain and its
6 care. The IOM concluded that quote, "A population level
7 prevention and management strategy is needed to address
8 pain treatment, as well as to address and mitigate the
9 risks of non-medical opioid abuse." This is a good
10 starting point.
11 Ensuring appropriate use, storage and
12 disposal of prescription opioids are challenges that
13 must be addressed more effectively by FDA, by industry,
14 by healthcare providers, by patients, by law
15 enforcement and the public working together. It can't
16 be done by any group alone.
17 Let me briefly review the evidence supporting
18 the petition or proposals and other actions. We
19 provide additional analysis in our written submission
20 and may provide an additional supplement to our
21 submission.
22 First, there is no evidence that arbitrarily

1 limiting the maximum daily prescribed dose of opioid
2 analgesics will deter unethical prescribing or abuse.
3 This action would be more likely to have a chilling
4 effect on ethical medical practitioners and hurt people
5 with pain. Arbitrarily setting a maximum dose will
6 impede individualized care.
7 Furthermore, the data show that the dose of a
8 prescribed opioid is not typically the main cause of
9 opioid overdose deaths. These deaths often involve
10 concomitant use of other drugs, including alcohol,
11 benzodiazepines and others.
12 The petition at times conflates opioid
13 abusers and pain patients in its projections of rates
14 and other areas that we discuss in our written
15 submission in detail. But pain patients and opioid
16 abusers are not the same people, by and large. In
17 fact, most people being treated for pain do not and
18 will not abuse opioids.
19 Conversely, most abusers of opioids get their
20 opioids outside of medical care and healthcare system,
21 probably without labels. The 2009 National Survey on
22 Drug Use and Health showed that nearly 70 percent of

1 non-medical opioid users obtain their opioids from
2 family or friends. Seventeen percent obtain the drug
3 from one or more doctors, nine percent purchase them
4 from friends, dealers or the internet.
5 Furthermore, we have quite a bit of evidence
6 that most opioid-related deaths involve multiple drugs.
7 My colleague, Dr. Ed Cone, studied more than 1,000
8 oxycodone-related deaths in a study reported in 2002.
9 He found, and the team found, that only 3.3 percent
10 involved oxycodone alone; 96.7 involved at least one
11 other drug that may have contributed to the death.
12 These included alcohol, benzodiazepines, cocaine and
13 other opioids.
14 A 2010 study of opioid-related emergency
15 department visits by Braden and colleagues quote, "Did
16 not observe a clear dose response effect. Other
17 factors, including benzodiazepines were reported."
18 Such studies emphasize the differences in
19 non- medical users and patients. They support the need
20 for improved prescriber and patient education that
21 emphasizes the risks posed by these drugs, and proper
22 use, including dose titration, improved patient

1 monitoring, and advice about use of other drugs.
2 Reducing overdose outside of medical care
3 will not likely be addressed by labeling changes. This
4 will require stronger efforts by substance abuse
5 control programs, including increased access to drug
6 abuse treatment.
7 The new FDA guidance on abuse deterrent
8 opioids is encouraging, likely to accelerate the
9 development of beneficial opioids with a reduced abuse
10 potential. This guidance reflects the evidence that
11 formulation, rate of onset and other factors make a
12 difference. There are a variety of approaches in the
13 pipeline. We encourage FDA to use this regulatory tool
14 to foster the development of such advances.
15 Patient care can be improved, and abuse
16 reduced by more effective education. We have to study
17 if our education is working well, and find out how to
18 make the labels that we have work better, and improve
19 them where it does make sense. We've heard some
20 discussion of this already.
21 I wanted to comment that FDA is, we know,
22 considering recommendations to reschedule hydrocodone

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1 products. We feel that this will do little to deter
2 abuse and will likely have a chilling effect on the
3 treatment of people with pain. We encourage FDA to
4 look for alternatives, perhaps working with IOM and
5 pain groups.
6 In conclusion, we are encouraged by several
7 ongoing and emerging efforts. More must be done to
8 address prescription opioid abuse and the broader
9 problems of opioid and other drug abuse, but changing
10 labels is not the answer to better patient care or
11 control of opioid abuse and overdose. More effective
12 education is necessary.
13 And finally, we really need to match the
14 diversity of opioid-using populations and problems with
15 evidence-based risk management. We look forward to
16 working with the FDA and others to find effective
17 solutions to these problems. Thank you very much. FDA
18 Questions
19 DR. THROCKMORTON: Thank you very much. I'd
20 ask the panelists if any of them have questions for the
21 speakers. John?
22 DR. JENKINS: Yeah, I apologize if I get your

1 name wrong. Dr. Cloeren, you mentioned that your
2 association has guidelines that recommend against use
3 of opioids for chronic, non-cancer pain. But you also
4 showed data that shows that doctors don't follow that
5 type of guideline.
6 Do you have insights on why you think doctors
7 aren't following those guidelines about chronic use of
8 opioids for non-cancer pain? Are they being influenced
9 by other factors, the label, the promotional materials?
10 Are there other guidelines that do recommend long-term
11 use? What do you think is the reason they're not
12 following those professional guidelines?
13 DR. CLOEREN: Let me first clarify that the
14 ACOEM guidelines recommend against the routine use of
15 opioids for chronic, non-cancer pain. The guidelines
16 do acknowledge that there are some situations for non-
17 cancer pain for which chronic opioid use may be
18 appropriate, with using the guidelines.
19 I think it's a combination of things. And
20 I'm speaking probably for myself than for the college
21 right now. But what I see is that sometimes doctors
22 feel like they really understand the patient and that

1 they trust. You know we are taught to trust the
2 patient's history. So I think that sometimes doctors
3 are taken in by people who maybe are not forthright
4 with the doctor in some cases.
5 I think that the other reason that the
6 guidelines are not being used routinely, I think some
7 of it is education. I think sometimes the doctors are
8 not -- just because you have guidelines doesn't mean
9 that anybody's really familiar with them. But I think
10 that some things that are recommended in the guidelines
11 are actually pretty hard to do.
12 So how do you get the person that you -- so
13 you do the screening and you recognize that they have
14 symptoms of depression and anxiety, how do you access
15 care for that patient?
16 You know, it depends on the system that
17 you're in. If this is a primary care, then they may or
18 may not have mental health benefits. If it's Workers'
19 Compensation, the system may be adverse to paying for
20 that care. So there may be some logistical challenges
21 in obtaining what is needed, according to the
22 guidelines.

1 I don't know why people are not referring to
2 the prescription drug monitoring programs. I mean
3 those are pretty widely available now, and a minority
4 of doctors really are using them. I can't answer the
5 reason why. That would be an interesting thing to
6 research, to try to find out why doctors are not taking
7 advantage of some of the things that are easier to do.
8 Some of it has to do with not getting
9 reimbursed for the time. You know you've got a very
10 limited amount of time in clinic, and to come up with a
11 written pain management plan, you know with a written
12 contract and checking the prescription drug monitoring
13 program, and checking the urine drug monitoring results
14 and changing your treatment based on that, you know
15 where is the reimbursement for that time?
16 So I think it's a combination of things. And
17 you know any changes that are made are going to have to
18 address the system impediments to doing care right.
19 DR. JENKINS: Yeah, I may have missed it. In
20 your presentation, did you specifically comment on the
21 recommendations that are in the petition about
22 labeling?

1 DR. CLOEREN: We did not.
2 DR. JENKINS: Do you have any position on
3 those recommendations?
4 DR. CLOEREN: ACOEM has not taken a specific
5 position related to the PROP petition.
6 DR. JENKINS: All right, thank you.
7 DR. CLOEREN: You're welcome.
8 DR. THROCKMORTON: I had a question for Dr.
9 Cloeren, too. So you did make some comments in your
10 presentation about diagnosis, understanding and
11 treatment of patient pain, which was one part of what
12 we'd asked people to comment on.
13 You talked about earlier use of tools to
14 decide when patients should in fact use opioids and
15 then when they shouldn't be using opioids, or having
16 them discontinue use.
17 Did you have tools in mind there? So that's
18 the first part of the question; are there specific
19 tools that you'd point to that you thought were
20 valuable to look at in that context? And then the
21 second question is, should I be putting those in the
22 same bucket as a patient provider agreement, or is that

1 a slightly different tool?
2 DR. CLOEREN: I don't know. Actually, I
3 worked with a small group of people, and this is again
4 ACOEM, but I worked with a small group of doctors from
5 a bunch of different specialties to try to develop a
6 tool for the patient who is on chronic opioids but
7 they're not working for them, for them to sort of
8 figure out whether this is the best choice, for maybe
9 to give them something to talk to their doctor about.
10 There's a dearth of information out there for
11 people in that position, for people who've been on
12 chronic opioids who are not better and who are thinking
13 that maybe they need to stop. So no, I don't have a
14 particular tool for you for that.
15 There is a foundation called the Informed
16 Medical Decisions Foundation that has developed a lot
17 of evidence-based tools to help patients decide about
18 things like knee surgery, back surgery, what kind of
19 treatment for their back pain.
20 They have not developed anything specifically
21 for opioids right now, but their approach may be one
22 that should be considered for informed collaborative

1 decision making for patients, both around whether or
2 not to use that -- what other approaches should they
3 use to treat their pain and whether to discontinue.
4 DR. THROCKMORTON: You said Informed Medical
5 Decisions Foundation?
6 DR. CLOEREN: Foundation, yes.
7 DR. THROCKMORTON: Thank you very much.
8 DR. CLOEREN: And if you want contact
9 information, I'd be happy to put you in touch with
10 them.
11 DR. THROCKMORTON: Thanks. Thank you very
12 much. Next group -- hold on just a sec here -- Dr.
13 Egilman and then Dr. Pavelka and then Dr. Ballantyne.
14 See who I have on my list. Mary, unless you've got
15 updates? Okay? And yes, collect the clicker.
16 DR. EGILMAN: Good morning. I'm awful sorry
17 I can't be with you there today. I had to be in
18 Granada, at St. George Medical School, giving some
19 lectures. My name is Dr. David Egilman. I'm a
20 clinical professor of family medicine at Brown
21 University. I'm the author of two chapters in the
22 textbook, Handbook of Warnings.

1 I've also served as an expert witness in
2 OxyContin litigation. As a result, I've been able to
3 review thousands of documents, and hundreds of pages of
4 deposition testimony, related to OxyContin and
5 OxyContin studies. Unfortunately, the FDA has not
6 received any of these, as far as I know, and I am not
7 sharing any of this information today because Purdue
8 Pharma will not let me do so.
9 I'm here to talk about one part of the label,
10 which is the strict Q12 dosing. This dosing interval,
11 which rigidly requires physicians to increase doses
12 twice a day, rather than increase the dose frequency
13 when the pain medicine isn't working, produces
14 addiction, while not sufficiently treating the pain.
15 As evidence for the fact that the dosing
16 interval is inadequate, when the OxyContin pill was
17 first permitted to go in the market, it was believed
18 that the 40 milligram dose would be sufficient to treat
19 pain in at least 90 percent of patients. However, this
20 wasn't the case.
21 And shortly thereafter, in 1996, the maximum
22 dose was doubled. Within four years, the maximum dose

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1 was quadrupled. As a result of deaths from the 160
2 milligram dose, the current dose was reduced to a
3 maximum of 80.
4 Why did this happen? Well, it's because Q12
5 dosing is not correct for many, if not most patients.
6 Some patients are slow metabolizers of the drug. And
7 the drug in these people treats their pain for 12 to 14
8 hours. Plus when they're given the pill every 12
9 hours, they're overdosed. Many more patients are rapid
10 metabolizers of the drug, and they get breakthrough
11 pain at 9 to 12 hours, or even faster.
12 Now when you have a patient who's on a
13 particular dose, say 40 twice a day, and then you
14 increase that dose to say 60 twice a day, but do not
15 change the dosing interval, it does not provide
16 sufficient medication to treat the pain.
17 It may increase the duration of pain control,
18 but for the most part, for most people, it will not do
19 so because the amount of OxyContin that's in the blood
20 is a function of how fast it is eliminated, not the
21 dose.
22 Now, why did we get to a Q12 hour dose? It

1 wasn't because of the data on efficacy of the drug. It
2 was because Purdue Pharma needed something to
3 distinguish its drug from other short-acting narcotics,
4 and this became the main marketing device to increase
5 profits.
6 On the other hand, the data showed something
7 else. As you can see, at 10 milligrams, the OxyContin
8 product release was effective for less than six hours
9 in at least 25 percent of patients. And the 20 and 30
10 milligram doses were effective for less than 10 hours
11 in at least 50 percent of patients.
12 Other Purdue studies, all of them in fact,
13 allowed rescue or short-acting oxy to cover patients
14 who had pain breakthrough before 12 hours. However
15 this does not -- and this information is omitted from
16 the label.
17 Doctors started to figure this out, and by
18 2000, 20 percent of prescriptions were written for a
19 shorter dose interval than Q12. Nonetheless, the label
20 encourages physicians to increase the dose on a Q12
21 basis rather than the appropriate basis, which would be
22 three times a day, or Q12 with rescue dose.

1 Producing a high dose with a 12 hour dosing
2 limit raises blood levels but does not, as I showed
3 before, necessarily allow the pill to work for 12
4 hours. But it does do something else. Withdrawal
5 symptoms are a function of the peak dose.
6 And by increasing the peak dose, which is a
7 function of the amount of drug per dose, you increase
8 withdrawal symptoms, opioid tolerance and dependence.
9 In other words, the Q12 dosing schedule is an addiction
10 producing machine. The label must be changed to
11 reflect the science and not Purdue's marketing needs.
12 DR. THROCKMORTON: Okay. Next is Miro
13 Pavelka.
14 DR. PAVELKA: Good morning. I'm Miro
15 Pavelka, President of the American Association of Oral
16 and Maxillofacial Surgeons, also a clinical professor
17 at Baylor College of Dentistry in Dallas, Texas. I
18 thank you for the opportunity to address this panel
19 this morning.
20 Oral and maxillofacial surgery is a surgical
21 specialty of dentistry which bridges a gray area
22 between medicine and dentistry in which we treat

1 multiple conditions of the head and neck region. In
2 conjunction with our medical colleagues, we attempt to
3 use evidence-based approaches to the diagnosis, as well
4 as treatment of our patients.
5 And you can see by this slide the multiple
6 factors that we consider when developing these
7 treatment plans, but what's not on the screen are the
8 two umbrellas under which we practice. There is a
9 moral imperative and an ethical imperative that guides
10 us when we do elect to treat patients, and one of those
11 addresses pain control after surgical procedures that
12 we perform.
13 The other thing that's not on that slide is
14 our recognition that there are indeed regulatory
15 agencies that look over our shoulder every single day.
16 And both of those factors guide us in the way we
17 develop these treatment plans, and hopefully everyone
18 practices to the standard of care that's expected of
19 our specialists.
20 To that end, our training programs at 102
21 residencies throughout the United States are very
22 intense. They're hospital-based. We do get a lot of

1 pharmacology as we treat patients and move off and
2 serve on other services.
3 But I what I would like to stress this
4 morning is the fact that the dental profession has been
5 listening. I can attest to curriculum changes that are
6 both didactic as well as clinical as relates to the
7 prescribing of opioids to address, fortunately for us,
8 more often than not, acute pain in surgical situations
9 involving the head and neck.
10 There are some patients who do present with
11 chronic symptoms, and we feel very fortunate to be able
12 to reach out to our pain control colleagues that will
13 assist us in addressing those measures. I will tell
14 you, I've got Schedule II pads locked up in a safe in
15 my office that are yellowing because I really don't use
16 them. And I think that's really the thrust of what I
17 would like to address this morning.
18 Much has been said about the negative aspect
19 of hydrocodone, but I will tell you, in the 34 years
20 that I've been practicing, this drug has been very
21 effective managing pain for dental patients. What pays
22 my bills is taking out wisdom teeth on high school and

1 college kids, and everybody knows that that's what we
2 do. My concern is for unintended consequences.
3 If hydrocodone is moved to a Schedule II
4 classification, it's going to tie my hands and tie the
5 hands of several of my colleagues in taking care of
6 patients. And when the 16-year-old daughter comes to
7 the office to have four impacted wisdom teeth taken
8 out, and ibuprofen alone is not doing it, and I get the
9 call in the middle of the night and I cannot call in on
10 the phone a Schedule II narcotic, you know it's a trip
11 to the emergency room, some other out to get the
12 necessary pain medication for that patient.
13 I'm sure some of the physicians on this panel
14 have treated patients with salicylate intoxication when
15 the only thing available to them are over-the-counter
16 meds. And as you know, salicylate intoxication can be
17 potentially life-threatening, given all the sequelae
18 associated with that.
19 So my ask of this panel would be, if the
20 consideration to move hydrocodone to a Schedule II
21 classification is made, please be mindful of the
22 unintended consequences that that might incur. Also,

1 help us, as practitioners and healthcare providers,
2 develop programs that speak to the practitioner and
3 give them best practice choices to make as far as
4 informing patients, informing parents, informing fellow
5 practitioners, what's the best way to address pain for
6 these types of patients.
7 I hope that this can be done. I would like
8 for you to know that my association is committed to a
9 culture of safety, and we stress it in every
10 publication we have, we stress it at every single
11 meeting. Patient welfare is number one on our list and
12 certainly I've never met an oral maxillofacial surgeon
13 that was intent on turning a patient into a drug
14 addict. That's just not on our radar. I thank you for
15 your attention and for the opportunity to be here
16 today.
17 DR. THROCKMORTON: Thank you very much. Dr.
18 Ballantyne?
19 DR. BALLANTYNE: Good morning. And thank you
20 for the opportunity to present to this panel. I'm Jane
21 Ballantyne. I'm a professor of anesthesiology and pain
22 medicine at the University of Washington in Seattle.

1 This slide summarizes -- sorry, I have
2 previously presented clinical outcomes data to the FDA,
3 and that evidence synthesis is in the public record.
4 This slide actually summarizes the conclusions from
5 current evidence.
6 While there's strong evidence of good short-
7 term efficacy and safety, both efficacy and safety are
8 not sustained at longer durations. Many safety
9 concerns increase in direct correlation to dose, and
10 higher doses have also been associated with
11 deteriorating analgesia.
12 Importantly, new and convincing evidence
13 suggests that those that stay on opioids tend to be a
14 self-selected group of complex and often desperate
15 patients who may have difficulty with strict
16 compliance, and are thereby at higher than expected
17 risk.
18 Whereas there's now a considerable body of
19 evidence suggesting lack of efficacy and poor safety
20 for high-dose, long-term opioid pain treatment, there
21 are no convincing clinical data to support the view
22 that lack of availability of long-term opioid therapy

1 would increase the suffering of people with chronic
2 pain.
3 I realize that the FDA is looking for hard
4 scientific evidence, but I'd like to add a personal
5 viewpoint to the evidence I've already submitted. I've
6 been treating pain patients and involved in pain
7 education and research for 24 years. When the more
8 widespread use of opioids for chronic pain began in the
9 1990s, things looked pretty good, because we were only
10 looking at newly treated patients. Now we have a
11 population that consists of patients who've been on
12 opioids for years.
13 In my practice, I see complex and difficult
14 cases, but I don't see any patients I can convince
15 myself are doing better on chronic opioid therapy than
16 if they had never started. I see many patients with
17 very sad lives who start using opioids to deaden their
18 pain, but sooner or later they don't get much benefit,
19 and they're left with a desperate need to continue
20 despite lack of benefit. The opioids have made their
21 lives worse, not better.
22 Although we will always need more clinical

1 outcomes data, we do have a scientific basis for
2 understanding the neuro adaptations that arise with
3 continued opioid use. It's now established and
4 accepted that addiction is an irreversible neuro
5 biological disease, and that drug addiction arises when
6 continued drug use is combined with drug-seeking
7 behaviors.
8 Pain patients seek pain relief, not euphoria.
9 But there's a tendency for their behaviors to evolve
10 into drug seeking because they conflate opioids with
11 pain relief. Although there's no suggestion that
12 seeking of pain relief is the same as persistent
13 recreational drug seeking, biologically dependence on
14 opioid analgesia is similar to addiction and equally
15 refractory to treatment.
16 The figure on this slide depicts what we see
17 clinically when patients become dependent on opioids,
18 either during recreational use or during pain
19 treatment. With time, the opioid no longer produces
20 euphoria or pain relief, but is needed to simply feel
21 normal and avoid the worsening pain that occurs with
22 withdrawal.

1 Getting patients off established opioid
2 therapy is not at all easy, except for the most
3 motivated patients, usually requiring a great deal of
4 support, for an example, an intensive inpatient or
5 outpatient program. Even after such intensive support
6 and successful weaning from opioids, there are high
7 rates of returning to opioids.
8 A common clinical picture that we see in pain
9 practice is the patient for whom no dose is ever
10 enough. Pain levels are high, but those patients
11 cannot possibly conceive of being better without
12 opioids. The figure on this slide attempts to show why
13 tolerance and dependence, which are inevitable neuro
14 adaptations to continued opioid use, are key factors in
15 the clinical picture of refractory pain despite
16 opioids.
17 This slide is not readable, but it's intended
18 to show how many studies there are now that support
19 that people who are successfully weaned present a
20 remarkably consistent clinical picture. Their pain
21 doesn't either worsen or improve, but they feel better
22 and they feel liberated. Despite this, many who are

1 successfully weaned will go back to opioids.
2 Nothing is more compelling than the testimony
3 of patients themselves. As part of a clinical trial in
4 our department, which is a tapering trial, we've made
5 videos of some of our patients' experiences. These are
6 patients who've been successfully weaned.
7 I'd like to close my remarks with some quotes
8 from one of these patients. This is Karen, who has
9 given permission for me to speak her words in this
10 session. And she's one of many patients who say very
11 similar things.
12 "My experience with opioids has been
13 terrible. It felt like I was a walking zombie. At
14 first, I didn't mind that because it took the pain
15 away, but after a while, I didn't like it. It was not
16 me. It was not my personality. My skin was dry, my
17 hair was falling out my teeth hurt, I was not feeling
18 pain, not feeling life, not feeling anything. Later,
19 the pain was getting worse. I was not doing anything
20 different, why was the pain getting worse?
21 "Getting off was not easy but I had the
22 support of my husband and that helped. The pain is

1 still there. It's just as intense, but I deal with it
2 in a different way. No matter what way it is, I know
3 that once I've used one of the tools, I feel better.
4 I'm not groggy, I'm not absent minded, and I really
5 enjoy doing it a different way. But you need to have
6 these alternative tools to help deal with the pain,
7 like yoga or massage."
8 Thank you. FDA Questions
9 DR. THROCKMORTON: Thank you. Are there
10 questions for the panel? And then just, given the
11 weather and all of those sorts of things, I'm going to
12 continue into the next panel. The people that are
13 presenting for the rest of the time, save one, have all
14 checked in, and so we are going to see if we can work
15 through those before lunch, and if not we'll continue
16 after lunch.
17 But let's start with questions. And then Dr.
18 Ballantyne, maybe I'll start with you only because of
19 the quote that you used at the very end. So I had
20 asked a previous speaker about tools, either to decide
21 when opioids were appropriate, and then tools for how
22 to decide when discontinuation, or I guess how to

1 discontinue opioids was probably it.
2 So I know you have a lot of expertise in the
3 discontinuation of patients off of opiates. I'm
4 interested in your comments on those tools as well.
5 DR. BALLANTYNE: Well since you ask the
6 question, maybe I'll use it as an opportunity to say
7 the tools that we use, I mean these remarks were
8 actually tools that the patient made in terms of what
9 tools she uses. And we have very strong behavioral
10 medicine in our clinic and the behavioral tools are
11 extremely useful.
12 But in terms of getting patients off opioids,
13 Suboxone is a really useful tool. And we have -- you
14 know it's maybe another issue, though I know it's not
15 the issue at the forefront of this particular meeting,
16 but we often have our hands tied in terms of Suboxone
17 because it's labeled for use as addiction treatment and
18 therefore often only reimbursed for addiction
19 treatment. So we as pain physicians who are not
20 addiction specialists cannot say, even though some of
21 us actually have the waiver, we still can't get
22 reimbursement for our patients to switch them.

1 They can do the wean much more easily with
2 the aid of Suboxone than they can without it. Without
3 it it's a very long and slow process, or it requires,
4 if you want to do it more rapidly, really inpatient
5 service, which again is not available for most of these
6 patients.
7 DR. THROCKMORTON: Thank you. Other
8 questions that people have for any of the speakers?
9 DR. STAFFA: My question's for Dr. Pavelka.
10 I was wondering if your association or you were aware
11 of any data that's available on the quantity and volume
12 of prescriptions that are actually dispensed by
13 surgeons in the treatment of wisdom tooth extraction,
14 et cetera. We have data on prescriptions coming out of
15 pharmacies, but I know there's a lot of dispensing that
16 comes right out of the offices and I wonder if there's
17 any collection of that data.
18 DR. PAVELKA: Yes, there is. I'm not
19 familiar enough with it to cite numbers this morning.
20 But I will tell you, from a clinical standpoint, at
21 Baylor College of Dentistry, it is usual for a student
22 who has removed teeth for a patient to bring me a

1 prescription to sign that has 12, 5 milligram
2 hydrocodone tablets, no refills. In my personal
3 office, the typical prescription is 5, 500, 20 to 24
4 depending upon the difficulty of the surgery.
5 Since I have the microphone, if you'll
6 indulge me for just a moment. We stress to the
7 students to be very mindful of off-label uses. And
8 it's the big caution, don't do it. And when I hear
9 off-label mentioned in this format, it makes me
10 nervous. You know, my profession plays by the rules.
11 And if rules are going to be established, we'd sure
12 like them in black and white and very understandable.
13 Thank you.
14 DR. THROCKMORTON: I had a question for Dr.
15 Pavelka, too. I would say personally I'm very aware of
16 a lot of the work that the various oral surgeons and
17 dental associations have been working on in terms of
18 education and things. But do you have plans for trying
19 to assess the impact of the educational efforts and
20 things that you've done?
21 DR. PAVELKA: Yeah, I'm not involved at that
22 level at our school, but I've heard those discussions,

1 yes. And the thing that we try to really stress is if
2 you can manage the patient's discomfort without using
3 opioids, please do. But you know, don't put them
4 through many days of discomfort just to prove some kind
5 of research study.
6 DR. THROCKMORTON: Thank you very much.
7 Thanks to all of the panelists. Why don't we move on
8 then to the next panel, which is, I have Anita Roach,
9 Fred Brason, Rebecca Kirch and Robert O'Connor. If
10 they're in the room. And then I guess Mr. Israel,
11 you're going to be speaking for Cheryl Placek and Randy
12 Cohen is the other person. Thanks. Ms. Roach,
13 whenever. Thanks.
14 MS. ROACH: Good afternoon. My name is Anita
15 Roach, Program Coordinator for the Interstitial
16 Cystitis Association. The ICA commends the FDA for its
17 interest in establishing regulations that balance
18 patient safety with appropriate access to opioid use
19 for chronic pain conditions.
20 ICA appreciates this opportunity to describe
21 the needs and priorities of patients who suffer from
22 IC, a chronic disease described by pain in the bladder

1 and pelvic regions. Many IC patients who suffer from
2 severe and unrelenting pain turn to fast-acting and
3 long-acting opioids.
4 The ICA urges FDA to ensure that patients
5 with chronic pain conditions like IC continue to have
6 access to these critical pain medications as the agency
7 moves forward with regulatory work on the serious issue
8 of opioid addiction and misuse.
9 The ICA was founded in 1984 and remains the
10 only nonprofit organization dedicated to improving the
11 lives of those affected by IC. The ICA provides an
12 important avenue for advocacy, research and education
13 relating to the painful condition. Since its founding,
14 the ICA has acted as a voice for patients, establishing
15 support groups and empowering patients.
16 The ICA advocates for the expansion of IC
17 knowledge base and the development of new treatments,
18 including investigator initiated research. Finally,
19 the ICA works to educate patients, healthcare providers
20 and the public at large about IC. IC is a chronic
21 condition that consists of recurring pelvic pain,
22 pressure or discomfort in the bladder and pelvic

1 region. It's also associated with urinary frequency.
2 It is estimated that as many as 12 million
3 Americans have these symptoms. The effects of IC are
4 pervasive, damaging work life, psychological wellbeing,
5 personal relationships and general health. The impact
6 of IC on quality of life is equally as severe as end-
7 stage renal disease.
8 In 2011 the AUA established guidelines for
9 the diagnosis and treatment of IC, with the help of
10 five members of the ICA medical advisory board. Part
11 of the guidelines in IC diagnosis is given when other
12 conditions are excluded.
13 For instance, in order to rule out cancer as
14 a source of pain, urologists may perform cystoscopy,
15 bladder biopsy, and cytology. IC healthcare providers
16 gather detailed information on their patients' pain to
17 find possible causes and triggers, and to build a
18 multimodal treatment plan.
19 Providers often ask their patients to keep a
20 pain diary. Also self-report instruments such as the
21 O'Leary-Sant Symptom and Problem Questionnaire, and the
22 Pelvic Pain and Urinary Frequency Questionnaire are

1 used to assess pain and other symptoms.
2 These tools help healthcare providers to
3 better understand patient pain and gives insights to
4 the initial pain management. Pain management for IC
5 includes a variety of therapies including physical
6 therapy, CAM, OTCs and other non-opioid medications;
7 however, for some patients opioid therapy is needed.
8 Thank you again for this opportunity to
9 provide comments. On behalf of all people suffering
10 from IC, the ICA strongly encourages FDA to ensure that
11 IC patients continue to have access to opioid therapies
12 for chronic pain, and that the FDA does not implement
13 barriers that will impede a patient's ability to seek
14 these therapies in their time of need. Thank you.
15 DR. THROCKMORTON: Thank you very much. Fred
16 Brason?
17 MR. BRASON: Thank you. I'm very pleased to
18 be able be here. I am Fred Brason from Project
19 Lazarus, based out of North Carolina. I come today as
20 an advocate for individuals seeking care for their
21 pain, as well as an advocate for those families and
22 victims who have overdosed, and trying to strike a

1 balance through all of that with the work that we've
2 been doing, and seeing the issue as being a public
3 health issue, and developing a comprehensive approach
4 to address all of that.
5 And to ensure that again, that the patient
6 that needs the care can receive the care and the
7 medication and or treatment for that, as well as the
8 individual who does have an addiction or dependence
9 issue, to be able to find safe and effective substance
10 abuse treatment, and to strike that balance in our
11 communities.
12 That's what we approached in Wilkes County,
13 North Carolina. And this is a snapshot of the model
14 that we have developed through the public health work
15 we've been doing in Wilkes, and now all of North
16 Carolina bringing community awareness to the issue,
17 building coalitions within those communities to address
18 it across the board, not only the clinician aspect, but
19 also law enforcement, also faith community, also the
20 schools.
21 And then using data and evaluation to not
22 only use the data to drive the awareness and the

1 attention and the advocacy to the issue, but also to
2 study exactly what we are doing and what we are
3 accomplishing regarding the overdoses and the care in
4 emergency departments.
5 The community education piece is all of that.
6 It's getting to the parent to make sure that they're
7 locking up their medications. It's getting to the
8 young person to realize that they should not be sharing
9 medication with each other. It's getting to the senior
10 citizen to be aware that your medication should not be
11 sitting out on the counter where it's freely accessible
12 to other individuals.
13 It's getting to the hospital emergency
14 departments to ensure that they've got appropriate
15 administrative policies on prescribing opioids and
16 other controlled substances. Because when somebody's
17 walking in for dental pain or other pain, you know
18 there's a realization that they're going to probably
19 receive something.
20 So we've developed administrative policies to
21 address that, to make sure that the care is provided
22 but to make sure also that the individual in the

1 emergency department that might be there for the wrong
2 reasons is appropriately referred, or for long-term
3 care for their chronic pain to a pain specialist or
4 primary care physician, whatever that needs to be.
5 Then diversion control; working with law
6 enforcement to ensure that those individuals have not
7 turned their medication into a commodity. And we do
8 have that on a routine basis, unfortunately. And it
9 isn't just you know the bad guy over there, we have
10 senior citizens that have realized that they can sell
11 some of their medication and supplement their social
12 security and so forth. So it's trying to reverse all
13 of that and to ensure that again that the person who
14 has the addiction issue, who might be drug seeking and
15 creating that diversion.
16 And we know that 70 percent of those who
17 admit taking a prescription that is not theirs, they
18 get it from a friend or family member, whether it was
19 bought, stolen or shared. And that's a very hard thing
20 to police, but you know it's a community involvement to
21 change the public health perspective regarding
22 prescription medications and how they're used and

1 hopefully not abused.
2 And then the pain patient support.
3 Supporting that pain patient in whatever treatment and
4 whatever care that is necessary, and giving them viable
5 alternatives to everything that is necessary to
6 appropriate their care so that they can function in
7 life as they desire, whether that is through medically
8 assisted treatment or other avenues and alternatives
9 that may be more available in certain areas but in
10 other areas not available.
11 And then harm reduction; providing the locks
12 on co-prescribing the antidote to an opioid overdose to
13 that individual who is at risk for an overdose, and
14 that isn't just somebody who has an addiction issue. It
15 is an individual who was on opioid therapy because of
16 their chronic pain, and they may have emphysema, COPD,
17 renal issues and so forth that raises that level of
18 risk.
19 And in North Carolina we've started pilots to
20 where we are now co-prescribing Naloxone. The U.S.
21 army at Fort Bragg is now doing it. The
22 Eastern Band of Cherokee Indians are doing it. Some of

1 our emergency rooms in the hospitals are now doing it,
2 at the hospital's expense, when they find a patient who
3 is at risk.
4 Medicaid in North Carolina is now -- it's on
5 their formulary and it's now being dispensed that way.
6 We've got federally qualified health centers now co-
7 prescribing Naloxone to their patients who may be at
8 risk.
9 And I'm thankful to say Monday night we had
10 another save in Wilkes County because somebody who had
11 overdosed was able to -- an individual was able to
12 obtain that Naloxone and save their life through the
13 first responder.
14 And then drug treatment, raising the levels
15 of that so that when a doctor, when we're asking them
16 as a clinician to assess that patient, determine when
17 you're looking at the pain you're also looking at
18 mental health, you're also looking at substance abuse.
19 When you're talking about the military, you're looking
20 at traumatic brain injury and PTSD surrounding all of
21 that pain.
22 When you do that appropriate assessment, and

1 you find that there is an at risk possibility here, or
2 there has been a history of abuse, then you've got to
3 determine you know what do I prescribe? How do I
4 prescribe that? Do I start low and go slow? Or do I
5 have to refer them to appropriate mental health or
6 substance abuse treatment?
7 And do I have those available in the
8 community for that individual to step into? Those are
9 all issues that only the community can address to
10 ensure that that patient is receiving the appropriate
11 care, treatment, and if they are on the medication
12 that's needed for their care, that they are aware to
13 take it safely, take it correctly, store it securely,
14 dispose of it properly, and never share it.
15 That's part of the public health issue; we
16 share things. And if I had five people in a circle
17 right now, sitting at a table, and one of them said you
18 know my back is really aching from the work I was doing
19 on Saturday, there would be one of the other four that
20 would say, you know, I think I have something at home
21 that might just help you.
22 You know, and that's part of the issue about

1 public health, about what we're dealing with, with
2 prescription medications. And changing that
3 perspective is not easy. And we can't just redline
4 things to say that's going to fix it today. We didn't
5 get here overnight, we're not going to reverse this
6 overnight. And we have to ensure ongoing that our
7 communities are empowered to make those changes.
8 So that's where we came in with a provider
9 education. We created a prescriber's toolkit for
10 chronic pain management, for appropriate prescribing.
11 And all the tools that are necessary from universal
12 precautions to the pain agreements, to using our state
13 PMP, the prescription drug monitoring program.
14 That is gold for a prescriber and we're
15 consistently increasing the level of prescribers
16 utilizing that system and working with other states so
17 that we can have access to their information and they
18 can access ours, and working with the providers.
19 And so working with all of that, we're able
20 to move things forward like in Wilkes County, and all
21 of North Carolina, because as we studied our
22 communities in North Carolina, and looking at this

1 bubble graph, you can see that six percent of the North
2 Carolinians on average are receiving an opiate
3 prescription. That's the mean average. Your larger
4 bubbles on this graph are your more urban areas,
5 whether that's your Charlotte, Raleigh-Durham, Winston-
6 Salem and so forth.
7 But you get into like Wilkes County and some
8 of the smaller spheres there, those are our more rural,
9 mostly western or southeast communities in North
10 Carolina, and we've realized that those communities
11 have a tendency to have above the North Carolina
12 average for prescribing of opioids.
13 Looking at those factors as to why -- well
14 some of them, that is the only alternative for any kind
15 of pain treatment, pain care within those communities,
16 is to be able to appropriate and write that
17 prescription to that individual in order to have a
18 functioning life, to be able to go to work every day,
19 whether it's chicken farming, cattle farming, logging,
20 whatever it may be, because they can't afford to take
21 off. They have to function in life and take care of
22 their families and they desire to do that.

1 But when we look at these communities and we
2 say all right, they do have an above average
3 prescribing level, but they're also economically
4 depressed. There's also high unemployment. There's
5 also high poverty areas within those communities.
6 So we realize that if we're asking a
7 prescriber to look at that patient and to personally
8 prescribe what is necessary for them, not just
9 routinely doing it across the board, but personally
10 prescribe to them. We look at these communities and
11 determine we need to personally look at these
12 communities to determine how at risk are they in the
13 prescribing levels that are going on within those
14 communities?
15 Not to say that any of those prescriptions
16 shouldn't be written, but also realizing that we've got
17 to have more education, more awareness, both to the
18 general public, to the clinicians, to law enforcement,
19 to every aspect of the individual's lives within that
20 community, about prescription medications and their
21 abuse, their misuse, their diversion, their overdoses
22 and whatever treatment may be necessary for that.

1 And that's the model that we're not
2 appropriating in every community in North Carolina.
3 Because as we studied the communities, and we have 89
4 health departments in North Carolina servicing 100
5 counties. Seventy-eight percent of those responded to
6 our survey, and we asked them what's going on in your
7 community? Pill take back days, number one. The fixed
8 disposal sites for getting rid of old medications,
9 number two.
10 Then we go downhill. School-based
11 prescriptions, medical education on chronic pain,
12 mandatory use of PMP in the hospital emergency
13 departments. ED, emergency room case management for
14 those individuals that are frequent flyers, that are
15 trying to get appropriate care, or unfortunately maybe
16 drug seeking.
17 Overdose prevention in the prisons or jails
18 because they're more likely to overdose upon release
19 because they aren't aware of tolerance level changes
20 and so forth about their issues before they went in.
21 And then co-prescribing.
22 We realized our successes in Wilkes County,

1 all of these we're pushing to the 50, 60, 70 and 80
2 percent mark, so we realize that our other communities
3 need to boost these areas in order to bring about
4 change. Change and stop the overdoses from happening,
5 but ensuring that the pain patient has appropriate care
6 and the one person that has addiction has the effective
7 substance abuse treatment.
8 Because we found in part of our survey, that
9 the counties with coalitions had a 6.2 percent lower
10 rate of emergency department visits for substance abuse
11 than counties with no coalitions addressing this issue.
12 However counties that had a coalition within a health
13 department, more of a professional, engaged, embedded
14 community organization that was working on substance
15 abuse, working on prescription medications, those had a
16 23 percent lower rate of emergency department visits
17 within those communities, yet they had a 1.7 percent
18 higher prescribing for those communities.
19 So coalitions, public education can make the
20 difference in those communities. We've had a 69
21 percent drop in Wilkes County, from being third in the
22 nation for overdoses in 2007, over the past two years,

1 yet our prescribing levels have not changed.
2 They have maintained the same rate of
3 prescribing for opioids within our community. It's
4 above the state average, but it has maintained the
5 same. So we have not robbed somebody of the ability
6 for treatment, but we've ensured that they're taking it
7 safely, and they're not having the overdoses and the
8 adverse consequences to that.
9 And we did study those who did die from an
10 overdose, and in 2008, 82 percent came from a Wilkes
11 County prescriber, down to zero in 2011. We're still
12 having overdoses but they're getting it from other
13 sources and other places.
14 We are now going statewide with this. The
15 state Medicaid system office of rural health and the
16 Kate B. Reynolds trust, $2.6 million, we are taking
17 this to the entire state, both to every county, every
18 hospital, every clinician, with all of this education
19 and work over the next two years. So I can report back
20 to you in just over two years exactly what has occurred
21 addressing this as a public health situation. Thank
22 you.

1 DR. THROCKMORTON: Thank you. Ms. Kirch?
2 MS. KIRCH: Good morning. I am Rebecca
3 Kirch, the American Cancer Society's Director of
4 Quality of Life and Survivorship, and I thank you very
5 much for convening this meeting.
6 You all have asked the right questions of us,
7 and it's fair to say we would all like to have a larger
8 volume of concrete clinical evidence available
9 regarding the effectiveness of opioid use and other
10 integrated therapies in relieving pain for the various
11 populations and conditions.
12 But that said, we've actually made some
13 progress as a result of this meeting and the
14 conversations leading up to it. We may still disagree
15 about whether the available evidence supports the
16 requested labeling and other changes, but the
17 respectful exchange that we've had this week has been
18 refreshing and it's appreciated and important to
19 recognize.
20 Significantly, this discussion has identified
21 some areas where we have common ground. And we really
22 needed to turn that corner to move ahead. The proven

1 value of working together to achieve our mutual
2 objectives is actually what I want to focus my comments
3 on here this morning.
4 So to start, I've highlighted some key cancer
5 statistics from this year's facts and figures that the
6 American Cancer Society report was released just last
7 month. This was a big year in the cancer world,
8 because for the first time ever we actually saw a 20
9 percent decrease in U.S. cancer death rates. And
10 that's a statistic that translates to 400 lives saved
11 every day.
12 Importantly, a major source of this success
13 was the nation's concerted efforts to dramatically
14 reduce the harms caused by another highly addictive and
15 deadly substance, tobacco. And I'm pointing to this
16 collaborative achievement because it offers useful
17 strategic guidance for us in considering the options to
18 meaningfully and measurably address over-prescribing,
19 misuse, without harming patient care and access to pain
20 medications that many need to preserve function and
21 quality of life.
22 But specifically, this tobacco strategy

1 didn't rely on FDA regulation alone to get us to have
2 the job done. In fact that authority came much later
3 in the game. What the community did so effectively was
4 join forces early and pulling together. The multiple
5 diverse stakeholders worked together to develop a
6 comprehensive menu of options for strategic action. And
7 that menu emphasized smoking prevention, and risk
8 awareness strategies targeting youth, while also
9 increasing cessation services quality and access.
10 In this pain community, our hope has been to
11 initiate a similar coordinated effort and cohesive
12 framework for action. Implementing the Institute of
13 Medicine's 2011 Pain Report recommendations, alongside
14 the comprehensive drug control strategies outlined in
15 the ONDCP plan, offers us a very strong start, as does
16 working with FDA and the stakeholders here through
17 meetings like this.
18 But sadly the statistics on this slide also
19 show we have miles to go. The pain rates for people
20 facing cancer have remained persistently high for
21 decades. And the literature has offered a variety of
22 reasons and explanations that we all know well. As

1 shown here, our ACS cancer call center data, gathered
2 in late 2008, delivered similarly dismal findings about
3 the pain picture in cancer. Sixty-five percent of our
4 callers that we asked over a three-month span, from all
5 50 states, were experiencing pain with two-thirds
6 saying it was moderate to severe.
7 But more startling here, what we've found is
8 that the majority said they told their clinical team
9 about their pain, they made it a clinical issue, yet
10 two-thirds of those patients were still having pain
11 that they described at moderate to severe level.
12 There are two other studies that I've noted
13 here on this slide as an important cautionary tale for
14 us as well concerning pain disparities and the
15 importance of making sure we don't broaden that gap.
16 The breast cancer study, reported in last
17 month's Journal of Pain, found that one-quarter of
18 women had significant and persistent breast pain six
19 months post-surgery. It also identified four patient
20 characteristics associated with severe pain: younger
21 age, less education, lower income, and being non-white.
22 Another study, reported in the Journal of

1 Clinical Oncology last April, out of MD Anderson, found
2 the odds of under-treatment for cancer pain in
3 outpatient settings twice as high for minority
4 patients.
5 So why has this pain prevalence held so
6 steady, even in cancer where opioids have been
7 considered a mainstay for providing relief? One key
8 reason is the tone of our messaging that the public
9 does hear and absorb. Most often, reporting emphasizes
10 data and stories about the devastation of abuse and
11 addiction, and these stories are essential for all of
12 us to hear, ingest and share.
13 But we collect comparatively little data to
14 quantify the pain problem in communities. There's very
15 little ink or air time that covers the preventable
16 suffering that many people with pain endure. And these
17 stories are equally compelling and difficult and also
18 must be heard.
19 The unfortunate irony here is that while the
20 strong messages about pain killers and risks of
21 addiction may not be reaching the public and
22 professional audiences who most need to know to help

1 prevent harm, these messages certainly do influence and
2 outright scare many patients and families facing
3 unrelenting pain. And often also chill prescribing by
4 practitioners that patients are relying on to help them
5 relieve it.
6 It's up to all of us to work together in
7 crafting and communicating responsible and balanced
8 messages for consumers and clinicians that cover both
9 sides of the story, explaining the risks of addiction
10 and misuse, as well as the effectiveness of these
11 medicines as a lifeline to restoring function and
12 quality of life when used appropriately.
13 So one of the questions that you've asked of
14 us requests the methods used for distinguishing cancer
15 and non-cancer pain. That's the big theme here. And
16 the short answer from the American Cancer Society is
17 that we don't draw any such line in policy or practice.
18 The opioid receptors, they don't know or care if
19 someone has cancer. Nor do those receptors respond
20 only when someone is nearing the end of life.
21 We've heard from several speakers, yesterday
22 and this morning already, about how pain is a dynamic

1 and varied experience, including and perhaps especially
2 in patients with cancer, or having a history of it, no
3 matter where they are in their illness trajectory.
4 I've included here three quotes provided by
5 clinicians that we gathered around the time that REMS
6 was being developed for long-acting opioids to help
7 further illustrate the point. Each of these quotes
8 from the clinicians highlight how different patients
9 will respond differently to different therapies.
10 Just as with many other areas of medical
11 research, including cancer treatment itself, our pain
12 science and the understanding of addiction simply is
13 not yet, and may never be sufficiently precise so it
14 can tell us with certainty who will respond to what
15 medication in what way and why.
16 What we do know with certainty is that all
17 people experiencing chronic pain that interferes with
18 their quality of life and daily functioning,
19 irrespective of diagnosis or prognosis, should have
20 access to a full range of integrative pain therapies,
21 including opioid analgesics, to get the relief they
22 need.

1 Unfortunately, the federal funding for pain
2 control and addiction prevention research, and
3 intervention initiatives, is not currently resourced at
4 a level that will help us achieve our goals. This
5 slide, a comparative snapshot of the funding landscape
6 for oncology and palliative care as measured by
7 publications output supported by federal grant funds.
8 It's my David and Goliath motivating baseline slide
9 every morning.
10 My point here is simply to illustrate the
11 relative priorities and research emphasis that results
12 from having a national research enterprise that's
13 largely diseased focused in its framework and its
14 function. When you have pain and palliative care
15 positioned as a stepchild of all and favorite of none
16 across the NIH institutes and centers, it's no wonder
17 that we come up short on having the evidence we need,
18 and that you at FDA need, to better understand pain,
19 its treatment and the resulting outcomes.
20 And that's going to bring me back to my
21 opening message about the value of working together to
22 pursue the evidentiary answers and policy solutions

1 that we most need. Stopping suffering has been a
2 common theme for all of us participating in this
3 meeting. It's a powerful motivator and it is our
4 common denominator.
5 Until now, the pain policy atmosphere has
6 felt and been increasingly polarized, sometimes even
7 pitting addiction specialists against clinicians who
8 care for people with pain. And perhaps worse,
9 positioning families who have lost loved ones to
10 addiction against families who are losing or have lost
11 loved ones to pain.
12 I believe there's recognition now however,
13 like we've not really had before, among all the
14 stakeholders that such divisiveness rarely if ever
15 leads to progress or good policy. And if we don't show
16 we have our act together, it gives policy makers,
17 regulators and all every reason or excuse to resist
18 taking action that we collectively want and need.
19 We have an opportunity in the aftermath of
20 this meeting to try and work better together to promote
21 development of research and policies that make pain
22 relief and responsible prescribing a priority, and set

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1 high standards for education and practice.
2 Some of our options for coordinated federal
3 and state actions are listed here. And I want to
4 highlight that in addition to our ongoing work with you
5 at the FDA, we have to engage the NIH and the
6 appropriators, who make the funding allocations, to
7 boost our research, the CDC to help improve the
8 messaging and understanding for the public, and HRSA to
9 apply its professional training expertise in helping us
10 improve all clinicians' knowledge and skills in pain
11 assessment and management, including how to optimally
12 and responsibly use opioid-based therapies, as well as
13 undertake core steps in substance abuse risk screening
14 and knowing when to refer people for specialized
15 treatment.
16 So I want to close with my personal thanks
17 again to FDA and to everybody who travelled here for
18 this meeting, particularly the parents who shared their
19 stories, and the clinicians who shared theirs. I've
20 been in these meetings for about a decade myself, and
21 today, for me it's become personal as well. And I
22 wanted to share for you the personal experience that

1 I've had with the pain and powerlessness that comes
2 from losing a loved one to addiction.
3 My brother Eric died of lung cancer at age
4 47, that's how old I am now. And this was payback for
5 a 30-year addiction he had to tobacco. He'd taken up
6 smoking when he was 14 years old, and literally tried
7 everything to stop. It was only his Stage 4 diagnosis,
8 meaning the cancer had already spread to his brain, and
9 the breathlessness from a collapsed lung that brought
10 him to the hospital, that would be the triggers that
11 finally helped him to quit, but there was no turning
12 back that time clock.
13 I'd already been working for the ACS for
14 several years, so I prepared my family for that lung
15 cancer trajectory. But there was no way we could be
16 prepared for the destruction of Eric and us caused by
17 the unrelenting and unrelieved pain he suffered right
18 until the night he died.
19 His oncologist had prescribed pain medicine,
20 but Eric was afraid of becoming addicted, even when he
21 was dying. So he took those meds rarely and
22 reluctantly, and got very little relief. That pain

1 robbed his kids and all of us from enjoying the
2 precious time that we had left together. And like many
3 of you here, that personal experience put fire in my
4 belly to take action and find others to help.
5 So I'll finish with this quote from Helen
6 Keller, as we go into lunch I presume, that I hope will
7 serve as our inspiration. And I offer it as my
8 assurance as well to everyone here that the American
9 Cancer Society takes very seriously its charge to save
10 lives and stop suffering. And we stand ready to work
11 with FDA, our other partners and all stakeholders to
12 help meet this challenge head on. Thank you. FDA
13 Questions
14 DR. THROCKMORTON: Thank you very much. Do
15 members of the panel have questions for the speakers
16 that we've heard? Yes, Bob?
17 DR. RAPPAPORT: For Mr. Brason. Can you tell
18 us a little bit more about the educational programs for
19 the prescribers and how you implement that and how many
20 prescribers are actually getting that education?
21 MR. BRASON: Yes. Well when we started in
22 Wilkes, we did face-to-face. I mean we only had, we

1 only have 21 medical practices in the county. But
2 going statewide, we're doing it through a combination
3 of efforts. We have a direct partnership with the
4 Community Cares of North Carolina, which is the
5 Medicaid management system.
6 So through their chronic pain coordinators,
7 now hired in each network, they will be going practice-
8 to-practice and meeting with those physicians,
9 providing the toolkit and the information about chronic
10 pain management, and what they're doing to support that
11 individual patient that's got chronic pain.
12 We're doing, with the Governor's Institute
13 for Substance Abuse, they will do at least, minimum, 40
14 CME events throughout the entire state on chronic pain,
15 appropriate prescribing and how to assess and refer
16 those individuals that might have other issues.
17 We're also partnered with the North Carolina
18 Hospital Association, the North Carolina Medical
19 Society, the North Carolina Academy of Physicians'
20 Assistants, the family practice group, psychiatrists.
21 And we're doing individual CMEs, dinners, case
22 management meetings, grand rounds, emergency department

1 visits, nothing's off the table. We're meeting where
2 they are and providing the education.
3 And just through the provider network for the
4 Medicaid, there will be over 5,000 medical practices
5 reached. Through the hospital association, every
6 single hospital will be reached as well as every single
7 emergency department over the next two years.
8 So we're funneling it through every resource
9 that we possibly can. And all of those individual
10 groups that I've talked about are on board 100 percent
11 with the project.
12 DR. THROCKMORTON: Okay. We are going to
13 break for lunch now. And then when we come back after
14 lunch we'll do the open public hearing and the last
15 panel. We have one individual hoping to sort of get in
16 there in time to make their presentation, and I don't
17 want to prevent that. So why don't we come back say at
18 five minutes to 1:00 and we'll reconvene then. Thank
19 you very much.
20 (Lunch Break)
21 DR. THROCKMORTON: All right. We're going to
22 start the afternoon. And if Dr. O'Connor is here and

1 could come up, that would be terrific, and then we'll
2 do Mr. Israel. And then we'll do a couple from the
3 open public hearing. That would be great. Thank you.
4 And welcome to start whenever.
5 DR. O'CONNOR: Okay, I'll go first. Okay,
6 well thank you for hosting this important hearing. Just
7 I want to tell you briefly about myself. I'm a
8 practicing emergency physician. I've been in practice
9 for over 25 years. I'm also the secretary treasurer of
10 the American College of Emergency Physicians. I
11 coauthored our current opioid prescribing physician
12 paper, which I will summarize portions of. But my main
13 job is professor and chair of emergency medicine at the
14 University of Virginia in Charlottesville.
15 You know as a specialty in emergency
16 medicine, we treat many patients with pain. In fact,
17 the management of pain is incorporated into our
18 residency training. I've educated residents for almost
19 my entire career, and we run a fine balance between
20 proper treatment of pain and not overprescribing. So
21 we try to give the right amounts so the patients get
22 pain relief.

1 We're very cognizant of the fact that
2 patients come in with painful complaints. Over 40
3 percent of our patients present with pain syndromes,
4 usually acute. So we try to treat them in a
5 compassionate and thorough manner. We typically give
6 parenteral injectable opioids in the acute setting, and
7 then if needed, we follow up prescriptions with pretty
8 much a wide array of analgesics, which include opioids,
9 non- steroidal, anti-inflammatory drugs and even
10 acetaminophen. Typical patients that we see are ones
11 with acute fracture, kidney stone and the like.
12 We prescribe, as a specialty, about four
13 percent of all opioids that are prescribed; this in in
14 2009 according to FDA data, and that's -- I've had
15 trouble nailing down that figure. You may have heard
16 other percentages quoted, but that's the best
17 information that I could find.
18 We write about 12 percent of all
19 prescriptions. The number of pills, I think the reason
20 the numbers may differ is if you look at prescription
21 versus number of doses administered, we're a little bit
22 higher on the prescriptions, lower on the doses. It's

1 very infrequent for me to prescribe more than several
2 days' worth of analgesic.
3 We, as I mentioned, incorporate prescribing
4 into our resident training. We support CME training
5 for prescribing opioids. As I said, we have a policy
6 statement which is available on the web as well as
7 through Annals of Emergency Medicine.
8 One thing that I wanted to bring forth, from
9 our membership, is we are opposed to any sort of
10 mandatory training for opioid prescribing. We believe
11 it is incorporated into our residency training programs
12 and our rigorous recertification program for the board
13 exam.
14 The other point is we strongly support
15 prescription monitoring programs. I find them very
16 useful in terms of managing patients. If you look at
17 the literature, it results in increasing the dose about
18 40 percent of the time, decreasing it about 40 percent
19 of the time, and having no effect about 20 percent of
20 the time. So it really does help us assess how much
21 pain management we're going to have to provide. So
22 it's pretty much all over the map. It could be -- it's

1 very helpful though.
2 The other thing about monitoring programs is
3 we are opposed to programs where there's required
4 access to prescription monitoring programs. Just as I
5 choose to look at old records or not, I think the same
6 should hold for the prescription monitoring programs.
7 If I find the information useful, I would like to be
8 able to go get it. I would not want to be required to
9 go get it, which some states are implementing. And it
10 adds several minutes of time, which we really don't
11 have in a busy department. It detracts from other
12 patients.
13 The other side of this is we strongly -- I
14 mentioned education a minute ago. I think there's an
15 opportunity here to educate the public, specifically
16 the ones who are getting their first prescription for
17 an opioid analgesic, to tell them this is a drug that
18 potentially could lead to abuse. To tell them if they
19 have a history of mental illness, history of substance
20 abuse in the past, including alcohol, that they are at
21 higher risk for falling victim to becoming habituated.
22 That could go into the package inserts. I think we as

1 a specialty, because we see so many patients with -- we
2 see so many patients period, that there's an
3 opportunity for us to educate as well.
4 There's also -- the final point I want to
5 make -- is there's a belief amongst emergency
6 physicians that patient satisfaction scores, which we
7 are beholden to, our reimbursement will be linked to it
8 in the future, are somehow impacted by whether we
9 prescribe opioids and how much. And I think that's
10 probably a myth but I would call for assistance in
11 trying to come up with data to show that there is no
12 correlation so I can dispel that myth amongst our
13 providers.
14 And then I guess that wasn't my final point.
15 The last one is we would like to propose screening
16 patients for substance abuse in the emergency
17 department as we discharge them with prescription, and
18 think that that would be helpful, not so much to
19 influence our prescribing practices, but to heighten
20 the awareness among the patient that they may be at
21 increased risk and really provide education for them.
22 So thank you for your time and I'll take any questions

1 if that's appropriate.
2 DR. THROCKMORTON: We'll have an opportunity
3 for questions at the end. Thank you. Thank you very
4 much. Mr. Israel?
5 MR. ISRAEL: I'm here to speak on behalf of
6 Cheryl and Daniel Placek. Cheryl and Daniel Placek
7 lost their only son, Daniel Jr., on January 26th, 2012.
8 Daniel was a Navy veteran who was every parent's dream.
9 He got out of the Navy, was able to get into a
10 profession, making his own money, bought his own house,
11 and lived a normal life, until one day, two years ago,
12 where he hurt his back.
13 Daniel hurt his back and the first thing that
14 was prescribed to him was hydrocodone. That went on
15 for two years, and obviously in the beginning it helped
16 him, but after a while hydrocodone did not do the job
17 for him, and Daniel started getting hallucination,
18 paranoia and thoughts of suicide.
19 So his doctor decided to send him over to the
20 biggest pain management doctor in Western New York, Dr.
21 Gosy. Dr. Gosy upped the prescription and sent him on
22 home. That took on another few months and Daniel

1 became worse. His pain did not go away. His paranoia
2 got worse, to the point where he started locking
3 himself in the house and not getting out.
4 His parents took him back to see Dr. Gosy and
5 according to Cheryl and Dan, Dr. Gosy took the whole
6 situation very lightly and decided to prescribe Daniel
7 Suboxone. Gave him Suboxone and sent him on home.
8 Well, a couple of days later, they called Dr. Gosy
9 back, and Dr. Gosy suggested that they'll go and get
10 Daniel into the emergency room, which is what Cheryl
11 and Daniel did.
12 They took Daniel into the VA hospital, left
13 him there; thought he was in good hands. At around
14 12:30 at night, they got a phone call. Daniel hung
15 himself in his room. This is what a long-term opiate
16 treatment did to Danny. Twenty-seven years old, loved
17 to race motorcycles, a dream of a kid, ended up dead,
18 hanging himself at the VA hospital. That's their only
19 kid. They missed out so much.
20 But getting away from Danny and then getting
21 back to what we've been discussing over here for the
22 past couple of days. The one thing that I haven't

1 heard here, or heard very little of, is the addiction
2 nature of opioids.
3 I mean, everybody knows, and what I hear a
4 lot of is abuse, that people abuse the pills. And I
5 really, really resent that. I don't think Daniel
6 abused the pills. I know my son, Michael didn't abuse
7 the pills. I find it very disturbing that people will
8 talk like that, like it doesn't mean anything, you
9 know.
10 And I really find it very disturbing that
11 we've known the problem for such a long time and the
12 FDA keeps waiting, and I don't understand why. What
13 are we waiting for?
14 Why aren't we doing something? I mean every
15 time there's a problem with a bag of lettuce, the FDA's
16 right on TV and we're calling back all the lettuce. But
17 here we have people who are dying every day, every day,
18 and nobody's doing anything.
19 I don't understand. What are you waiting
20 for? I really don't understand what the FDA's waiting
21 for. I understand that you have a whole lot to look at,
22 but we're looking at one specific type of medicine over

1 here.

2 I mean, I have two pills over here that if I

3 turn around and ask the public, if you'll allow me to

4 do that. I have two pills over here. This is Motrin

5 and this is synthetic heroin. What would you rather

6 take? Motrin? Raise your hand, don't be shy. How

7 many of you would like to take synthetic heroin? That's

8 what I thought.

9 The problem is we need to inform the people.

10 We need to let the people know what is in those pills,

11 how bad addiction is. I, as a parent, did not know how

12 bad the addiction got hold of my son. There's no one

13 that could tell you. All I knew is Michael was taking

14 pain pills. And my reply was, okay, taking pain pills

15 Michael, you better careful, that could be addicting.

16 And that's as far as I went.

17 No one tells you how bad the addiction grabs

18 a hold of you. No one tells you, doctors don't tell

19 you, the FDA doesn't tell you, no one tells you how bad

20 it is. And then when you find out, you're thinking

21 it's just like quitting smoking. Oh well, why don't

22 you quit them Michael, I quit smoking, why can't you

1 quit opioids? You can't. You can't do it on your own.
2 We all know that.
3 You can't take that five days in detox.
4 Three-quarters of the kids get out after five days of
5 detox and go right back to it. You take 28 days of
6 rehab, and they come out and go right back to it. The
7 best thing, in my opinion, is let's stop talking.
8 The status quo, the way it is right now, is
9 not working. You got to stop the overprescribing. You
10 got to educate the public. You got to educate the
11 parents. And you got to educate the doctors. And
12 until that gets done, how many Michaels do we want to
13 lose? How many Daniels? My God, this is a genocide in
14 this country.
15 We got to do something. You know, put some
16 warning on. Let the doctors know that this is really a
17 medicine that should be watched. If you have cancer,
18 yes, take that medication. But if you twisted your
19 ankle, take two aspirins and call me tomorrow. That
20 will work a lot better. How did we get to the point
21 where we need to take a pill for every little thing?
22 How did we get here? Thank you. Open Public Hearing

1 DR. THROCKMORTON: Thank you. Mary, I have
2 Jeff Fudin in the public hearing. And sir, if you'd
3 like to come up and make your comments, that would be
4 terrific.
5 DR. FUDIN: Now? Yes, good. Thank you. I
6 would like to thank the panel in front of me for a
7 very, very difficult job. I wouldn't want your job for
8 all the money in the world. I respect what you're
9 doing and appreciate the time.
10 I want to start by saying that, also that, in
11 a way sort of, we owe PROP and Dr. Kolodny a debt of
12 gratitude because had they not brought some of these
13 issues forward and forced the issue, perhaps we
14 wouldn't be here in this hearing where there's been a
15 lot of dialogue.
16 My name is Dr. Jeffrey Fudin, F-U-D-I-N. And
17 shortly after I read the PROP petition, at the end of
18 July, I formed a group called PROMPT, P-R-O-M-P-T. And
19 that stands for Professionals for Rational Opioid
20 Prescribing and Pharmacotherapy.
21 My affiliations are that I am an adjunct
22 associate professor of pharmacy practice at the Albany

1 College of Pharmacy and Health Sciences. I also am a
2 clinical pharmacist with a specialty in pain management
3 at the Stratton VA Hospital in Albany, New York.
4 I want to clarify that the statements I'm
5 going to make are not the opinion of the Stratton VA or
6 anybody in the Department of Veteran's Affairs, not
7 necessarily the opinion of the Pharmacy College, but in
8 some cases are certainly the opinion of PROMPT.
9 I also was one of the coauthors of the 2009
10 guidelines that were put together by the American Pain
11 Society and the American Academy of Pain Medicine. And
12 I would like to mention that there was two other
13 coauthors that are members of PROMPT, and they are Dr.
14 Jane Ballantyne and Dr. Roger Chou.
15 Okay. I have no disclosures to make with
16 regard to drug company financing. I'm here of my own
17 accord. I would like to respectfully ask that in the
18 spirit of good faith, and maintaining an equal playing
19 field, I would like to point out that several of the
20 presenters today displayed that they had no conflict of
21 interest, quote, with any pharmaceutical companies.
22 Considering some of the data that we saw

1 yesterday, regarding Workers' Compensation, considering
2 some of the special interest groups, other than
3 pharmaceutical industry, I respectfully request that
4 all participants presenting at this meeting be required
5 for the record to disclose any and all funding sources
6 for travel and related professional activities directly
7 connected with his hearing and future hearings, whether
8 it be the pharmaceutical industry, related or
9 otherwise, including but not limited to organizations
10 that could potentially have a financial interest in the
11 reduction of prescriptions that are written.
12 For example, it is clear that opioid use has
13 gone up, and that the street availability has increased
14 with the number of prescriptions written. I suspect
15 that it is also very clear, and graphically
16 superimposable, if we were to look at the payments put
17 out by various insurance companies, including Workers'
18 Comp. So they have an inherent interest to reduce the
19 number of prescriptions written.
20 We've heard that oxycodone and heroin are
21 practically one and the same chemically, I intend to
22 clarify that. While I don't dispute this, I offer for

1 the record that buprenorphine, while very safe in
2 comparison to a lot of opioids, is equally chemically
3 similar to heroin.
4 Furthermore, dextromethorphan, which is an
5 ethylated dextrorotatory isomer of levorphano, which by
6 the way is a very potent opioid, are both phenanthrene
7 derivatives and very similar to heroin. So minute
8 chemical differences, as most physicians and scientists
9 know, can make dramatic differences in the chemical. So
10 to call oxycodone synthetic heroin is completely
11 inappropriate.
12 To suggest that oxycodone or any pure opioid
13 is more or less similar without divulging all the facts
14 is misleading and does not serve any productive
15 outcome, other than riling the media and the families
16 of patients that have already suffered and continue to
17 suffer.
18 I want to address for a minute the morphine
19 maximum daily dose. I think that we heard yesterday
20 that those patients receiving 100 milligrams or more of
21 morphine equivalents per day had a higher rate of
22 death. But that data is shortsighted considering that

1 the dose prescribed is likely prescribed to a
2 population of sicker patients, compared to those on
3 lower doses.
4 While this data tells us is that there's a
5 higher correlation between persons receiving at least
6 100 milligrams of morphine equivalents daily and death,
7 compared to lower doses, but it does not tell us what
8 that correlation is.
9 With specific regard to morphine equivalents,
10 I wanted to share two projects with you. The first is
11 a publication that came out this past December, which I
12 authored with two others. It was published in the
13 Journal of Pain and Palliative Care Pharmacotherapy,
14 and it was entitled Rifampin Reduces Oral Morphine
15 Absorption: A Case of Selection Based on
16 Morphine Pharmacokinetics.
17 In that study, we identified a patient; it
18 was a patient case that came to our hospital. This
19 patient was admitted for endocarditis because of IV
20 drug use with heroin. That patient, we wanted to,
21 while he was in the hospital, get serum levels of
22 morphine so that when he was discharged, and we

1 followed him upon discharge, that we could see whether
2 he was compliant with the medications.
3 This particular patient did have chronic low
4 back pain, so we had a dual diagnosis of substance
5 abuse and back pain, at least presumably requiring
6 opioids, which I wasn't sure was the case. In any
7 event, we did serum levels. It was in a controlled
8 environment. The nurse was giving him this drug. Serum
9 levels came back about 25 percent of what we'd expect.
10 We had expected about a 65 nanogram per mil serum
11 level, came back around 15. I knew he was taking the
12 drugs. Had he come in as an outpatient, someone may
13 have thought that he was taking a quarter of his drugs
14 and diverting the rest.
15 As it turns out, after a lot of research and
16 piecing together various professional literature, we
17 discovered that there was a drug interaction between
18 Rifampin and morphine, something we would never expect
19 because morphine is not metabolized through the P450
20 system, like methadone is.
21 The interaction was one of absorption from
22 the GI tract because of the effect on G-glycoprotein

1 efflux pumps. Okay, so this is a fellow that had
2 significantly a lower dose of serum morphine. The
3 intent was to start him on buprenorphine.
4 We couldn't do that because presumably he was
5 on too high of a morphine dose. But by serum levels,
6 it turns out that he was on an adequate dose to start
7 him on buprenorphine. My point is that it's not a
8 simple matter of just prescribing a dose of 100
9 milligrams or the equivalent.
10 The second thing I wanted to share with you
11 in this regard is that just last week, maybe the week
12 before last, I assigned a class of pharmacy students,
13 in their fifth year, in my pain elective course, a
14 project. And that was I'm going to give you five
15 different opioids, and I'm going to ask you to convert
16 those five opioids three different times, with three
17 different resources, you can use anything you want. You
18 can use online opioid calculators. You can use a peer
19 review journal, a textbook, a package insert, whatever
20 you want to do.
21 The results were staggering. So 15 students
22 looked at this. There were 16 unique different

1 references. There was five drugs, hydrocodone 80
2 milligrams, fentanyl patch 75 micrograms per hour,
3 methadone 40 milligrams, oxycodone 120, and
4 hydromorphone 48. This has all been posted on my
5 website.
6 Just to give you one example of the extent of
7 deviations were staggering. For a 75 microgram patch,
8 the doses calculations of morphine equivalents were
9 anywhere from 135 milligrams to 540. One standard
10 deviation was 132 milligrams; another reason why we
11 cannot put a simple milligram amount on these drugs.
12 The other thing is that, with regard to this
13 P-glycoprotein drug interaction I just told you about,
14 there's going to be a similar publication coming out,
15 hopefully soon, that looks at the G glycoprotein in
16 telaprevir. And telaprevir, of course, is a drug that
17 we use in hepatitis patients whom often are also
18 comorbid substance abusers and need to be on methadone,
19 which is also quite an extensive problem.
20 So, I'm just about done here. The problem is
21 as presented this hearing of substance abuse, misuse
22 and addiction, street access; I think that really some

1 of us are missing the point. Everybody here has an
2 inherent concern of substance abuse. We're all
3 concerned and feel horrible for the families that lost
4 children or spouses. It's a horrible thing. No doubt
5 about it.
6 However, I think that we need to make it
7 clear that the issues, the common theme that I'm seeing
8 here, is that the clinicians have not continually
9 reassessed these patients. That has got to happen.
10 That has not happened time after time. I've heard this
11 physician did that. This physician did that. They
12 continue to prescribe the drug for two years. That is
13 wrong and it needs to stop.
14 Drugs are flowing to the wrong hands. All
15 those issues are separate issues from treating pain.
16 That problem of pain management needs to be delineated.
17 The commonality is that education is essential, not
18 only to prescribers for managing pain, like Dr. Argoff
19 nicely summarized some of the differences of pain and
20 how lots pains do not even respond to opioids as well
21 as non-opioids.
22 It needs to include recipients of these

1 medications at the point of the prescriber. Equally
2 important is that pharmacists cannot evade their
3 responsibility of counseling upon dispensing of a
4 prescription simply by asking a patient to sign a
5 statement saying that they refused counseling. That is
6 inappropriate.
7 An extension of the REMS, ETASU for
8 transmucosal fentanyl products to the community
9 pharmacy setting for all opioids could be a step in the
10 right direction. But it can't stop there. It should
11 include the prescribers, and a minimal knowledge base
12 on how to interpret urine drug screens.
13 It's not enough to order the screens. Quest
14 presented some nice information, but if a clinician
15 does not know how to clearly interpret those screens,
16 or doesn't understand them, the utility, the pitfalls
17 and the benefits, and when or when not to order a serum
18 analysis as a follow-up, then the screens are only as
19 good as the clinicians that are evaluating them.
20 With regard to dentists, I've given lots of
21 lectures to dentists in many, many states and dental
22 surgeons. And I was glad to hear this morning from the

1 fellow that talked about the maxillofacial practice. I
2 suggest that dentists should not be allowed to give
3 refills on any medication, and that they should be
4 limited to about a 48-hour supply for routine root
5 canals and extractions.
6 If there are more complex procedures, they
7 should be required to enter a code to so designate that
8 on the prescription as NSAIDs, unless they are
9 medically unacceptable, are generally more effective
10 for dental pain with simple root canals or extractions.
11 If that is not the case, then they should designate on
12 their prescription that it's not one of these simple
13 procedures.
14 To put these in perspective in closing, we've
15 heard a lot of numbers and statistics, but to be honest
16 with ourselves, I think we need to look at the bigger
17 picture. There are more deaths caused each year by
18 tobacco use than by all deaths from human
19 immunodeficiency disease, illegal drug use, alcohol
20 use, motor vehicle injuries, suicides and murders all
21 combined. That information is available by CDC and
22 other references as well if you need that. I'm sure

1 you all have access to that.
2 In closing, I wish to stress the importance
3 of a prescription monitoring program that stretches
4 across all states and allows prescribers and
5 pharmacists to access real time data that must be
6 evaluated prior to ordering or dispensing controlled
7 substance prescriptions, regardless of the scheduling
8 and regardless of the state. Such an effort must, must
9 include all federal government facilities, including
10 the Department of Defense and the Department of Veteran
11 Affairs as opioids often find their way from federal
12 institutions to the hands of civilians.
13 Limiting opioids by tying the hands of
14 providers is not in the best interest of patient care
15 and will likely cause a whack a mole effect, resulting
16 in escalation of heroin use and or other agents. The
17 key is to work together and use computerization to
18 better monitor where these drugs are coming from and
19 where and when they're dispensed in real time.
20 We must educate providers, pharmacists and
21 families on the risk and benefits of opioid therapy. I
22 think we can learn from the Lazarus Group and we must

1 extend the opioid REMS programs as they currently
2 exist. Thank you very much.
3 DR. THROCKMORTON: Thank you. And Mary, we
4 have one video and then we'll have some questions.
5 VIDEO (VARIOUS SPEAKERS): I got my life
6 back, now I can enjoy every day that I live. I can
7 really enjoy myself. And before, even a good day was
8 hell. I mean I couldn't enjoy nothing, but now I can
9 enjoy myself. That's what you can say is wonderful. I
10 look at the future the same way a young guy, 25, 30-
11 year-old would.
12 His biggest problem was he would sleep a lot,
13 and I mean he was at the point where he was -- could be
14 sitting in here talking, like I'm talking and fall
15 right off asleep while he's talking. I went to the
16 point where I had to put his socks and shoes on, his
17 clothes on, his shaving, wash his hair, look out at him
18 just like he would look out at a two or three-year-old.
19 He said I'm in so much pain I've got to have that pain
20 medicine. He said I just cannot live without that pain
21 medicine.
22 People would look at him and literally think

1 well, he's got to be drunk, or he's got to be high on
2 something. They didn't know, you know, he was just on
3 a lot of medicine.
4 And my phone rang and it was him, and he says
5 I can't go no farther. And the highway patrolman told
6 me within five minutes, after I got off the phone with
7 him, he run off the road. That's when he run off the
8 road. And they said what happened, eye witness behind
9 him, said that they thought maybe he'd got distracted,
10 which I knew what was wrong with him. He fell asleep
11 from that medicine. I knew what it was.
12 I think when I first started I was on 20
13 milligrams in the morning and 20 in the evening. And
14 it worked. It worked.
15 Since I've been on this new pain medication,
16 I have not missed one day of work, and my boss really
17 appreciates that. Lauren is there every day. So I'm
18 able to be very productive. I'm a productive person
19 again, which is really great.
20 Eventually it stopped working, and I
21 increased. I think it was 40 in the morning and 40 in
22 the evening. And then eventually that got increased.

1 This went on for years. It went on for years. I just
2 knew eventually I was -- you know, I'd probably kill
3 myself, OD, taking this medicine. I would never take
4 another OxyContin. You couldn't get me to take another
5 OxyContin, never again.
6 Physical therapy hopefully will get me strong
7 enough where eventually I won't need to use the drug
8 therapy. But the drug therapy allowed me to do the
9 physical therapy, which in turn lowered my blood
10 pressure and lowered the blood levels.
11 Periodically, he and I would go have lunch
12 together. In the conversation was always the fact that
13 he was taking lots of meds, he had just seen the
14 doctor, or he was just going to see the doctor, or he
15 was about to meet a new doctor. So the word doctor and
16 meds and pain, those words came up over and over and
17 over again. And I would say where's the pain? I did
18 ask him that. And he'd say all over, all over,
19 especially my back and my arms and my shoulders, all
20 over.
21 DR. THROCKMORTON: Are we having technical
22 challenges with that one? Oh, I see. Okay, that's

1 all, the more that we're able to play on that. Okay,
2 thank you. Do members of the panel have questions for
3 any of the three people that have provided us comments
4 here? Go ahead. FDA Questions
5 DR. STAFFA: My question is for Dr. O'Connor.
6 I was wondering if you could just explain a little bit
7 more. You've said that you found the prescription drug
8 monitoring information very helpful, in your position
9 as an ER doctor. And I'm wondering why you don't want
10 to require that, given that it may not be possible to
11 pick out the patients for whom you should be looking at
12 that information for. If you could just talk a little
13 bit more about that.
14 DR. O'CONNOR: Yes. It's very similar to
15 wanting to access old records. It's a way -- it's a
16 clinical decision about whether that information would
17 be useful. And to require it in each and every case, I
18 think would waste our time. I don't consult the
19 prescription monitoring program for every single case.
20 For example, if the patient is not on any
21 medications, doesn't have any records within our health
22 system, and I'm prescribing a limited number of

1 opioids, I probably wouldn't look them up. Whereas if
2 I suspect someone's coming in with an acute
3 exacerbation of chronic pain, then I would most
4 certainly look them up.
5 So I wind up looking -- I probably look up
6 three-quarters of the patients, somewhere in that
7 range. But there are cases where I'm pretty sure that
8 the information wouldn't help me. And the requirement
9 is, it takes time. And you know I think to have it
10 available is key. Many states don't have it. I think
11 about 40 plus have some system in place, but the
12 reciprocity's very limited.
13 I would like to see a national program of
14 prescription monitoring where you could look up a
15 patient by some identifier that would tell you,
16 nationwide, what they've been prescribed. But the
17 requirement, I think it's just a little bit too onerous
18 for us.
19 DR. THROCKMORTON: Yeah, I had a similar
20 question because at the -- Dr. O'Connor. At the end of
21 your comments you said you did feel as though you
22 should be screening, which of course is time occupying

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1 as well. So it was a little hard for me to use the
2 time as a rationale for not looking at a subset of
3 patients who are using opioids for instance, but then
4 not to worry about that same challenge when it came to
5 the screening of the same patients.
6 DR. O'CONNOR: Yeah, the screening could be
7 very brief. It would just heighten awareness, in the
8 patient's mind, about the potential risk of these
9 medications, and would help stratify them as to whether
10 they're very susceptible or not to substance abuse. It
11 would probably three or four questions --
12 DR. THROCKMORTON: I see, yes.
13 DR. O'CONNOR: -- that could be part of
14 patient education at the time of discharge.
15 DR. THROCKMORTON: Thank you. And then my
16 second question was related to the 40 percent, 40
17 percent, 20 percent comment that you made. Did you say
18 there's a reference to that? Because that's a very
19 interesting statistic. I think we're all interested in
20 understanding PMP use and outcomes and things. And
21 that one would be very useful for -- at least I'm not
22 familiar with that one. If you could provide it, it

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1 would help us.

2 DR. O'CONNOR: Okay, I'd be happy to.

3 DR. THROCKMORTON: Great. Thank you very

4 much. Are there other questions? I'm looking down to

5 see if I have. Oh, Dr. Fudin, you mentioned an

6 interaction with Rifampin, very interesting interaction

7 related to the transporters. Is that well-known, or do

8 you believe -- I don't know if that's in labeling, for

9 instance at present. And if not, beyond that paper,

10 are there other references related to that interaction

11 that you're aware of?

12 DR. FUDIN: That's a great question. I think

13 that it's not well-known amongst general practitioners.

14 I think that trends have been seen a lot amongst pain

15 specialists because they deal with this so often, and

16 to some extent infectious disease doctors. I know this

17 because I was so surprised myself that I reached out to

18 some of my colleagues by LISTSERV.

19 And I found from them that many of them knew

20 that this was an issue, that patients had lower -- or

21 seemed to crave opioids when they're on Rifampin or

22 other powerful inducers of the P-glycoprotein but they

1 couldn't really explain it.

2 So the whole premise of this article, to

3 answer the question specifically, is that I need to

4 piece together information from other articles. For

5 example, there was one article that looked at quinidine

6 and digoxin, where we see the exact opposite effect,

7 okay. There was another article that looked at an

8 enzyme efflux inhibitor in patients that were either on

9 morphine orally, or they're on morphine by IV. Of

10 course the IV was not affected.

11 So I think that it is not well-known amongst

12 primary care providers. I hope to expose this in a

13 bigger way because I think that G-glycoprotein is not

14 considered that often.

15 I'm particularly concerned in the interaction

16 with methadone. Because on methadone, we're talking

17 about inhibition on the G-glycoprotein, which can not

18 only raise serum morphine levels, but that enzyme is

19 also an important enzyme as a carrier protein into the

20 blood-brain barrier. So not only will it raise serum

21 levels, but it will also raise levels in the CNS. And

22 besides that, because it has an effect on 3A4

1 inhibition, the methadone will also not be metabolized.
2 So I think, considering that methadone
3 represents two percent of all prescribed opioids, but
4 30 percent of all deaths involve methadone, I think
5 that this is something that's grossly underappreciated
6 and needs to be studied.
7 DR. THROCKMORTON: Thank you. And you said
8 your paper was in the Journal of Pain. Is that right?
9 DR. FUDIN: It was in the Journal of Pain and
10 Palliative Care Pharmacotherapy in December.
11 DR. THROCKMORTON: If you could just give us
12 the reference or something, that would be appreciated.
13 DR. FUDIN: Absolutely. I'd be happy to do
14 that.
15 DR. THROCKMORTON: So that I can pass that on
16 to my pharmacologists so that we're aware.
17 DR. FUDIN: You know, I would like to make
18 one other quick comment if I can. Based on the
19 question that Dr. Staffa just asked with regard to
20 testing these patients in an emergency room, and
21 believe me, I have an appreciation of not wanting to
22 check all these patients because I get called -- all I

1 do all day is pain management, and I work a lot with
2 emergency room physicians.
3 But based on what we've seen in pain clinic,
4 I mean just two weeks ago I had 83-year-old woman who
5 came in dressed to the nines, knew her well, never
6 would have expected a problem. She was getting chronic
7 morphine around the clock. She tested positive for
8 cocaine and negative for morphine.
9 So really, unfortunately we can't tell. You
10 know, pardon me, so like God bless her. She's 83 years
11 old and she wants to snort cocaine, let her do it. But
12 the other part of the cycle, if we're providing
13 morphine, it's a problem.
14 DR. THROCKMORTON: Thank you very much. Just
15 a question, whether there's anyone else that has other
16 public comments that they'd like to make at this point.
17 Otherwise I'll thank the panelists, thank the comments
18 that we've received, and we'll -- ah, you're standing
19 up but going the other direction. So I'll assume
20 that's a -- please.
21 DR. CARR: Good afternoon. Thank you for
22 allowing me to make a comment on this.

1 DR. THROCKMORTON: You just need to identify
2 yourself, that's all.
3 DR. CARR: My name is Debra Middleton Carr.
4 I'm a pharmacist. And there were a lot of things that
5 were said here, and this is actually the first time
6 I've been here and I have learned a lot about what it
7 takes to make drugs legally legal listed. But what's
8 really happening here, we got a lot of suggestions, no
9 solutions, and that's why we're here.
10 I wanted to mention about the Opana and the
11 OxyContin. At this time, even with dispensing this, a
12 prior authorization is needed. So we don't see a lot
13 of this as happening or being given to the patients.
14 The gentlemen, they're not here today -- they
15 may be here, Covectra and MedicaSafe -- they did have
16 good suggestions. This is what we are needing to code
17 a lot of these products to monitor, but we have to
18 again look at can patients afford it, will it be mailed
19 out, is it going to be at the retail level, and what
20 about the insurance costs? Because a lot of patients
21 do not have the money to pay for a lot of these
22 expensive, great idea products. So we have to look at

1 that.

2 The Suboxone and this Subutex, is something
3 that we should really look into, to helping the
4 patients to control a lot of the addiction that they
5 have with this. I see probably one percent of this. At
6 this time the Suboxone tablets have been removed. A
7 lot of patients who are familiar with this, are not
8 able to get this drug because now it's on the film,
9 which has been changed. That is a problem with a lot
10 of the patients. For one, the strips can deteriorate
11 very quickly, so the patient's not able to get the
12 drugs, like the medication that is needed to help them
13 with the addictions that they have occurred using a lot
14 of the opioids.

15 I have not seen a lot of -- someone from the
16 board pharmacy which I would like to see, someone from
17 NADDI, and someone from the medical examiner groups. I
18 mean we need to have a conglomerate of a lot of
19 different divisions. We have groups, but we need to
20 make now a complete circle of what's going on.

21 I mean, I'm surprised I'm the only pharmacist
22 at this time that is here. I heard another pharmacist.

1 We're not aware of a lot of this stuff that is going
2 on. By the time it gets to us, you guys have already
3 made the decisions. A lot of this is put on the
4 weights of the pharmacists' shoulders. So we have to
5 stay in mind 14 hours a day, trying to decide what
6 we're going to do in giving patients medications. So
7 that's one thing we have to look at.
8 There's another division, again is the NADDI
9 group, a very strong force that what we need to inform
10 us of what's going on in the world out there. But I'm
11 pretty sure they're thinking the same thing, this is
12 the FDA problem. But everybody's above us, the FDA,
13 the Board of Pharmacy, the DEA, the doctors.
14 But when it comes down to me, because now
15 sitting, here, I seem like I'm the bad guy. Yes, I
16 have the right, and the legal right to dispense because
17 of what has been given to me. But yet, I look like the
18 monster. I hear all the stories. I hear all the
19 patients that have got addicted to the drugs.
20 I myself am the pain specialist, and I just
21 consider myself the pain specialist because I try to
22 control the drugs that I dispense at my pharmacy. Right

1 now no one can dispense those besides the specialty,
2 like cancer, drugs -- besides pain management, let me
3 put it that way.
4 I take the responsibility, Monday through
5 Thursday, to do this. I'm pretty sure they've come
6 there and they're like where's Debra, she's not here.
7 What do they do? They wait until I get back. Can they
8 go somewhere else? It's very difficult for them to go
9 somewhere else because most places don't have the drug.
10 They say they can't get the drugs, but I get the same
11 drugs from the same suppliers like everyone else.
12 So the thing is that what are we going to do?
13 I'm tired of being the only one with this weight on my
14 shoulders. When I go home at night, I have to think
15 about the same things. Can I help the patient? Did I
16 help the patient? They're actually intimidating at
17 points.
18 I even ask the doctors, I call doctors, okay,
19 what are you doing? I need credentials. I need for
20 you to tell me exactly what do you know about this
21 patient and what do you know about pain management?
22 You've taken about 50 to 100 hours of pain management,

1 but yet I have to dispense because you write the
2 prescription?
3 I still have a choice to make. And I need to
4 help myself. I need to help the patient. And I need
5 to have the doctor understand why I'm questioning what
6 is going on. Well, they've been on it for years. Yes,
7 usually. They start with different type of
8 medications, then they go to the hydrocodones. You see
9 that first. Then from the hydrocodones you go to the
10 opiates. Okay, what are we doing? But I don't have, I
11 don't have all that time to decide and to speak to
12 doctors about educating about pain management.
13 Half the time I can't get them. But if I
14 don't get them, the patient now is -- the patient does
15 not get the medicine at that particular time until I
16 actually find out what are you doing, why are they
17 here, how long have they been getting this medication,
18 and what are we doing to try to better the pain levels
19 for this patient? That's why when I said 1 to 10, what
20 does that mean to me? What does it mean to you? How
21 do you help these people?
22 But the thing is that by the time it gets to

1 me, it's already over. It's finished. I can't do
2 anything. I can't go into the person's brain that says
3 okay, you're addicted. I can't give them every
4 indication of why you should not be taking this drug,
5 if the doctor has given it to you.
6 So again, it's a very difficult world that
7 we're in. A lot of pharmacists have no idea about what
8 this meeting is about today. I'm here because I'm
9 frustrated. I'm tired. And to hear, and to come and
10 walk in here to hear patients, the parents, speak about
11 what's going on, I feel like the legal, yes, drug
12 pusher that's causing a lot of this to happen. The FDA
13 must do something.
14 And putting C2s, C3s, hydrocodones to a C2, I
15 don't think that is going to work at all. The
16 comparisons of the blues and whites to pinks, these
17 people know what they're doing. They know what they're
18 asking for. Some of them do have abuse, innocent
19 abuse. Some of them, yes, are very addicted.
20 But we must understand and realize I have a
21 tough job. I'm the we here now. I'm here standing as
22 I, but I am the we, and I will take all the information

1 back to my colleagues. Because I've asked pharmacists,
2 do you have any idea? There's an FDA meeting going on,
3 it's about opiates. Okay, well, let me know what
4 happens when you get there because we do not really
5 understand.
6 But by coming to this meeting, I see the need
7 for us as a group, the FDA, the DEA, the Board of
8 Pharmacy, NADDI, all of us, pharmacists, because I am
9 at the end of this. I'm the police of this drug. And
10 to get it out and not have the doctors be responsible
11 for helping me, to help the patient, is a problem.
12 Now, I either can step back, or I can stand
13 up and make a change. But I will basically take all
14 the information that I need, that I have gathered here,
15 to other pharmacists, to let them know this is a
16 serious matter. I've been practicing 23 years; this is
17 the first time I've ever been here, because I'm
18 frustrated.
19 And there's one more thing as far as --
20 there's a test survey that I like to do.
21 DR. THROCKMORTON: Ask you to be brief,
22 please.

1 DR. CARR: Okay. Test survey, coffee
2 drinkers. How many coffee drinkers do we have in the
3 house today? All righty. How many Kool-Aid, orange
4 juice, fruit juice, smoothie drinkers do we have in the
5 house today? How many great water drinkers do we have
6 in the house today? Okay, it's kind of even. But the
7 point I'm making is that I see most coffee cups on this
8 counter. Think of that as C2s. I think the juicers,
9 sweet drinks, think of those as the hydrocodones. The
10 water drinkers as the non-drug users.
11 Now when you can make the comparisons of
12 those to those, to C2s, to C3s, and non-drug use, I
13 think we'll have a better way of trying to understand
14 why we do what we do, and why people feel that they
15 need to have drugs and can't get off of it. And that's
16 just the point I wanted to make. Just make it simple.
17 Make a comparison to those. And I thank you. FDA
18 Questions
19 DR. THROCKMORTON: Thank you. If anyone at
20 the table has questions. Closing Remarks an Adjournment
21 DR. THROCKMORTON: So on behalf of the FDA, I
22 am going to close the meetings by just making a few

1 comments. First, I'd like to take this opportunity to
2 thank everyone who has participated in this very
3 important public hearing over the past two days.
4 You've provided us important information
5 around three areas that we'd asked you for help in:
6 diagnosis and understanding patient pain;
7 understanding the labels of pain drugs and how you use
8 them in your day-to-day practice, your prescribing and
9 your use as patients; and the potential effects of
10 limiting opioids in various ways, and changing the
11 labels in various ways, on both patients, prescribers,
12 payers, and et cetera.
13 Also, you provided us other important
14 comments separate from those three areas. Comments
15 that include personal narratives that we need to keep
16 in the front of our minds as we move forward in this
17 important area. All of the comments are a part of a
18 larger societal conversation about opioids, how they
19 should best be used, what role the federal government
20 has in supporting those uses.
21 There is an unquestioned epidemic of abuse
22 and misuse, an epidemic that we need to address as a

1 society. There is also an unquestioned need for
2 appropriate access for patients in pain.
3 Finding the appropriate balance is an ongoing
4 challenge, one that the FDA is confronting in a variety
5 of different ways, and we greatly appreciate all of
6 your help in this one terribly important part of that
7 larger issue. We will carefully consider your comments
8 and all of the information that you've provided to us
9 as we proceed.
10 To close, I would like to thank all the
11 public speakers for their thoughtful comments.
12 Separately, FDA greatly appreciates those who took time
13 to submit comments to the docket, and we will review
14 those comments carefully.
15 And then finally, I am grateful to the FDA
16 staff who have helped coordinate and prepare this
17 meeting. I look forward to talking with each of you in
18 the future. Have a safe trip and thank you so much.
19 And I will close the meeting with that.
20 (Whereupon, at 3:52 p.m., the Meeting was
21 adjourned.)
22

1 CERTIFICATE OF COURT REPORTER

2 I, ERICK MCNAIR, the Court Reporter before whom
3 the foregoing proceeding was taken, do hereby certify
4 that the proceeding was recorded by me; that the
5 proceeding was thereafter reduced to typewriting under
6 my direction; that said transcript is a true and
7 accurate record of the proceeding; that I am neither
8 related to nor employed by any of the parties to this
9 proceeding; and, further, that I have no financial
10 interest in this proceeding.
11
12
13 ______________________
ERICK MCNAIR
14 Digital Court Reporter
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1 CERTIFICATE OF TRANSCRIPTION

2

3 I, Cindy McAllister, hereby certify that I am

4 not the Court Reporter who reported the proceeding

5 and that I have typed the transcript of the

6 proceeding using the Court Reporter's notes and

7 recordings. The foregoing/attached transcript

8 is a true, correct and complete transcription of the

9 proceedings.

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13 Transcriptionist

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