Dr. Fishman: Welcome to the Advances in Pain and Addiction webcast series. My name is Dr. Scott Fishman. I am the chief of the Division of Pain Medicine and vice chair for Pain Medicine and Faculty Development, and professor of anesthesiology at the University of California, Davis School of Medicine.

The program today is the last in the series of three accredited segments. Each segment will focus on the recent evidence and advances impacting clinical practice in chronic pain and dependency. The topics we will be covering in this series include: Clinical Aspects of Risk Management in Opioid Prescribing; Chronic Pain and Opioid Addiction – Emerging Disease States Driven by Advances in Neurobiology, Genetics, and Neuroimaging; and Challenges in Clinical Practice.

Today’s session will address challenges in clinical practice and it is titled, “Ten Commandments of Opioid Prescribing, Safe, Effective, and Responsible Approaches.” Upon completion of this program, the intended audience will be able to summarize regulatory issues surrounding opioid prescribing and identify practical methods clinicians may use to contain risk, and identify advances in understanding and management of a chronic pain as it relates to opioid therapy. It is my great pleasure to introduce our speaker today, Dr. Todd Sitzman. Dr. Sitzman is the medical director of Advanced Pain Therapy, a comprehensive pain clinic located in Hattiesburg, Mississippi. Dr. Sitzman is also the past president of the American Academy of Pain Medicine and one of the leading advocates for advancing the cause of pain medicine throughout the United States. It is my pleasure to welcome Dr. Sitzman.

Dr. Sitzman: Thank Dr. Fishman and I just wanted to say thank you for allowing me the opportunity to present what I consider a mainstay of my practice and that affording me the opportunity to present on how to prescribe opioid therapies in a safe, effective, and responsible way. A brief overview of the talk, I am going to discuss some chronic pain facts, some opioid use and abuse facts, as well as myths associated with these therapies. Clinical challenges that all physicians face, at least we face these on a near-daily basis, some regulatory issues, and then finally, I am going to break down and summarize those 10 commandments that we will focus on.

If pain was in isolation, it would be a pretty simple clinical phenomenon to treat. We could treat the pain and everything else would be rosy with that patient’s life, but that is not the case. Untreated chronic pain can lead to loss of function, to disabilities,
increasing stressors, depression. The stressors do not necessarily have to be from work or loss of function; they can be emotional, depression, loss of income, loss of family relationships. So, in the treatment of chronic pain, we really have to intercede at multiple points along this pathway. When a patient comes to see me, often their pain has been treated with first-tier and even second-tier therapies. At the onset of treatment of chronic pain, a diagnosis should be made and first-tier therapy should be instituted. Oftentimes, those include nonsteroidal anti-inflammatory drugs, drugs either over-the-counter or prescription, other adjuvant-type medications, physical therapies, nerve blocks. When those fail, then we move to the second-tier therapies, often opioid analgesics known as chronic opioid therapy, psychological therapies such as cognitive behavioral-type therapies, neurolysis, and then lastly the advanced pain therapies would include surgeries, neuromodulation techniques, neuroablative techniques.

A goal of chronic opioid therapy is pretty straightforward. Most clinicians face these goals regardless of the specialty they are in – reduce pain, improve function, minimize prescription side effects, get that patient to return to work, and decrease health care utilization. I have said it before and my staff know that I do not want a patient dependent on me, dependent on our clinic for their livelihood. I want to empower them. I would like for them to understand their disease process, to decrease the utilization of my therapies, and lead a more independent lifestyle.

What are the target sites for chronic pain therapies? In the broadest sense, we only have two therapeutic interventions. We can either inhibit pain transmission by blocking it from the periphery toward the brain, or we can enhance the body’s pain inhibitory mechanisms, either through medications or through neuromodulation therapies. This slide gives a brief overview of some of those categories within the two main target sites.

Pharmacologically, it is a pretty simple regimen we are dealing with. We are dealing with FDA-approved categories including nonsteroidal anti-inflammatory drugs, acetaminophen, COX-2 inhibitors, tramadol, opioid analgesics, and a broad-range of analgesic adjuvants. The definition of an adjuvant is any medication not specifically FDA-approved for the purpose of treating that condition, but with chronic pain on an hourly basis I use adjuvant therapies. They can include your typical antidepressant therapies, neuromembrane stabilizing medications such as gabapentin, alpha-2 agonist such as clonidine or tizanidine, local anesthetics, NMDA receptor antagonists, neuronal calcium channel blockers among others.

With regard to opioid analgesics, I want demystify the pharmacotherapies that are available. We only have less than 10 available medication types for chronic opioid therapies; morphine, oxycodone-based, oxymorphone, hydromorphone, fentanyl, buprenorphine, hydrocodone, methadone, and levorphanol. Those medication types, those drug themselves can be delivered in many ways, either through sustained-release mechanisms orally, sustained-release mechanisms transdermally, or orally immediate-release medication preparations, but as you see here, the types of drugs available are limited to under 10, but the delivery mechanisms can change, and physicians must keep this in mind.
Some pain facts on a national basis: 39% of all adults report pain on a monthly basis, this does not surprise me; 20% report severe pain on a monthly basis; 63% of adults have spoken to medical professionals about their pain. Surprisingly, it is not even higher than that because these are individuals with pain. They should be speaking with their physicians. With regards to lost productivity, it is estimated that approximately 4.6 hours per week are lost due to pain, and the pain can be migraine headache-related pain, chronic back pain, osteoarthritic pain, and that equates to approximately 61 billion dollars per year due to lost productivity.

Now, 50 to 70 million Americans have undertreated pain. We know this. We also know that up to 16% of Americans have addictive disorders, be they substance abuse, substance use, or truly addictive disorders. We cannot exclude one population of those with chronic pain just because they have an addictive disorder, but it should heighten our vigilance. Only 19% of physicians receive any type of medical school training to identify prescription drug diversion. Drug diversion is a highlighted abuse at this time. It is medications that are being utilized for non-intended or non-medical intended purposes. Only 39% of physicians received any training whatsoever to identify prescription drug abuse and addiction. That is surprising, but it underscores the need for better education, improved knowledge, and improved clinical skills of clinicians – 74% of physicians refrain from prescribing controlled substances because of concerns of patient addiction. This is surprising to me, and hopefully those of you watching this program today will obtain the knowledge base and the clinical skills in which to safely and responsibly prescribe opioid analgesics to patients who need these therapies.

What are some of the major myths associated with chronic opioid therapy prescribing? One myth is that toughing it out is always better than relying on painkillers. Just the opposite. If someone has a degenerative condition or any type of medical condition that requires chronic opioid therapy, there is actually a physical sequela that by not treating it, you are actually be harming the patient; decreased immune response, decreased life expectancy in some instances. So treating chronic pain, allowing that patient to live a more functional lifestyle can actually improve their overall health. Patients on opioid analgesics are always impaired and cannot safely drive or safely work. Just the opposite. Those individuals who have a chronic pain condition, when they are adequately treated, when they have no side effects associated with the chronic maintenance type therapy of opioid analgesics, they actually perform better on skills testing. They perform better on judgment and reaction times. Studies have been performed to show this. When taken as directed, opioid analgesics are more likely to hospitalize or kill you than nonsteroidal anti-inflammatory drugs. Once again, just the opposite, many, many more patients die annually because of upper GI bleeds or acute renal failure secondary to overuse and abuse of nonsteroidal anti-inflammatory drugs. Unfortunately, these circumstances do not reach the sensational headlines, do not garner the media attention that an acute overdose of opioid does. Lastly, accidental overdose is common among chronic pain patients. Just the opposite. It is much more common among individuals who try the medication for the first time, who truly are less tolerant to the effects of opioid analgesics, try it and then succumb to respiratory depression.

Other myths are that most get addicted accidentally. Addiction is a psychological condition. It is a true psychiatric disorder and if you are going to become addicted, it is not going to be accidentally. There is a large genetic, as well as social phenomena
associated with true addictions. Another myth is that addiction is inevitable if opioids are taken for a long term. Just the opposite. Those individuals who were prescribed chronic opioid therapy for underlying painful condition can be safely tapered when that condition is stable, when that condition has been reversed, can be safely tapered off of all opioid analgesics and do not have the same addictive urges. Opioid withdrawal is life-threatening. I often hear from other physicians and/or patients, they say “I ran out of medications, I had to go to the emergency room because I was afraid of dying from my withdrawal.” Just the opposite. Alcohol, benzodiazepines, those can lead to possibly fatal withdrawal reactions, but rarely is opioid analgesic withdrawal going to be life-threatening. It will present as increasing pain, it may also present as intense flu-like symptoms that resolve over two to three days, but it is not life-threatening. Physicians who suspect addiction should drop the patient without tapering medications. Just the opposite. If a physician suspects that someone on chronic opioid therapy has an addiction, the last thing they should just do is drop the patient. The last thing they should do is taper the patient to off. They should understand what is going on to that patient, seek additional therapies for the patient’s addiction. Once again, you can have two comorbid conditions; a chronic pain condition and an addiction, both have to be managed effectively.

In the United States annually, hydrocodone has historically been the #1 prescribed medication. An analgesic is the #1 prescribed medication in this country leading one to suspect that “Okay. We got a medication, it has been used for short-term pain relief, but it is also highly abused.” Please pay attention to the remainder of this presentation because I would like for the clinicians listening today to understand that just because it is the highest prescribed medication, it does not mean it has to be the most abused medication. We have ways in which to limit its abuse potential.

Some opioid facts: 10 deadliest drugs. Now, before I go to the next slide or at least display what these top 10 deadliest drugs are, I would like for you to envision in your own mind what you think that they would be. Appropriately so, five of the top 10 are opioid analgesics, and these are FDA reported deaths that are either accidental or overdose related. Oxycodone, fentanyl, morphine, acetaminophen, methadone. What would round out the top 10? Antipsychotics for two of the top 10, and then lastly some of the disease-modifying rheumatologic agents round out the top 10.

Concerning opioid-related deaths, there has been a significant increase in the number of opioid-related analgesic deaths in the early part of this decade. A 275% increase, there have been over 11,000 unintentional opioid-related deaths annually. My goal in my community and hopefully your goal in your community is to educate patients, educate your society, your own communities about curbing opioid abuse so that it can be prescribed in an effective and safe manner.

There are challenges associated with chronic opioid therapy. These challenges include addiction, dependence, tolerance, pseudoaddiction, and regulatory compliance issues. I am going to define each one of these individually.

What is addiction? Addiction is a primary, chronic, neurobiological disease influenced by genetic, psychosocial, and environmental factors. For the diagnosis of addiction, you have got to have an impaired control over the use of that drug. You are going to be taking it despite its regimen despite it being prescribed to you, you are going to
have compulsive use, continued use despite harm either to yourself, your work, and an intense craving for the medication. That is an addiction.

With pain and addiction, we know that once again upwards of 19% of Americans, 3-16%* of Americans have an addictive disorder; 23% of patients in pain rehabilitation programs meet the diagnosis of addiction. Roughly one-quarter of those patients being treated for chronic pain in a chronic pain rehabilitation program have addictive disorders. There has been a 35% increase in opioid prescription use in the past 20 years. That is significant. In the same period, drug abuse cases have also increased. One would think that, "Okay you have had a 35% increase in opioid prescription use during the same period, shouldn’t there be a correlate to an increase in drug abuse cases?” Well, that has not been the case. Trends of increasing medical use of opioids does not appear to contribute to increases in opioid addiction.

What are abuse behaviors? This is separate from an addictive disorder. An opioid abuse can occur in the absence of addition. It is usually characterized by misuse or non-medical purposes. The patient taking the medications to relax when they get home, or patients having difficulty falling asleep so they take their pain medication even though they are not hurting. Examples of these abuse behaviors or drug-seeking behaviors can include: Calls to your clinic at the end of the day. They know you are busy. They know you are trying to wrap up for the day, so they assume that, “Okay, you are going to be a little bit more lax with looking up their medical records and it is easy to call in a prescription at the end of the day”; Repeated loss of prescriptions. This should at least trigger you to think, “This patient has lost a prescription before.” I often flag my charts and I have the electronic medical records as do many of you, but we also have a very thin paper chart, so I will put an asterisk and the date next to aberrant behaviors so that in the future I can look up and quickly reference these behaviors in the past; Reluctance to provide prior medical records or to undergo further testing. Any patient who tells you, “Yes I have seen Dr. so and so. I do not know what they treated. I do not have any of these medications.” Or they will tell you that, “Yes he had me on 60 mg of morphine twice daily,” and yet you have no medical records to corroborate that; Doctor shopping. It is a phenomenon in which a patient will go to multiple doctors at the same time for the same condition and receive multiple prescriptions. This is at least putting more responsibility on the physicians using prescription drug monitoring programs to investigate individuals who are suspected, but everyone should be a suspect because you have responsibility to the patient to safeguard them.

*Dr. Sitzman misspoke when he said 16-19%, the correct data (3-16%) has been noted above.

There is physical dependence. It is different than addiction. It is different than abuse. It is a neurophysiologic adaptation manifested by drug-specific withdrawal without those other characteristics, without the abuse. Physical dependence is withdrawal. It can be with opioid analgesics, it can be with antihypertensive medications. There are several antihypertensives if the patient is quickly discontinued from them, they will have a hypertensive crisis. That is a withdrawal crisis. Withdrawal does not equal addiction. Dependence on the medication does not equal addiction.
What is tolerance? Tolerance is a neurophysiologic adaptation in which exposure to a drug results in its decreased effectiveness over time. This phenomenon is not exclusive to opioid analgesics. It occurs with many, many other medication classifications including blood pressure medications, including hypoglycemic or glycemic control medications. Tolerance, in its broadest definition, is decreased effectiveness over time.

What is pseudoaddiction? Pseudoaddictions are drug-seeking behaviors suggesting drug abuse or addiction, but it is really not drug abuse or addiction. It is someone with chronic pain who needs more medication to decrease their pain. For example, it is probably a little less common in the outpatient setting, but I see it on a monthly basis on an inpatient setting. I will be consulted in the hospital and the nurses will say, “We cannot keep up. They keep asking for their medicine and they are screaming out. They want more medicine. I think he is addicted.” And that what you are looking at, I would look at the medical records, I speak with the patient and they are prescribed intravenous morphine every two to three hours. Their pain is lasting continuously and the intravenous morphine is lasting one hour, and for the next two hours, before their next prescription, they are wanting more and more medication. Well, that is simply resolved by placing the medication on a long-acting opioid analgesic or another preparation in which they are able to deliver themselves their own medication with a patient-controlled analgesic device. But what characterizes pseudoaddiction from true addiction is that it resolves once the pain is relieved. It differs from addiction in that those dysfunctional behaviors in addiction continue despite dosage increases.

There is another phenomenon called opioid-induced hyperalgesia. It is a true phenomenon in which increased sensitivity to painful and non-painful stimuli occur. In its broadest definition, it is really a nociceptive sensitization associated with higher and higher doses of opioids. It can occur with numerous opioid analgesics. It is not exclusive to one classification. The proposed mechanism of action is sensitization of pathways. Those sensory and painful pathways in the spinal cord, as well as activation of the NMDA receptors within those pathways such that those pathways become open. Those pathways become highly sensitive to even small amounts of pain and pain sensory input, and treatment of that usually involves tapering of the opioids or it can involve an NMDA receptor antagonist such as ketamine or methadone.

With this next slide, I would like to highlight a case that I was faced with six months ago. This was a gentleman who was admitted to our hospital. I had never seen him before. He had metastatic renal cell carcinoma. He was admitted from a home-based setting in severe pain. He was admitted on October 15th. He was on over 3700 mg equivalence of morphine per day at home. The next day, on October 16th, obviously, as many of you clinicians realize, you only get called with these on a weekend and at night and this was my Saturday night call. I got called on October 16th. By that time, they have treated the person with an additional of 250 mg of morphine thinking that the more they gave, the better his pain would be. Just the opposite. This gentleman could not be comfortable. He was screaming out. I was called in to see him on the 16th and early the next morning, we instituted ketamine, an NMDA receptor antagonist, and we were able to bring his pain from a 10 down to a 2 within 48 hours. He had also decreased his opioid analgesic consumption, his morphine-equivalent consumption 10-fold such that at the end of hospitalization, he was down to under 300 mg per day of morphine. His pain was under a 2. He was talking and very appreciative.
of our efforts. So, it can be done. This phenomenon does exist. We do not know the
threshold at what should occur, but it is certainly a clinical phenomenon seen by many
pain physicians and many physicians.

Chronic pain does require a multidisciplinary management. This has got to be a
coordinated care of the patient because their underlying painful condition is not
curable in most instances. It involves long-term treatment strategies. It involves the
willingness of the clinician to follow that patient longitudinally over time. Physicians,
nursing staff, it is our responsibility to establish that diagnosis, establish treatment
plans, educate, advise, and perform multidisciplinary therapies directed towards
enabling that patient’s pain to decrease, improving their function, improving their
home life and their work life. It could involve physical therapists. If you are not using
it, you are going to lose flexibility. You are going to lose function and coordination.
Physical therapists can be of paramount importance. Psychologists to address the
mood, coping mechanisms, behavioral changes initially with diagnosis and through the
course of therapy.

There are risks and benefits associated with opioid analgesics. I would not be giving
this talk today if it was risk-free. We have to realize that drug abuse and undertreated
pain are both serious public health issues. Both have got to be addressed, but the
solution to drug abuse is not simply to restrict access to effective chronic opioid
therapies for patients. It is not to say, “Well I am not going to contribute in this drug
abuse phenomenon going on nationally, so I am not going to prescribe any opioid
analgesics.” Well, that is not the approach to take, in my opinion.

I tried to condense what I felt to be the most important aspects of chronic opioid
therapy prescribing from a safe, patient perspective, from a manageable perspective
for physicians, as well as meeting all regulatory requirements and not to be irreverent
by choosing the word “Ten Commandments,” but I do feel it is appropriate that these
are the do’s and don’ts, these are the thou’s and thou shall not’s of chronic opioid
therapy prescribing.

The clinician must make an appropriate diagnosis. It is not acceptable to say, “This
patient has chronic back pain, so I am going to prescribe higher and higher doses of
opioid analgesics until they feel better.” Make the diagnosis and if it takes referral to a
specialist, fine. It should be chronic back pain secondary to annular disc tears or to
disc herniation or to spinal stenosis, not just simply back pain. Before committing
yourself and the patient to chronic opioid therapy, make an appropriate trial of that
opioid therapy. Use other adjuvant medications to minimize the total doses of the
opioid analgesic. Utilize the nonsteroidal anti-inflammatory drugs or the
antidepressant-type therapies. We know that combining different medications can
often lead to decreased side effects of any one medication and can allow the patient, in
my opinion, a more functional lifestyle.

It is not enough just to say, “Here is your prescription. Take this medication.” It is not
enough to do that. You got to do pre- and post-opioid assessment of their pain and
their level of function. Ask the patient, “Since we started this medication last month,
have you had a decrease in pain?” Even though their numerical pain score may still be
a 6 or a 7, at least get him to commit to you if their function has improved. You do not
want to treat a patient higher and higher doses of opioid analgesics just to have them
go home and sleep away most of the day. Certainly, they will come back and say, “My pain was a 2. It felt great. I did not do anything though.” That is not the goal of chronic opioid therapy.

Psychological assessment including the risk of addiction. This is important. Once again, the multidisciplinary approach to the patient with chronic underlying painful condition will require psychological-type therapies. If you are fortunate enough to have a clinical psychologist in your area that has been trained in cognitive behavioral-type therapies, utilize their services, embrace them because they can help you. They can help the patient’s decreasing disease stressors, can help improve their sleep function, and can be your advocates as well with compliance issues.

Number 5 of my commandments is informed consent. The informed consent is just like any other informed consent for therapy. Consider it like a surgical informed consent or procedural informed consent. Patients have got to be informed of the treatment itself. They have got to be informed of the potential side effects of that therapy, and you have to allow them time to ask questions. Within this informed consent, you also have to highlight their responsibilities and your responsibilities.

Separate from the informed consent is the treatment agreement. I utilize a treatment agreement that was actually introduced by Dr. Fishman years ago and it involves a three-way agreement between myself, the patient, and the patient’s primary care physician. I want to allow that patient the opportunity to continue with their therapies, not under a veil of secrecy between me and the patient. I want everything to be in the open. I want the primary care physician to know what I am prescribing, why I am prescribing it, what the goals are. This treatment agreement outlines my responsibilities, it outlines the patient’s responsibilities, and the primary care physician is made aware of this and once the patient becomes stable on their chronic opioid therapy dosage, their regimen, it allows the primary care physician to then co-manage along with you.

Number 7 is reassessment of the patient’s pain score and level of function, and I say this should be done in every visit. It does not take long to do. It takes two minutes in the clinical history, but it can at least support why you are prescribing the medication. It can allow you the opportunity to look for side effects and ways of improving their function.

With regard to surveillance at each visit, a commonly used tool is the 4 A’s. These 4 A’s are analgesia, activity, adverse effects, and aberrant drug use. If you document these 4 A’s at each visit of a chronic opioid therapy prescribing visit, then at least it is giving you the opportunity to look for any type of ways of improving the patient’s pain, function, and decreasing side effects, as well as aberrant behaviors. So, ask the patient, “Has your pain improved? Are you able to function better? Give me an example of functioning better. Are you able to participate in sporting activities with your child? Are you able to go to your grandson’s graduation?” If that is your goal, we are going to meet that goal. “Are you having any side effects?” And quite frankly, if you are not asking the patients if they are having constipation, sedation, nausea associated with the medications, then you are not doing your due vigilance in helping minimize these side effects. Lastly, look for aberrant behaviors. These aberrant behaviors could include missed appointments, could include taking the medications
inappropriately, or ask for patients to bring in their medications, your account of their medications, and truly a pill count is one example, may show that this patient is complaining of a 10/10 pain and yet when you look at their medications, they have only taken half of the opioid prescribed that month. It is an example of underutilization, but instead of increasing the dosage, instead of increasing the amount of medications you are prescribing, just educate them on how to use it appropriately and when to use it.

Other aberrant drug behaviors, and clinicians prescribing chronic opioid therapies should at least be vigilant for aberrant behaviors. They can include unexpected urine drug testing results and those results can either be medications that should not be in there, drugs of abuse, illicit drugs in there, or no presence of the drug that you are prescribing. Either of these is an unexpected UDT result. Frequent requests for dosage increases may or may not be an aberrant behavior, but if they do it time and time and time again, then you should start looking, especially if their underlying condition is stable. Failure to follow dosage schedules. Saying, “Yes, I took all my medicines in the first three weeks and I ran out the last week.” Well, that is certainly not following the schedule. Frequent loss of prescriptions. I see it on a monthly basis. A patient will call in and say “I lost my medication” or “I lost my prescription.” Part of that treatment agreement that was signed earlier states that lost and refilled medications will not be refilled before the next visit, and that is your responsibility to uphold that. Frequent visits to the emergency room for pain should not be tolerated unless it is a true medical emergency. They should not be going to the emergency room or urgent care outside of your treatment if they have a stable pain condition. Missed follow-up appointments, request for urgent appointments, having prescriptions from other prescribers, especially scheduled medications. Prescription drug monitoring programs have enabled the physician to actually investigate and to look into these issues.

Number 9 commandment is a periodic review of the diagnosis including a periodic review of addictive-type behaviors. These are individuals that you are going to be seeing three or four times a year for the rest of their lives. You should reassess to see if their underlying condition has changed. In a chronic spine degenerative condition, it is going to get worse with time, but the answer is not simply to prescribe more medication when there may be other therapies that can help this individual.

And lastly, document. It is important to document what we just talked about. I am going to give you a verbal assessment of a history of present illness in someone who is on a chronic opioid therapy regimen who is doing well with their treatment who is having no side effects and this is just a quick clinical vignette of how to document appropriately. It does not have to take a lot of time and I will just take for example a Mr. John Smith presents today with chronic low back pain from degenerative disc disease.

So your chief complaint will be chronic low back pain. History of present illness, well Mr. Smith presents today for a two-month followup. His low back pain symptoms have been present, but well managed on his current therapies. He denies any sedation, constipation, itching, or nausea associated with his morphine regimen. He reports compliance with our chronic opioid therapy policies. At this time, he denies any other interval health changes. My assessment at that time will be chronic opioid dependence, continuous, with oral opioid analgesic regimen, no evidence of aberrant drug use.
Number two diagnosis may be degenerative disc disease of the lumbar spine. Number three diagnosis may be any other comorbidities that he presents with. And my recommendations, I would fully discuss once again the purpose of chronic opioid therapy. I discuss compliance and the need for compliance with our chronic opioid therapy policies. On an annual basis this individual would re-sign and renew his treatment agreement with me. And then fourth down the line on my recommendations would be to refill the medications and to contact me should there be any changes in his clinical conditions or should he develop any side effects. It does not take long.

Once again, the goals of my clinical practice in treating patients with chronic pain are the same as yours, and you can be in primary care, you can be in endocrinology, you can be an orthopedic surgeon, we have the same clinical goals; reduce pain, improve function, minimize prescription side effects, get that person to return to function, to return to work if that is the case, and to decrease health care utilization.

There are resources out there for the physicians. The resources are available online. They can include the model policies for controlled substances and use from the Federation of State Medical Boards. *Emerging Solutions in Pain* is a wonderful resource for clinicians prescribing opioid analgesics or taking care of anyone with chronic pain. It provides tools, assessments. It provides copies of these opioid agreements that I discussed earlier, and it highlights many of the things I am talking about today.

Many states have prescription drug monitoring programs. In the state of Mississippi, we have one which allows me to assess the patient’s history of prescription use over the past six months or within the past two years. It depends on how long I want to query. I can literally do an assessment. It takes 30 seconds online. DEA has detailed step-by-step outline of the proper use and policies of chronic opioid use and controlled substance use. Lastly, Legal Side of Pain provides an overview of the legal aspects of pain therapies and compliance issues for physicians.

I want to thank Dr. Fishman and thank you for allowing me to present what I feel will provide you a safe and effective use of chronic opioid therapy. I want to demystify use of these therapies that can be quiet effective. Thank you.

**Dr. Fishman:** Thank you Dr. Sitzman for that very global and informative lecture. We have a couple of questions we would like to ask you and I am going to start with one question, which I think if anybody watches TV or reads newspapers knows that there is a lot of attention on opioid therapy and particularly around abuse and unintended death. Why do you think there is such diverse views on using opioids including those of people who feel that they are indispensable and we need to use them more often versus those of regulators who recently, through the president’s office, the Whitehouse, the office of the National Drug Controlled Policy, the FDA, and the DEA announced a new action plan for reducing prescription drug abuse?

**Dr. Sitzman:** I think it is clear to me why this issue can become quite polarizing. It depends on which side of the fence you are on. It does not have to be that way. If individuals, be they clinicians, politicians, patients, realize that this is merely a therapy to decrease pain, to improve function, that avoiding the other issues, which you cannot avoid, but at least looking at it from a medication purpose perspective, do these therapies offer benefit for patients? Undeniably, they do. Are these same medications
a source of anguish from many families whose child has suffered from an unintentional death or from violence associated with illicit drug activity? Yes, but once again, the action should not be to withdraw these medications from the market or to restrict their use even further than what they already are being restricted. Keep an open mind, and I know that is not answering your question, because there are probably books written on this topic, but from a clinician who practices in a community in which we have seen both sides of that fence, we have seen the abuse in my community, we have seen the emergency room visits. I have talked to families, I have gone to the hospital of family members who have suffered an overdose-related death. It is not a pleasant situation, but we have got to keep a very open mind that these medications serve a purpose and if they are being prescribed effectively, if they are being prescribed responsibly, that we can avoid many of these sensational-type situations.

**Dr. Fishman:** You have effectively stressed that the basis of what we do in medicine is deal with the risk-benefit analysis, and these drugs have benefit, they also have risks. You also stressed the point that we need to get informed consent when we treat patients and I am wondering, do you feel that the risk of addiction should be something that is part of the informed consent process or discussion?

**Dr. Sitzman:** Without question, because addiction is going to be present whether the patient is taking the medication or not. It is the potential to abuse that medication and the potential to have addictive-type behaviors when on this medication, that should be stressed. Also, at the time of prescribing that informed consent can also allow the patient to understand the potential risks of these medications and the fact that you are not going to dismiss them if they do have a history of addiction, that both chronic pain and addiction can be treated. They are both treatable conditions and it may not involve opioid analgesic strategies, but it tells the patient that you are willing to work with them.

**Dr. Fishman:** Dr. Sitzman, you said that addiction is present. I assume you meant that the risk of addiction is always present and it needs to be considered.

**Dr. Sitzman:** Correct.

**Dr. Fishman:** You also mentioned opioid-induced hyperalgesia which is an interesting phenomenon, and as you said it is a phenomenon that has largely been seen in animals. It is questionable with humans, but do you believe that it is a real human phenomenon and if so, should we consider a tapering trial for everyone on chronic opioid therapies?

**Dr. Sitzman:** I do feel that it is a true clinical phenomenon and once again, what is opioid-induced hyperalgesia? It is a state of nociceptive or pain pathway sensitization. It is just the opposite of tolerance. With tolerance, you are going to have a desensitization of these same nociceptive pathways, this is actually the medication causing a heightened sensitivity. In patients who dose escalate, a common term meaning that they need more medication to have the same effectiveness, it should be at least considered as part of that differential diagnosis. Certainly, not everyone on chronic opioid therapies develops opioid-induced hyperalgesia. We do not know those true underlying mechanisms. We do not know the epidemiology of it like who is at risk and who is not at risk. I suspect it has an equally important genetic role, so if someone
is on chronic dosage regimen for years and years, there is no need to taper their medication to off and give them a holiday so to speak, but those individuals who go on higher and higher dosages to get the same effect or those patients who develop sensitivities beyond their initial underlying disease mechanism, and for example someone with chronic low back pain who subsequently develops a hypersensitivity to all stimulation. These individuals can say that everything hurts on them. Their joints hurt, they are sensitive to deep pressures, they now feel it anytime they move. I am not saying that they develop acute musculoskeletal myofascial-type pains when their initial diagnosis was underlying low back pain, but they do become sensitive to all nociceptive input. These individuals certainly would warrant a dose decrease trial, or changing the medications. Not all opioid analgesics bind to the same opioid receptor. Changing the medication, changing the type of opioid that has a different affinity to different receptors may improve that condition.

Dr. Fishman: One last question. How does the average primary care doctor adjust their practice so they can adequately perform the risk management tasks needed for responsible opioid prescribing?

Dr. Sitzman: I feel that chronic opioid therapies can be effectively managed by the primary care physician, that it does not take a specialist to do it in the majority of cases. They may have to adjust their practice. They are going to have to educate themselves and their staff. They are going to have to develop the clinical skills and at least knowledge of the regulatory issues, and through programs like this they are obtaining that knowledge, but it does not have to be exclusive of their other care. Initially, that primary care physician may say, “Look I want you to come in Mr. Jones or Mr. Smith for your annual discussion of chronic opioid therapies and at that time, during a separate visit we are going to exclusively discuss why you are on this medication, we are going to discuss the chronic opioid therapy policies of our clinic, we are going to discuss the treatment agreement, and this will be the sole purpose of this visit.” And so in 15 minutes, a primary care physician can assess, address, and at least put forth the basis for this chronic therapy. It is difficult if they are trying to squeeze it in with Mr. Jones’ or Mr. Smith’s other five medical conditions. They are going to have to take the time.

Dr. Fishman: I have heard others say that if you can manage other chronic diseases like diabetes and heart disease, you can manage chronic pain, but we are going to have to stop. I want to thank Dr. Sitzman for a wonderful presentation. I do hope you enjoyed today’s segment of the annual Advances in Pain and Addiction. If you are a physician or a pharmacist please complete the post test and evaluation form to receive continuing education credit. Please be sure to view all three segments in the annual Advances in Pain and Addiction series. Thank you and have a great day.