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EXECUTIVE SUMMARY

Substance use and misuse affect all constituents of the United States health care system—patients and caregivers, health care providers, payers, regulators and policymakers, life sciences industry, and research. ECRI Institute’s 23rd Annual Conference on the Use of Evidence in Policy and Practice entitled Health Systems and Addiction: The Use and Misuse of Legal Substances addressed all of these aspects. The conference was held November 16-17, 2016, in Washington, DC, at the National Academy of Sciences.

The conference began with a framing of the issues—scientific, political, and personal, before moving onto a session focused on the brain science and epidemiology of addiction. Both genetic and environmental factors impact the likelihood of developing a substance use disorder.

Three case studies on opioids, attention deficit hyperactivity disorder (ADHD) medications, and marijuana examined how these drugs enter the health care system and the interface between science, society, and FDA regulation. The following session examined the roles of the military and Veterans Affairs health systems in treating people with pain and substance use disorders. These 2 very large health systems have made effective, coordinated efforts to prevent and treat substance use disorders.

The next session focused on how other providers are delivering care in the community setting, both in health care settings and recovery support systems. The integration of substance use disorder treatment into primary care is seen as a key to improving access to treatment. The final session of the first day was dedicated to examining how public and private payers are addressing use and misuse through payment and reimbursement practices. Reimbursement has the ability to encourage needed changes in payment structures and incentives in the delivery of care.

The second day of the conference began with a focus on what health systems are doing to address misuse. Chief executive officers from three diverse health systems discussed how they are addressing and ensuring appropriate use of legal substances. Attention shifted to what are the barriers and solutions to effective prevention of misuse. The Centers for Disease Control and Prevention (CDC) opioid prescribing guidelines, CVS Health pharmacy programs, and Kaiser Permanente’s integrated health care delivery system were all highlighted for their ability to provide solutions to preventing misuse.

Moving beyond preventing misuse, discussion focused on barriers and solutions to successful treatment. Regulations such as 42CFR Part 2 provide privacy to patients, but can also impact providers’ ability to deliver effective and timely treatment. Patient activation and engagement can encourage patients to be active participants in their own care. An evolving criminal justice system that includes drug courts is providing solutions to successful treatment for many people. The capstone session centered on the Governor of Vermont’s experience of handling his state’s opioid epidemic. These issues transcend partisan politics and must be addressed in a bipartisan way.

The conference was organized by ECRI Institute in cooperation with AcademyHealth, the Agency for Healthcare Research and Quality (AHRQ), the American Association for the Advancement of Science (AAAS), the Bipartisan Policy Center (BPC), the Department of Veterans Affairs, the Jayne Koskinas Ted Giovanis Foundation for Health and Policy, Kaiser Permanente (KP), the Leonard Davis Institute of Health Economics (LDI), the National Institute on Drug Abuse (NIDA), the Patient-Centered Outcomes Research Institute (PCORI), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the University of Pennsylvania Health System.
SESSION 1: INTRODUCTION–A CONVERSATION
FRAMING THE ISSUES

Panel: Alan Leshner, PhD; Keith Goodwin, MBA; Patrick J. Kennedy; and Charles O’Brien, MD, PhD

Alan Leshner, PhD, CEO Emeritus, American Association for the Advancement of Science (AAAS), moderator for Session 1, started the session with some comments on addiction. He discussed the core problem of dual use of legal substances as an underlying principle of the conference. Leshner cautioned that we must not prohibit the use of highly effective substances because they have an addictive quality and instead we must control and regulate their use. Addiction is not limited to illegal substances only, but to anything that can induce compulsive and uncontrollable craving, seeking, and use.

Charles O’Brien, MD, PhD, Professor of Psychiatry and Founding Director, Center for Studies of Addiction, University of Pennsylvania, spoke briefly on the concept of addiction. Years have been spent debating how to define addiction. It is currently impossible to define addiction biologically only and in the future we hope to define addiction with biomarkers. O’Brien discussed how the term addiction has a negative connotation for many patients and led to the use of the term drug use disorder in the most recent DSM manual. The DSM-5 defines drug use disorder in both behavioral and biological terms. Addiction includes intense activation of the brain reward system and learned associations. O’Brien encouraged health systems to combine drug-based treatment with behavioral treatment for patients suffering from drug use disorder.

Keith Goodwin, MBA, President and Chief Executive Officer, East Tennessee Children’s Hospital and Chairman, Tennessee Hospital Association, explained his recent experiences in treating babies born with neonatal abstinence syndrome (NAS). NAS is a group of problems that occur in a newborn who was exposed to addictive opiate drugs while in the mother’s womb. Symptoms include low birth weight, breathing and feeding problems, excessive crying, and sensitivity to light and sound. Tennessee ranks second in the number of NAS cases behind West Virginia and has approximately 1,000 babies born a year with NAS. Goodwin’s hospital has created a NAS unit with private rooms that allows for better control of sound and light and gives mothers an opportunity to be involved in the care of their newborn. He has worked with his state legislature, insurers, and pain clinics to address this problem upstream as much as possible. The hospital recently started a program to follow these children up until kindergarten to ensure they receive the care they need. Goodwin finished his comments by reminding the audience that health systems need to work to improve long-term health status, not just treat the immediate health problems.

Patrick J. Kennedy, Former U.S. Representative (D - RI) and Founder of the Kennedy Forum, explained the importance of treating addiction like all other chronic illnesses or diseases. He spoke of his involvement in the writing and passage of the Mental Health Parity Act in 2008. This involved negotiations with his father Edward Kennedy, former U.S. Senator (D – MA). Patrick Kennedy explained that his father came from a generation that believed addiction was a character flaw. In order to address parity, the Kennedy Forum has started a parity registry where consumers are encouraged to file a complaint if they are denied treatment for addiction by a payer. Kennedy urged the audience to help educate and inform the new Congress and President on these issues to ensure that treatment for addiction is paid for and reimbursed by all insurers.
SESSION 1: INTRODUCTION—A CONVERSATION
FRAMING THE ISSUES

Leshner opened the Q&A portion of the session with a question for O’Brien about accidental and “intentional” addiction. O’Brien explained that there is a strong genetic component that plays a major role in determining if someone will become addicted. Many people try drugs, but most do not get addicted because they are not genetically predisposed to addiction.

Leshner next questioned Goodwin as to what role hospitals should take in addressing mothers who have delivered children with NAS. It takes approximately 1 month for a newborn to detox and most mothers are at the hospital every day during this period. Goodwin sees this time as a chance to introduce the mother to recovery services offered by the hospital and greater community, and prevent future pregnancies.

Next, Leshner asked Kennedy to explain what must be done politically to overcome public and policymakers’ ideology that addiction is a moral failing. Kennedy commented that we will not change stigma in a single generation, but the current federal law states that parity for mental health and addiction treatment is the standard. Insurers and payers must not be allowed to practice overt discrimination against those with mental health conditions, including addiction. Coverage of these treatments must be seen as a moral issue and social movement is needed.

The conversation turned back to O’Brien with a question on alternatives to opioids for treating pain. While there are currently no equally effective additional medicinal alternatives at this time, more research is needed in the effectiveness of marijuana to treat pain. O’Brien encouraged the use of multidisciplinary therapy to treat pain—talk therapy, medications, exercise, and alternative therapies like acupuncture. He also cautioned that there needs to be more training in medical school on the treatment of pain and the prescribing of opioids.

The discussion returned to NAS and the ability of health systems to address the issue. Goodwin thought most hospitals are able to perform the basic clinical intervention that addresses the baby’s immediate needs. There is a greater need at the next level to address the mother. Obstetricians need to screen for drug use and develop appropriate interventions. Collaboration across many stakeholders is needed after the birth of an NAS baby for both the child and mother.

Before turning to audience questions, Leshner asked Kennedy for any other insights he might have in managing and treating addiction politically. Kennedy commented that as someone in recovery he considers addiction to be “a physical allergy, mental obsession, and spiritual malady.” All three components must be addressed in order to treat addiction. Kennedy also commented on the legalization and social acceptance of marijuana. He views the growing acceptance as a problem and reminded the audience that marijuana is an addictive substance.

At this point the discussion turned to audience questions. Karen Drexler, Department of Veterans Affairs, asked Goodwin if mothers who give birth to NAS babies are offered medication-assisted treatment for their opioid use disorder and he answered affirmatively that they are. Further questions focused on improved access for physicians and physician assistants to medication-assisted treatment under the TREAT Act, treatment of incarcerated populations, and how craving is defined in DSM-5.
SESSION 2: SCIENTIFIC FOUNDATIONS–BRAIN SCIENCE AND EPIDEMIOLOGY

Panel: Joel Kupersmith, MD; Nora Volkow, MD; and Carlos Blanco, MD, PhD, MS

Joel Kupersmith, MD, Director, Veterans Initiatives, Georgetown University, session moderator, opened the session by commenting that both epidemiology and brain science are crucial to understanding addiction and are the foundation for the rest of the conference. Addiction is a change in brain chemistry while epidemiology is the characteristics and trends of what we are seeing today in regards to drug use and addiction. Kupersmith stressed that whatever role one plays in healthcare, whether physician, nurse, policymaker, there is a need to have some understanding of addiction, scientifically and epidemiologically.

Nora Volkow, MD, Director, National Institute on Drug Abuse, started her remarks by acknowledging the healthcare system’s responsibility for the ongoing opioid epidemic and highlighting the partnership between policy, science, and health care systems that is needed to address this epidemic. Volkow went on to next discuss some basics of brain science and addiction. Great progress has been made over the last 50 years in understanding changes in the brain that cause people to use drugs, despite unfavorable and undesirable outcomes. All addictive substances have a common pharmacological effect, the release of dopamine, that activates the main reward system of the brain. Addictive substances and the resulting increased released of dopamine hijack the neuralcircuitry of the brain resulting in neuroplastic changes. Volkow discussed imaging studies that showed that repeated drug use changes the brain, weakening the brain dopamine system by reducing levels of dopamine D2 receptors.

Volkow went on to discuss the very good animal models that exist to investigate addiction. She discussed a study in which genetically engineered mice with low D2 dopamine receptors were inserted with D2 receptors, and in turn, their alcohol consumption dramatically decreased. Volkow pointed out that higher levels of D2 dopamine receptors protect animals from consuming large amounts of addictive substances. Studies have also shown that down regulation of D2 receptors affects the entire frontal cortex, in turn impairing frontal functions. The frontal cortex is the part of the brain that controls important cognitive skills in humans, such as emotional expression, problem solving, memory, language, judgment, and sexual behavior. It is, in essence, the “control panel” of our personality and our ability to communicate.

Volkow said that studies estimate that 10% of those exposed to drugs will become addicted. Addiction involves multiple factors including development/genes and environment. Lastly, Volkow reminded the audience that addiction can and should be treated. The brain of an addict can recover from the changes that were made during the period of addiction.

Carlos Blanco, MD, PhD, MS, Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, commenced his presentation with a remark that the title of his presentation, Science = Solutions, was incorrect because science alone cannot solve our addiction crisis. We must incorporate science with policy to move the field of addiction. Blanco commented that Volkow showed that addiction is a brain disease, but consideration must also be given to environmental and developmental factors. These factors include genes, biology, family and peers, neighborhood and community, and laws and culture. All of these things can create vulnerabilities for drug use and dependence. These vulnerabilities do provide opportunity for intervention and solutions at several levels. Blanco discussed the wide variety of aspects of life that drugs can affect besides causing addiction. These included medical—neurotoxicity, obesity, AIDS, hepatitis, cancer, and mental illness; economic—healthcare costs, productivity loss, and accidents; and social—homelessness, crime, and violence.
Blanco next talked about the epidemiological events we are seeing. First, there is the well-known increase in overdoses of both prescription opioids and heroin. Statistics were provided to help understand why this happening. From 1991 to 2013, there was a near tripling of opioid prescriptions from U.S. retail pharmacies. In 2014, there were over 15.5 billion prescription opioid tablets dispensed in retail pharmacies in the U.S. This is enough for each American adult to have 50 tablets. In addition to the mass increase of prescription opioids, the price of heroin has decreased significantly and it is easily available for purchase around the US. 

Two additional epidemiological events are the increase in neonatal abstinence syndrome and the increase in HIV and Hepatitis C infections.

While there is a natural course of recovery from addictive substances, this recovery can take between 10 and 50 years, depending on the substance, explained Blanco. While the natural recovery takes place, recovering addicts will still need to deal with other consequences, such as job loss and acquired medical conditions. Blanco also discussed a study that examined longitudinal trends in recovery. This study showed that after 3 years of abstinence, the odds of relapse decrease dramatically. Blanco covered a question that he gets asked consistently: Are addicts likely to switch addictions to a second substance? He answered that with a resounding ‘no.’ There is a very low probability of switching addiction to another substance if the user is able to abstain and recover from the first substance.

Blanco went on to discuss ways outcomes can be improved. We need to increase the delivery of existing affective treatments. While we have effective treatments, we have not seen an increase in their use. This may be due to lack of training and supervision. There is also staff turnover that must be considered. Development of new, more effective interventions are needed along with intervention at multiple levels.

Briefly, Blanco covered treatment elements that include medications and behavioral therapies. He also discussed the need to treat medical comorbidities and psychiatric disorders while treating the addiction. He covered next what is needed of the health care system. This includes: readily available treatment; individualized treatment; more treatment than medically assisted detoxification (as it is only the first stage of addiction treatment and by itself does little to change long-term drug abuse); and adequate periods of treatment. Treatment barriers such as insurance coverage, stigma, distance to providers, and lack of training of providers must continue to be addressed as well.

Blanco completed his presentation by reiterating that multiple evidence-based practices are available—medications for opioids, tobacco, alcohol addiction; behavioral treatments; infectious disease testing and treatments; and overdose intervention, but yet, few evidence-based practices are widely used. He implored the audience to consider and find ways to improve.
SESSION 2: Q&A

Kupersmith opened the Q&A portion of the session with a question regarding the definition of addiction. While addiction is currently defined by behavioral factors, when can we expect a definition based on biological markers? Volkow confirmed that different institutes within the National Institutes of Health are working towards this being possible. More research is needed to develop biomarkers so that PET scans are not needed to make a diagnosis. It is currently practical for health care practitioners to use behaviors to diagnose addiction.

Kupersmith next laid out a common situation. An outpatient surgical patient is given two weeks of prescribed opioids. He then asked what has happened to the patient’s brain during that time period. Volkow explained that most likely that patient has developed a physical dependence during that time period, but not an addiction. Physical dependence happens quickly while addiction develops more slowly. Physical dependence can cause withdrawal symptoms when the opioid is stopped and patients should be tapered off the prescribed opioid. Volkow emphatically reminded the audience that they should not equate physical dependence with addiction. The conversation turned to how to predict who will become addicted. While there are certain factors that can help predict the likelihood of addiction, there is no tried and true way of knowing at this time. Prescribers should consider these risk factors when prescribing and monitoring patients.

An audience member raised the question of time course to addiction and pattern of addiction, and the lack of this information making it difficult to treat pain. Volkow acknowledged there is a lack of understanding of chronic pain and more research needs to be done to find the interaction between pain and addictiveness of opioids. Animal models show that having chronic pain modifies the reward system of the brain making these animals more prone to administer large doses of opioids. Research has also shown that the higher the dose the more likely addiction is. Blanco added that there are certain risk factors that affect the time course and pattern of addiction.

The next audience question addressed whether there are more studies that show longer periods of abstinence leads to lower risk of relapse. Blanco explained that he has been involved in two studies, one on tobacco and the other on cannabis, that have shown the same results as the study that was discussed during his presentation.

The next set of questions focused on brain recovery from addiction. A question was asked of whether blocking dopamine D2 receptors is an effective treatment of addiction. Volkow explained that it does not work because it exacerbates the dysfunction of the prefrontal cortex, leading to low executive function. Kupersmith asked whether this a correlation between the lowered rate of relapse after three years of recovery and the recovery of the D2 receptors. Volkow indicated there is speculation to that effect, but measurements have not been done past 1 year. There is variability in the recovery of dopamine D2 receptors and it has been found that individuals with more D2 receptors have better frontal activity and a higher likelihood of sustained recovery. Blanco added that there is interest in studying whether brains fully recover or if there is long term “scarring.” Kupersmith asked what the effect of medication assisted treatment is on the brain. Volkow explained that these medications help stabilize the brain and help with functional recovery. She speculated that they do help with brain recovery, but research has not been completed at this time.

The next audience question asked what causes addiction in individuals with normal levels of dopamine D2 receptors. Volkow explained that other environmental and social factors can drive drug-taking habits. The last question asked Drs. Volkow and Blanco to talk about community programs that are having the greatest impact on preventing and treating addiction. Blanco highlighted the Communities That Care (CTC) program run by the Center for Substance Abuse Prevention within SAMHSA. CTC identifies community risk factors to tailor prevention and treatment efforts.
SESSION 3: THE CHANGING LANDSCAPE OF USE AND MISUSE

Panel: Jeffrey C. Lerner, PhD; Barry Meier; Alan Schwarz; Susan Weiss, PhD; and Douglas Throckmorton, MD

Jeffrey C. Lerner, PhD, President and Chief Executive Officer, ECRI Institute, session moderator, laid the groundwork for the session. The session would consist of three case studies on opioids, attention deficit hyperactivity disorder (ADHD) medications, and marijuana. These case studies would look at how these drugs enter the health care system and the interface between science and society. Lerner explained that the session would end with the FDA’s perspective on these issues.

Barry Meier, Reporter, New York Times, and Author, Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death, has been covering opioids as a journalist for more than 15 years. He first heard of OxyContin in 2001 as a reporter at the New York Times. The newsroom received a call from a pharmacist in Ohio about this drug that was being marketed as less prone to abuse and was popping up on the streets for sale. Meier said at the time he did not know much about opioids, pain, or drug abuse, but over the next two years he learned a great deal about those topics along with greed, scientific folly, and regulatory passivity, misjudgment, and arrogance surrounding opioid use. Meier wrote extensively about opioids for some time and then moved onto other subjects feeling he had exposed what mattered to the public.

Meier explained that he sees opioids as a “good drug gone bad.” In his opinion, opioids are excellent drugs for a limited population. The problem comes when these drugs are marketed to a much larger audience and are mainstreamed to the health care system. He questioned whether opioids are the appropriate treatment for pain.

Around 2013, Meier noticed that rates of opioid prescriptions and overdoses had skyrocketed in the 10 years since he had first written about opioids. He realized that the investigate writing he had done had made no difference. He needed to step back, do more research, and figure out what was going on. Meier authored another book that looked at the emerging science and research on pain treatment, and alternatives to opioids for treating pain.

Meier described that there are two main sets of users of opioids—recreational and medical. While it is nearly impossible to control recreational use, the health care system can be encouraged to regulate and control opioid use. He recognized that more groups and organizations, such as the Department of Defense, Veterans Affairs, state governments, health systems, and the American Medical Association, are working to address the problem. Meier wrapped up his comments by stating that while it may be more expensive for insurers and health systems, there are alternatives to opioids for treating pain.

Alan Schwarz, Author, ADHD Nation, and Former Reporter, New York Times, spoke next on Attention Deficit Hyperactivity Disorder (ADHD). He acknowledged there is an appropriate use for ADHD medications. According to the American Psychiatric Association, in most cultures the rate of ADHD diagnosis is 5%, but in the U.S. 15% of children are diagnosed with ADHD. The CDC reports that 1 in 5 boys are diagnosed and are prescribed medications. Schwarz next highlighted his book ADHD Nation. The book includes the history of ADHD and focuses on two cases studies—a misdiagnosed child and a young man who abused ADHD medications for academic purposes. Schwarz detailed what he sees as proper and improper use of ADHD medications by both physicians and patients. Proper use by a doctor includes a thorough ADHD diagnosis, explanation of benefits and side effects of medications, assessment of feigning of symptoms, and continued monitoring of use, benefits, and side effects. Improper use by a physician includes a cursory diagnosis and use of medications as a diagnostic tool. Improper use by a patient includes use for solely studying and focus, and sharing and selling medications.

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SESSION 3: THE CHANGING LANDSCAPE OF USE AND MISUSE continued...

Schwarz then highlighted responses of the medical community in regards to the high levels of diagnosis and treatment. CDC data showed that 1 in 5 boys are diagnosed with ADHD by the time they leave high school. Perhaps even more startling was the 20,000 2-3 year olds that were diagnosed. Schwarz was appalled at the lack of response of high-level individuals at the rate of diagnosis. He also highlighted the extensive messaging and marketing of these medications. Much of the marketing makes it sound like a “prize” to be diagnosed and that medications can make children into perfectly behaving, smart kids.

Schwarz finished by imploring the public to learn from the opioid epidemic. While we should not deny ADHD exists, we must be more judicious and thorough in diagnosing ADHD and prescribing medications. This could save children from being told there is something wrong with their brains when there is not. He asked for more scrutiny of the media and marketing of ADHD medications.

Susan Weiss, PhD, Director, Division of Extramural Research, National Institute on Drug Abuse, next addressed marijuana and cannabinoids. Weiss stated she was going to be taking an agnostic approach to her talk and focus on the medical properties of marijuana. She started with some basic background on marijuana. Marijuana/cannabis contains over 100 different cannabinoids plus other chemicals in varying concentrations. The two most researched and utilized cannabinoids are tetrahydrocannabinol (THC), which is responsible for the psychoactive properties of marijuana, and cannabidiol, which is used to treat seizures. Marijuana is currently illegal under federal law, but has been approved by 28 states and the District of Columbia for medical use. States vary on allowable conditions, routes of administration, dispensaries/home growth, use of registries, amount of cannabis, testing and regulatory requirements. A strain of marijuana with high levels of cannabidiol is also legal in 16 states for medical use. There are versions of active ingredients approved or in clinical trials for medical indications in U.S. and other countries.

Weiss pointed out that there are adverse effects tied to chronic use of marijuana. While evidence levels vary, some associated adverse effects include addiction, abnormal brain development in adolescents, progression to use of other drugs, schizophrenia, diminished lifetime achievement, motor vehicles accidents, and symptoms of chronic bronchitis. She also emphasized that while these adverse effects may be negligible to someone being treated for a serious disease, a user of marijuana needs to be aware of these possible side effects.

There are 51 medical conditions for which marijuana is approved by a state. The strongest evidence exists for the use of cannabinoids to treat pain, and more specifically neuropathic pain. Recent meta-analysis and reviews show that cannabinoids can be useful in the treatment of chronic neuropathic non-cancer pain. There are limitations to these studies, but with the opioid epidemic, Weiss stated that we need to consider alternatives to treating pain including cannabinoids. She mentioned recent studies have shown states with medical marijuana laws or dispensaries have decreasing rates of overdose deaths; fewer opioid treatment admissions; fewer opioid prescriptions; savings in Medicare spending; and patient-reported decreases in opioid and other pain medication use. Weiss commented that animal models and research have shown that the cannabinoid system is involved in pain and that cannabinoids can enhance the effect of opioids.

Weiss next summarized what we currently know. Cannabis is a plant lacking FDA approval, but widely available for medical use. Physicians recommend it without evidence-based guidelines to inform practice and patients obtain it from dispensaries (or grow their own) and choose their preferred strain, formulation, dosage, and route of administration (sometimes on the advice of “budtenders”). At the same time, the opioid epidemic has led to nearly 19,000 deaths in the U.S. in 2014. Patients continue to suffer from unrelenting severe pain. Among medical cannabis users, the most common reason for use is pain. There is significant preclinical and clinical
data supporting efficacy of cannabinoids in treating pain and preliminary data that cannabis/cannabinoids may enhance the anti-nociceptive effects of opioids, or reduce the need for them. On the horizon are cannabis products (e.g., nabiximols) that are currently going through the FDA approval process.

An opportunity exists to learn from what is already happening in states, explained Weiss. Research needs to be completed on those who are already using cannabis for medical conditions. Information and evidence to be collected includes patient characteristics, conditions/symptoms being treated, cannabis products used (high THC/high CBD), how much/often being consumed, route of administration, clinical outcomes/adverse effects, and tolerance development. Other questions to be addressed are how cannabis use affects use of other medications/other abused substances and are there groups that are high risk for abuse based on age, gender, pregnancy status, comorbid conditions, or drug interactions?

Lastly, Weiss stated there is concern around development of a large cannabis industry like tobacco or alcohol. Profit motives and conflicting values are concerns that will need to be addressed if the cannabis industry moves to the medicinal side.

Douglas Throckmorton, MD, Deputy Center Director for Regulatory Programs, Center for Drug Evaluation and Research, Food and Drug Administration, spoke next on the FDA's perspective on regulating drugs. Throckmorton reminded the audience that first and foremost, the FDA is a public health agency. While they are regulators, they must conduct their work in a public health framework. He commented that the three examples show the problems regulators face.

Throckmorton highlighted the four areas in which he sees challenges for regulators. The first is societal challenges. Social media drives use and misuse more than ever. The second challenge is data and science gaps and a third challenge is the authorities in law. The law bounds regulators in what they can and cannot do and society sometimes needs a better understanding of what the FDA can do under current law.

Throckmorton addressed a comment made by Barry Meier about what the FDA did wrong in the face of the opioid epidemic. He explained that the FDA failed to question assumptions that were being made to support the use of opioids. In turn, Throckmorton gave some ideas of what the FDA should do to avoid and respond to such situations. He stated that the FDA must be ready to act, even in the face of inadequate data and evidence. The FDA must stay data driven to the extent possible, but be honest about lack of data. Finally, the FDA must be prepared to assess the impact of regulatory decisions and in turn, act if the outcomes are undesired.
SESSION 3: Q&A

Lerner started the Q&A portion by stating that often the public perception is that the FDA’s role is to keep the public safe, but in reality that is not their purview. Other federal agencies have that role. Lerner then opened up the discussion to audience questions.

The first audience question focused on the rate of ADHD in today’s children. There is some evidence that shows early exposure to electronics and screen time leads to kids that are used to rapid changes in their environment. Has this, along with lack of recess, physical education, and free play led to higher rates of ADHD? Alan Schwarz explained that some experts believe that ADHD is a disorder you are born with and is only influenced by environmental factors. Therefore, these experts believe these environmental factors have no role in the rate of ADHD. Schwarz went on to say there is a need to distinguish between ADHD-like behaviors and a clinical diagnosis of ADHD. Lerner added that expectations of children have also changed over time and Schwarz chimed in that tolerance of behaviors also influences clinical decision-making.

The next question moved to actions the FDA could take when a problem is recognized. Labeling is the first tool that can be utilized and extends up to the severest level of warning, a black box label. Throckmorton explained the recent situation around the concomitant use of benzodiazepines and opioids and how a black box warning was added to increase awareness that the two drugs should not be used together. He also mentioned that he would continue to encourage greater awareness of the effects of concomitant use.

An audience member asked when we could expect to see required education to prescribe opioids like there is to prescribe buprenorphine. Meier stated, “Never.” He went on to explain that there has been a push since 2010 for mandatory training, but groups such as the American Medical Association have blocked action. Throckmorton explained that the FDA has been looking into best ways to accomplish this, but he also recognized other organizations like the Centers for Medicare & Medicaid Services and state medical societies may need to play a role.

Two final questions broached the topic of shaming those doctors who prescribe inappropriately and promoting best practices and best care. Panelists recognized that both ways have merits and issues and may need to be utilized to achieve desired outcomes.
SESSION 4: THE UNIQUE AND CHANGING ROLES OF THE MILITARY AND VETERANS AFFAIRS HEALTH SYSTEMS

Panel: The Honorable Dr. David Shulkin; Terry Adirim, MD, MPH, FAAP; Chester “Trip” Buckenmaier III, MD; and Karen Drexler, MD

The Honorable Dr. David Shulkin, Under Secretary for Health, Department of Veterans Affairs, session moderator and speaker, explained that this session was initiated because of the military’s long history of treating pain, both visible and invisible. Shulkin explained that the two components of the military health system share customers as patients start in the military health system and when their service is completed they become part of the Veterans Affairs health system.

Terry Adirim, MD, MPH, FAAP, Deputy Assistant Secretary of Defense for Health Services Policy and Oversight, Department of Defense, started her remarks by giving some background on the military health system that treats active duty soldiers and their families. The military health system (MHS) is housed within the Department of Defense, while health care for veterans resides in the Department of Veterans Affairs. Both departments work closely though. The MHS is like an integrated system, comprised of a direct care system and a health plan. The direct care system is composed of 55 inpatient hospitals and medical centers, 373 ambulatory care clinics, hundreds of dental clinics, over 550,000 network providers, almost 3,800 TRICARE network acute hospitals, and over 800 behavioral health facilities. The system serves 9.4 million beneficiaries. The MHS is not subject to the same regulations as the private health care system, such as the Affordable Care Act.

Adirim next shared information on the rate of substance use disorders in the population served by the MHS. The overall rate of substance use disorders is low compared to the general population. Adirim explained this is because of a robust testing program within the DoD that enforces consequences for testing positive for substances. This testing program exists to ensure health and readiness of soldiers. The program tests for marijuana, synthetic cannabinoids, cocaine, methamphetamines, ecstasy, PCP, opioids including heroin, and benzodiazepines, among other substances. Testing takes place upon entry to the military and if a commanding officer suspects addiction.

Within the MHS, there is higher incidence of painful conditions where narcotics may be necessary. Like professional athletes, active duty Service members may use substances to meet performance requirements. Certain life stresses like food, housing, and health care are provided for by the highly structured environment of the military. The military system is motivated to prevent and address problems so military personnel can perform their duties.

Adirim discussed misuse prevention efforts by the MHS. As mentioned previously, there is drug testing of active duty Service members. Pharmacy drug monitoring programs encourage lower, but effective, opioid dosing. The MHS curbs “medication shopping” through technology that monitors prescription distribution in all venues. There are limit refills for Schedule III-V medications and restrictions on Schedule II medications to 30-day prescription with no refills. MHS has partnered with the Drug Enforcement Administration (DEA) on all Drug Take-Back (DTB) events since 2010. During the last two DTB events, 113 participating medical treatment facilities collected approximately 18,000 pounds of unwanted, unused, or expired medications.

Adirim addressed treatment and training next. There are published policy and procedural guidelines for all military medical providers and facilities. Treatment is available as both inpatient and outpatient within the MHS. Beneficiaries can access private care if military care is not available where they live. Access to medication-assisted therapy was improved by removing the prohibition on opioid replacement therapy. MHS
SESSION 4: THE UNIQUE AND CHANGING ROLES OF THE MILITARY AND VETERANS AFFAIRS HEALTH SYSTEMS continued...

Providers are given training which includes newly revised training modules for opioid prescribers. These training modules include interactive, video-based training that raises awareness of potential prescription drug misuse in clinical settings; the essentials of pain management including evidence-based pain management techniques; and diagnosis and treatment of substance use disorders for primary care providers.

Lastly, Adirim spoke on a recent regulation issued by the MHS, the Mental Health and Substance Use Parity Rule. This rule ensures TRICARE’s substance use disorder (SUD) benefit matches and aligns services with the standard-of-care, including coverage for opioid treatment programs (OTPs) and office-based opioid treatment. The regulation eliminates: the lifetime limit of three SUD treatments; day limits for inpatient and partial hospital care at substance use disorder rehabilitation facilities; any differential in cost-sharing between mental health and SUD benefits and medical/surgical benefits; and prohibitions on SUD care and applying the same benefit coverage rules as other medical and surgical benefits. Additionally, the regulation expands covered SUD treatment under TRICARE, to include coverage of intensive outpatient programs (IOPs) and venues for medication-assisted treatment (MAT) for opioid use disorder (i.e., buprenorphine, methadone). The process for SUD providers to become TRICARE authorized providers was streamlined and there is development of new TRICARE payment options for newly recognized SUD treatments, IOPs and OTPs.

The Honorable Dr. David Shulkin, Under Secretary for Health, Department of Veterans Affairs, next provided information on the Veterans Affairs health system. The Department of Veterans Affairs is the second largest federal department only behind the DoD, but its health system is double the size of the MHS. Shulkin showed there is a higher incidence of substance use disorders in veterans than the U.S. adult population. Over 560,000 veterans (9.7%) were diagnosed with a SUD in FY2015. The VA is seeing an increase in incidence, thought to be related to the types of conflict seen in service. Shulkin shared which substances they are having the most problems with—cannabis, cocaine, opioids, and amphetamines.

The VA recognized opioid abuse before the private sector and undertook several efforts to address the problem within their own system. In 2009, the National Office for Pain Management Practices was established, while in 2011 standardized metrics for pain management therapies were created. The Opioid Safety Initiative launched in 2013, and in 2014, targeted interventions for opioid reduction began. Shulkin explained they were able to track the impact of their efforts in 2012-2016. Impacts include: 170,000 fewer Veterans were prescribed opioids (25% reduction); 51,000 fewer (42% reduction) concomitant use of opioids and benzodiazepines; and 19,000 decreases (32% reduction) in dosage of those on chronic opioids. Shulkin expressed pride in these outcomes and welcomed those that have had better success to show the VA how they did it.

The VA has multiple approaches to opioid abuse and SUDs. Guidelines and best practices have been implemented. The VA is using informatics tools to leverage big data. Their Stratification Tool for Opioid Risk Mitigation employs predictive analytics for identifying those most likely to abuse opioids. Additional informatics tools include the Opioid Safety Initiative dashboard and the Psychotropic Drug Safety Initiative. Shulkin explained that the VA has worked hard to identify alternatives to opioids for pain management including both pharmacologic and non-pharmacologic therapies. The VA has provided provider and patient education on opioids as well as academic detailing using 285 pharmacists. The VA, like the MHS, participates in medication take back programs. Lastly, all patients must sign an informed consent document before being prescribed an opioid.

Shulkin provided more details on the clinical practice guidelines that the VA and DoD have developed together for substance use disorders. The guidelines cover several dimensions including: screening and
brief intervention tools, treatment options including pharmacotherapy and psychosocial interventions, co-
occurring mental health conditions and psychosocial problems, the need for continuing care guided by ongoing
assessment, and stabilization and withdrawal treatment. He also mentioned that care given is patient-centered
based on shared decision-making.

The VA has increasingly been utilizing medication-assisted treatment for opioid abuse, Shulkin explained.
Distribution of naloxone kits has also been a priority for the VA, with the VA recording 172 lives saved as of
February 2016.

Shulkin provided some concluding thoughts. The VA believes that SUDs are chronic brain diseases that
respond to recommended treatments. The VA strives to utilize the highest levels of evidence and is open to
learning from others around best treatment options. In this vein, the VA launched the Center for Compassionate
Innovation to continuously pursue opportunities for improvement to support Veterans in recovery and welcomes
the opportunity to partner with others.

Chester “Trip” Buckenmaier III, MD, Director of the Defense and Veterans Center for Integrative Pain
Management (DVICPM), Uniformed Services University of the Health Sciences, heads up the DVICPM,
a center of excellence for pain and the nexus between the DoD and VA. As a pain specialist, Buckenmaier
cautions that when we cut off opioids we need to be cognizant that pain still exists for many people. We
must get better at treating pain using alternatives to opioids. Buckenmaier showed a video that will be used to
train every provider within the DoD and VA on pain. This video, one of many that will be utilized, detailed and
differentiated acute and chronic pain. The video reviewed treatment options when treating chronic pain and
laid out the different facets that must be considered in a whole person approach to treating pain. These facets
include thoughts and emotions, diet, lifestyle, personal history, and physical activity.

Buckenmaier reviewed the history of DVICPM and other federal activities that tie into their work. He explained
that activities of the DVICPM are geared to the function and readiness of soldiers. The activities address four
main areas: delivery of measurement based care, establishment of consistent models of care, ensuring patient
safety, and standardizing education and training.

Buckenmaier commented that he would like to see how patients are asked about pain changed. Providers
currently check off a box that focuses on pain intensity. In his mind, pain management should maximize both
physical and emotional function. The Defense and Veterans Pain Rating Scale addresses this by using a 0-10
metric that is rooted in functional language. It is an improved, objective way to measure pain that has been
validated and can be used across clinical settings.

Karen Drexler, MD, National Mental Health Program Director, Addictive Disorders, Department of Veterans
Affairs, started by reviewing the success the VA has had in reducing unsafe opioid prescribing.
Since the fourth quarter of FY2012, VHA has reduced the number of patients receiving opioids by 27%;
reduced the number of patients receiving >/= 100 mg Morphine Equivalent Daily Dose (MEDD) by 40%;
dispensed over 41,000 naloxone rescue kits; and increased the percentage of patients with opioid use
disorders (OUD) receiving medication assisted treatment (MAT) to over 34%. Drexler raised some subsequent
questions:
• Has risk factor reduction actually reduced adverse events?
• How can we best provide treatment for patients with prescription pain medicine use disorder?
• Can we develop continuing care management models for these chronic conditions?
Several models for MAT in general settings have been reviewed in the literature. Drexler, like Shulkin, asked for those that have been successful to share with the VA. She next reviewed an innovative model that is currently being utilized within the VA. The contingency management “Rewards for Life” Program promotes recovery by rewarding verified drug abstinence. The program is currently used for stimulant use disorder. Future directions include monitoring adherence to monthly naltrexone-XR injections for OUD and alcohol use disorder (AUD) and abstinence from cannabis and tobacco smoking.

Drexler provided some information on academic detailing (AD). AD is a scholarly approach to balanced evidence based information and a service-oriented outreach for healthcare professionals by healthcare professionals. Clinical pharmacists provide AD within the VA system. Drexler provided some more information on the informatics tools mentioned by Shulkin. Screenshots of the Opioid Use Disorder Dashboard showed how facility leadership can see how they are doing compared to a national average, how individual providers compare in identifying and treating SUD, and how patients can see information that pertains directly to their care.

Drexler touched on how shared decision-making is used. A clinician provides risks/benefits for a menu of recommended options while the patient then makes an informed choice. Outcomes are measured and the plan is adjusted as needed. Besides looking at outcomes, risk and protective factors are measured using the Brief Addiction Monitor. Risk factors include craving, sleep problems, mood problems, risky situations, family/social problems, and physical health. Protective factors include self-efficacy, self-help, religion/spirituality, work/school, income, and social support for recovery. Drexler provided an example of a patient that was initially using alcohol and drugs heavily. The patient completed 28-day rehab and was clean upon release. He did relapse within the next 60 days, but with a much lower amount of alcohol and drugs. At the 180-day mark, he was abstinent and had not relapsed again. During this period, his risk factor score went down and his protective factor score went up. It was important to measure more than just whether he was using. Measuring substance abuse, risk factors, and protective factors provide a clearer picture of the likelihood for successful, long-term abstinence.

Drexler concluded by stating the VA is making tremendous progress in preventing and treating substance use disorders, but we still have a way to go. Continued dissemination of personalized, evidence-based treatment for these chronic conditions remains a challenge. Future directions include leveraging the VA electronic health record and integrated healthcare system to provide the right care at the right time to veterans with substance use disorders.
The first audience question asked about the outcome for an active duty soldier that tests positive for a monitored substance. When a soldier tests positive, the results are referred to the commanding officer. As substance use disorder is incompatible with service, a soldier would be sent for treatment and the outcomes would be dependent upon the effectiveness of treatment. The soldier does remain tied to the military during treatment.

The existence of specialty treatment courts was the subject of the next question. Shulkin described a recently initiated VA program where local police departments are sending veterans with SUDs and related offenses to the VA health system, rather than prison and the traditional judicial system.

Lerner, ECRI Institute, framed his question by expressing that the DoD and VA have been at the forefront of addressing social issues. He asked if they are striving to be ahead on addressing mental health parity. Buckenmaier said, “The only winner in war is medicine.” The military and VA health systems have been under a great deal of stress due to ongoing conflicts and have needed to address mental health parity. The VA has been addressing it for 20 years, while for the MHS it has been the last 10-15 years. Buckenmaier hopes the programs they have developed can serve as models for the civilian systems and once again pointed out that these programs are free for anyone to use. Shulkin added that the MHS and VA do not have to worry about reimbursement like the private sector does, freeing them to address social determinants of health. He also highlighted the integration of primary care and mental health as contributing to their success.

The next question focused on what policies are in place for prevention of pain. Buckenmaier described the military’s acceptance and recognition of non-pharmacologic approaches to treating pain. They have embraced complementary approaches like acupuncture, biofeedback, and massage for treating injuries. There is an integrated, multimodal approach that extends across the health system from field medic to tertiary center.

The use of measurement-based care and the Brief Addiction Monitor were highlighted in the next question. It was asked how do we apply these tools to patients in the civilian world that move insurance and providers. Drexler explained that this program will be rolled out fully in 2017, so at this time there are no answers of how to apply it to a more diverse patient population.

An audience member asked what is the most successful MAT utilized by the VA and DoD. Drexler explained that the VA/DoD guidelines have the most evidence and data for buprenorphine and methadone. For those patients that those drugs are not their choice, extended release injectable naltrexone is also well supported by data.

The effectiveness of the collaboration between the DoD and VA was extolled by an audience member. An ensuing question asked how civilian organizations could partner with them. Shulkin explained that the VA is working to develop more integrated, coordinated networks that will include civilian health systems. Part of these collaborations include the ability to exchange information easily through health information exchanges. The VA has focused on making it easy for patients to share their own medical records. They have also been working to communicate with community doctors through webinars and other materials on how to work with the VA. The VA is looking to be more innovative and open in the future. Adirim mentioned efforts to strengthen the connection between military health and the VA, especially in the handoff of those with mental health conditions. Ideally, these would provide examples for civilian health care systems.

Shulkin finished by asking each panelist a separate question. He asked Buckenmaier, because of his vantage point on both systems, where do you see the greatest opportunities? Buckenmaier said there is great power
in collaboration. The two departments have different missions and different strengths. The VA has well established relationships with major medical centers and the DoD has greatly influenced the practice of medicine over the last 15 years of continuous military conflict. Buckenmaier finished by lamenting that the biggest failure would be if what was learned by the DoD and VA over the last 15 years of conflict was not put into action by the greater civilian health care system.

Shulkin asked Drexler how we get all 300,000 practitioners in the VA to use what we have learned and laid out in guidelines and other products. Drexler returned to two of the items she had highlighted—academic detailing and leveraging information systems. She mentioned webinars and individualized consultations as two other methods to educate and inform practitioners.

Adirim was asked what the DoD does best. Adirim, who only recently joined the DoD from civilian medicine, said she has been impressed with several elements of the DoD. The first is the amount and quality of collaboration and coordination with the VA. The second is the access to care for soldiers and their families—they are able to access whatever they need through the MHS. The third element is the high quality of trauma care. Survival rates from battlefield injuries are high and practices learned through the MHS are transferred to civilian practice and in turn improves survival there. Lastly, Adirim said she was impressed by the amount of research and education taking place in the MHS.

There was time for one additional audience question. Lerner, asked the panel to comment on two substances that were focused on in Session 3—amphetamines and marijuana. Buckenmaier explained that amphetamines are no longer used within the DoD and marijuana is illegal under federal law and is not found in the military. He does not like the term medical marijuana, but is very interested in cannabinoid research and chemistry, and the development of pharmaceuticals derived from marijuana. Drexler chimed in it is illegal for VA practitioners to recommend marijuana and illegal on any VA property to carry marijuana. However, like other substances, the VA would like to be aware of use. Ideally, they would like to track use to see how it correlates to the rest of health care.
SESSION 5: HOW PROVIDERS ARE DELIVERING ADDICTION CARE

Panel: Victor Capoccia, PhD, MSW; Constance M. Weisner, DrPH, LCSW; Patrick Gerard O’Connor, MD, MPH, FACP; and Keith Humphreys, PhD

Session moderator Victor Capoccia, PhD, MSW, Senior Scholar, AcademyHealth, gave some statistics on addiction. 20 million people are facing addiction and the current health care system reaches 10% of them. He had three questions. How to identify those with the condition? What do we do when we find them? What are the outcomes?

Constance M. Weisner, DrPH, LCSW, Associate Director, Behavioral Health, Aging, and Infectious Diseases and Director of Faculty Development, Kaiser Permanente Division of Research, started her comments by addressing where patients with addiction are found and identified. She showed some data from a study done in one northern California county. The study showed that over 55% of identified cases of alcohol addiction were found in a primary care setting. Weisner thought that number would be even higher if emergency rooms were included.

Weisner showed that both adult and adolescent addiction medicine patients have more medical conditions than matched controls. For adults this included anxiety, depressive disorders, and psychoses while for adolescents this included asthma, sleep disorders, pain conditions, STDs, and psychiatric conditions. She discussed further the role of primary care in finding and treating addiction. At Kaiser Permanente, primary care physicians screen for addiction and provide some types of treatment including medications. Referrals to specialty care are made when needed. Weisner showed that the elements of continuing care after treatment include regular primary care as an anchor, readmission to treatment when needed, and psychiatric services when needed. In support of providing a continuum of care, Weisner highlighted a 9-year follow-up study of patients at KP addiction medicine clinics. The study looked found that those who used services across the care continuum were more than twice as likely to be remitted over the 9 years and were less likely to have ER visits and hospitalizations. An additional finding was that patients used far fewer services then their access provided. Weisner commented that this patient population does not use health care the way health care systems want them to. This is in part because of the separation of specialty addiction treatment from the rest of health care. Many addiction patients only utilize specialty care and ERs and do not know what they should use the rest of the health care system for. To address this, Kaiser Permanente conducted a study where patients in specialty treatment were taught patient activation and empowerment skills to better engage in health care. Patients that participated were found to be more engaged in their health care and were reporting their drug and alcohol problems to their primary physicians more often.

Weisner highlighted some of the opportunities that exist to address and treat addiction. There is greater access to treatment because of the Affordable Care Act. Health IT can help address access and disparities, provide innovations to link patients to treatment, and help physicians through clinical practice guidelines available in EHRs. There are advances in evidence-based psychosocial treatments and medications. Lastly, Weisner quickly reviewed some existing challenges that included:

- Lack of insurance, especially in those states that did not expand Medicaid
- Privacy concerns and 42CFR, Part 2
- EHR interoperability between systems (health care and specialty treatment)
- Gaps in implementing MAT
- Workforce shortages and training (in both primary care and specialty treatment)
- Referrals from primary care to specialty treatment
Patrick Gerard O’Connor, MD, MPH, FACP, Dan and Amanda ‘97 Adams Professor of General Medicine; Chief, General Internal Medicine, Yale School of Medicine, spoke next about available treatment options. He explained that it is part of his mission to ensure his primary care colleagues treat addiction like a chronic disease. Treatment of addiction is highly effective and includes evidence-based behavioral therapy and counseling, and medication therapies, or a combination of both. Effective treatment is available for tobacco, alcohol, and drugs.

O’Connor reviewed the evidence that supports the use of FDA approved medications, disulfiram, acamprosate, Naltrexone PO, and Naltrexone IM, to treat to treat AUD. There are numerous studies that show the effectiveness of these medications to treat AUD. O’Connor’s next example focused on the enormous amount of evidence to support methadone for the treatment of OUD. Methadone treatment has been shown to decrease heroin and other drug use, HIV and hepatitis B/C infection, and crime and social dysfunction, while improving obstetric and birth outcomes, and overall survival. While highly effective, there is restricted and limited access and in some areas of the country there are no methadone clinics. Patient acceptance is an additional limitation. Evidence also exists that supports cognitive behavioral therapy to treat addiction.

Despite vast amounts of evidence that treatment is effective, an addiction treatment gap exists in the US. In 2011, according to NIDA, 21.6 million Americans needed specialized treatment for addiction, however, only 2.3 million received treatment. O’Connor asked if we would tolerate this lack of access for treatment of diseases like diabetes, cancer, asthma, or myocardial Infarction. To address the treatment gap, O’Connor recommended enhancing access to current evidence-based treatments in traditional settings and developing new models of treatment.

O’Connor spent the rest of his time addressing new models of treatment. He suggested the first avenue to be addiction treatment in primary care and other general medical settings, rather than specialty care alone. This would increase entry points to addiction treatment and treatment capacity, allow coordination of addiction treatment and medical care “under one roof”, approach addiction like other chronic diseases, and engage patients in less stigmatizing medical settings. This could include primary care clinics and offices, and other general medical settings such as emergency departments and inpatient medical settings.

The initial efforts to treat addiction in primary care started in the treatment of AUD with office-based brief interventions. This focused on nondependent heavy drinkers and consisted of feedback and advice from a primary care physician during a routine office visit. A Cochrane review of 24 randomized trials concluded that brief interventions in primary care lowers alcohol consumption. A Yale study that looked at an alcohol dependent population treated with Naltrexone found similar outcomes across two control groups—patients that received Naltrexone from a cognitive behavioral therapist and those that received it in a primary care setting. Despite these results, the uptake of naltrexone in primary care has been slow.

O’Connor showed that pharmacotherapy for AUD is on par with drugs to treat other conditions based on numbers needed to treat (NNT). The NNT is 5-12 for pharmacotherapy vs placebo for maintaining abstinence and/or reducing heavy drinking days. A similar effect is seen in SSRIs vs placebo for a significant reduction in depression with a NNT of 7-9. Converely, the NNT for deep vein thrombosis prophylaxis vs no treatment to prevent one non-fatal pulmonary embolism is 345. Pharmacotherapy compares quite favorably to these other treatments that are widely practiced in primary care, but has not seen the same uptake.

O’Connor presented a study that compared buprenorphine in a primary care setting versus methadone clinics.
Patients fared similarly in both treatment settings, demonstrating that buprenorphine can be delivered in the primary care setting. The birth of office-based treatment of opioid dependence took place in 2000 with the passing of the Drug Addiction Treatment Act (DATA). This allowed office-based treatment of opioid dependence by qualified physicians. Qualified physicians included board certified addiction specialists, and physicians who take an 8-hour training course. The law allowed only DEA Schedule III-V drugs to be used and none were available in 2000. This changed in 2002 with the FDA approval of buprenorphine/naloxone.

O’Connor showed that buprenorphine was more effective in cases of prescription opioid abuse compared to heroin alone and heroin combined with prescription opioids. He next showed a study that compared the use of buprenorphine in its two FDA approved indications—maintenance and detox/taper. The study showed that patients fared better in the maintenance approach. An additional study showed that long-term maintenance with buprenorphine resulted in patients staying off opioids and being satisfied with treatment.

Next, O’Connor highlighted a study done at Yale that focused on addressing opioid dependence in the emergency department. They undertook a study that identified patients with OUD in the ED and started them on buprenorphine immediately. They then continued their care and buprenorphine treatment in primary care. Compared to referral and referral plus brief intervention, patients offered buprenorphine had higher rates of treatment engagement and less illicit opioid use in the 30-day period following enrollment.

The impact of office-based treatment is quite large. In 2001, 250,000 people were treated with methadone. By 2012, 270,000 were on methadone while over 400,000 people were being treated with buprenorphine. To help continue this progress in August 2016, the Department of Health and Human Services increased the number of buprenorphine patients a physician can prescribe to from 100 to 275. To participate a physician must have a current waiver to treat 100 patients to apply, hold additional credentialing such as board certification in Addiction Medicine or Addiction Psychiatry, and must practice in a qualified setting. Also in 2016, the Comprehensive Addiction Recovery Act (CARA) was passed. This legislation sought to improve access to opioid overdose treatment and increase access to medication-assisted treatment (MAT) for OUD. It expanded privileges to nurse practitioners and physician assistants who undertake 24 hours of required training, but state-by-state variability in prescribing laws do apply. Also included were grants to expand the availability of MAT and efforts to improve treatment for pregnant and post-partum women.

Briefly addressing the physician’s role in preventing addiction, O’Connor said that addiction medicine education must be improved in medical school and residency training. He commented that addiction medicine was recognized as a subspecialty in 2015. He concluded by reminding the audience that evidence-based treatments for addiction are well established, but access to these treatments is poor. New models to expand access to evidence-based treatments in primary care and other general medical settings can effectively help to fill this need.

Keith Humphreys, PhD, Professor, Psychiatry and Behavioral Sciences, Stanford University and VA Aging Clinical Research Center, Palo Alto, talked about recovery support services available in the health care system. If addiction is a chronic health problem, what are the sources of long-term support asked Humphreys. He started with self-help groups and recovery support services. Self-help groups are peer directed, not professionally led, and are often available freely or at nominal cost. Both self-help groups and recovery support services value experiential knowledge, are adaptive and adaptable, and possess a long-term chronic care perspective.
Humphreys asked, “so does it work?” He reviewed a study done at the Palo Alto VA on referral to Alcoholics Anonymous (AA) and Narcotics Anonymous (NA). Standard and intensive referrals were compared. The intensive referral included a 30-minute discussion where AA or NA was described, along with providing someone to accompany patients to their first meetings. Those patients that received intensive referral participated at higher rates in the 12-step programs. An additional study used instrumental variables analysis on over 2,300 patients in six trials to test the impact of AA free of selection bias. The study found that AA was effective in five of the six trials.

The next study Humphreys discussed looked at clinical and cost outcomes of patients participating in 12 step programs. The 12-step participating patients had slightly better clinical outcomes compared to patients receiving cognitive behavioral therapy after 1 year. A greater difference was seen in the cost outcomes of the two patient populations. The 12-step participating patients incurred lower costs because of fewer hospital admissions and doctor visits. The effects after 2 years of monitoring were even larger. Humphreys theorized this is because the 12-step programs provide services that patients may seek through a health system, but can be provided more economically elsewhere.

Humphreys also spoke about recovery support services. They are a mix of funded and voluntary services, usually staffed and created by people in recovery. Recovery coaching, recovery housing, recovery schools at the high school and college level, and recovery centers offer a wide variety of services to those in recovery. The strongest current evidence is for recovery housing and recovery case management. He provided information on a clinical trial of the Oxford House, which is a 12-step influenced, peer-managed residential setting. The clinical trial compared patients who lived in Oxford Houses and those who sought treatment as usual after inpatient treatment. At 24-months, Oxford House produced 1.5 to 2 times better outcomes in abstinence, employment, and incarceration.

Lastly, Humphreys raised the point that we are starting to a movement towards to recovery-oriented systems of care. He pinpointed Philadelphia as a leader in developing systems that address individual needs and focuses on giving long-term support to treat addiction as a chronic disease. Humphreys praised the recovery community for being politically active and expressing their desires and opinions.
Capoccia started the Q&A by remarking that we just heard about this great evidence and work being done, but in his experience around the country, he has heard people complaining they cannot get into treatment because of availability. Humphreys explained there is massive need for these services and the current treatment system is too small. The ACA provided coverage for these services for thousands of people that previously did not have access. Our health care system works by creating demand through benefit design and in turn, the system must then catch up with supply. Capacity can be developed in part by expanding participation of primary care.

Capoccia’s next question focused on the impact of the ACA and its possible repeal on treatment of addiction. Weisner explained that Medicaid expansion under the ACA provided access to millions of people that previously had been uninsured. The panelists expressed concern that repeal of the ACA would result in backtrack of progress made under the ACA in treating addiction and said that physicians will need to be activists for their patients.

The first audience question was on the acceptance of MAT in 12-step programs. The audience member commented that it is common in the Northeast U.S. for NA programs to be unaccepting of those on MAT. Humphreys clarified that the official position of NA is that MAT is acceptable and that NA’s role is not as medical provider. O’Connor expressed that in his clinical experience he has seen patients on MAT having to search more to find programs where they could be comfortable.

An audience member asked how to develop a workforce in communities that are woefully behind in treating addiction. O’Connor explained that detailing can provide primary care physicians with the information and tools they need to treat addiction using MAT and other therapies. He emphasized that these newly educated and trained physicians will need “back up” from time to time and they should have access to specialists when needed. Capoccia added that telemedicine could provide back up support.

The impact of cash only MAT facilities was the subject of the next question. The panel expressed the view that cash only payment policies are unacceptable. The point was raised that the legislation allowing some providers to expand their buprenorphine patient number also required that providers accept third party payment.

The roles of non-physician practitioners were discussed next. An audience member asked if it is possible to track who is providing the counseling mentioned in studies. O’Connor noted that a wide breadth of providers are filling different roles and gaps and that we should determine which non-physicians are providing the best care in different situations. Some recent studies have looked at involving nurses more in the office-based use of buprenorphine to expand capacity. We are moving to team-based care, but need to monitor outcomes.

The next question focused on what changes need to be made to the health care system. Weisner commented that addiction medicine specialists need to treat addiction like a chronic disease. Once the intensive treatment is completed, patients need to be returned to general medicine practice where they can be monitored and followed up with.

An audience member asked, “Does 42CRF Part 2 hinder integration of addiction care into mainstream/primary care?” The panelists agreed that 42CRF Part 2 does hinder feedback to primary care physicians and on their ability to learn if their treatment choices were right. This type of situation would be unheard of anywhere else in the practice of medicine. Humphreys suggested there is too much focus on the potential harm of sharing and not enough on the potential harm of not sharing.
The next question asked whether we have the science to identify patients with abuse disorders. Weisner explained that despite the lack of blood tests or biomarkers, we do have evidence-based screeners, short questionnaires, and structured instruments to look for dependence that work very well. The problem lies in getting practitioners to utilize these tools.

Capoccia posed the final question. While the panel showed that addiction is a chronic health condition and that specialty addiction care must be tied to general medicine, not much is happening around the country to make it happen. How do we accelerate and move forward to reach this ideal? Humphreys explained that the current siloed system originated in the 1970’s when efforts were being made to address addictions of the day. At that time a siloed approach was desired, which made addiction care a nomadic specialty. Payment, regulation, and care were handled separately from all other types of medical care. In order to make a change and have people work together, we need to put the money together. If the money can only be found in one place, people and organizations will be forced to work together, explained Humphreys.
SESSION 6: THE ROLE OF PUBLIC AND PRIVATE PAYERS IN ADDRESSING USE AND MISUSE

Panel: Gail Wilensky, PhD; Doug Nemecek, MD, MBA; James B. Becker, MD; and Patrick Conway, MD

Gail Wilensky, PhD, Senior Fellow, Project HOPE, and Trustee, ECRI Institute, introduced the session and speaking format. Doug Nemecek, MD, MBA, Chief Medical Officer, Behavioral Health, Cigna, spoke first on what Cigna is doing to address substance use disorders. SUDs have existed for a long time, but because of the Mental Health Parity Act and the ACA, payers are focusing more on how to address these disorders. Nemecek spoke of a recent study on a large commercial insurance population that showed a 1375% increase on claims paid for opioid use disorder treatment from 2011 to 2015. Cigna is addressing substance abuse disorders in four areas. The first is identifying people with SUDs or those at risk. Insurers historically have not been good at this, but Cigna is working to develop predictive models to identify those at high risk or already abusing substances based on claims and medical data. In order to better treat their adolescent population, Cigna has partnered with Shatterproof to disseminate evidence-based information to parents and families.

The second area of focus is to increase and expand their network of substance abuse treatment providers. One specific program is contracting with facilities and providing a designation that indicates better outcomes and lower cost, along with more efficient delivery of care. Cigna is also working to expand their network of providers that treat chronic pain. The third objective is to evolve reimbursement models for SUD treatment to focus on value. Cigna has made great strides on implementing value-based models on the medical/surgical side and is looking to catch up on the behavioral health side. Nemecek mentioned that one barrier to this is the lack of standardized measures and nationally accepted standards in the treatment of SUDs.

The final goal for Cigna is to better integrate care between primary care doctors and specialty treatment. Cigna is approaching this through their 165 primary care-based accountable care organizations (ACOs). They have been discussing with their ACOs how to better integrate SUD and behavioral health care. Ideally, there would be seamless referrals and information exchange. In addition, to address the opioid abuse epidemic, the ACOs have been asked to follow the CDC guidelines on opioid prescribing and share best practices to address opioid misuse.

James B. Becker, MD, Medicaid Medical Director, West Virginia Bureau for Medical Services, and Vice Dean for Government Affairs and Health Care Policy, Joan C. Edwards School of Medicine, Marshall University, spoke about his experience as West Virginia’s Medicaid Medical Director and how they have worked to address substance abuse disorders. When Becker joined WV Medicaid 8 years ago, concerns were starting to grow over the utilization of certain drugs including opioids, benzodiazepines, mood stabilizers, and stimulants in foster kids. These were the initial targets of what Becker described as an uncoordinated response. Actions were varied and included:

- Unit limits on prescriptions (dose and # of doses)
- Lock-in arrangements for both “bad apple” physicians and patients. Physicians could only prescribe through one pharmacy while patients could only receive prescriptions for controlled substances from a single prescriber.
- Buprenorphine regulations
  - Caps on dose for maintenance therapy
  - Worked with physicians to identify solutions
- Data pull on providers to identify outliers
- Broad, sweeping education for providers on appropriate opioid prescribing
- Robust prescription drug monitoring database (PDMD)
Becker said efforts today are more coordinated. West Virginia is applying for an 1115 Medicaid waiver for tailoring payment models for treating SUDs. They have developed guidelines for the use of urine drug screening in the management of chronic pain and with MAT. West Virginia established the first pediatric residential treatment nursing facility for babies suffering from NAS, along with adopting the CDC guidelines for opioids for chronic pain. Despite all of their efforts, West Virginia still suffers from overdoses, misuse of substances, and abuse of heroin.

Lastly, Becker revealed what he worries about at night. He is concerned about the interface of pain and addiction, and making sure pain is managed for those in need. He has concerns about treating substance use disorders in patients with comorbid conditions including mental health conditions. Finally, Becker said he is worried about new drugs that hold potential for abuse.

Patrick Conway, MD, Deputy Administrator for Innovation & Quality, Chief Medical Officer, Centers for Medicare and Medicaid Services (CMS), spoke about the role Medicaid and Medicare have in addressing substance use disorders. He started his remarks by telling the audience we have zip codes in our country where life expectancy is decreasing because of behavioral health and substance abuse. He gave a personal anecdote where he was trying to get services for a family member with postpartum depression and alcoholism. As the Chief Medical Officer of CMS and a physician, he struggled to assist his family member in receiving appropriate treatment. He wondered if he struggled this much, how much must others struggle to receive care.

Conway quickly covered some statistics about Medicaid. In 2014, Medicaid accounted for 21% of all SUD treatment costs among all payers. Roughly, 12% of adult Medicaid beneficiaries have a SUD while 15% of the ACA expansion population does. Comprehensive services can be available through Medicaid, but many benefits are optional as states have flexibility in benefit design. CMS has acted to encourage states to adopt practices that improve outcomes for beneficiaries with SUD conditions.

One key initiative addressing SUD conditions is the Medicaid Innovation Accelerator Program (IAP). This is a four-year commitment by CMS to build state capacity and to support states’ ongoing Medicaid delivery system reform efforts. The first program area picked by states to focus on, SUD, was addressed with a 6-state High Intensity Learning Collaborative (HILC). Other work within this program includes on-going support for HILC states; a four-part national webinar series for all states and stakeholders; available support to states interested in SUD waiver 1115; and tools and resources for states to be released in 2017. 48 states are engaged in these opportunities.

Conway spoke next about the Medicaid Parity Rule published in March 2016. Generally following commercial insurance rules, it applies to benefits provided to all Medicaid beneficiaries enrolled in managed care organizations, Alternative Benefit Plans (ABP), and CHIP beneficiaries (with some nuances). The Rule does include long-term care services and states must publish parity analyses on their Medicaid website within 18 months of the publication of the final rule. State Medicaid programs have until October 2, 2017 to be compliant with this new rule. Support will be given to state Medicaid agencies including:

- Parity analysis toolkit to help states assess compliance;
- Parity implementation roadmap to assist states in planning and organizing their implementation efforts;
- National webinars to introduce tools and resources and to address questions and evolving issues;
- Q&A factsheets; and
- Individual and group coaching to assist states with the development of implementation and monitoring strategies.
Conway provided some details on the Center for Consumer Information and Insurance Oversight (CCIIO) within CMS. CCIIO operates federally facilitated and state partnership healthcare marketplaces (Qualified Health Plans) and plays a regulatory role for the small group and individual insurance market by monitoring inclusion of essential health benefits (EHB) and provisions of the Mental Health Parity and Addiction Equity Act (MHPAEA). They provide consumer assistance through navigators, certified application counselors, enrollment assisters and agents/brokers. CCIIO also supports state-based marketplaces.

Providing some additional context, Conway explained that MHPAEA generally prohibits group health plans and health insurance issuers from imposing more restrictive financial requirements and treatment limitations for mental health and substance abuse treatment compared to those applied to medical or surgical benefits. It also made naloxone and MAT a prescription drug essential health benefit that must be covered and reimbursed.

Conway finished by highlighting programs and initiatives that are innovative and transformational. He spoke highly of the Medicare Collaborative Care Model for mental and behavioral health where primary care physicians work with psychiatrists and behavioral health specialists via telehealth or remote methods to address their patients’ needs. Initial studies have shown quality improvements and decreased costs, along with primary care doctors improving their delivery of SUD or behavioral health care because of receiving feedback through the collaboration. The program will go national in 2017 and Conway hopes that Medicaid and commercial insurers will institute similar programs.

Conway also addressed the integration of mental and behavioral health into ACOs. Progress has been made, but more work is needed. CMS will be working on accountable health communities in the future where social determinants of health will be addressed as they have a significant impact on behavioral and mental health. Conway finished his comments by calling for continued innovation in treating patients with SUDs and behavioral health conditions.
SESSION 6: Q&A

Wilensky asked Nemecek what would need to be done to address the lack of standardized outcome measures. He commented that Cigna looks for the right partners to work with as they realize that an insurer alone cannot determine measures. They look to work directly with provider groups and other interested groups. Nemecek explained that he receives weekly inquiries from substance abuse treatment providers looking to partner on innovative treatment models and work out novel and supportive reimbursement. Ultimately, the goal is to be able to make national comparisons and provide information to consumers so they can make educated decisions of where to seek treatment.

The panel elaborated on the barriers to better treatment. Nemecek mentioned two areas—standardized outcome measures and 42CFR Part 2. He emphasized that 42CFR Part 2 needs to be updated to allow information sharing and set privacy rules that will allow for sharing of information between providers and among other relevant stakeholders like insurers and ACOs. Becker talked about barriers to delivering care in rural settings. He advocated for more telemedicine and more credentialed providers in rural communities. Conway also spoke of workforce issues including low levels of participation by psychiatrists in Medicare. As mentioned previously in the conference, the silo'ing of budget, payment, and administrative oversight for substance use treatment and behavioral health continues to be a problem.

Wilensky mentioned that the Army extensively uses telehealth psychiatry. She asked Conway about Medicare’s use of telehealth. He explained that the Collaborative Care Model, being scaled nationally, does utilize telehealth. He also highlighted that several 2-sided risk ACOs have applied for waivers for telehealth and in turn are using it extensively.

The first audience question focused on the hub and spoke model of delivering addiction care where a specialist is the center and refers out to primary care and others for maintenance treatment. Nemecek indicated that Cigna does support such models of care along with many other models. Becker explained that the hub and spoke model is just making its way to West Virginia through the two academic medical centers.

As payers, what health economics and research questions regarding treatment of SUD would you like to see answered, asked an audience member. All three panelists provided answers that included:

- How to match patients to the best treatment at the lowest cost
- Reception of patients to injectable Naltrexone and patient characteristics for adherence
- How to treat SUD patients that have significant comorbidities
- Comparative effectiveness of available treatments
- Impact of SUD treatment integration into ACOs and primary care medical homes
- Patient engagement and adherence
- Factors that affect the spread and uptake of effective models and methods

The next audience question was on what efforts insurers were taking to better support pain treatment and limit addiction opportunities. Nemecek answered that Cigna is looking at all options to treat pain while limiting the use of opioids. This includes physical therapy, acupuncture, and chiropractic, among other alternative options. Cigna is also addressing the issue with value-based care models like episodes of care and quality bonuses. Nemecek mentioned that Cigna would be rolling out episodes of care for chronic conditions, including pain, in 2017. Conway conferred that CMS uses bundles and chronic care bundles as a way to encourage more physicians to evaluate all treatment modalities before prescribing opioids.
SESSION 6: Q&A continued...

The following question asked why hospitals do not do more to treat addiction. The panelists agreed that the addiction population can be very difficult patients and many hospitals find them difficult to treat. Insurance often lapses, patients leave against medical advice, and they often have comorbid conditions that need to be treated as well. Many hospitals are not equipped to deal with patients going through withdrawal. It was also pointed out the service lines that deal with addiction treatment and behavioral health are financial drains on hospitals. Financial incentives and penalties can be used to encourage more hospitals and ACOs to treat this patient population.
SESSION 7: HOW HEALTH SYSTEM CEOS PERCEIVE AND EXECUTE THEIR ROLES

Panel: Ralph Muller; Elizabeth Concordia; and Andrew McCulloch, MHA

Ralph Muller, President and CEO, University of Pennsylvania Health System, and Trustee, ECRI Institute, introduced his co-panelists and reminded the audience that in many areas of the country healthcare is the biggest employer. These large health systems educate a wide variety of health care practitioners along with contributing to national research on addiction. He asked the panelists to give a few details about their health care systems.

Elizabeth Concordia, President and CEO, University of Colorado Health, reported that UC Health is the only academic medical center in Colorado. It is a $3 billion operation that conducts 3 million outpatient visits a year. Colorado was the first state to introduce recreational marijuana and Ms. Concordia hopes to later talk about what impacts they have seen on both employees and patients.

Andrew McCulloch, MHA, President, Kaiser Foundation Hospitals and Health Plan of the Northwest, explained that his health system is mission-driven with an objective to provide high-quality, affordable care to their members and their community. Based in Portland, Oregon, the system is composed of 2 hospitals and 31 medical offices. The system writes over 5 million prescriptions a year and manages their own formulary allowing them to do some unique activities to manage drug prescribing and use on both the medical and dental sides.

Muller asked the panelists to discuss their roles as employers in addressing misuse and addiction and specifically asked Concordia to discuss UC Health’s experience with marijuana. Concordia explained the efforts UC Health has engaged in to address opioid and marijuana use in their employees. UC Health has 17,000 employees that are drug tested before hire. There is 0% tolerance for any level of THC before a person can be hired. There is access to opioids for healthcare providers and UC Health takes actions to limit diversion including locked and coded access to opioids and anesthetics. Concordia stated that starting December 1, 2016, UC Health would start randomly drug testing employees in safety-sensitive, high-risk positions. The drug test will not include THC because there is no established level of THC that causes impairment. Employees can also be tested if they are reported by a coworker or supervisor for suspicious behavior. UC Health has developed policies to address employees that self-report drug problems and get them appropriate help.

Muller told the audience that 5 years ago the UPenn Health system announced they would no longer hire tobacco smokers. They received some pushback that this rule would disproportionately affect lower socioeconomic applicants. He asked the other panelists if they have experienced this based on their policies.

McCulloch provided insights into KP’s policies. They do drug test at the time of employment, but not at any other point. There is much focus on the security and control of opioids. He explained there has been a rash of overnight robberies of KP pharmacies in California and the Northwest and they are working to develop employee policies to address this. Opioids are stored in steel, hardened cases after hours. KP does not have the same approach to employee behavior such as smoking, compared to UPenn, and instead uses incentives to drive employee health.

Muller asked McCulloch what are the advantages of an integrated delivery system (provider and payer combined) to addressing marijuana and opioid problems. McCulloch said the largest advantage is knowing the prescribing patterns for the 550,000 members covered by his health plan. He cautioned that you must have awareness and desire to look for abuse because you will find it. He told of his awakening to problems that
existed within his covered population. He received a call in 2010 from a U.S. Attorney General that informed him that there were more deaths from prescription drug misuse than homicides in Portland that year. This caused them to examine their experience with opioids at the population health level. Examination showed overutilization of opioids, but gave them an opportunity to address and improve care.

Muller stayed on this topic and asked if places like UC Health and UPenn are less able to address these issues because they are not integrated health systems. Concordia agreed that medical centers treat the patients that come to them, not a circumscribed population. It is tougher to treat SUD patients because you cannot see the total spend or all of the delivered care. Care is very episodic and no risk is assumed for the population, unlike integrated systems. To address these issues, UC Health refers emergency room patients with suspected SUD to primary care physicians that specialize in addiction.

Muller commented that it takes decades for a system to be integrated like Kaiser. For most health systems that are not integrated, what can they do? For example, he said that in Pennsylvania there are regulations that require prescribers to check a state database before prescribing a controlled substance, but physicians are complaining about the hassle and that it takes time away from providing care. McCulloch spoke about a program in Oregon called the Emergency Department Information Exchange (EDIE). Funded by hospitals and government bodies, the exchange links ERs across the state, allowing sharing of information to assess, diagnosis, and treat patients suspected of SUD. Kaiser also provides 4 hours of training on opioids for all new physicians. Concordia explained that UC Health’s approach is to prevent addiction through a use of a strict formulary that limits dispensing of opioids. This type of approach can reflect poorly on hospitals because of the use of patient satisfaction scores to rate hospitals. If patients feel their pain is not being treated appropriately, they are more apt to give low satisfaction scores. Concordia reported they are trying to embed addiction specialists in large physician practices to treat chronic pain and addiction, along with trying different types of providers for delivering addiction care. They are willing to try different solutions to find the best outcomes.

The next set of questions focused on payment for the team-based care that best serves SUD and behavioral health patients. McCulloch explained that while there is not direct payment to treat these patients in team-based care, it would cost money to not treat them that way. SUD patients are removed from a primary care physician’s panel of patients and are treated by specialists including anesthesiologists, pain psychologists, social workers, and physical therapists. They have found that this type of treatment improves care and limits their medical expenses. In the long run, the patient gets better and needs less care, and costs the health system less money. There is a dichotomy between being reimbursed for team-based care and being penalized for not delivering care that way. Concordia stated that they are not reimbursed, and deliver team-based care because it is the right thing to do for patients. By having social workers and behavioral health specialists handle care associated with SUD patients, primary care physicians are free to see more patients and produce more revenue that can be pulled to under-resourced areas, like SUD and behavioral health.

The conversation turned to the issue of value-based purchasing in health care systems and whether quality measures are perverse. Muller wondered if under future health care regulations, we would see more quality measures that are unfair to health systems that treat populations of SUD patients. He argued that poor performance may be reflective of patient characteristics, rather than quality of care.
SESSION 7: Q&A

An audience member asked how social determinants of health are being addressed. McCulloch talked about a program being conducted by KP to address homelessness of chronically mentally ill and SUD patients. They are building supported housing that will include onsite treatment. The panelists recognized that work must be done to address social determinants of health in these populations.

A succession of quick fire audience questions focused on the ability of physician assistants to deliver addiction care, the challenges of delivering health care in rural communities, the budgetary impact of costly, but cost effective, treatment like MAT, and training of health care practitioners to treat and respond to SUD patients.

Muller concluded by commenting that the session showed that science and payment systems are taking us in two different directions. The delivery of addiction care is reflective of payment dynamics and we must work to make payment reflective of how care should be delivered.
SESSION 8: BARRIERS AND SOLUTIONS TO EFFECTIVE PREVENTION OF MISUSE

Patrice A. Harris, MD, MA, Chair, AMA Board of Trustees and Chair, AMA Task Force to Reduce Opioid Abuse, session moderator, opened by introducing the panelists and the focus of the session.

Debra Houry, MD, MPH, Director, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), stated that we must work together across sectors and with patients to face the opioid epidemic. She described some of the work being done by the CDC and that one of their foci is primary prevention through safe prescribing. Since 1999, rates of opioids prescribed have quadrupled and the rate of death from prescription opioids have increased in lockstep, with 165,000 deaths since 1999. In March 2016, the CDC released prescribing guidelines directed at treating chronic pain in adult patients, with a focus on the initiation of opioids. Houry described the robust process of guideline development as including an AHRQ review, review of 130 additional research studies, convening an expert panel, and public comment. The CDC Guidelines remind physicians that first, they must do no harm. Opioids are not first-line or routine therapy for chronic pain. It asks physicians to exercise caution, prescribe the lowest effective dosage, and monitor all patients closely.

The CDC is working with insurers to help implement their guidelines. They are encouraging greater coverage for non-pharmacologic therapies and making it easier to prescribe non-opioid pain medications. They are asking for reimbursement for patient counseling, care coordination, and checking prescription drug monitoring databases. The CDC would like insurers to promote more judicious use of high dosages of opioids using mechanisms such as drug utilization review. They would like to see the removal of barriers to evidence-based treatment of opioid use disorder, such as elimination of lifetime limits on buprenorphine.

Houry understands that most physicians do not have time to read the 40-page Guideline. To address this and ease implementation of the guideline, they have developed a checklist for providers and are developing a mobile app. The CDC provides funds to 44 states to help prevent and address misuse of prescription drugs. This includes funding for prescription drug monitoring databases, research and policy studies, and rapid response projects. The CDC recognizes the need to educate patients and consumers and is working to develop tools. They are also working to educate health care providers. Medical and nursing schools have agreed to include the CDC guidelines in their curricula and the CDC plans to develop CME courses that cover the guidelines.

Thomas G. Davis, RPh, Vice President, Professional Services, CVS/pharmacy, CVS Health, spoke next on the role of pharmacists in community education. He provided some basic background on community pharmacists. There are 63,000 community pharmacies and 175,000 community pharmacists across the United States. In 2015, these community pharmacists filled 4.4 billion prescriptions. Community pharmacies are very accessible with 9 out 10 Americans living within 5 miles of a community pharmacy. In metropolitan areas, 9 out 10 people live within 1.7 miles of a community pharmacy. The net result is that pharmacists are uniquely positioned to educate members of the community.

Davis explained the multi-faceted approach CVS Health is taking towards addressing opioid abuse. CVS Health complies with regulations that are designed to create a secure, closed route of distribution of controlled substances from point of manufacture to final dispensing, administration or disposal. They have a major focus on loss prevention, both internal and external. CVS Health has programs and controls in place to ensure their pharmacists have the best training and framework in place to ensure they are exercising their profession discretion and judgment appropriately. The fourth approach is the Safer Communities Program. The program includes patient education, pharmacists teaching in the community, consumer drug disposal, and expanding access to naloxone.

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SESSION 8: BARRIERS AND SOLUTIONS TO EFFECTIVE PREVENTION OF MISUSE continued...

In addition to providing basic medical information, CVS Health has their pharmacists trained to deliver three key counseling points to safeguard against prescription drug abuse. They remind patients to take medications only as directed by prescriber, to keep medications secure in the home, and to properly dispose of any leftover medication. They have launched a web resource site for prescription drug abuse and are promoting the site through prescription bags, receipts, store circulars, and the CVS website.

Teenagers have been identified as a vulnerable population. In 2012, 1 in 4 teens reported having misused or abused a prescription drug at least once in their lifetime. CVS Health’s “Pharmacists Teach” puts pharmacists in the classroom to teach about the dangers of drug abuse. The purpose of the program is to dispel the myth among teens that prescription drugs are safer to experiment with or abuse than street drugs. In the 35-minute presentation for teens in a health class setting, a local CVS pharmacist gives a multi-media presentation that includes powerful, moving video testimonials from those whose lives have been affected by prescription drug abuse. The content was produced in conjunction with the Partnership for Drug-Free-Kids. During the 2015-16 school year over 2,800 presentations were given to 102,600 students in 39 states. Feedback from students and educators alike has been overwhelmingly positive.

Cynthia I. Campbell, PhD, MPH, Research Scientist, Kaiser Permanente, presented next on addiction prevention in an integrated health care delivery system. Campbell explained that the data she will present today is from Kaiser Permanente Northern California (KPNC). KPNC has 3.9 million members, 21 hospitals, over 7,400 active physicians, and a mature electronic health record. KP is an integrated system where medical, psychiatry, and substance use treatment services are found together. Integration of substance use with mainstream care can be vital in prevention. At KP, patients are screened and treated in primary care, referred to specialty care if needed, and sent back to primary care for monitoring.

In the PCORI-sponsored ACTIVATE study, outcomes of patients on long term opioids who receive a behavioral intervention in primary care are being studied. It is a pragmatic, randomized trial comparing a behavioral intervention versus usual care. The intervention is four 90-minute group sessions in primary care where topics covered include patient activation, pain management, self-management, health IT, and how to communicate with providers. Patient centered outcomes like pain, function, quality of life, and patient satisfaction are measured. This study was conducted to look at where opioids are most prescribed—in primary care. Patients could be identified upstream before addiction hits or becomes more severe. The intervention could serve as a bridge for those already with severe problems to other services (psychiatry, pain).

The KPNC Opioid Safety Initiative, a health system wide intervention, was launched in late 2013. A key focus was to reduce high-risk prescribing. Elements of the initiative included opioid agreements; measuring the 4As (analgesia, activities of daily living, adverse effects, and aberrant drug-taking behavior); screening for opioid misuse, alcohol and depression; checking the CA prescription drug monitoring program; and regular urine drug screens. There was also a heavy emphasis on provider education through trainings, online support, and department champions. Customized physician specific reports were fed back to providers to provide information on high dose patients. The EHR was modified to include decision support and to make tasks as simple as possible to comply with the initiative. Early results have shown an increase in signed opioid agreements and urine screens between 2014 and 2016, and a 44% decrease in morphine member equivalents from 2012 to 2016.

Campbell switched gears to focus on alcohol screening, brief intervention, and referral to treatment (SBIRT) in primary care. “Alcohol as a Vital Sign” (AVS) is an initiative where medical assistants screen for risky drinking and physicians deliver the brief intervention and referral to treatment. There was region-wide implementation in June 2013. AVS is consistent with system workflow for other screening initiatives and leverages EHR tools.
and data. As of September 2016, the screening rate is 87%. For those patients that screened positive for risky drinking behaviors, 66% received brief interventions in August 2016. This is a 2-fold improvement since the program started.

The last initiative Campbell discussed was the Prescription Opioid Registry, which is funded by NIDA and uses EHR data. Data elements include pharmacy/drugs used, substance use diagnoses, medical and psychiatric comorbidities, overdose, service utilization, mortality, and costs. Over 450,000 patients with any opioid use have been entered into the registry. They are conducting a variety of analyses to look at what predicts using opioids long term, developing misuse or addiction, and overdose. Results from analyzing overdose data show the following items are predictors of overdose:

- Younger age, male
- Co-existing psychiatric and medical problems
- Alcohol and other drug problems
- Smoking behavior
- Opioid dose, even at low daily doses (1-20, 20-50 mg)
- Benzodiazepine use

There was no relationship found to race or ethnicity in their studies. There are several potential uses for this data by health systems. Health systems could identify high-risk patients according to various criteria and tailor outreach. They could track outcomes of interest over time or identify providers for interventions and decision support. The registry could be used for ongoing disease management and collaborating with other health systems.

Harris provided some information on what the American Medical Association (AMA) is doing to address the opioid epidemic before moving on to questions. Two years ago, the AMA formed a task force, which Harris chairs, to address opioid abuse. The AMA Task Force to Reduce Opioid Abuse developed five objectives:

- Increase registration and use of prescription drug monitoring programs (PDMPs)
- Ensure safe, evidence-based prescribing
- Support comprehensive pain care; reduce the stigma of pain
- Reduce the stigma of substance use disorder; increase access to treatment
- Increase access to naloxone to save lives from overdose; support broad Good Samaritan protections

Harris spoke about where we currently are and what still needs improvement. 45 states now have naloxone access laws, but more physicians need to co-prescribe naloxone along with opioids to help curtail overdoses. Many pharmacies stock naloxone, but this needs to increase to allow all communities to have access. Insurance coverage at affordable prices remains a very large concern. We are seeing improvement in the number of physicians trained to deliver in-office buprenorphine, but we need to see payers remove administrative barriers to the medication. One lingering question is the coverage of non-opioids and non-pharmacologic options by payers and the impact on patient financial responsibility. Houry, later in the discussion, asked payers to remove prior authorization for non-opioids and limits on physical therapy visits.
Harris asked Davis to talk about drug disposal. He explained that 2 years ago the DEA put out regulations that allows pharmacies and other entities to be collection sites for controlled substances. Prior to those regulations CVS Health had a grant program for police departments to sponsor drug take-back days. They found there was an interest in ongoing collection at police departments so they started another grant program for drug collection boxes that have been donated to over 650 law enforcement agencies. Through those 650 collection boxes, over 46 metric tons have been collected thus far. Davis described a few other approaches. Walgreens recently announced they would start to put take-back kiosks in their stores. CVS has a mail take-back program and there are in-home disposal kits consumers can purchase. Davis thinks effective drug take-back programs will need a multi-pronged approach.

Harris asked Campbell about her experience with pushback from primary care providers treating SUD patients. She commented that these patients are already in waiting rooms, but physicians may not be aware of substance use disorders. In integrated systems like KP, primary care physicians have resources to treat SUDs. Physicians may struggle in having conversations with SUD patients and may take time to learn appropriate skills to talk with patients about these issues.

The first audience question focused on the robustness of undergraduate and graduate medical education on treating acute and chronic pain, and the use of opioids. Harris said the AMA recommendation is that education on these topics should start at the undergraduate level and should include standardized patient cases on these topics. Houry explained that the CDC is working with over 60 medical schools to update their curricula to include treating pain and prescribing opioids. They hope to work with nursing and pharmacy schools as well. Harris stressed the need to teach cultural competency as well.

Next, Houry was asked whether the CDC is planning to develop guidelines for the treatment of acute pain with opioids. She responded that the CDC would first measure the impact of their chronic pain guideline, and assess implementation and utilization, before moving forward on any other guidelines. Houry mentioned that two other organizations are already developing acute pain guidelines. In response to a follow up question, Houry confirmed that when new evidence arises, the CDC guideline would be updated.

Naloxone was the subject of the next question. Whether and when it should be co-prescribed with opioids was discussed. Consensus was that it should be co-prescribed for high-risk patients. It was also agreed upon that all pharmacies should regularly carry naloxone.

The relationship between prescription opioids and heroin was raised next. Have opioid restrictions driven people to heroin? Heroin is stronger, cheaper, and more accessible. Houry referenced two studies about the relationship between prescription opioids and heroin. A recent review article in NEJM showed that the move to heroin started before actions to limit opioids. A recent Health Affairs article showed that mandatory use of prescription drug monitoring programs and pill mill laws have decreased opioid deaths by 12% with no increase in heroin deaths.

Davis answered two questions about the Pharmacists Teach program. He explained that the program was volunteer based and did not target high impact areas. The program is not positioned to capture longitudinal data on participants and therefore cannot be measured.

The final discussion focused on the underlying causes of the opioid epidemic. Over-prescribing by physicians was a suggested cause. An audience member questioned why there is no certification for prescribers of long-term opioids when it requires certification to prescribe buprenorphine.
SESSION 9: BARRIERS AND SOLUTIONS TO SUCCESSFUL TREATMENT

Panel: Joe V. Selby, MD, MPH; Penney Cowan; Kimberly Johnson, PhD; The Honorable Maureen O’Connor

Joe V. Selby, MD, MPH, Executive Director, Patient Centered Outcomes Research Institute (PCORI), session moderator, spoke about the interest his organization has in funding research around addiction, substance abuse, and behavioral health. These topics currently comprise the largest funding area at PCORI.

Penney Cowan, Founder and Chief Executive Officer, American Chronic Pain Association (ACPA), spoke first about ACPA and patients with chronic pain. ACPA’s mission is to facilitate peer support and education for individuals with chronic pain and their families so that these individuals may live more fully in spite of their pain. They work to raise awareness among the health care community, policy makers, and the public at large about issues of living with chronic pain. Cowan provided some basic background on chronic pain. Chronic pain is the number one cause of disability in U.S. adults and is estimated to affect 100 million people. Pain costs an estimated $560 to $635 billion annually in lost workdays, medical expenses, and other benefit costs. Chronic pain can impact people in a variety of ways—a sense that pain totally controls your life, loss of ability to function, self-doubt, confusion, anger, frustration, loss of income, and loss of family and friends. For many patients fear of the pain is the most controlling factor when dealing with any long-term pain. It often prevents them from making long-term plans.

Cowan spoke about needing to take a balanced approach to pain management that includes more than opioids. Patients with pain cannot be passive and must be active participants in their own healthcare. She used the analogy of a car with four flat tires. A quick fix (i.e. opioids) may repair one tire, but you cannot drive around on 3 flat tires. All four tires must be addressed—meaning a multi-modal approach must be taken to treat pain.

The challenges of providers were covered next. Providers must get patients with pain to engage in their own treatment and be part of the treatment team. Time is also a challenge for many providers. Having enough time and how that time gets reimbursed for are both key challenges for physicians.

Ms. Cowan suggested that the solution is patient-centered care. She used the expression “nothing about us without us.” Too often people are given a prescription for their pain and nothing else. We have to ask, what is the goal of pain management? The goals of pain management should be to improve quality of life, increase function, and reduce sense of suffering. She highlighted that getting rid of all pain is not a goal and people can learn to live with a certain level of pain.

ACPA has developed communication tools that include a quality of life/function scale and a pain log that measures pain along with many other elements of daily living (stress, activity, food and alcohol intake, etc.). They also have pain maps where people can illustrate where and how they feel pain. Since pain is an ongoing event, these tools are freely accessible online and in a mobile app to allow patients to record and monitor symptoms and function. Longitudinal tracking is available and these tools can be used by patients with their physicians to allow them to better understand how a patient feels and functions.

Cowan explained what the responsibilities of a patient with pain are. A patient must accept the pain, get involved, set priorities and personal goals, understand basic rights, recognize emotions, learn to relax, exercise, have a balanced outlook, and engage in outreach. These skills are all addressed in programs and tools set forth by ACPA.

Cowan concluded her remarks by summarizing the solutions to treating chronic pain. Patients must be at the center of treatment and care must be individualized. Multi-modal treatment for pain management should be...
SESSION 9: BARRIERS AND SOLUTIONS TO SUCCESSFUL TREATMENT continued...

utilized and communication between patients and physicians is of utmost importance. Patients need to set realistic expectations and most importantly, their pain must be validated.

Kimberly Johnson, PhD, Director, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration (SAMHSA), focused on discrimination and privacy. Many people can use drugs and alcohol and never develop substance use disorders. In a sense, these people have the ability to “choose” whether or not to use substances. For others with SUDs there is no ability to make a choice. This is hard for many people to understand and results in ingrained discrimination against those with SUDs.

Through the years, this discrimination has caused a separation of treatment for SUDs. SUDs are not treated as a health care condition and have been criminalized. We cycle through how SUDs are treated—criminally, compassionately, and medically. The paradigm for addressing SUDs consists of treatment, research, enforcement, and prevention. Regulations, last updated in 1987, created separate treatment records and protected these records to shield patients from negative consequences and stigmatism. The original intent of the law was to reduce barriers to treatment. Circumstances and how care is delivered have changed dramatically since the regulations were put in place. Regulators like SAMHSA are tasked with updating the regulations and must regulate to the worst-case scenario. There are two worst case scenarios imagined by Johnson:

- Suboptimal care because providers do not talk to each other and information is not shared, and
- Suboptimal care because patients are discriminated against because of disease or previous treatment.

Regulators have the tough role of determining what is more important—protecting rights to privacy or ensuring adequate sharing of information.

The Honorable Maureen O’Connor, Chief Justice, Supreme Court of Ohio, opened by explaining that her remarks were going to focus on how the criminal justice system is addressing addiction, and specifically the role of judges. Criminal justice professionals recognize that we cannot arrest ourselves out of the opioid epidemic and that education, deterrents, and treatment are all needed. She is using her experience in Ohio drug courts to show what is possible. Ohio has 219 specialized dockets with 93 of those being drug courts. The first drug court was established in 1995 in Cincinnati. Courts are located across the state at all judicial levels of operation.

Chief Justice O’Connor explained that entry into a drug court is on arrest. Drug courts are reporting increasing numbers of opioid abusers. Drug courts must meet minimum requirements to operate and are certified by the Ohio Supreme Court. Each court sets criteria for inclusion and exclusion and violent felonies are almost always reasons for exclusion. A judge sends offenders to be evaluated for inclusion in the drug court program. The judge chairs the treatment team, which includes representation from the probation department and the community treatment provider. The treatment team monitors progress and compliance. Treatment required by the drug courts often includes medication, but also counseling and behavioral therapies.

According to Chief Justice O’Connor, drug courts provide monitoring, encouragement, accountability, and ultimately, treatment in lieu of conviction. Offenders that go through the drug court successfully will have better opportunities for employment because their record will be clean. Chief Justice O’Connor covered the best practice standards for drug courts put out by the National Association for Drug Court Professionals. She also discussed research studies that show that drug courts have reduced criminal recidivism and that drug courts provide direct cost benefits to the criminal justice system of $2.21 for each $1 put into drug courts.
SESSION 9: Q&A

Selby framed his first question for Penny Cowan. While her organization is priming and activating patients to be active participants in treating their pain, are physicians ready for patients like this? Cowan responded that it is very dependent on the physician. Some are ready and willing to treat patients with pain, while others are not prepared with knowledge, nor the time needed to handle patients with pain. Johnson interjected that in today’s world all types of patients have access to information online that they can take to physicians. Therefore, all types of physicians are dealing with activated patients and while some physicians like this, there are those that do not.

Selby asked Chief Justice O’Connor to explain more about how the judge works with the treatment team in a drug court. A drug court judge has a staff that may consist of several medical professions that assess and deliver treatment. Some treatment may be delivered within the drug court while other treatment is done at outside treatment centers, but monitored by a member of the drug court team. The judge has ultimate responsibility for the offender and makes decisions regarding discipline for non-compliance.

The first audience question focused on the use of medication-assisted therapy in treating opioid dependence in drug courts. The audience member was concerned by her research finding that only 50% of drug courts across the country allow MAT. Chief Justice O’Connor explained that this is not the case in Ohio. In Ohio, part of drug court certification is agreement to understand and follow evidence-based practices, which include the use of MAT.

The next question was about the use of peer support and impact on outcomes. Chief Justice O’Connor said that in her experiences at specialty docket graduations, she has seen far more peer support in veterans courts than in drug courts. Cowan considers peer support to be critical for those dealing with pain. Pain can be isolating and it often helps people to have peers that can provide long-term positive reinforcement.

An audience member expressed concern with balancing the prevention of addiction and treating pain. While the panel was not able to provide any solutions, they did agree that this is a valid concern. The next question was on updates to 42CFR Part 2. Johnson was not able to share what will be in the new regulation, but she hoped they would be released by the end of 2016. Related to this question, the next topic raised was discrimination. An audience member stated that she thought some of the discrimination we see today is due to the lack of understanding that SUD is brain disorder on the part of patients, physicians, and society. Johnson agreed that lack of knowledge might be partly to blame, but there is also an element of human nature that makes it hard for some people to accept that addiction is not a choice.

The final question posed was to Chief Justice O’Connor on the recent opioid summit she attended. Representatives from nine states took part in the regional summit that addressed how to deal with opioids from the criminal justice system position. State and regional action plans were developed. One key objective is to ensure the best treatment or treatment facilities are available to all, independent of geography. Chief Justice O’Connor did concede that several participating states currently have legislators that have not gotten on board with providing treatment for opioid abuse, rather than just punishment.
CAPSTONE SESSION: IS POLITICAL WILL OVERCOMING THE TRAGEDY OF THE COMMONS?

Panelists: Anand Parekh, MD, MPH, and Peter Shumlin

Anand Parekh, MD, MPH, Chief Medical Advisor, Bipartisan Policy Center, started the final session of the conference by asking Peter Shumlin, Governor, Vermont, to tell the audience about what has been accomplished since Governor Shumlin’s 2014 State of the State address that was dedicated to addressing the heroin and opioid epidemic in Vermont. Governor Shumlin stated that while they have not achieved all their goals, they have made significant progress. He explained that he made addressing the heroin/opioid epidemic of utmost importance because in his small state he gets to personally interact with his constituents and they were telling him personal stories and asking him to address their problems with opioids. When Governor Shumlin looked into the issues, he found several things that needed improving. First, he noticed the criminal justice system was missing opportunities for intervention. Therefore, he reformed Vermont’s criminal justice system to treat abuse as a disease and not as a crime. They offer wrap-around services for treatment so that certain offenders never see a judge or courtroom and have clean records when completing treatment. Vermont addressed long waits for treatment by building out treatment facilities. They also utilize the integrated hub and spoke model. Governor Shumlin made it a priority to have naloxone rescue kits for anyone who wanted one including law enforcement and emergency responders. Vermont enacted prescribing rules that limit the number of pills that can be dispensed, expanded opioid education, and improved their prescription drug-monitoring program to be integrated with neighboring states’ databases.

Parekh asked if these issues transcend politics. Very simply, Governor Shumlin said yes they transcend politics because everyone is affected and addiction does not discriminate. Parekh then asked Governor Shumlin for his advice to help other governors overcome these challenges. He implored other states and governments to step up and recognize the problem. He suggested that money is the driver behind much of what we have seen and legislators need to take on Big Pharma. He also suggested changes were needed at the FDA and that marijuana should be investigated for its pain relieving properties.

An audience question focused on efforts to stop heroin use. Governor Shumlin highlighted the economic model of heroin distribution that is very lucrative for dealers and how not much can be done to stop its flow into the U.S. Many people have told him that they started with prescription opioids before moving to heroin when their supply of opioids was cut off. Heroin is cheaper, more potent, and readily accessible. An audience member expressed concern that marijuana may be on the same path as opioids. Governor Shumlin stated he is supportive of more research on the medicinal uses of cannabis.

An impassioned audience member gave the final statement and question. She spoke on behalf of patients that have chronic pain and pointed out that 27 million Americans have disabling pain. These patients have no other options beyond opioids because research on other options is not robust and reimbursement is not available. She pointed out that chronic pain and substance use disorder are two sides of the same coin and you cannot address one without addressing the other. Governor Shumlin was sympathetic of those in pain, but questioned if the number of Americans in disabling pain is actually that high. Parekh agreed that both chronic pain and substance abuse disorders are public health problems and both need to be addressed in a way that does not harm the other. Parekh finished up the discussion by describing a very recent survey done by the Pew Charitable Trusts of Clinton and Trump voters. The one issue both groups agreed was a large problem facing America was addiction. Parekh thanked both Governor Shumlin and ECRI Institute for their dedication to the topic.