

**House Energy and Commerce Committee Health Subcommittee Hearing: Combatting the Opioid Crisis:
Helping Communities Balance Enforcement and Patient Safety
February 28, 2018**

On February 28th, the House Energy and Commerce Committee Health Subcommittee held the first of three hearings on legislative proposals to address the opioid misuse and overdose epidemic. Health Subcommittee Chairman Burgess (R-TX) noted that the hearing followed a Member's Day last fall where over 50 Members testified about legislative solutions to the opioid misuse and overdose epidemic. Additionally, full Committee Chair Walden (R-OR) said addressing the epidemic is a top legislative priority for the Committee this year.

Witnesses were divided into two panels with Susan Gibbons, Deputy Assistant Attorney with the Diversion Control Division at the Drug Enforcement Administration (DEA), serving on the first panel and the following witnesses on the second:

- Frank Fowler, Chief of Police, Syracuse Police Department
- Dr. Patrick Beardsley, Professor, Department of Pharmacology and Toxicology, Virginia Commonwealth University
- Dr. John Mulder, Director, Trillium Institute
- Dr. Ponni Subbiah, Chief Medical Officer, Indivior
- Dr. David Kan, President, California Society of Addiction Medicine
- Richard Nance, Director, Utah County Department of Drug and Alcohol Prevention and Treatment
- Thomas Cosgrove, Partner, Covington and Burling
- Dr. Andrew Kolodny, Co-Director, Opioid Policy Research, Brandeis University
- Richard Logan, Owner, L&S Pharmacy

The list of bills under consideration at the hearing included:

- H.R. 2063, Opioid Preventing Abuse through Continuing Education (Opioid PACE) Act of 2017
- H.R. 2851, Stop the Importation and Trafficking of Synthetic Analogues (SITSA) Act of 2017
- H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act
- H.R. 5041, Safe Disposal of Unused Medication Act
- H.R. ____, Special Registration for Telemedicine Clarification Act of 2018
- H.R. ____, Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018
- H.R. ____, Improving Access to Remote Behavioral Health Treatment Act of 2018
- H.R. ____, Tableting and Encapsulating Machine Regulation Act of 2018

Full witness testimony and the text of the bills are available [here](#). Subcommittee Chair Burgess' opening statement is available [here](#) and full Committee Ranking Member Pallone's (D-NJ) opening statement is available [here](#).

Some of the key issues covered during the hearing are summarized below. As noted above, the hearing was the first of three hearings the Committee has announced they will hold on legislative solutions for addressing the opioid misuse and overdose epidemic.

While dates have not been announced for the next two hearings, they are expected to cover topics related to public health and Medicare/Medicaid. Additionally, the Oversight Subcommittee is planning to hold a hearing specifically on DEA oversight the week of March 18th.

Prescriber Education

At the hearing Subcommittee Chair Burgess, a physician by training, expressed some reservations about mandatory prescriber education. Burgess stated in his opening remarks, “another bill aims to improve doctors’ understanding of pain management treatment guidelines and best practices, among other things, by mandating 12 hours of continuous medical education on these subjects every three years. This policy contained in H.R. 2063, the Opioid Preventing Abuse through Continuing Education (PACE) Act, authored by Rep. Brad Schneider, concerns me greatly because it seems to suggest that doctors are primarily at fault for the opioid epidemic. As we consider solutions critical to blunting this crisis, we must strike a careful balance before casting blame.”

Following Burgess’ remarks in his opening statement full Committee Ranking Member Pallone responded to Burgess that he believes doctors are part of the problem – not because they were trying to do anything wrong or bad but because they feel like they have to prescribe to alleviate pain as they were taught in medical school.

Additionally, during the question and answer period with the second panel of witnesses Burgess said to Dr. Kolodny, who is an advocate for mandatory prescriber education, that if we treat doctors as adversaries they will be and some will just give up which will lead to untreated pain.

Kolodny responded that doctors are not to blame, but responded to a brilliant marketing campaign. He said the pill mills need to be stopped because they are killing people, but the bigger problem is the well-meaning doctors and dentists who are inadvertently creating a market for the pill mills. Kolodny advocated for requiring education for prescribers who want to prescribe more than 3-days worth of opioids.

Burgess said that he did not remember prescribing more than 12 doses when he was in practice and said it seemed like the world changed since the 1990s. Kolodny responded that it did – that prescribing started to explode as a result of pharmaceutical marketing which is why education should be required now. Burgess responded “that’s where you and I disagree” and said that prescribers could be forced to take a course, but he was not sure it would alter behavior.

Kolodny also noted during the hearing that there is an 8 hour course for physicians who want to prescribe buprenorphine and after that point they are limited in the number of patients they can take. However, there is no federal training requirement or limit on the drugs that cause addiction.

Ms. Gibson from the DEA said that DEA supports prescriber education and they have started to ask doctors for information regarding training on a voluntary basis. Dr. Burgess stated to Ms. Gibson that he received training on the potential use and misuse of opioids and that it was called “medical school.” He asked if the DEA is set up to handle educational activity, which is traditionally regulated by states. She responded that DEA thinks continuing medical education (CME) is paramount and that they work closely with states and do not dictate exactly what the CME looks like.

Ms. Gibson noted that one of DEA’s goals for the year is to have conferences for prescribers because they want to make sure prescribing is done correctly.

Rep. Buchson (R-IN), also a physician by training, said he had been talking to the Association of American Medical Colleges (AAMC) about implementing more training programs on assessing and treating pain. Dr. Kolodny responded that the problem is really with older physicians as younger physicians are more aware and less likely to fall for the “nonsense” that patients will not get addicted.

Telemedicine & Technology

Dr. Kan testified that while no silver bullet exists, changes to facilitate treatment with buprenorphine via telemedicine and increasing the use of the new implantable and injectable buprenorphine formulations are steps Congress should take to expand treatment access.

Mr. Nance testified about the barriers that prevent community health centers from using telemedicine. He said that the Ryan Haight Act allows for a prescription for a controlled substance without a prior face to face meeting only in limited circumstances such as if the patient is treated at a DEA-registered hospital or is being treated by a DEA-registered provider off-site. He said that in order to register with the DEA, the hospital or clinic must be licensed by the state and many community mental health and addiction treatment centers are not “state licensed” according to DEA’s interpretation of the regulations.

Dr. Bucshon asked Ms. Gibson if the DEA had a timeline for drafting special regulations for telemedicine. She said that they will make it a priority and that they need to get out to the 1.7 million registrants that it can be done. She said the special registration has nothing to do with the telemedicine that can be done now.

Rep. Matsui (D-CA) asked about challenges to treatment and Mr. Nance responded that rural and frontier areas have higher rates of opioid misuse and abuse. He said that telehealth is needed so rural patients can get treatment from a doctor in a more urban area. He said if they cannot get treatment, the death rate will be higher than it already is. He described the long distances patients or physicians would have to travel for in-person treatment and said his addiction medicine physician would be forced to be out of the office for two full days.

Matsui said there are concerns about fraudulent prescribing and asked how clinics are authorized. Nance said they are authorized by the Utah Department of Health and Human Services and received 3 – 4 oversight visits from various agencies each year.

Buchson asked Dr. Kan if the existing law requiring an in person evaluation is a problem. Kan responded that ASAM does not have a position on this specific issue, but in his practice he estimates that they lose 20% of patients because they cannot get to them.

Workforce

Rep. Castor (D-FL) noted that Dr. Kan’s testimony cited that 80% of Americans with an opioid use disorder do not receive treatment and asked why there is such a large addiction treatment gap. She said she hears at home that there is no capacity and that even with mandatory coverage of mental health and addiction treatment as required by the Affordable Care Act (ACA), it is just not happening. Dr. Kan responded that telemedicine is one piece of the puzzle and more broadly there needs to be a reduction in stigma. He said telemedicine can help with that because someone does not need to walk into a clinic. He added that Medication Assisted Treatment (MAT) and counseling are

important to keep people alive. He said he does not worry so much about the patients who he treats – he worries about the patient who disappears.

Mr. Nance concurred with Rep. Castor that capacity is a problem and said they can only treat 25% of the people who need treatment in Utah, which is largely because of workforce shortages. Rep. Castor responded that there needs to be more workforce training and Mr. Nance said all providers need more education.

Later in the hearing, Dr. Kan noted that primary care and other physicians need to know where to send a patient they suspect has a substance use disorder. He promoted Vermont's hub and spoke model where a patient is stabilized with a specialist and then cared for by primary care.

MAT

Dr. Kan testified about the evidence base for MAT but also the barriers to MAT, which he said include an insufficient number of physicians who can prescribe buprenorphine and patient difficulties with accessing treatment. Some of the barriers patients face include limited provider hours and a scarcity of providers enrolled in the Medicaid program.

Rep. Castor asked Dr. Kolodny for recommendations for tackling barriers to access. Kolodny responded that there needs to be a massive federal investment of billions of dollars to create a treatment system that does not currently exist. He echoed Dr. Kan's testimony and said the majority of programs that do not offer buprenorphine do not have the providers to prescribe it and many patients have to pay out of pocket for their doctors visit because their health plan will only cover the prescription. He closed by saying that getting treatment needs to be easier than buying a bag of dope.

Rep. Guthrie (R-KY) asked how common it is to pair MAT with cognitive behavioral therapy and if there could be unintentional consequences to changing the Ryan Haight Act that could cut off access to therapy. Dr. Kan responded that they use multi modal therapies and 100% of their patients receive therapy.

Rep. Bucshon asked how the Substance Abuse and Mental Health Services Administration (SAMHSA) is doing with implementing Section 303 of the Comprehensive Addiction and Recovery Act (CARA). Dr. Kan said he could not comment and that would be a question for Dr. McCance Katz, the Assistant Secretary for Mental Health and Substance Use. Rep. Bucshon responded that he was asking because he had asked her and did not like her answer.

Bucshon noted that HHS increased the buprenorphine prescribing limit and asked if that had been implemented. Dr. Kan said yes. Dr. Subbiah from Indivior added that many physicians are still not prescribing up to their capacity and stigma remains a problem. Later in the hearing Mr. Nance noted that a friend with the DEA told him that 501 doctors have a buprenorphine waiver in Utah, but only 125 of them are active and only 70 are listed online.

Bucshon asked Dr. Subbiah if insurers and the Centers for Medicare and Medicaid Services (CMS) are reimbursing for Indivior's new product, the first monthly extended release buprenorphine injectable. She responded that it just got approved and will be on the market in March. They have not received a coverage decision from CMS yet.

Naloxone

Rep. Griffith (R-VA) asked Mr. Logan about naloxone and if allowing pharmacists to prescribe naloxone has increased access. Logan said it is a life-saving drug that should be in the hands of as many people as possible.

Prescription Drug Monitoring Programs (PDMPs)

Dr. Burgess asked Mr. Logan if he understood him correctly that he gets people showing up from out of state at his pharmacy with prescriptions for opioids that he might think are overly generous. Lance said yes, that's the case and when he sees multiple prescriptions for multiple people in one car in excess of 180 OxyContin's he would say that is too much.

Burgess said that he was under the impression that even in the absence of PDMP, that every prescription was going into some kind of a database and that CMS or other payers have the data on who is receiving a high number of prescriptions and the pharmacies filling them. Logan said that an inordinate number of these prescriptions are cash – so there is no claim and, if there is no claim, then it does not go into a PDMP and it is like it never happened.

Burgess countered that someone must be keeping track of the pills and the pharmacy must be keeping a record. Logan said that it is the pharmacist's duty to determine if the prescription is legitimate and legal. He said that an independent pharmacist such as himself may have more latitude in deciding whether or not to fill a prescription versus a pharmacist at a chain pharmacy.

Scheduling/Research Concerns

Rep. Pallone said in his opening remarks that he has serious concerns with HR 2851, the Stop the Importation and Trafficking of Synthetic Analogues (SITSA) Act of 2017. Pallone said he was concerned about the bill and a discussion draft that would propose scheduling tableting and encapsulating machines like controlled substances because both would “give the Attorney General broad and unprecedented new authority, including criminal penalties, as a way to deter traffickers that fuel our opioid crisis.”

Dr. Burgess asked Ms. Gibson if the DEA had concerns regarding research being limited as a result of the scheduling proposed in HR 2851. She responded that the DEA supports research and has never denied a valid research application. She said over 600 researchers are currently approved.

Subcommittee Ranking Member Green (D-TX) also raised concerns with research on a schedule I substance and the burdens associated with that. Ms. Gibson responded that it is a strict process because they have to prevent diversion, but reiterated that they will approve valid applications. She added that she will expedite an analogue application because research is needed.

Green and Rep. Griffith (R-VA) also asked Dr. Beardsley about the hurdles associated with research on Schedule I drugs. Beardsley said the barriers are significant, slow research and cost significant time with submitting the paperwork.