Senate Finance Committee
Hearing on “Examining the Opioid Epidemic: Challenges and Opportunities”
February 23, 2016

Orrin G. Hatch (R-UT)
Committee Chairman

Ron Wyden (D-OR)
Committee Ranking Member

Witnesses

- Mr. Allan Coukell, Senior Director, Health Programs, Pew Charitable Trusts, Washington, DC
- Dr. Nancy K. Young, Director, Children and Family Futures, Lake Forest, CA
- Mr. David Hart, Assistant Attorney-In-Charge, Civil Enforcement, Financial Fraud and Consumer Protection Section, Oregon Department of Justice, Salem, OR

What You Need to Know

- Republicans and Democrats were both supportive of two bills (Comprehensive Addiction and Recovery Act of 2015 (S. 524) and Stopping Medication Abuse and Protecting Seniors Act of 2015 (S. 1913)) that would enhance opioid enforcement and treatment while enabling Medicare to use insurance tools to better coordinate care for those taking opioids, respectively.
- Democrats urged the Finance Committee to put some funding behind opioid enforcement and treatment, while Republicans remained silent on the funding issue.

Background and Overview

Partially in response to a hold on Robert Califf’s nomination to be FDA Commissioner, the FDA announced in early February an action plan to reassess the agency’s approach to opioid medications. The FDA intends to better balance opioid abuse while still providing access to effective pain relief by seeking guidance from outside experts (pain management and drug abuse), convening independent advisory committees, and strengthening requirements for drug manufacturers to generate post-market data on the long-term impact of using opioids.

The FDA is not the only HHS agency that has been active in the opioid fight in the past few months. CMS, as part of its effort to confront the opioid crisis, recently issued guidance that outlines Medicaid pharmacy benefit management strategies to stunt prescription drug abuse, ways to increase the use of naloxone to reverse opioid overdose, and how to prescribe methadone appropriately for pain relief. And the CDC released a revised draft of the agency’s opioid prescribing guidelines in December 2015, urging physicians to be more conservative in their prescribing of opioids to treat pain. However, the National Institutes of Health’s Interagency Pain Research Coordinating Committee (IPRCC), which includes representatives from FDA, Department of Defense, Department of Veterans Affairs and other federal agencies, objected to the CDC’s opioid prescribing guidelines because of lack of evidence to support the
After noting that opioid abuse has become an epidemic and a significant public health problem in both Utah and other states, Committee Chairman Orrin Hatch (R-UT) heaped praise on the Stopping Medication Abuse and Protecting Seniors Act of 2015 (S. 1913) and Comprehensive Addiction and Recovery Act of 2015 (S. 524) (CARA) which passed out of Judiciary Committee recently (Hatch is on this Senate Committee too). With respect to S. 1913 which allows Medicare to impose a patient review and restriction (PRR) or “lock-in” policy on opioid drugs, Hatch noted the bill’s strong bipartisan support and the inclusion of the provision in the Administration’s recent budget proposal.

Hatch next turned to the effect the opioid epidemic is having on families and the foster care program. He said that Senator Wyden and he have been working on bipartisan legislation that would provide states the flexibility to use federal child welfare funds to address issues of substance abuse and other risk factors. With this flexibility, states could then shift funds from putting kids in foster care and keeping families together through better treatment and family courts. He concluded by saying that the opioid epidemic is a complex problem that needs a multi-faceted solution.

Agreeing with Hatch, Ranking Member Ron Wyden (D-OR) emphasized that solving the opioid epidemic will require a fresh approach by combining prevention, treatment and enforcement into one combined effort. (Later all three witnesses agreed that this fresh approach was appropriate). Wyden also gave his support for the CDC guidelines on opioid prescribing and criticized the IRPCC’s potential for conflict of interest. Wyden said that funds need to be spent more wisely and a prerequisite to solving the problem is access to substance abuse treatment. Making the connection between mental

HHS Secretary Burwell has also fielded questions in recent budget hearings on opioids at which she said the Administration’s budget seeks more than $1 billion on opioid-related initiatives that will stress safe prescribing practices, extend medication-assisted treatment (MAT) options and provide naloxone as an antidote for victims of overdose.

Congress has also been active on the opioid epidemic recently. The Senate Judiciary Committee reported the Comprehensive Addiction and Recovery Act of 2015 (S. 524) a few weeks ago, and it is likely to come to the Senate floor in the next week or so. The bill, termed CARA for short and sponsored by Portman and Whitehouse among other Senators, directs HHS to convene a Pain Management Best Practices Inter-Agency Task Force to develop: (1) best practices for pain management and prescribing pain medication, and (2) a strategy for disseminating such best practices. CARA also amends federal criminal laws to have DOJ issue grants for a variety of opioid abuse enforcement activities. HHS is also to award grants to jurisdictions with heroin or other opioid addiction problems to expand treatment activities, including MAT. A similar measure (H.R. 953) has been introduced in the House.

Another bill, Stopping Medication Abuse and Protecting Seniors Act of 2015 (S. 1913) (sponsored by Toomey/Portman/Brown/Kaine), was introduced into the Senate in July 2015 and would allow Medicare Advantage and Part D plans to use patient review and restriction (PRR) programs like they are used in Medicaid and commercial plans. PRRs are a tool to identify individuals at risk of overdose and other harms, and to ensure they receive coordinated care. PRRs specifically identify patients who are receiving these drugs from multiple healthcare providers, assigning them to designated pharmacies and prescribers to obtain their controlled substance prescriptions. Through this mechanism, PRRs allow plan sponsors and providers to improve care coordination and prevent inappropriate access to medications that are susceptible to abuse. A parallel PRR provision was passed by the House as part of the 21st Century Cures effort.

**Hearing Summary**

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health treatment and opioid abuse, Wyden also said we as a nation need to rethink emergency treatment requirements (e.g., the IMD exclusion).

Three topics featured for the remainder of the hearing: (1) current legislation; (2) child welfare issues; and (3) enforcement.

**Current Legislation**

Allan Coukell of the Pew Charitable Trust talked primarily about the Stopping Medication Abuse and Protecting Seniors Act of 2015 (S. 1913) and patient review and restriction (PRR) or “lock-in”. After explaining that PRRs specifically identify patients who are receiving drugs from multiple healthcare providers, and PRRs lock-in or assign patients to designated pharmacies and prescribers to obtain their controlled substance prescriptions. Through this mechanism, PRRs allow plan sponsors and providers to improve care coordination and prevent inappropriate access to medications that are susceptible to abuse.

Later in the hearing, Senator Pat Toomey (R-PA) praised S. 1913 for its potential to stop overprescribing and decreasing the diversion of opioids. Toomey said that the National Governor’s Association (NGA) supported the Medicare PRR/lock-in bill, and its principles were contained in the 21st Century Cures bill that passed the House. He echoed Coukell’s sentiment that the bill was supported by many, and Coukell confirmed for Toomey that PRR has lots of consumer protections such as appeals and situation specific sensitivities such that PRR is not onerous on patients.

After pointing out that CARA met Wyden’s fresh approach of prevention, treatment, and enforcement, Senator Rob Portman (R-OH) also played cheerleader for S. 1913. He said it was a very important bill and would get patients into better treatment protocols. The other Senator from Ohio, Sherrod Brown (D-OH), agreed that it made no sense that PRR/lock-in programs were not used by Medicare.

Senator Tom Carper (D-DE) agreed that lock-in would work for Medicare Advantage, but questioned how it might be operationalized for Part D in a fee-for-service world. Coukell replied that even in Part D, the plans would have medication histories for patients and could track prescription habits. Senator Tim Scott (R-SC) seemed to agree with Carper and was skeptical on the operational issues. Scott asked whether implementation of a lock-in for Medicare would have the same flexibility for Medicare Advantage and Part D as the program did for South Carolina Medicaid. Coukell assured the Senator that S. 1913 required some federal guidance on lock-in for Medicare but allowed states to customize operationally.

Scott picked up on the theme of the correlation between mental health issues and opioid abuse. He said about one-third of opioid abusers had mental illness. Thus, Scott said that the legislation discussed today was not a full solution, but does help stem the epidemic.

**Child Welfare Issues**

Witness Nancy Young gave perspective of the opioid epidemic from a child welfare and human services view. She said that although the data is not as good as it could be, the data is consistent with showing a large uptick in opioid abuse cases since 2013, and particularly in the case of newborns. Young said policy makers could learn from the methamphetamine epidemic’s seven best practices/policy strategies for families:

1. Identification: A system of identifying families in need of substance use disorder treatment
2. Timely Access: Timely access to substance use disorder assessment and treatment services
3. Recovery Support Services: Increased management of recovery services and monitoring compliance with treatment
4. Comprehensive Family Services: Two-generation family-centered services that improve parent-child relationships
5. Increased Judicial Oversight: More frequent contact with parents with a family focus to interventions
6. Cross-System Response: Systematic response for participants based on contingency contracting methods
7. Collaborative Structures: Collaborative non-adversarial approach grounded in efficient communication across service systems and the courts

Third, Young said implementation of these seven strategies leads to the 5R outcomes: recovery, remain at home, reunification, reduced reoccurrence, and reduced re-entry of children into out-of-home care. She said to facilitate these outcomes however, better data is needed from the states. And the high demand for substance use disorder treatment as a result of Medicaid parity laws means that pilots and demonstrations are not enough; funding and systemic state reforms are needed.

Senator Debbie Stabenow (D-MI) agreed with Young that we must go beyond pilots and demonstrations. Stabenow points to legislation she wrote with Senator Blunt (R-MO) on behavioral health care treatment facility certification similar to FQHC certification. She said this law was currently operational in 8 states, but needed further funding to apply to all 24 states who wished to participate. Her point in bringing up this law was that community level treatment was needed to address the opioid epidemic.

**Enforcement**

Witness David Hart, a member of the Oregon Attorney’s General Office, focused his testimony on the effects of opioid marketing and promotion. He explained how in the OxyContin litigation, the pharmaceutical company violated unfair trade practices law in part by its aggressive promotion of the drug. If Mr. Hart had known then what an adverse impact this promotion would have on the public (leading to the opioid epidemic), he would have sought more remedial action.

Senator Dan Coats (R-IN) asked where the pharmaceutical industry was now in the process of providing better, non-addictive pain medication. Where is the FDA on this, Coats asked. Coukell responded that opioids will continue to very important to pain care for the foreseeable future. Hart countered that other alternative treatments besides taking a pill were available, particularly for chronic pain like back pain (e.g., physical therapy). Hart also said in response to Senator Robert Menendez (D-NJ) that mid-level providers should have more prescribing rights so that they could prescribe more than just pills.

In response to a question from Wyden, Hart said that policy needs to address prescribing habits starting with pain education classes in medical school and CME classes not funded by the pharmaceutical industry. This is why clinical guidelines are so important, Hart said. Guidelines are voluntary, but give information to physicians on appropriate treatment.

Senator John Thune (R-SD) asked Hart about the availability of naloxone, and Hart said that an intranasal version was now available that should make it easier for first responders. Hart said this nasal version of naloxone should be made available in schools as well.

**Next Steps**

A last theme in today’s hearing – increasing funding for prevention, treatment and enforcement -- was espoused by Democrats only. As Senator Charles Schumer (D-NY) put it, laws like CARA and S. 1913 are “necessary but not sufficient.” More funding is needed to pay for additional substance abuse
counselors, courts, and other facets of solving this crisis, Schumer said. Sherrod Brown (D-OH) and Robert Menendez (D-NJ) agreed with Schumer.