

# Congress and Federal Agencies Address Opioid Abuse Epidemic, But Will New Initiatives Be Successful?

Stephen Barlas

Representative Buddy Carter (R-Georgia), a pharmacist, was a lead GOP cheerleader for a package of 18 opioid abuse prevention, treatment, and law enforcement bills that came up for a vote on the floor of the U.S. House of Representatives on May 13, 2016. The bills created new programs, studies, task forces, and other initiatives at multiple federal agencies. The 18 bills were eventually tacked on as an omnibus amendment to an opioid bill—the Comprehensive Addiction and Recovery Act of 2016 (S. 524)—that passed the Senate in March 2016.<sup>1</sup> In July, a House–Senate conference committee merged the two bills, which were not identical, and will send the final bill to President Obama for his expected signature.

The Senate and House each passed their initial bills (S. 524 and S. 524+18) by overwhelming bipartisan majorities. That is almost always an indication that a bill doesn't do very much and omits key provisions that were deemed important by various parties. That was the case with these two bills, with both Republicans and Democrats in the House complaining that amendments to the 18 bills were not allowed to be offered on the House floor or in committee. Not only did the two bills omit key provisions, they both included no funding for new grant programs that were among the multiple, diverse provisions. During the House–Senate conference committee meeting in July, Democrats were unable to convince Republicans to include funding for some of the new grant programs in the final bill. Representative Frank Pallone (D-New Jersey), the top Democrat on the House Energy and Commerce Committee, conceded, "This legislation takes only a small step at a time when the American people need us to run."

Carter stressed in his speech on the floor that he hoped the pharmaceutical industry would do more to develop medications that would fill the treatment gap between ibuprofen and acetaminophen on one hand and opioids on the other. "There are very few alternatives in between there in that gap," he said. "Once you get past tramadol and a couple of others, there is nothing else for us to use, there is nothing else for us to prescribe. I have confidence in the pharmaceutical manufacturers, and I call on them to fill in that gap, to fill in that void." But there were no incentives in either the House or Senate bill for drug companies.

On the House floor, Representative Jared Polis (D-Colorado) complained that among the bipartisan amendments blocked from coming up for a vote was one that would have allowed the Department of Health and Human Services to award grants to recovery community organizations and another that would

authorize grants for the creation of comprehensive systems to provide support for prescribers with regard to patient pain and substance abuse.

While Carter in the House worried that the pharmaceutical industry isn't doing enough, U.S. Senator Ron Wyden (D-Oregon) complained it was doing too much. When the Senate bill came up on the floor for a vote, he offered an amendment to another amendment offered by U.S. Senator Pat Toomey (R-Pennsylvania). Toomey's amendment authorized the

Medicare Part D program to create a lock-in program forcing at-risk beneficiaries to use a single prescriber and pharmacy for frequently abused drugs. Medicaid and private insurance companies already use such lock-in programs. The Toomey amendment had wide bipartisan support and was backed by the American Pharmacists Association (APhA). Wyden wanted to add an amendment to the Toomey amendment that would have doubled the penalties for opioid manufacturers that provide kickbacks to prescribers in order to boost their profits by promoting the unapproved

use of opioids. Wyden lost that vote.



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## Difficulties Making Inroads

One might have thought that harder-hitting proposals needed to be contemplated given the country's recent record on preventing (or not) opioid drug abuse. That record is unimpressive. The national concern about rapidly rising deaths from opioid abuse has climbed multiple rungs on the legislative and regulatory priority ladder over the past decade, at least based on the rhetoric expended. President Obama has issued a National Drug Control Strategy every year since 2010 that focuses heavily, but not exclusively, on reducing deaths from opioid addiction. But solutions do not appear to have matched rhetoric, as partisan disputes, both on Capitol Hill between the political parties and beyond Capitol Hill between various interest groups, have blunted a more significant response at the federal level.

That doesn't mean the Obama administration and Congress have done nothing. But what they have done doesn't appear to be close to what they could or should be doing, according to various statistics. U.S. Senator Thomas Carper (D-Delaware) quoted one such set of statistics at hearings in the Senate Homeland Security Committee in May 2016: "According to the Centers for Disease Control, there has been a dramatic increase in opioid-related overdoses in recent years with the number of incidents actually quadrupling since 2000," he reported. "And opioids, primarily prescription pain relievers and heroin, are the main cause of overdose deaths. All told, there were just over 47,000 drug overdose deaths in 2014 in our country, up from just under 44,000 in 2013, a more than 6% increase in just one year."

Carper's reference was backed up by testimony that day

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from Diana Maurer, Director of Homeland Security and Justice in the U.S. Government Accountability Office (GAO). She presented the GAO's latest report entitled, "Office of National Drug Control Policy [ONDCP]: Progress Toward Some National Drug Control Strategy Goals, but None Have Been Fully Achieved."<sup>2</sup> Maurer discussed seven goals related to reducing illicit drug use and its consequences set in 2010 by the ONDCP. The aim was to reach those goals by 2015. "As of May 2016, our analysis indicates that ONDCP and federal agencies have made moderate progress toward achieving one goal, limited progress on three goals, and no progress on the other three goals," she stated. "Overall, none of the goals in the strategy have been fully achieved." That is despite the fact that federal spending for treatment and prevention has steadily increased from fiscal year (FY) 2007 through FY 2016; spending in these two programs went from \$8.4 billion in FY 2007 to \$14.7 billion allocated in FY 2016. Federal spending on drug control at law enforcement agencies has increased from \$21.7 billion in FY 2007 to approximately \$30.6 billion in allocated funding in FY 2016. But spending on supply reduction programs, such as domestic law enforcement, interdiction, and international programs, remained relatively constant at \$13.3 billion in FY 2007 and \$15.8 billion allocated in FY 2016.

### Funding

Neither the House nor the Senate bill provides funding sources for any of the new grant programs they authorize. Maybe that is because legislators are aware that spending on opioid abuse prevention and treatment programs has been rapidly escalating, per the GAO figures, without a concomitant reduction in opioid overdose deaths. So maybe more money isn't the answer. At the same time, one could argue that the 18 House bills and many of the Senate provisions that were merged don't really require much funding because they don't authorize many new programs, and the couple of significant initiatives don't require funding. For example, the Opioid Review Modernization Act of 2016 (H.R. 4976) requires the Food and Drug Administration (FDA) to work closely with expert advisory committees before making critical product approval and labeling decisions.<sup>3</sup> That is already the case, so this piece of legislation is a head scratcher. H.R. 4641 establishes an inter-agency task force to review, modify, and update best practices for pain management and prescribing pain medication.<sup>4</sup> The task force must be convened by December 14, 2018, not exactly an endorsement of urgency. The Examining Opioid Treatment Infrastructure Act of 2016 (H.R. 4982) requires the Comptroller General of the United States to issue a report to Congress on substance abuse treatment availability and infrastructure needs throughout the United States.<sup>5</sup> The James Thomas Decker Act of 2016 (H.R. 4969) amends the Public Health Service Act to direct the Centers for Disease Control and Prevention (CDC) to study what information and resources are available to youth athletes.<sup>6</sup> The National All Schedules Prescription Electronic Reporting Reauthorization Act of 2015 (H.R. 1725) reauthorizes funding for grants to states and territories for prescription drug monitoring programs (PDMPs), which are plagued by shortcomings.<sup>7</sup> The bill makes no significant changes in either the law or in the funding available. It authorizes a paltry \$10 million a year.

A couple of bills at least attempt to get something solid

done. The Co-Prescribing to Reduce Overdoses Act of 2015 (H.R. 3680) would establish a grant program for co-prescribing opioid reversal drugs for patients who are at a high risk of overdose.<sup>8</sup> Lali's Law (H.R. 4586) amends the Public Health Service Act to authorize grants to states for developing standing orders for naloxone prescriptions and educating health care professionals regarding the dispensing of opioid overdose reversal medication without person-specific prescriptions.<sup>9</sup>

### Budget Constraints

In passing their initial bills without funding, the House and Senate laid the need for any new funding at the door of their appropriations committees. President Obama had already staked out his ground in his 2017 budget request that included \$1.1 billion in new funding for opioid abuse prevention programs. The overwhelming portion of Obama's \$1.1 billion increase would cover two years and fund a new program at the Substance Abuse and Mental Health Services Administration (SAMHSA) at \$460 million annually. That money would go for state-targeted response cooperative agreements to help expand access to treatment for opioid use disorders. An additional \$15 million over two years would go for a new effort to evaluate the effectiveness of medication-assisted treatment (MAT) programs.

The Senate so far has turned up its nose at the Obama request. According to a press release from the Senate Appropriations Committee on June 9, 2016, spending on current opioid programs in fiscal 2016 was \$135 million spread over the CDC, SAMHSA, and the Health Resources and Services Administration.<sup>10</sup> On June 9, the Appropriations Committee passed its fiscal 2017 bill that increased that amount to \$261 million. That was still short of the \$1.1 billion requested by Obama and backed by many pharmacy groups, including the American Society of Health-System Pharmacists (ASHP), which noted the bills passed by the House and Senate fell short of providing the funding requested by the White House. "We believe that additional funding, above and beyond the additional \$126 million that was approved by the House Appropriations Committee, is necessary to meet the goals of the legislation," said Christopher Topoleski, Director of Federal Legislative Affairs for ASHP.

### Current Federal Programs Also Have Shortcomings

Some may think that rather than more funding for new programs, the SAMHSA needs to improve its current programs, which wouldn't necessarily take new funds. One of its more important programs with regard to opioid abuse prevention is the agency's regulation of opioid treatment programs (OTPs) and private practice physicians who use MAT, in which a patient receives buprenorphine, a Schedule III controlled substance, in combination with behavioral health services to provide an individualized, whole-patient approach to the treatment of substance use disorder, including opioid use disorder. Office-based physicians must apply for a waiver from the SAMHSA in order to use buprenorphine, and relatively few do that now, which is considered a big limitation on opioid abuse treatment.

There are a number of reasons for that, including a limit on how many patients a physician can treat in a given year. Expanding the number of physicians who would apply for a

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buprenorphine waiver is the focus of one of the House bills called the Opioid Use Disorder Treatment Expansion and Modernization Act (H.R. 4981).<sup>11</sup> It would allow physicians in office settings to treat more patients using MAT programs. The bill bumps up the ceiling to 250 patients a year, with additional certifications, and authorizes nurse practitioners and physician assistants to become qualifying practitioners. Physicians cleared to treat 250 patients would have to implement a diversion control plan as well as obtain a written agreement from each patient that they will receive periodic assessments and understand that receiving regular counseling services is critical to recovery.

States such as Massachusetts and Vermont allow nurses to provide screening, intake, education, and other ancillary services for patients treated with buprenorphine. This enables practitioners to treat additional patients and to provide the requisite psychosocial services. However, in order to afford a nurse or other clinician dedicated to providing evidence-based treatment for an opioid use disorder, practitioners need a minimum volume of patients. Allowing practitioners to treat up to 250 patients at a time would be a step toward supporting practitioners that seek to hire nurses and other clinical staff to reduce practitioners' time requirements and to provide the ancillary services of high-quality MAT with buprenorphine.

The SAMHSA finally increased the number of patients office-based physicians can see to 275 in a final rule it published on July 6, 2016. But that final rule falls a bit short in three respects, according to interested parties. The American Society of Addiction Medicine wanted the patient limit increased to 500, so neither the SAMHSA decision nor the congressional legislation meets its recommendation. Pharmacy groups are unhappy with both the bill and the SAMHSA rule because neither gives pharmacists the standing as allied health providers to get the waivers the House bill proposes for nurse practitioners and physician assistants. The SAMHSA says it does not have the authority on its own to grant waivers to any nonphysician providers.

The APhA, the National Community Pharmacists Association, and the Academy of Managed Care Pharmacy submitted joint comments to the SAMHSA before it finalized the rule. They stated that 48 states and the District of Columbia allow pharmacists to enter into collaborative practice agreements with physicians and other prescribers to provide advanced care to patients.

"We are aware of at least five states that allow pharmacists to prescribe Schedule III, IV, and V controlled substances," they said. "In addition, pharmacists are already partnering with physicians to provide MAT. When such relationships form, pharmacists have taken the lead in developing treatment plans, communicating with patients, improving adherence, monitoring patients, identifying treatment options, and performing tasks to alleviate the physicians' burden. Thus, pharmacists have both the knowledge and experience to provide MAT but treatment is limited because of regulatory barriers."

Even though the SAMHSA lifted the limit on the number of patients who can be offered MAT by office-based physicians, that won't necessarily put the services offered by office-based physicians on a par with those offered by OTPs. Kathryn E. Spates, Director of Federal Relations for the Joint Commission,

explained that practitioners who treat patients with the same diagnosis in an office-based setting are not required to offer the same support services as those enrolled in OTPs; they are only required to refer patients to such services should they be deemed necessary. The Joint Commission maintains that it is reasonable to create a continuum of care whereby all patients with the same diagnosis receive equally high-quality, evidence-based care, treatment, and services, regardless of whether they are treated in an OTP or office-based setting. "The current two-tiered system results in patients with the same diagnosis receiving markedly different quality and intensity of services," Spates argued.

The SAMHSA also provides grants to the states for opioid abuse prevention and treatment, as does the CDC, which does not have a regulatory portfolio as SAMHSA does. The CDC does provide grants to states for expanding their PDMPs. Twenty-nine states receive up to \$1 million from the CDC's Prevention for States program. However, the state PDMPs suffer from myriad problems limiting their effectiveness. Lynn R. Webster, MD, a former president of the American Academy of Pain Medicine, stated, "Although PDMPs have significant potential to improve public health and patient care outcomes, they remain a substantially underutilized resource. Reasons for this include differences in the data individual state PDMPs collect, whether and how data quality is ensured, the kinds of data analyses and reports that are produced, and to which users and under what conditions data are made available."

### Whither the FDA?

But the CDC and the SAMHSA may have a smaller impact on the opioid abuse problem than the FDA, which approves new pain medicines, including those with abuse-deterrent characteristics. One of the first things Robert Califf, MD, did as FDA Commissioner was publish a new opioid abuse action plan in February 2016 that had a number of features, none of them earth-shattering or likely to open the floodgates to new submissions of applications for novel opioid replacements.<sup>12</sup> One of the planks in Dr. Califf's plan is: "support better pain management options, including alternative treatments." How the FDA plans to do that, Dr. Califf doesn't say.

Of course the FDA can only do so much if manufacturers aren't submitting applications for new nonopioid pain medications or opioid products with abuse-deterrent properties. Purdue Pharma's abuse-deterrent version of Oxycontin (oxycodone hydrochloride) is the category heavyweight by far. Companies large and small have tried to bite off a share of the market, with less than significant results. However, Oxycontin continues to be abused, as shown in a study by Washington University School of Medicine in St. Louis finding that close to one-third of opiate addicts were still abusing the new abuse-deterrent Oxycontin right before entering rehab.<sup>13</sup>

Drug companies apparently have not heeded Representative Carter's plea to come up with new pain products. Companies are working on new abuse-deterrent formulations, but none appears foolproof. In June, two joint FDA advisory committees recommended approval of Pfizer's Troxyca ER, an oxycodone-naltrexone extended-release capsule with abuse-deterrent properties. The panel also recommended that the product, if approved, be labeled as offering abuse deterrence for nasal and intravenous

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ingestion, but recommended against such labeling for oral abuse deterrence.

Xtampza ER (oxycodone, Collegium Pharmaceutical, Inc.) encases its oxycodone in wax and fatty acid or “microspheres,” using what the company calls its “DETERx” technology platform. “It can still be abused if a user extracts oxy from microspheres, which can take a considerable time,” said Doug Carlson, a spokesman for the company. “The time and effort is the deterrent.”

Maybe the best thing Congress could do would be to authorize and fund a drug industry–National Institutes of Health project where the best scientists and technologists in the country pooled their intelligence and set a short timetable for coming up with one new nonopioid pain medication and one fool-proof abuse-deterrent formulation. That would be better than passing a bunch of mediocre bills that have no hope of slowing the opioid abuse epidemic.

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