



February 12, 2018

Chairman Orrin Hatch
Senate Finance Committee
US Senate
Washington, DC 20510

Ranking Member Ron Wyden
Senate Finance Committee
US Senate
Washington, DC 20510

RE: Opioid Epidemic Take-Back Recommendations

Dear Senator Hatch and Senator Wyden:

I am writing on behalf of Stericycle in response to your February 5 request for feedback pertaining to issues within your Committee's jurisdiction (Medicare and Medicaid) and policy recommendations to effectively respond to the opioid epidemic. We would assert that preventing diversion is critical to addressing this national emergency. We offer proven strategies in this area such as take-back and mail-back programs. Such programs reduce potential access to medications by other individuals, and prevent potential opioid addiction and abuse, the costs of which are significantly borne by Medicare and Medicaid. However, recent studies (including one from the GAO) indicate that take-back programs, due to regulatory compliance issues (DEA, DOT and State issues), liability, and costs, are not fully utilized and thus are not fully accessible to the public. In fact GAO found that only 3% of the eligible pharmacies in the US currently host drug take-back collection kiosks. Expanding take-back programs through addressing the concerns raised in the GAO report will help prevent opioid abuse and will reduce Medicare and Medicaid expenses.

Stericycle (www.stericycle.com), is the nation's leader in health care waste management, and has nearly thirty years of experience in pharmaceutical waste solutions, including safe and compliant disposal of controlled substances. We are a global company with over 15,000 US employees operating in all 50 states. Our mission is *"to provide solutions that protect people, promote health and safeguard the environment."* For instance, during the 2014 Ebola crisis, we worked closely with Federal agencies and provided critical expertise for transporting and disposing of wastes generated from infected patients. As a national leader in pharmaceutical waste disposal take-back, we provide compliant kiosks for take-back programs as well as mail back envelope solutions for the disposal of controlled substances wastes generated by the public. Our programs comply with regulations at the state and Federal levels related to transportation and appropriate disposal of these controlled substances.

The "Secure and Responsible Drug Disposal Act of 2010" became law (PL 111-273) in October 2010. Its preamble noted: "...drug disposal programs (often called "take-back" programs)... facilitate the collection and destruction of unused, unwanted, or expired medications. These programs help get outdated or unused medications off household shelves and out of the reach of children and teenagers. Individuals seeking to reduce the amount of unwanted controlled substances in their household

consequently have few disposal options beyond discarding or flushing the substances, which may not be appropriate means of disposing of the substances. "

The bipartisan sponsors of the legislation were Senators Cornyn (R-Texas) and Klobuchar (D-Minn). On the enactment of the legislation, Senator Klobuchar said: "Prescription drug abuse is a serious issue, especially among young people, and expanding take-back programs is key to combating this abuse. the Secure and Responsible Drug Disposal Act will enable people to safely dispose of their unused drugs and reduce the chance that they will fall into the wrong hands." Senator Cornyn added: "The effects of this law will be significant and substantial; reducing the likelihood that unused medication will be diverted by drug abusers..."

The law required that the DEA implement regulations for the disposal of pharmaceutical controlled substances by ultimate users in accordance with the Disposal Act. Four years after it became a law, and in September 2014, those regulations were finalized. The DEA noted: "The goal...[of this regulation] is to set parameters for controlled substance diversion prevention that will encourage public and private entities to develop a variety of methods for collecting and destroying pharmaceutical controlled substances in a secure, convenient, and responsible manner. ...As a result of these regulations, the DEA hopes that the supply of unused pharmaceutical controlled substances in the home will decrease, thereby reducing the risk of diversion or harm."

Stericycle provided public comments to the regulations (see attached). In essence, we commented that the DEA, in their laudable efforts, nevertheless failed to achieve a regulatory balance that would provide incentives for pharmacies or other authorized entities to participate. In other words, as written the regulations presented pharmacies (who wished to participate) a host of regulatory compliance challenges, potential liabilities, and significant costs. Stericycle expressed concerns that the take-back programs, which we strongly supported, would not reach their full potential under the regulations as written. This continues to be our position.

Since 2014, the take-back programs as envisioned by the DEA have certainly had some success, but the challenges of which Stericycle warned have clearly emerged, resulting in extremely low participation rates by pharmacies throughout the country, as recently validated by the GAO. As an example of significant and continuing concerns regarding compliance, attached is a letter to the DEA written in October 2017 by several state and local governmental entities. They requested greater clarity concerning the Disposal Act's regulations and guidance documents. They emphasized that such clarity was "critical to the provision of safe and secure medication disposal for our residents."

While pharmacies may have felt sidelined, not all is lost. October 28, 2017, was the 14th and most recent DEA Drug Take-back Day. According to the DEA's press release: *"Americans nationwide did their part to reduce the opioid crisis by bringing the DEA and its more than 4,200 local and tribal law enforcement partners a record-setting 912,305 pounds—456 tons—of potentially dangerous expired, unused, and unwanted prescription drugs for disposal at more than 5,300 collection sites. That is almost six tons more than was collected at last spring's event. This brings the total amount of prescription drugs collected by DEA since the fall of 2010 to 9,015,668 pounds, or 4,508 tons."* Now in its eighth year, National Prescription Drug Take-back Day events continue to remove ever-higher amounts of opioids and other medicines from the nation's homes, where they could be stolen and abused by family members and visitors, including children and teens. "More people start down the path of addiction through the misuse of opioid prescription drugs than any other substance. The abuse of these prescription drugs has fueled the nation's opioid epidemic, which has led to the highest rate of overdose deaths this country has ever seen," said Acting Administrator Robert W. Patterson." This is a crisis that

must be addressed from multiple angles. Educating the public and removing these medications from households across the United States prevents misuse where it often starts”

However, even with these successes, so much more can and should be done. In March 2016, Senator Grassley (R-Iowa), and Senator Ernst (R-Iowa) wrote the Comptroller General requesting a GAO report. Their letter said in part:

“We have heard from constituents in Iowa that a convenient place to return unwanted and unused controlled substances is to the same place they received them – their local pharmacy. However, some stakeholders have suggested that the regulations currently in place make it difficult and costly for retail pharmacies to participate in the program. Indeed, some of these same concerns were also raised in public comments provided to the DEA during the rulemaking process. We appreciate the challenge of creating new avenues to return unwanted and unused controlled substances, while at the same time guarding against the diversion of these drugs. However, we also want to ensure that compliance and participation costs do not act as a deterrent to pharmacies that want to voluntarily provide this important service to their communities. As such, we respectfully request that GAO review the DEA’s regulations, stakeholder concerns with them, and participation rates in the program, and submit a report to Congress with recommendations on how Congress and the DEA can address existing regulatory barriers in order to expand the voluntary participation of retail pharmacies in this important program as much as possible.”

In September 2017, Senators Grassley and Ernst also urged the President’s Commission on Combatting Opioid Abuse to include expanded take-back programs in their final report’s recommendations. On November 1, 2017, the final report was issued. Here is an excerpt from that report, and Recommendation 17: “The National Prescription Drug Take-back Day, organized by the DEA with state and local partners, provides communities a safe and convenient way to dispose of their unneeded prescription drugs, while educating the public about the dangers for the public of abuse and misuse. The Commission recommends community-based stakeholders utilize Take-back Days to inform the public about drug screening and treatment services.”

On November 13, 2017 the GAO issued its report: <https://www.gao.gov/assets/690/687719.pdf> . GAO interviewed the DEA and stakeholders and found that “about 3 percent of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so.” GAO noted that stakeholders cited costs (page 13) and concerns about how to comply with the regulations (page 14) as the main factors which depressed participation. Said differently, stakeholders were concerned about being out of compliance, especially when the take-back Federal regulations seemed to conflict with other Federal and state regulations.

Recommendations

Stericycle recognizes that the opioid crisis cannot be addressed with any one “silver bullet”, and we do not presume to have expertise in the entire area which is the focus of this Committee. However, we certainly do have expertise in take-back programs, and believe they should be an important component in combatting this crisis. Effective and expanded take-back programs will prevent diversion and opioid abuse and will reduce Medicare and Medicaid expenditures.

Some of the matters you might consider as policy changes will likely be costly and can only be implemented over the long term. However, the expansion of take-back programs can be implemented with immediate results. The structure is already in place, but more can be done to increase the availability and effectiveness of these important programs.

As a preliminary step, highlighting the “participation” problem as found in the GAO report will bring greater public awareness to this issue. Frankly there has been little media attention or Congressional attention to the findings of that report thus far. We hope that your Committee will help to bring greater public awareness to the GAO Report, possibly holding a hearing with the GAO, the DEA, and stakeholders as witnesses.

The DEA also should be directed by the Administration/Congress to revise its regulations to encourage more participation by pharmacies and other eligible entities in take-back programs. We would invite your Committee and the DEA to review/reconsider our full comments to the original regulations. We believe addressing the concerns we raised would help to enhance participation in the programs as well as the lessons learned over the last three years in implementing take-back and mail back programs.

With increased Congressional funding to combat opioid abuse along with the CARA legislation which listed take-back programs as eligible for grants—we would submit that Congress should examine ways to direct greater technical assistance, education and funding to eligible entities (to defray costs of kiosks, etc.) which might wish to participate in expanded take-back programs.

We commend the Committee for considering these issues as the opioid epidemic continues. We hope that the information provided here and the comments of others will lead to further discussion on providing the necessary tools in combatting this issue. We appreciate the opportunity to comment. Should you have any further questions or comments please feel free to contact me at shoboy@stericycle.com or 847-943-6685.

Sincerely,



Selin Hoboy
Vice President - Legislative and Regulatory Affairs
Stericycle, Inc.