

United States Senate

WASHINGTON, DC 20510

March 31, 2016

The Honorable Gene Dodaro
Comptroller General of the United States
Government Accountability Office
441 G Street N.W.
Washington, D.C. 20548

Dear Mr. Dodaro:

We are writing to request that the Government Accountability Office (GAO) provide Congress with a report on the Drug Enforcement Administration's (DEA) regulations related to the secure disposal of controlled substances by registrants and ultimate users, and potential barriers to participation by retail pharmacies.

Prior to the enactment of the Secure and Responsible Drug Disposal Act of 2010 ("Disposal Act"), the Controlled Substances Act only permitted the ultimate users of controlled substances themselves to destroy any unused substances, and they were unable to return unused substances to a pharmacy, hospital, or other health care provider. In 2010, Congress passed and the President signed into law the Disposal Act¹ to amend the Controlled Substances Act to authorize ultimate users to deliver their pharmaceutical controlled substances to another person for the purpose of disposal in accordance with regulations promulgated by the Attorney General. Pursuant to the Disposal Act, the DEA promulgated rules to implement the Act and outline how certain entities may voluntarily collect unused controlled substances at a DEA-registered location.

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.

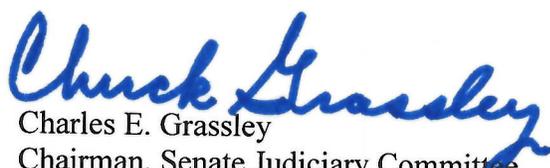
We appreciate the challenge of creating new avenues to return unwanted and unused controlled substances, while at the same time guarding against the diversion of these drugs. However, we also want to ensure that compliance and participation costs do not act as a deterrent to pharmacies that want to voluntarily 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.

¹ Public Law No. 111-273

Thank you for your time and attention to this matter. If you have any questions, please reach out to Danielle Janowski or Taryn Frideres of Senator Ernst's staff at (202) 224-3254 or David Bleich of Senator Grassley's staff at (202) 228-0927.

Sincerely,


Charles E. Grassley
Chairman, Senate Judiciary Committee


Joni K. Ernst
United States Senator