From: Funk, Andrew [IBPE]
To: Jorgenson, Debbie [IBPE]
Subject: FW: Ernst, Grassley Call for Review of Regulatory Barriers Iowa Pharmacies Face in Federal Drug Take Back Program
Date: Monday, April 04, 2016 12:33:13 PM

Debbie,

Can you include this as an FYI for the Board in May?

Thanks,

Andrew Funk, Pharm.D.
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Iowa Board of Pharmacy
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From: Hoelscher, Doug [IGOV]
Sent: Thursday, March 31, 2016 4:02 PM
To: Funk, Andrew [IBPE]; Clabaugh, Gerd [IDPH]; Thompson, Deborah [IDPH]; Pottebaum, Nic [IGOV]
Cc: Groen, Stephanie [IGOV]
Subject: Fwd: Ernst, Grassley Call for Review of Regulatory Barriers Iowa Pharmacies Face in Federal Drug Take Back Program

FYI

Sent from my iPhone

Begin forwarded message:

> **From:** "Press, Ernst (Ernst)" <Ernst_Press@ernst.senate.gov>
> **Date:** March 31, 2016 at 3:01:24 PM CDT
> **Subject: Ernst, Grassley Call for Review of Regulatory Barriers Iowa Pharmacies Face in Federal Drug Take Back Program**

JONI ERNST
UNITED STATES SENATOR
for
IOWA

FOR IMMEDIATE RELEASE
March 31, 2016

Contact: Brook Hougesen or Angela Zirkelbach
Press@Ernst.Senate.Gov
Phone: 202-224-3254

Ernst, Grassley Call for Review of Regulatory

Barriers Iowa Pharmacies Face in Federal Drug Take Back Program

WASHINGTON, D.C. – U.S. Senators Joni Ernst (R-IA) and Chuck Grassley (R-IA) today sent a letter to the Government Accountability Office (GAO) to request that the agency provide Congress with a report on the Drug Enforcement Administration's (DEA) regulations that create potential barriers to the participation of local pharmacies in federal drug take back programs. The letter comes on the heels of Senate passage of the bipartisan *Comprehensive Addiction and Recovery Act (CARA)*, legislation to help local organizations and municipalities engage in the fight against the nationwide opioid epidemic.

The Senators wrote, *"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," **the Senators continued**, *"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 a recent op-ed, Senator Ernst stressed her commitment to ensuring that local pharmacies that wish to participate in the federal drug take back program are able to do so. She wrote, in part, *"Based on feedback from Iowa pharmacists, I am working on a request to the Government Accountability Office (GAO) to conduct a thorough review of the program and report to Congress with recommendations to address the barriers to participation that local pharmacies face. These recommendations will help us to find appropriate ways to maximize participation in the program and ensure that this important service to the community is widely available."*

As Chairman of the Senate Judiciary Committee and the Caucus on International Narcotics Control, Senator Grassley led the Senate to overwhelming passage of the Comprehensive Addiction and Recovery Act. Prior to that, he led the bill through the Judiciary Committee. The Community Anti-Drug Coalitions of America recognized that without his leadership, the bill would not have passed

the Senate. In addition, Senator Grassley successfully urged the Obama Administration to re-instate the DEA's highly effective prescription drugs take back days, which it had discontinued. Grassley was an original cosponsor of the Secure and Responsible Drug Disposal Act, which initiated take back days and encouraged communities to establish programs to collect unused medications year-round.

The full text of the letter can be found here and below.

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 Act[1] 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.

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

# # #

[1] Public Law No. 111-273

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