March 17, 2023

The Honorable Diana Harshbarger 167 Cannon House Office Building Washington, DC 20515

The Honorable Debbie Dingell 102 Cannon House Office Building Washington, DC 202515

Re: Block, Report, And Suspend Suspicious Shipments Act

Dear Representatives Harshbarger and Dingell:

Our organizations representing pharmacists and the regulators of pharmacy practice write to offer feedback regarding H.R. 501, the Block, Report, And Suspend Suspicious Shipments Act (BRASSSA). We support your efforts to protect controlled substances from being diverted from the pharmaceutical distribution chain and putting Americans at risk, but recommend clarifying the requirement to conduct due diligence regarding suspicious orders.

According to the Centers for Disease Control and Prevention (CDC), 2.7 million Americans suffer from opioid use disorder (OUD).¹ The National Center for Health Statistics and CDC report that deaths from OUD have risen steadily since 1999, with around 80,400 opioid-related overdose deaths in 2021.² Diversion of controlled substances from the pharmaceutical distribution chain can pose a serious risk to public health. Pharmacists use real time electronic state-based prescription drug monitoring programs (PDMPs) that track the dispensing of controlled substance prescriptions to patients in a state to stem diversion and inappropriate dispensing, at the point of sale.

BRASSSA requires that registrants act with due diligence upon discovering a suspicious or series of suspicious orders, including recording actions of due diligence, declining to fill such orders, and notifying the DEA. Specifically, registrants must use due diligence upon discovering a suspicious order or series of orders for controlled substances. BRASSSA also requires DEA to publish regulations setting forth indicators that should give rise to suspicion. However, BRASSSA does not define "due diligence."

We recommend that BRASSSA allow pharmacists to satisfy due diligence requirements by querying a PDMP database. We also support the provision to require further definition of a suspicious order in regulations within one year of enactment.

¹ https://www.cdc.gov/dotw/opioid-use-disorder/

² https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates

Thank you for your work on this issue. We look forward to continuing to work with you on BRASSSA to ensure controlled substances are not diverted from the distribution chain. If you have any questions please contact Frank Kolb at fkolb@ashp.org.

Sincerely,

American Association of Colleges of Pharmacy

American Association of Psychiatric Pharmacists

American College of Clinical Pharmacy

American Pharmacists Association

American Society of Health-System Pharmacists

American Society of Consultant Pharmacists

Hematology/Oncology Pharmacy Association

National Alliance of State Pharmacy Associations

National Association of Boards of Pharmacy

National Pharmaceutical Association