VIA ELECTRONIC DELIVERY

February 5, 2019

Dr. Scott Gottlieb
Commissioner, U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Commissioner Gottlieb:

On behalf of the Collaborative for Effective Prescription Opioid Policies (CEPOP), we are writing to follow-up on one of the issues raised in our April 23, 2018 meeting with you and your team – safe disposal of prescription medications. CEPOP is actively involved in advancing best practices in this key area both among our participants and with policymakers, including through the recently-enacted Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (P.L. 115-271). We believe this new law provides important tools for the Food & Drug Administration to advance nationwide adoption of safe disposal strategies, particularly in the home, and to move beyond less effective and environmentally undesirable approaches.

Since launching in 2015, CEPOP has convened over 80 national organizations to develop, share, and advocate for best practices to reduce opioid misuse, abuse, and diversion. We know, of course, that the path to addiction, overdose, and other tragic consequences too often begins in the home when unused and unwanted prescription medications are diverted by others for illicit use or profit. In July 2017, CEPOP held a briefing in the U.S. Capitol focused specifically on controlled substance diversion prevention with a core focus on safe storage and disposal strategies.

Our review of the current landscape for pharmaceutical disposal options indicates there are evidence-based systems on the market today which can substantially improve on the nation’s experience with safe disposal of excess drugs and provide more patients and caregivers the opportunity to rid medicine cabinets of pharmaceutical products that may be prone to misuse or diversion. We know that many people simply will not or cannot participate in take-back initiatives, so we need to employ a comprehensive, multi-faceted approach around what works for the broadest array of individuals, which we urge include appropriate at-home drug disposal.

Effective at-home disposal is a convenient option, alongside National Drug Takeback Days and drug takeback boxes, leading to higher individual uptake. When these pharmaceutical products are rendered non-retrievable and unrecoverable through use of a bioavailable disposal unit, the process remains environmentally sound. As you know, Section 3032 of the SUPPORT Act embraces safe disposal technologies and incorporates the definition of what constitutes “non-retrievable” as defined in section 1300.05 of Title 21 in the Code of Federal Regulations.

Put simply, we believe both federal and state initiatives around safe disposal of unused or unwanted prescription medications have an unique opportunity to embrace innovative, at-home systems to
significantly lower the risk of misuse, abuse, or diversion of these products. We urge the FDA to incorporate this approach into options for appropriate disposal under the new law.

Thank you for considering these views. We look forward to continuing to work with you and your colleagues to address the opioid misuse epidemic.

Sincerely,

AmerisourceBergen Corporation
Community Anti-Drug Coalitions of America, CEPOP Co-Convenor and Steering Committee Member
Kentucky Office of Drug Control Policy, CEPOP Steering Committee Member
Mothers Against Prescription Drug Abuse
National Association of County City Health Officials
National Association of Drug Diversion Investigators
National Association of State Alcohol and Drug Abuse Directors, CEPOP Steering Committee Member
National Athletic Trainers’ Association
National Safety Council
SAFE Project
Shatterproof
The Gerontological Society of America
The Honorable Mary Bono, CEPOP Co-Convenor and Steering Committee Member