PRODUCT STEWARDSHIP INSTITUTE

Sustainable Solutions to Protect Our Environment

February 19, 2013

Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 2252

Re: Docket No. DEA-316

Dear Colleagues:

The Product Stewardship Institute, Inc. (PSI) submits the following comments regarding the Drug Enforcement Administration's (DEA) Notice of Proposed Rulemaking for the Disposal of Controlled Substances.

The Product Stewardship Institute (PSI) is a national nonprofit organization dedicated to reducing the health and environmental impacts of consumer products. With a robust membership base of 47 state governments and over 200 local governments, as well as partnerships with more than 95 companies, organizations, universities, and non-U.S. governments, PSI advances both voluntary programs and legislation to promote industry-led product stewardship initiatives.

We would first like to thank the DEA for issuing its proposed regulations ("proposed rule"). We applaud the DEA for listening to the comments PSI and others submitted at the public meeting held on January 19-20, 2011 following the passage of the Secure and Responsible Drug Disposal Act. It is evident that the DEA took into account many of the experiences and suggestions of those operating pharmaceutical take-back programs around the country in developing the proposed rule. Overall, we are very supportive of the majority of the proposed rule and agree with its intent to prevent the diversion of controlled substances while increasing the flexibility of collecting unwanted pharmaceuticals (including controlled substances) by expanding the take-back collection options available. We have summarized the highlights of the proposed rule we agree with below:

- ***Ability to collect controlled substances with non-controlled substances.*** Even with proper signage and outreach, the general public is not able to distinguish controlled substances (e.g.,

Schedule II – V drugs) versus other prescription drugs. Allowing authorized entities to collect controlled substances with other medicines will streamline the message and offer the greatest convenience for the consumer. Since controlled substances are likely to continue to amount to a small portion collected through take-back efforts, this also makes mail-back envelopes or collection receptacles less desirable targets for theft since most of their contents will *not* be valuable for illegal sale or use.

- ***Expanding pharmaceutical take-back options to allow retail pharmacies and other authorized collectors (e.g., manufacturers, drug distributors, and reverse distributors) to participate in collection.*** We enthusiastically support the element in the proposed rule that allows retail pharmacies, pharmaceutical manufacturers, drug distributors, and reverse distributors to become authorized collectors, in addition to law enforcement agencies. Retail pharmacies are well-equipped with the necessary safety protocols and knowledgeable staff to participate in pharmaceutical take-back. For many consumers, retail pharmacies are the most logical and convenient place for consumers to bring their unwanted medicines. With more than 60,000 retail pharmacies across the country, there is great potential for these pharmacies to play a key role in establishing a comprehensive system for drug take-back. We believe that the authorization of manufacturers, drug distributors, and reverse distributors as collectors will also play a critical role in a comprehensive system for the proper disposal of unwanted pharmaceuticals across the country. Since these entities are involved in production and distribution of medicines, we agree with DEA that these entities can serve as authorized collectors to participate in take-back systems.

- ***Allowing a mail-back option to be operated by authorized collectors.*** We commend DEA for providing multiple options for the proper disposal of controlled substances, as this is a significant improvement over current restrictions. A mail-back option will likely provide increased convenience for certain populations throughout the country (e.g., elderly or home-bound), particularly in rural areas. We support the ability of retail pharmacies, government agencies, and other entities to distribute mailers as part of a mail-back program. We also support the ability of law enforcement agencies operating a mail-back program to be able to transport collected drugs for destruction, or to partner with a reverse distributor to handle destruction. (We address additional comments on reverse distributors operating mail-back below.)

- ***Allowing law enforcement agencies to continue to handle, store, and transport controlled substances for destruction according to established procedures.*** We commend DEA for acknowledging that it is not their intent to change existing law enforcement agency procedures for the handling, storage, and transfer of controlled substances.

- ***Adoption of "non-retrievable" standard for the destruction of controlled substances.*** We are pleased to see DEA's clarification that flushing and trash disposal *do not* meet the "non-retrievable" standard established by DEA in its proposed rule. Collected medicines

must be fully degraded by a destruction method to prevent their misuse or diversion as pharmaceutical agents, and to prevent the potential for harm to people or the environment as chemical agents. As described, this standard allows for flexibility in specific technology to be used now and in the future. Furthermore, insisting that destruction must comply with all federal, tribal, state, and local laws is important to ensure public safety as well as environmental protection.

- ***Authorizing others to dispose of a decedent's unused medications.*** Extending the authorization beyond an ultimate user to lawfully entitle persons to dispose of a decedent's unused controlled substances will result in increased collection of these medications for destruction, therefore avoiding improper disposal (e.g., flushing). (We provide additional comments on authorization to dispose of an ultimate user's medications under certain circumstances below.)

Comments Regarding Cost and Convenience

As a national organization, many of our members are directly involved in operating or promoting pharmaceutical take-back collection programs. Therefore, we are most concerned with provisions of the proposed rule that may *increase* operational costs for take-back or result in *a loss of convenient options* for consumers. We support the increased convenience of pharmaceutical take-back efforts that DEA provided by expanding methods for collecting controlled substances. We also acknowledge that some existing pharmaceutical take-back programs will have to make adjustments to fully comply with the final rules.

In terms of the costs, on page 75805 of FR 77 (246), DEA conservatively estimates that the voluntary provisions for collectors, reverse distributors, distributors, and law enforcement agencies will have a net economic impact of nearly zero, and invites comment on this estimate. PSI is concerned that some of the provisions in the proposed rule may increase costs of staffing, storing, transporting, and/or disposing of controlled substances safely and securely. In this regard, we have outlined the following comments below:

- ***Law enforcement staffing.*** The proposed rule requires that only full-time government employees with authority to carry a firearm, make arrests, and serve warrants [1317.02(a)] can accept controlled substances at take-back events or mail-back services. *However, we believe this requirement is too restrictive and suggest that civilian law enforcement employees who meet the same requirements as authorized employees of other collectors, such as retail pharmacies, should be allowed to handle returned materials following the agencies' secure protocols similar to their evidence room practices.* As noted in the proposed rule, it is not DEA's intent to change established law enforcement agency procedures for the handling, storage, and transfer of controlled substances. We believe that this suggested change will allow greater flexibility for law enforcement agencies to operate pharmaceutical take-back programs, leading to reduced costs.

- ***Storing, transporting, and disposing of all collected pharmaceuticals according to requirements for controlled substances.*** On page 75785 of FR 77 (246), the proposed

rule allows all controlled substances collected through take-back events, mail-back programs, and collection receptacles to be comingled with non-controlled substances. While we strongly support this provision, we recognize that comingling will result in larger volumes of collected drugs that need to be stored, transported, and disposed of according to the appropriate requirements for controlled substances. A number of our members have expressed concern over the logistical challenges and cost increases this may represent for law enforcement agencies and other authorized collectors.

  - *Suggestion: Allow registered pharmacists to pre-screen controlled substances from non-controlled substances prior to placing the drugs in a collection receptacle under the strict oversight of a law enforcement officer operating a take-back collection event.* Allowing law enforcement to work with participating pharmacists to identify and separate out controlled substances from non-controlled substances may serve to address the increased volumes of pharmaceuticals collected at take-back events. More clarification from DEA in its final rule about whether this pre-screening with participating pharmacists is allowed would be useful.

  - *Clarification needed: Storage of inner liners by authorized retail pharmacy collectors.* Clarification is needed on how sealed inner liners may be stored by retail pharmacies prior to pick-up by a distributor/reverse distributor or shipment via common carrier to a distributor/reverse distributor. Can a retail pharmacy transfer the trackable, sealed inner liner to a secure warehouse facility prior to pick-up or shipment?

- ***The role of reverse distributors in operating mail-back programs.*** On page 75785 of FR 77 (246), the proposed rule states that only law enforcement agencies or collectors with on-site destruction capabilities can operate mail-back programs. However, we believe that limiting the destruction of mail-back packages to only reverse distributors with on-site destruction capabilities may increase costs since there are a limited number of reverse distributors that meet this requirement. *We suggest that the DEA allow all reverse distributors to accept and temporarily store mail-back packages as long as they meet all safety and security requirements to protect against diversion.*

We recognize that the 2010 Secure and Responsible Drug Disposal Act and ensuing DEA proposed rule do not authorize DEA to require anyone to participate in pharmaceutical take-back collection options. As mentioned, DEA conservatively estimates that the voluntary provisions for collectors, reverse distributors, distributors, and law enforcement agencies will have a net economic impact of nearly zero. However, we want to acknowledge the reality of the current situation across the country – there is no sustainable source of funding for law enforcement agencies and other registered collectors to participate in providing a collection program for unwanted pharmaceuticals. Furthermore, we know that many take-back programs currently operating across the country have relied on the DEA National Prescription Drug Take-Back Days (five one-day events have been held since 2010) to properly dispose of medications that were previously collected. Given the current uncertainty as to whether DEA

will continue to hold these national events after the final rule is adopted, these programs may not be able to continue if alternative funding for destruction is not available.

The costs of piloting and operating pharmaceutical take-back collection programs have been borne by local governments, law enforcement, individual pharmacies, and other key stakeholders, severely limiting their scope and effectiveness. Therefore, we continue to advocate for a product stewardship solution where drug manufacturers assume responsibility for funding and managing pharmaceutical take-back collection programs. In fact, the structure that the DEA establishes in the proposed rule allows for such an approach since drug manufacturers are able to become authorized collectors. Even though the issue of sustainable funding is outside the scope of the proposed rule, it nonetheless remains a critical barrier to establishing comprehensive take-back systems to collect controlled substances and other unwanted medicines for proper disposal.

Comment Regarding Data Collection

On page 75785 of FR 77 (246), DEA clearly states that controlled substances collected by collectors may not be individually counted or inventoried. While we agree with DEA's intention under this provision to protect against diversion activities once drugs are collected, we strongly encourage DEA to establish an *exception* in the final rule. *We suggest this provision allow for research entities to apply for an exemption to carry out carefully-regulated studies to characterize and quantify the medicines returned through take-back programs using statistically-valid sampling of the returned medications*. Safe and secure protocols can be developed to allow research studies on the type and quantity of medicines disposed. Many of our members have expressed great concern that data collection efforts that inform source reduction activities would cease to exist if DEA does not allow approved research entities to continue their work. These data are invaluable from a health care management perspective, as well as from an environmental and waste reduction perspective.

Comments Regarding Long-Term Care Facilities (LTCFs)

As stated above, we support allowing registered retail pharmacies to voluntarily operate collection receptacles at LTCFs. Solutions for LTCFs to safely and securely dispose of leftover medicines are critical, especially since many LTCFs have no other choice but to flush their leftover drugs. On page 75803 of FR 77 (246), in the narrative section, DEA clearly states that neither flushing nor municipal solid waste disposal meet the "non-retrievable" destruction standard. *We suggest that DEA should make this clear in the rule itself so as to close out those inappropriate disposal options for LTCFs uniformly across the country.*

Even so, a number of our members were concerned that the option for LTCFs to participate in pharmaceutical take-back programs through retail pharmacies (which maintain a collection receptacle at the LTCF) is still too limited under DEA's proposed rule. Therefore, *we suggest that LTCFs be allowed to partner with an authorized collector to use mailers to properly dispose of leftover controlled substances from ultimate users.*

Lastly, we recognize that the term Long-Term Care Facility includes a wide range of institutions, from large nursing homes with skilled nursing professionals that function similarly to hospitals to small family-homes and other small assisted-living facilities without skilled

nursing care. There is much variety state-by-state as to how these LTCFs are regulated. The issue is further complicated by the fact that DEA and the U.S. Environmental Protection Agency (EPA) approach disposal of pharmaceutical waste from LTCFs differently. *We ask that DEA clarify which types of LTCFs are allowed to be served in its final rule, and work with EPA on this distinction,if necessary.*

The comments outlined above represent the provisions we believe are most important. A few additional suggestions pertaining to specific details of the proposed rule are outlined below.

Additional Comments and Suggestions

- ***Broaden scope of individuals legally authorized to dispose of ultimate user's leftover controlled substances.*** We would like to see a provision included that allows individuals authorized to dispose of an *incapacitated* ultimate user that would extend beyond an ultimate user's "member of his household" per the definition of ultimate use [21 U.S.C. 802]. This provision would be in addition to allowing ultimate users, as well as individuals legally authorized to dispose of ultimate user decedent's property, to dispose of leftover controlled substances using one of the proposed collection methods, as outlined on page 75785 of FR 77 (246).

- ***Clearly define "common and contract carriers" used in the proposed rule*** [1317.05(a)(2), 1317.05(b)(2), 1317.05(c)(2)(iii) and 1317.05(c)(2)(iv)]. We would like further clarification of this term in the final rule. It would be helpful for DEA to reference the Department of Transportation or other definition being used.

- ***Allow reasonable amount of time for destruction by reverse distributors.*** On page 75802 of FR 77(246), DEA invites comments on the practicality of implementing the "as soon as practicable but no later than fourteen calendar days" requirement while also maintaining effective controls against diversion. We support a reasonable destruction timeframe that fits with standard practices at reverse distributors and hazardous waste incinerators, and look to those businesses to best comment on this issue. In addition, it would be useful for DEA to clarify at what point the fourteen day requirement begins.

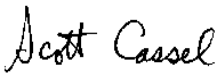
- ***Visual pre-screening for noncompliant items at take-back events and collection receptacles.*** While DEA is silent on this issue in the proposed rule, we would like to encourage law enforcement officers and other authorized collectors to visually pre-screen unwanted medications brought in by residents to minimize the collection of non-compliant items at take-back events and at collection receptacles (e.g., mercury-containing products, medical sharps, etc.). Furthermore, we suggest that DEA consult with EPA to develop a solution that prevents noncompliant items from being sent for destruction and that does not compromise the safety and security requirements for sealed liners.

Conclusion
PSI greatly appreciates the opportunity to comment on the proposed rule. However, we also want to encourage DEA to take all necessary measures to swiftly finalize the rule, since the adoption of the final rule is absolutely critical to allow all parties involved in pharmaceutical take-back efforts across the country to move forward. Uncertainty resulting from the lack of a final DEA rule has had a great impact on our government members, organizational and corporate partners, and other key stakeholders. For example, essential planning activities for operating effective pharmaceutical take-back programs (e.g., plans for hiring, training, fundraising, etc.) are hindered. We recognize that many existing take-back programs will need to make changes to their current operations. We want to ensure a quick and smooth transition so that pharmaceutical collection options available to residents do not decrease overall.

In summary, we support secure, effective pharmaceutical take-back programs as a critical part of a comprehensive strategy to reduce the epidemic of overdoses that result from the misuse and illicit use of medicines and accidental poisonings, and to reduce pharmaceutical pollution through proper disposal of unwanted medicines. With the adoption of the final rule, we look forward to working with DEA and other key stakeholders to achieve a comprehensive system for pharmaceutical take-back in the U.S.

Thank you for your consideration.

Sincerely,



Scott Cassel
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