



August 13, 2010

Mr. Burke Lucy
Integrated Waste Management Specialist
Department of Resources, Recycling and Recovery
1001 I Street
Sacramento, CA 95812

RE: Comments on CalRecycle's Report on Home-Generated Pharmaceuticals Programs in California

Dear Mr. Lucy:

The California Retailers Association (CRA), the California Pharmacists Association (CPhA) and the National Association of Chain Drug Stores (NACDS) appreciate the opportunity to provide comments to the California Department of Resources Recycling and Recovery (CalRecycle) regarding its report "Evaluation of Home-Generated Pharmaceutical Programs in California" and the July 20, 2010 Workshop. We recognize the comprehensive nature of the report and considerable efforts of CalRecycle in preparing the report and appreciate CalRecycle engaging the stakeholders in this process and the Workshop.

We share the goal of working towards a safe and appropriate system to allow consumers to dispose of their unused medications for destruction. To reach this goal, we believe that such programs need to be properly structured and come within the framework of key principles. The report identifies four key factors from SB966: safety (security), accessibility, cost effectiveness and efficacy. The report also identifies several challenges and barriers that must be addressed in any program. Looking at all these considerations, we believe there are key principles that are critical to finding a safe and effective means for consumers to dispose of their lawfully obtained unused medications that do not add risks to the health care system. These key principles are:

- (1) Protect public health and safety and the safety and security of the drug distribution supply chain;
- (2) Provide consumers with a safe and effective means for disposal of their unused drugs; and
- (3) Ensure a sustainable funding source.

Protect Patient Health and Safety and Integrity of the Drug Distribution System

In our view, in order to protect patient health and safety and preserve the integrity of the drug distribution system, consumers' unused drugs must be returned to locations that are *separate and apart from pharmacies where drugs are dispensed, such as local law*

Via email Burke.Lucy@CalRecycle.ca.gov

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Page 2 of 3

enforcement facilities and regulated and law enforcement supervised collection programs. Having pharmacies take back dispensed prescription drugs creates potentially hazardous public health circumstances since the drugs have left the secure drug distribution system and could be contaminated or adulterated. The drugs could be contaminated with infectious diseases or other hazardous substances posing potential risks to the public through inadvertent exposure to such contaminants or potentially contaminating other products in the retail establishment.

Placing containers in pharmacies for consumers to return unused drugs is not a solution for providing consumers with a safe and effective means for disposal of their unused drugs. Pharmacies are not designed to accept returned drugs. Many pharmacies lack the space to take back consumers' returned drugs. In addition, state laws and regulations may prevent pharmacies from taking back drugs. Although relatively secure, pharmacies can never achieve the same level of security as can law enforcement facilities and law enforcement supervised collection programs. In fact, the use of in-store collection systems will increase the risk of crime directed against pharmacies and their employees as these collection sites may be seen as easy targets for criminals seeking drugs to divert into the illegal market.

In addition, the current federal controlled substances laws and regulations prohibit pharmacies from taking back controlled substances from consumers. Consumers are only permitted to return their controlled substance medications to law enforcement officials, and only if permitted by the state. Controlled substances account for as much as 15% or more of all prescriptions, so these barriers are significant reason that pharmacy-based take-back programs are not an appropriate solution.

Provide a safe and effective means for consumers' disposal of their unused drugs.

A program for consumers' return of their unused pharmaceuticals must be readily understandable for consumers, maintain the integrity, safety, and security of the drug distribution system, and protect against diversion of the returned medications.

Prepaid mail-back envelopes, distributed through pharmacies, are an option. The concept of mailing is universally understood by consumers. It would be readily understandable through public service announcements and consumer education efforts which would foster public acceptance and involvement. It would also maintain the separation between pharmacies that dispense drugs and the facilities that accept unused drugs for disposal.

Another option is collection events conducted by law enforcement at pharmacies or law enforcement supervised collection events. Pharmacies are willing to assist law enforcement with pharmaceutical waste collection events, but these programs must be designed with appropriate security considerations to remove the potential for diversion of these medications.

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Page 3 of 3

Ensure Sustainable Funding

Ensuring sustainable funding must be a major consideration in any program. These costs cannot be borne by community retail pharmacies. Lawmakers and regulators should bear in mind that retail pharmacy is a low profit margin business, retaining a net profit of less than 2%. Pharmacies are facing ever-declining reimbursement levels in

public and private programs. As such, pharmacies are not in a position to fund take back programs, which are neither within its area of expertise nor core to its healthcare delivery business model.

In considering the Potential Options for Further State Action detailed in the report, it is our conclusion that Option 4, a statewide collection program with state oversight and funding through an advanced disposal fee is most likely to result in a successful program for handling pharmaceutical waste. This approach would offer a uniform and understandable program for consumers.

The key focus should be on security, consumer education and funding. We believe the best approach should incorporate the following components:

- 1) Funding by way of an advanced disposal fee;
- 2) Secure collection of pharmaceutical waste at local law enforcement facilities and law enforcement supervised collection events;
- 3) A comprehensive consumer education and outreach program at pharmacies, medical offices, clinics, hospitals, public libraries and other public facilities;
- 4) Distribution of disposal prepaid mail-back envelopes and packaging at pharmacies and other drug distribution sites that could either be mailed to a mail-back disposal facility or brought to a local law enforcement-based disposal site.

Finally, in conjunction with any pharmaceutical waste disposal program should be a component to continually assess and evaluate the actual need for these programs. The report makes clear that "safe collection of pharmaceuticals is expensive." In moving toward a sustainable safe and secure, accessible and efficient collection system, we need to keep in mind that a long term solution to disposal of pharmaceutical waste will involve significant direct or indirect costs to consumers. The cost incurred needs to result in some real and measurable benefit to the environment and to the public.

Sincerely,



Missy Johnson
Government Affairs Director
CRA



Lynn Rolston
Chief Executive Officer
CPhA



Mary Staples
Regional Director
NACDS