

November 21, 2008

Jim Cropper
California Integrated Waste Management Board
1001 I St.
Sacramento, CA 95812

RE: Comments on Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs

Dear Mr. Cropper:

The Pharmaceuticals Committee is an Ad Hoc committee of professionals from local government, non-profit and the pharmaceutical reverse distribution industries working towards pharmaceutical take-back programs to protect human health and the environment. We submit our comments on the model program procedures with a sincere interest in developing procedures that foster pharmaceutical collection programs.

SB 966 established a clear intent from the Legislature to foster the proper disposal of unwanted and expired pharmaceuticals. The CIWMB was tasked with coordinating stakeholders in the development of model programs:

“To encourage a cooperative relationship between the board and manufacturers, retailers, and local, state, and federal government agencies in the board's development of model programs to devise a safe, efficient, convenient, cost-effective, sustainable, and environmentally sound solution for the disposal of drugs.”

Furthermore, the CIWMB was given the authority to modify or make regulations in the creation of these model programs.

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(d) Model programs deemed in compliance with this article shall be deemed in compliance with state law and regulation concerning the handling, management, and disposal of drug waste for the purposes of implementing the model program.

(e) (1) The board may develop regulations pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that are necessary to implement this article, including regulations that the department determines are necessary to implement the provisions of this article in a manner that is enforceable.

(2) The board may adopt regulations to implement this article as emergency regulations. The emergency regulations adopted pursuant to this article shall be adopted by the department in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, and for the purposes of that chapter, including Section 11349.6 of the Government Code, the adoption of these regulations is hereby deemed an emergency and shall be considered by the Office of Administrative Law as necessary for the immediate preservation of the public peace, health, safety, and general welfare. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, any emergency regulations adopted by the department pursuant to this section shall be filed with, but not be repealed by, the Office of Administrative Law and shall remain in

effect for a period of two years or until revised by the department, whichever occurs sooner.”

In addition, the CIWMB has been strongly supportive of Extended Producer Responsibility through adoption of its Strategic Directive No. 5.

Unfortunately, rather than taking an approach of fostering pharmaceutical take-back by creating a problem statement, researching opportunities, identifying barriers and issues, exploring voluntary vs. mandatory programs, exploring funding options and engaging stakeholders, the model procedures side-stepped these components and developed models that relied solely on voluntary models, erected barriers rather than removed barriers, and excluded viable Extended Producer Responsibility options that could be similar to Canada’s take-back program.

Specifically, the Pharmaceutical Committee recommends the following be added to the Model Procedures Report:

1. A summary of the issues surrounding pharmaceutical take-back with research and summarized input from the stakeholders, which should include:
 - a. Problem statement. Why does a pharmaceutical take-back system need to be created?
 - b. Issues and barriers. A list of issues and barriers to implementing take-back programs and who has expressed those concerns, such as manufacturers, retailers, pharmacists, state agencies, local government, etc.
 - c. Regulatory barriers. A discussion of what regulations exist or do not exist that help or hinder in the fostering of pharmaceutical take-back.
 - d. Voluntary vs. mandatory. A discussion about the potential success of voluntary programs and how voluntary programs will be evaluated to understand whether mandates are necessary.
 - e. Existing programs. A summary of existing programs both within California and around the world noting their strengths and weaknesses and collection rates. A discussion of the pharmaceutical industry and potential opportunities, such as working with the reverse distributors.
 - f. Controlled Substances. The challenges and limitations on controlled substances and how they impact all pharmaceutical take-back programs.
 - g. Funding. A discussion of the cost of pharmaceutical take-back and the funding sources.
2. An Extended Producer Responsibility model program procedures, such as the Canadian pharmaceutical take-back program.
3. Recommended changes to regulations that will support and promote pharmaceutical take-back programs, specifically the models developed.

The Pharmaceutical Committee also wants to bring to the CIWMB’s attention the multiple barriers created in the models as presented in Attachment 1 of the CIWMB Agenda Item 4

from November 13, 2008. Comments have been integrated into the agenda item, see attachment.

We respectfully request that the CIWMB acknowledge the intent of SB 966 to foster the take-back of pharmaceuticals, and to take on the challenges posed by this worthy endeavor. The Legislature gave the CIWMB the authority to write regulations, which can address the barriers in regulations. The Legislature gave CIWMB the direction to seek out models local and international. The Legislature gave the CIWMB the direction to work with stakeholders. In order to meet the expectations set forth by the Legislature, the CIWMB must reach beyond existing programs, must remove barriers - not erect them, must engage the stakeholders and must return to the Legislature with a fully realized set of implemented models to continue the discussion of how to best address the risks posed by waste pharmaceuticals. The Pharmaceutical Committee and its members want to partners in realizing SB 966.

Sincerely,



Lesli Daniel, Chair
Pharmaceuticals Committee

Karin North, Chair
Bay Area Pollution Prevention Group

Jen Jackson, Vice Chair
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