

August 20, 2010

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Emailed to: [PharmaSharps@CalRecycle.ca.gov](mailto:PharmaSharps@CalRecycle.ca.gov)

**Re: Comments on CalRecycle's "Evaluation of Home-Generated Pharmaceutical Programs in California" Report**

CPSC is an organization of over 90 California local governments in addition to hundreds of business partners, interested non-profits and individuals who support a product stewardship system where producers have the primary responsibility, while all the stakeholders along the product chain share in the responsibility to manage product waste.

CPSC and its members commend CalRecycle staff for their exhaustive effort to analyze and present information about pharmaceutical waste management programs in California, across the country and outside the US in their "Evaluation of Home-Generated Pharmaceutical Programs in California" Report ("Report"), but we are troubled with how the mandate given to you under SB 966 was interpreted and represented in this report. Our primary concerns are the lack of clear policy direction given in the report, despite your own overwhelming evidence showing EPR as the long-term sustainable solution, and that the tone and data presented in the report may falsely lead the readers (i.e. the legislature) to believe that successful pharmaceutical collection programs do not exist.

SB 966, Section 47123 asks CalRecycle to do three things:

- 1) Analyze model pharmaceutical waste collection programs based on four criteria: efficacy, safety, statewide accessibility, and cost effectiveness.
- 2) Consider the incidence of diversion for unlawful sale and use.
- 3) Make recommendations for the implementation of a statewide program and statutory changes.

**1) Analysis of Model Programs**

An unnecessary and complicating factor of this Report is its analysis of all pharmaceutical collection programs in California, rather than an analysis of model programs only, as mandated by SB 966. According to the Report, 65% of the programs discussed in the Report are not model programs. Including non-model programs in the analysis of model programs confuses the results of the study because it combines non-compatible data. The result is an unfair conclusion that non-model programs (the majority of current California programs) are without success or credibility.

Compounding this result is the lack of acknowledgement in the report that SB 966 did not create a requirement for California pharmaceutical waste collection programs to meet CalRecycle's February 2009 Criteria and Procedures for Model Home Generated Pharmaceutical Waste Collection and Disposal Programs ("Guidelines"). Furthermore, the Report does not indicate that the majority of the pharmaceutical waste collection programs analyzed in the Report were established prior to the passage of SB 966, and again, were under no obligation to modify their programs to meet CalRecycle's Guidelines.

In addition, as stated on page 11, under the "Limitations" paragraph: "Incomplete surveys could result in the failure to meet the Guidelines, regardless of what the answer might have been had the response been provided." To make a leap from incomplete data to incompliant programs, only further skews the results of both model and non-model collection programs towards perceived failure.

Finally, while we understand that this comment period is for the Report and not for the previously developed Guidelines, the results of this Report overwhelmingly show a lack of ability or willingness of California collection programs (65%) to meet or follow CalRecycle's Guidelines which, we believe, speaks more to problems with the quality and rationality of the Guidelines than it does about the numerous, otherwise considered successful, long-running pharmaceutical waste collection programs taking place around the State.

## **2) Consideration of Incidence of Diversion**

There is no dedicated section of the Report addressing the SB 966 mandate to consider the incidence of diversion for unlawful sale and use. Anecdotally, we are aware of no incidents of diversion among our colleagues' collection programs across the State. But more importantly, CalRecycle's survey that informed the results presented in the Report, asked a specific and direct question about incidents of diversion. Why are the results of this question not included in the Report?

The place in the Report where diversion is discussed is in the "Safety" section of Part II-3, where diversion is essentially equated to safety. In addressing diversion in this section, the reader is misled to believe that the current programs in place in California are woefully unsafe. How else would one interpret data that shows 93% of pharmacy collection programs fail at least one of the Guideline's safety standards? Instead of making conclusions about diversion based on what could happen, data on diversion should be based on what has happened, i.e. actual California cases of diversion. If CalRecycle is concerned that the information provided by survey participants is not fully accurate, then another source of data such as Washington State's 2006-2008 pilot pharmaceutical waste collection program, involving 39 pharmacies and zero incidents of diversion, could be discussed in the Report.

## **3) Recommendations for the Implementation of a Statewide Program**

We are pleased to see the Report properly summarizes the achievements of international programs – the most successful of which take place at pharmacies, and are funded by the pharmaceutical industry through an EPR system based on your results. Yet, despite your results clearly indicating EPR-funded, pharmacy-based collection programs as the most

effective and least costly model, you do not make this the primary, if not only, policy recommendation to the legislature. In fact, the most important element of the Report – Section V: Potential Options for Further State Action – is disappointingly the weakest section of the Report. It's our interpretation that SB 966 tasks CalRecycle to bring forth a solid, defensible, and clear policy direction for the legislature. Instead the report offers every possible option, without any ranking, including the obviously problematic option to maintain the status quo. Given all these factors, if the report is not going to direct the legislature to call for an EPR-mandated pharmaceutical waste collection system, we strongly believe that each policy option should show a nexus to the results or analysis within your report. i.e. include a substantive, research-based reason for inclusion of each policy recommendations. In addition, Section V should be renamed to reflect the mandate of SB 966 to make recommendations for the implementation of a statewide program and statutory changes. We suggest naming it "Recommendations for Further State Action."

It should also be noted that there is a clear contradiction in CalRecycle not recommending an EPR approach when in 2007, your agency adopted a set of Strategic Directives, one of which self-directs your agency to "seek statutory authority to foster "cradle-to-cradle" producer responsibility and develop producer-financed and producer-managed systems for product discards."

In summary, while we commend CalRecycle staff for their exhaustive effort to develop this Report, we are concerned that in its current form the Report may lead to confusion, resulting in lack of action by the legislature, and ultimately sabotaging the intent of SB 966 to develop a long-term, convenient, and cost-effective solutions for pharmaceutical waste disposal.

Please do not hesitate to contact us if you would like to discuss our comments. Marjaneh Zarrehparvar is our point person for this subject. She can be reached at (415) 355-3756 or [marjaneh.zarrehparvar@sfgov.org](mailto:marjaneh.zarrehparvar@sfgov.org)

Sincerely,

A handwritten signature in black ink, appearing to read "Robert D'Arcy", with a long horizontal line extending to the right.

Robert D'Arcy  
Board of Directors, Chair