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August 12, 2010

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Mr. Burke Lucy
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**Re: Comments on “Evaluation of Home-Generated Pharmaceutical Programs
in California; CalRecycle Background Paper for July 20, 2010, Workshop,”
Issued July 12, 2010**

To the Department of Resources Recycling and Recovery:

The following comments expand upon those which we registered with CalRecycle on behalf of our client, GlaxoSmithKline (GSK) at the July 20, 2010, workshop in Sacramento held to discuss CalRecycle’s evaluation of “model” pharmaceutical waste collection programs in California, in preparation for forwarding this evaluation, and “recommendation for the potential implementation of a statewide program and statutory changes.”

Prefatory Comments:

As the background paper issued July 12, 2010, “will serve as foundational material as CalRecycle prepares the required report to the Legislature(,)” our relatively brief comments at the workshop, now furthered in detail in this letter, pointed out analytical and structural deficiencies (a) in some of the “data” upon which the department relies, and (b) in CalRecycle’s “options.” We also raised questions about CalRecycle’s “fee versus tax” characterizations of funding for its options which need to be accurately reframed if advanced to the Legislature as

part of any policy recommendations. These are considerations, together with those that follow, that we believe CalRecycle must take into account as part of the final version of its “foundational material,” as a basis for its eventual report to the Legislature.

Detailed Comments

1. Data contestability:

•Figure 1 – page 5 - While there may be inferences to the contrary in the department’s paper, there are **no** documented cases where home generated unused medicine disposal of any kind has caused or is likely to cause “Environmental Damage,” which is equated to “Improper Disposal” in the representation. As the paper accurately concedes, the vast majority of pharmaceuticals (at least some of the data considered by CalRecycle would set that level at 90%) enter the aquatic environment from excretion following patient use. Human excretion, the “major pathway for pharmaceuticals to reach the environment,” however, is not considered as “it occurs before pharmaceuticals become home-generated wastes (sic).”

•Bullet 3 – page 6 - The upper estimates of the volume of unused medicines are, to put it charitably, overblown, and the conclusions reached are methodologically suspect. Peer reviewed literature puts the probable volume of unused prescription medications in the range of two percent (2%) to thirteen (13%). To our knowledge, there are no valid assessments that measure the disposal of readily-available, over-the-counter (OTC) medications acquired by the public. The CalRecycle paper references are principally from the Seattle program reports (Page 40, fn 5). The high numbers characterized as disposal rates are largely drawn from quoting patient consumption non-compliance numbers - which for some products can be quite high – as an equivalent to disposal. Alternatively, reliance upon the data supplied by the Teleosis Institute ignores that the Institute’s conclusion as to percentages of unused medication stems from estimates emanating from their collection events of the percent of pills remaining in returned, incompletely used prescriptions compared to what was originally in a particular returned container. This method fails to measure, let alone account for, the length of time and volume of consumption of medications as prescribed to generate more credible estimates. For example a patient might have taken blood pressure medicine for one year, then, perhaps, switched medicine, or died, suddenly leaving half a bottle. Using the Teleosis method in that instance, 50% of the prescribed medication went unused when, in fact, in such an instance, the percentage of unused medication – properly taken in context – may actually have been quite small, ranging to the low single digit percentages.

The 3 of the 4 peer reviewed literature studies included were estimating the cost of unused medicine. While cost is not the same as volume, the conclusions there appear more rational, in finding:

- Long term care facility (LTCF) 6.7% unused based on financial data.¹
- LTCF 13.1% unused based on financial data.²
- General public 2.3% unused based on financial data.³

One general public study in Sweden however did look at actual counts rather than financial data, and found:

- General Public 3% unused based on unit counts.⁴

2. Program Evaluation Standards:

The standards do not take into account all of the Resource Conservation and Recovery Act (RCRA) and Homeland Security mandated security measures when evaluating a HHW facility. The need for an HHW program to segregate medicines from other poisons is seems both unnecessary and duplicative, when the RCRA already requires strict controls, and cradle to grave tracking reconciliation on all of RCRA regulated poisons. To deter removal of controlled substances from a drum of mixed, but somehow accessible, poisons a requirement that DEA-regulated substances be immediately dumped into a solvent would seem dispositive of the issue. RCRA workers are trained to do waste identification so it should be a simple matter to train them to segregate out controlled substances.

3. Challenges and Barriers:

Page 26, No.3 and Page 36, Option 3. The CalRecycle paper discusses a “product stewardship approach” which, in terms of waste minimization has a fairly specific hierarchy: first reduce, then reuse, then recycle and, as a last resort, dispose.

For patient safety reasons, unused medicine from the general public cannot be reused or recycled. On page 6, the paper declares that reducing the amount of medicine that goes unused (i.e. by improving compliance and product consumption of products designed, generally, to be fully consumed in a course of therapy) is out of scope, and only the status of products as home generated unused pharmaceuticals is addressed, CalRecycle has effectively narrowed “product stewardship” to the last resort in the hierarchy - disposal.

¹ Medication destruction and waste measurement and management in long-term care facilities, Paone RP, Vogenberg FR, Caporello E, Rutkowski J, Parent R, Fachetti F, The Consultant Pharmacist, 1/1/1996, Vol. 11, 3

² The Cost of Medication Waste, Bolvin M, Canada Pharm Journal, 5/1/1997, , 5

³ The economic impact of Wasted Prescription Medication in an outpatient Population of Older Adults, Morgan TM, The Journal of Family Practice, 9/1/2001, Vol. 50 No. 9, 6

⁴ Drugs up in smoke: a study of caseated drugs in Sweden, Isacson D, Olofsson C, Pharm World Sci 1999, 1/1/1999, Vol. 21(2), 11

The two environmentally acceptable disposal methods under the Federal Policy (see page 30) are take back and household trash disposal. Also not covered in their evaluation was household trash disposal. Since the CalRecycle notion of product stewardship has (1) effectively eliminated all of the non-disposal options, (2) eliminated all but one (take it back) of the available disposal options – notwithstanding testimony and waste management input that leachate from California waste landfills is nominal to nonexistent), and (3) not considered any of the environmental impacts (e.g. carbon emissions and air pollution) from that additional product transportation associated with take back programs around incineration, reconsideration of this “option,” is warranted to eliminate the obvious bias that favors it.

Product stewardship programs are designed to contain end-of-life waste that is designed into a product (e.g. a dead battery, electronic equipment, tires, etc.) Medicines, as noted, are designed to be completely consumed by the patient (there is no designed-in end of life waste). Also, a key reason for collecting end of life waste is to reuse the products, or recycle the components into usable new products. However, in the case of unused medicine the only reason it is being collected is to dispose of it. Thus, product stewardship properly applied to unused medicine should be about how to reduce the amount of medicine that goes unused (i.e., Reduce – the first element in the hierarchy) and what disposal method will cause the least harm to the environment. Neither are addressed in the background paper.

Also, by CalRecycle concession (Page 36, Option 3, Paragraph 3) the cost of a product stewardship program is ultimately born by the consumer. The expectation, thus, is that regulated parties would implement the least costly, most effective option(s). According to CalRecycle summary rankings (Page 23, Figure 21) the most effective programs are Continuous Collection - Law Enforcement programs (No. 1) and Continuous Collection – HHW facilities and pharmacy take back (tied No.2). However household hazardous waste disposal costs are about half as much any other disposal method. The CalRecycle analysis unavoidably suggests that any mandated, industry-funded, take back program should use the existing infrastructure of law enforcement or household hazardous waste programs.

4. International programs:

One issue drawing considerable focus in the paper is the suggestion that manufacturers are supporting pharmaceutical take back programs in Europe and Canada, but are unwilling to do so in the U.S. To ensure informed context, the following background should be considered:

- European programs were initiated, along with their packaging directives, because European countries were simply running out of land fill space, not because of pharmaceuticals in water.

- Europe still has active unlined landfills.
 - Research results regarding the EU programs have produced the following:
 - Public participation rate are less than 20% (<200%).
 - Associated research has not demonstrated reductions in pharmaceuticals in water.
 - Despite the programs, no data demonstrates reductions in either drug abuse (diversion) or drug-related poisonings.
 - Canada: While a take back program has been in place in British Columbia since 1996, it is noteworthy that what started as a voluntarily established Medications Return Program (formally called British Columbia EnviRx) in November 1996, was summarily converted to a government-mandated program 1997 under the *Post-Consumer Residual Stewardship Program Regulation*. Brand-owners of pharmaceutical and consumer health-care products are currently regulated under the *Recycling Regulation*.
 - Significantly, the latest available annual report (2008) regarding the program contains the following findings by the Canadian Council of Ministers of the Environment in their proposal of several criteria to measure the impact of pharmaceuticals on humans and the environment.:
 - Researchers have found the hazard potential of pharmaceuticals on human health or the environment “to be very low.”
 - The anticipated duration of the “very low” effects could be considered medium term.
 - Pharmaceuticals products are not significant by volume or weight to the waste stream.
- Notwithstanding opinions to the contrary, industry experience in the EU and Canada does not warrant support of take back programs for unused medicine in California.

Concluding Observations

Existing Programs: We would encourage CalRecycle’s consideration, mention and discussion, under “National Programs” (Page 30) of the SMARxT DISPOSAL program that did not previously earn a mention, despite the fact that it is an established U.S. Fish and Wildlife Service, American Pharmacists Association (APhA), and Pharmaceutical Research and Manufacturers Association (PhRMA) cooperative program.

Similarly, we would encourage consideration, mention, and discussion of U.S. Food and Drug Administration (FDA) guidance on pharmaceutical disposal.

We respectfully submit that, upon proper examination, CalRecycle will find as to its current preferred option(s) (a) that the scientific evidence does not support establishing programs to take back unused medicine, as the take back programs do not reduce the amount of

Burke Lucy, Integrated Waste Management Specialist
Department of Resources Recycling and Recovery (CalRecycle)
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pharmaceuticals in water over the reductions that can be achieved by household trash disposal, and (b) do not reduce the incidence of drug diversion over the reductions that would occur with proper household trash disposal as outlined in the SMARxT Disposal™ and the FDA guidelines.

GlaxoSmithKline appreciates the stakeholder process, the opportunity to provide substantive input, and looks forward to revised policy recommendations developed by CalRecycle. If we may provide any additional information, background, or input, please do not hesitate to call upon us for a prompt response.

Sincerely,

A handwritten signature in black ink that reads "John R. Valencia". The signature is written in a cursive style with a large initial "J" and "V".

JOHN R. VALENCIA

JRV

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