



Monday, November 30, 2015

Environmental Health Division
Los Angeles County Department of Public Health
5050 Commerce Drive
Baldwin Park, CA 91706

Dear Director Bellomo,

On behalf of the Generic Pharmaceutical Association (GPhA), the nation's leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry, we strongly oppose the draft Extended Producer Responsibility (EPR) Ordinance. Generic pharmaceuticals account for 88% of prescriptions dispensed in the United States, but only 28% of the cost. Generics saved California \$21.5 billion in health system savings in 2014 alone¹.

What is the problem the EPR Ordinance is intended to solve?

No data or evidence has been presented to prove that discarded drugs have harmed or will harm the environment. There have been no studies presented that associate pharmaceutical residues in our water with human health problems. Research has shown that over 98% of residual pharmaceuticals enter the water supply through excretion^{2,3,4,5}. EPR programs in British Columbia have consistently found that the bulk of human pharmaceuticals found in waterways most likely got there by way of sewage. It is questioned whether take-backs have any real environmental and safety benefit⁶.

The draft EPR Ordinance is based on a failed approach, will increase the costs of prescription and over the counter drugs to County residents, and will not work.

The EPR program in Alameda County, upon which this program is derived, is failing. The Alameda County Board of Supervisors unanimously passed the Alameda County Safe Drug Disposal Ordinance in July 2012. *Over three years later, zero kiosks for returning drugs have been installed outside public law enforcement locations.* Only one new kiosk for returning drugs has been installed at a Police Department headquarters. DEA regulations make it difficult for a pharmacy to be a collection site in this type of program. An Alameda-type program will not succeed.

The generic industry operates as a commodities market with razor thin profit margins on the majority of our products. When factoring in Medicaid rebates, our manufacturers may actually lose money on certain products. Generic products are not sold directly to patients, but go through a robust distribution supply chain of wholesalers, re-packagers, group purchasing organizations, pharmaceutical benefit managers, and chain drug stores. Any change in the supply chain, such as the significant cost of an Alameda-style program, would cause a ripple effect leading to higher prices for patients and payers. For example, just the mail-back envelopes

1 Generic Drug Savings in the U.S. Seventh Annual Edition: 2015.

2 Schwab, et al. Human pharmaceuticals in US surface waters: A human health risk assessment. Regulatory Toxicology and Pharmacology, Volume 42, Issue 3, Pages 296-312 (August, 2005).

3 Webb, et al. Indirect human exposure to pharmaceuticals via drinking water, Toxicology Letters, 142, 157-167. (2003).

4 Mons, M.N., Pharmaceuticals and drinking water supply in the Netherlands, Kiwa N.V. Water Research. (2003).

5 Tischler, et al. Landfill Disposal of Unused Medicines Reduces Surface Water Releases. Integr Environ Assess Manag., Vol 9, No. 1, 142-154 (2012).

6 Health Product Stewardship Association Annual Report, "Annual Report to the Director 2012," p 11.



mentioned in the draft cost upwards of \$4.00 an envelope, which is equal to the cost of many generic prescriptions. Implementing a program in Los Angeles County will inevitably lead to increased costs for generic medicine that will disproportionately impact low and moderate-income families who rely on high-quality and lower-cost generic pharmaceuticals.

The end of life for a generic medicine when prescribed and adhered to should be ingestion. GPhA supports proper prescribing practices and patient adherence, for example taking the entire course of medication as prescribed so none is left over, as a way to lower costs for the healthcare system and help Californians live healthier lives. In the United States, prescription non-adherence is estimated to cost about \$300 billion annually⁷ including \$100 billion alone for excess hospitalizations. With generic drug costs at record lows the last thing Los Angeles County needs is to mandate a program that could easily double the cost of many low-cost prescriptions. Research shows that consumers worry about the cost of the program impacting medicine costs and county resources.

We will help fund our FDA-approved alternative proposal.

The Food and Drug Administration and the Environmental Protection Agency recommend household solid waste disposal (using a sealable plastic bag and an obscuring substance like kitty litter or coffee grounds) and supplemental, periodic federal and local government take-back days. We are prepared to support and help fund a public education program to ensure that people who live and work in Los Angeles County are better informed and empowered to properly use, store and dispose of unused generic medicine. We believe this approach will be much more effective than an EPR program in changing behaviors around proper storage and disposal. A major component of the success of this program will be whether it is convenient and easy for the patient; nothing is more simple than following the best practices and using an in-home solid waste disposal method.

GPhA is prepared to support and help fund a public education initiative in partnership with other stakeholders and the County. The draft ordinance based on EPR will not work, it is based on a failed approach, and it will increase the costs of prescription and over the counter drugs to County residents. We recommend rejection of the EPR approach and the draft EPR Ordinance.

Thank you,

A handwritten signature in blue ink that reads "Brynna M. Clark". The signature is fluid and cursive, written in a professional style.

Brynna M. Clark, Esq.
Senior Director of State Affairs
Generic Pharmaceutical Association

CC: Supervisor Hilda L. Solis
Supervisor Mark Ridley-Thomas
Supervisor Sheila Kuehl
Supervisor Don Knabe
Supervisor Michael D. Antonovich

⁷ New England Healthcare Institute. 2009. Thinking Outside the Pillbox, and Sokol et al. 2005. Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost. *Med Care* 43(6), 521-530.