CLSA
California Life Sciences Association

November 30, 2015

Pharmaceutical Working Group
c/o Angelo J. Bellomo, REHS, QEP,
Deputy Director for Health Protection
5050 Commerce Drive
Baldwin Park, CA 91706

RE: Opposition to the Los Angeles County Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance

Dear Mr. Bellomo:

On behalf of the California Life Sciences Association (CLSA), I am writing to oppose the Los Angeles County Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance. CLSA is the leading voice for California's life sciences sector and serves over 750 biotechnology, pharmaceutical, medical device, and diagnostics companies, research universities and institutes, investors and service providers. Overall, California's life sciences sector directly employs more than 281,000 people and indirectly employs another 581,000 – totaling nearly one million California-based jobs. In Los Angeles County alone, over 56,000 are directly employed in the sector.

The stated goals of preventing the abuse of prescription medicine and diversion of pharmaceutical waste from the environment are laudable, but there is no science that suggests drug takeback is a better option for disposal versus household trash. Additionally, the ordinance as drafted will be difficult to administer, and places an unprecedented burden on a single industry. Lastly, the program contemplated in the ordinance will not achieve your stated goals.

<u>Pharmaceutical takeback programs do not improve water quality</u>

One of the stated desired outcomes of the ordinance is to reduce the amount of active pharmaceutical ingredients found in waterways. However, there is no evidence that takeback programs achieve that goal, and there is significant evidence that the current practice of household trash disposal is a safe and preferable alternative. Consider the following:

- According to an editorial in the San Francisco Chronicle on January 4, 2011 by former Greenpeace leader Patrick Moore, the trace amounts of active pharmaceutical ingredients ("APIs") are at such low levels that they are measured in parts per trillion, equal to one drop of water in 20 Olympic swimming pools.

San Diego
9191 Towne Centre Drive, Suite 450
San Diego, CA 92122
PH (858) 551-6677
F (858) 551-6688

Sacramento
1201 K Street, Suite 1840
Sacramento, CA 95814
PH (916) 233-3497
F (916) 233-3498

South San Francisco
250 E Grand Ave, Suite 26
South San Francisco, CA 94080
PH (650) 871-3250
F (650) 871-7555

Washington, DC
1350 I Street, NW, Suite 830
Washington, DC 20005
PH (202) 743-7566

- Europe has long had takeback programs for unused medicines, but it has not resulted in any measurable reductions of API in European waterways. These programs were established by article 127b of the European Union Directive 2004/27/EC which requires that, "Member states shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired." Studies in European countries with mandatory take-back programs show that there are no discernible changes in the concentration of pharmaceuticals in surface waters after enactment of pharmaceutical take back programs (Ternes 1998; Wick et al. 2009; Coetsier et al. 2009).
- Proponents of the measure claim that disposal of unused medicines by flushing them down a sink or toilet contribute to the amount of pharmaceuticals in the water, but it is a minor source of pharmaceuticals in the environment compared to patient excretion of medicines. Indeed, the past four annual reports from the British Columbia takeback program state, "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 benefit."[1]
- The pharmaceutical industry among others has studied the environmental fate of unused medications disposed in household trash and sent to landfills. In 2006, Tischler and Kocurek studied the potential for release of 23 APIs to surface waters through disposal in Subtitle D municipal solid waste (MSW) landfills. The potential landfill releases were compared to the releases occurring from patient use and excretion to wastewater treatment systems. Despite several conservative estimates designed to over-predict the occurrence and release of APIs in landfill leachate, the authors found that the average contribution of landfill leachate to the total load of APIs in surface water ranged from 0.21% to 0.78%. In other words, only a fraction of one percent of all APIs discharged to surface waters was estimated to originate from drugs disposed in landfills.
- The proponents have additionally not considered the costs to the environment that this approach would itself entail. Since all collected waste would have to be transported across state lines to one of only two approved incineration facilities for medical waste in the United States (one is in Utah, the other in Louisiana), it is quite likely that the ordinance will negatively impact air quality in a more substantial way than it positively impacts water quality.

---

[1] Health Product Stewardship Association Annual Report, "Annual Report to the Director 2012," p. 11.

Sharps takeback programs pose significant risk and cannot replace consumer education

The ordinance is the first of its kind to add a mandatory sharps take back program. There is a significant risk in having disposal kiosks for used sharps due to potential hazardous material and non-sharps waste being deposited in them. The Board of Pharmacy has also expressed concern about retailers taking back used sharps. There are currently both effective public and private sector solutions available to consumers. Consider the following:

- Patients can already access a list of 616 sites on www.calrecycle.ca.gov to dispose of their used sharps. Many jurisdictions also offer 'at your door' or curbside pickup for sharps as well. LA County and its Cities have successful sharps disposal programs in place that include promotion and consumer education. There are in fact over 100 home-generated sharps consolidation points spread across the County, from Calabasas to Downey, Inglewood, Compton, Los Angeles, Northridge, San Pedro, West Covina, and many others throughout the County.
- Patients using self-injectable therapies at home are educated by their health care providers on how to properly dispose of their used sharps. Materials on safe disposal are also available in packaging inserts that come with their medicines. Some manufacturers currently offer support and training on using and disposing of sharps on their product websites.
- An enhanced consumer education platform would result in a significantly increased understanding of proper sharps disposal for legally obtained prescription medicines. An infrastructure for a program is available through www.calrecycle.ca.gov.
- Education should also provide information on the advances in needle technology that have been developed to help prevent needle sticks. The use of pre-filled pens, needles with a safety sheath and existing manufacturer mail back programs should be recognized as a proactive step in patient safety.
- The ordinance being proposed does not address syringes found on beaches and other collateral damage resulting from illegal drug and needle use. Current needle exchange programs encourage safe disposal within this segment of the population.

Stewardship programs are cumbersome for private entities to implement and manage

The stewardship program proposed in the ordinance bestows the responsibilities of county government upon a private industry, yet withholds granting the industry any authority to compel other parties to participate in the implementation of the program. We are also extremely concerned that the ordinance also mandates or

proposes several scenarios that would force industry to violate local, state, and federal law due to conflicting regulations among the laws at those various levels of government and this ordinance. Specifically:

- Unlike the County of Los Angeles, we do not have the authority to mandate the necessary participation of other private entities in the implementation of the law, such as pharmacies, healthcare providers, law enforcement, patients, and practitioners.
- The ordinance states that private industry could provide incentives to encourage participation in the program by retail pharmacies. This concept of incentivizing pharmacies to encourage their participation ignores prohibitions in federal anti-trust law forbidding companies from collaborating in ways that would affect their respective competitive positions within the marketplace. It additionally ignores anti-kickback statutes that govern what monetary incentives pharmaceutical companies can and cannot provide to pharmacists and retailers.
- As industry has no legislative authority in the County of Los Angeles, should companies need to modify the program contemplated in this ordinance to remain in compliance with applicable state and federal laws, they would have no choice but to petition Los Angeles County for successive amendments to the stewardship plan, or to sue for injunctive relief. Should the County design and implement a stewardship program itself, it should be able to easily modify the program to comply with state and federal law.

Shared responsibility among all parties in the supply chain is conspicuously absent here

While proponents have stated that shared responsibility should be a guiding principle in the design of a takeback program, ultimately the proposed approach institutes the exact opposite of shared responsibility, i.e., it requires that the responsibility should fall solely on biopharmaceutical and sharps manufacturers. Even the surveying of citizens to gauge awareness of the program is left to industry, and the County has no responsibility to show that the program is actually accomplishing the goal of reducing waste and preventing diversion. This is inequitable and, more importantly, unworkable.

- The sale of pharmaceuticals and sharps products in the United States is extremely complicated. It entails manufacturers, wholesalers, doctors, hospitals, nursing facilities, insurance companies, government programs like Medicare and Medicaid, as well as thousands of retail outlets from pharmacies to corner stores and ultimately the patient. Placing the entire burden of waste on the manufacturers ignores this complex supply chain, attempts to regulate this matter without any significant input from and participation by other stakeholders, and will ultimately fail.

- The proposed approach provides retailers with an exemption from participating in the drug takeback program. We have concerns with this exemption. At a minimum, participation by retail pharmacies should be mandatory if Los Angeles County is serious about implementing a program with retail takeback as its central feature. Additionally, various retailers have been levied multimillion dollar fines for illegally dumping expired pharmaceuticals in California[2, 3, 4]; and thus it is not clear why retailers would be exempt.
- In addition, our industry has no legal means to compel retailers to participate, and the legislation explicitly exempts them from any mandatory participation in the program. Recent DEA regulations[5] require any private entity participating in a drug takeback program to register as a collector and keep meticulous records of the transfer of recaptured pharmaceuticals. This makes it unlikely that any for-profit entity would assume the liability and potential for fines that come with hosting a takeback kiosk or takeback event that deliberately or inadvertently accepts controlled substances.

Unlike other disposal programs, this ordinance ignores consumer accountability

The proponents of the ordinance claim that there is broad public support for drug takeback programs, and that even without their extensive lobbying and media campaigns for this policy, the public would still demand takeback programs. Yet, this ordinance is a radical departure from other recycling paradigms in place already and imposes unrecoverable costs on a single industry for its implementation. This is all in an attempt to shield county residents, taxpayers, and even the federal government—which solely oversees the Medicare program and incurs the bulk of Medicaid costs—from the price tag of an unnecessary program.

- California has several recycling programs in place to manage disposal for particularly challenging products. The state has mandatory fees to cover the cost of end-of-life management for cell phones, computers, mattresses, tires, and televisions. Those fees are paid by the consumer and disclosed up front at the point of sale.
- Proponents often point to the paint industry, which recently volunteered to manage their own stewardship program at no cost to consumers. Paint manufacturers, unlike pharmaceutical companies, can adjust the cost of their

---

[2] Rite Aid Fined $12.3 Million in Illegal Dumping of Toxic Waste. October 7, 2013. http://www.omsj.org/ current_issue_media /12070.
[3] Safeway ordered to pay nearly $10 million for illegal dumping in California. January 5, 2015. http://www.sacbee.com/news/business/article5466600.html .
[4] Walgreens must pay $16 million in fines for illegally dumping old drugs. December 13, 2012. http://www.insidebayarea.com/breaking-news/ci_22185751/walgreens-must-pay-16-million-fines-illegally-dumping .
[5] Federal Register, Vol. 79, Issue 174. http://www.gpo.gov/fdsys/granule/FR-2014-09-09/2014-20926

product to recover the costs of taking back unused paint. As the majority of pharmaceutical products are sold to public payers under the Medicare and Medicaid programs, it is impossible for our companies to recuperate the costs of the program mandated here, as those federal programs do not allow for reimbursement of costs related to takeback programs. Paint manufacturers also enjoy direct relationships with the retailers that sell their products, while pharmacies purchase their inventory not from the manufacturers, but companies that specialize in the wholesale trade of pharmaceuticals.

- This ordinance sets a very dangerous precedent since there is zero accountability downstream should the program not produce the results promised by the proponents, as the costs will be hidden from consumers and constituents alike. Los Angeles County is abdicating its public duty to consider the benefits **and** the costs of its policy proposals. Instead, the proposed approach requires that all of the costs be paid by private entities while providing neither demonstration of benefit nor a mechanism to gauge the efficacy of the program once in place.

Sound solutions already exist to educate patients about proper drug disposal

Our member companies recognize that illicit diversion of prescription drugs is a real problem in the United States, and we are happy to work with the proponents to provide education and outreach where appropriate to prevent prescription drugs from falling into the wrong hands. To that end, we have endeavored via several public awareness campaigns to provide education on safeguarding all drugs in the home—not just those that are expired or unwanted—from getting into the wrong hands. We also provide information regarding the appropriate and affordable household disposal options currently available to consumers.

- In response to a growing concern about the improper disposal of unused or expired medications, our industry has funded various outreach and education programs, including Mind Your Meds™, My Old Meds™, and SMARxT DISPOSAL™.
- Mind Your Meds™ and My Old Meds™ both utilize various forms of traditional and new/social media to provide information to consumers and parents about the risks of prescription drug abuse, as well as responsible in-home disposal options when drugs are no longer needed or expired.
- SMARxT DISPOSAL™ is a consumer-focused outreach program designed to educate American consumers about the proper disposal of unused medicines through the current household trash disposal infrastructure. The program recommends that consumers put unwanted medications into a sealable plastic bag, add kitty litter, sawdust, or coffee grounds to the bag (crush any pills in the bag, or add water to dissolve) before placing the sealed bag into the household trash (www.smarxtdisposal.net).

In conclusion, the stated rationale for this ordinance is to protect the water system and the environment, to prevent drugs from being used or sold illegally, and to provide guidance to patients on how to properly dispose of drugs and sharps. Yet, no evidence is available to suggest this program will do anything to prevent abuse or reduce the levels of API in the environment. Additionally, given that drugs and sharps are regulated at the state and federal level, any solutions for end-of-life disposal should be forged at the state and federal levels to ensure uniformity in the guidance that is given to patients regarding handling of drugs and sharps when they are expired or no longer needed. The implementation of various local ordinances will do little more than create a patchwork of inconsistent regulations that will only confuse consumers and forestall conversations at the state and federal level around truly effective and equitable solutions.

For all the reasons stated above, we strongly oppose the Los Angeles County Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance. Please feel free to contact me with any questions or concerns.

Sincerely,

Sara Radcliffe
President & CEO
California Life Sciences Association

cc : Members, County of Los Angeles Board of Supervisors