



**BARBARA FERRER, Ph.D., M.P.H., M.Ed.**  
Director

**JEFFREY D. GUNZENHAUSER, M.D., M.P.H.**  
Interim Health Officer

**CYNTHIA A. HARDING, M.P.H.**  
Chief Deputy Director

313 North Figueroa Street, Room 806  
Los Angeles, California 90012  
TEL (213) 240-8117 • FAX (213) 975-1273

[www.publichealth.lacounty.gov](http://www.publichealth.lacounty.gov)

**BOARD OF SUPERVISORS**

**Hilda L. Solis**  
First District

**Mark Ridley-Thomas**  
Second District

**Sheila Kuehl**  
Third District

**Janice Hahn**  
Fourth District

**Kathryn Barger**  
Fifth District

December 13, 2017

TO: Each Supervisor

FROM: Barbara Ferrer, Ph.D., M.P.H., M.Ed.  
Director *Barbara Ferrer*

SUBJECT: **TECHNICAL EXPERT REVIEW OF PHARMACEUTICAL AND SHARPS COLLECTION AND DISPOSAL STEWARDSHIP POLICY (NOVEMBER 22, 2016 AGENDA, ITEM NO. 22)**

On November 22, 2016, the Board of Supervisors directed the Department of Public Health (DPH), in collaboration with the Department of Public Works (DPW), on behalf of the Extended Producer Responsibility Working Group (EPR Working Group), to consult with technical experts that could review and provide input on the proposed Los Angeles County Pharmaceutical and Sharps Collection and Disposal Stewardship Ordinance (Ordinance). DPH was further directed to issue a written report to your Board summarizing pertinent findings and recommendations, including a discussion of available data that supports the approach of the Ordinance or similar ordinances that have been implemented in other jurisdictions.

Based on your Board's direction, DPH, in collaboration with DPW and on behalf of the EPR Working Group, consulted with qualified researchers and scientists (technical experts), with experience and professional recognition in their respective fields to provide analysis and input on the proposed Ordinance. Their input is intended to assist in decision-making on approaches to reduce the amount of expired and/or unused medications and sharps that are stockpiled and/or disposed of in an unsafe manner.

The following technical experts participated in the review process: (1) Regina LaBelle, Esq., Former Chief of Staff of the Office of National Drug Control Policy; (2) Justin Malan, M.S., California Conference of Directors of Environmental Health/Ecoconsult Company; (3) Angela



Batt, Ph.D., Research Chemist (affiliated with U.S. Environmental Protection Agency); and (4) Keith Maruya, Ph.D., and Alvina Mehinto, Ph.D., Southern California Coastal Water Research Project. A brief biography is provided for each expert in Attachment I.

The technical experts were asked to evaluate the efficacy and evidence associated with issues presented by the proposed Ordinance as they relate to health and water quality. Further, they were instructed to examine the public health and environmental findings referenced in the proposed Ordinance and other data sources, describe the impacts of unused/unwanted pharmaceuticals and sharps on public health and the environment, and opine on whether the proposed Ordinance, which follows an extended producer responsibility (EPR) approach for the collection and disposal of unwanted pharmaceutical drugs and sharps, would meaningfully address these issues.

Methods used by the consultants included review of the May 3, 2016 Board correspondence on this issue, including the proposed Ordinance and public health and environmental findings; review of available data and scientific literature; analysis of the *State Auditor's 2016-2017 Home Generated Sharps and Pharmaceutical Waste Report*; and review of similar ordinances in other jurisdictions with interviews of program managers from existing pharmaceutical and sharps take-back programs. DPH analysts reviewed and evaluated each technical report. Their complete analysis and synthesis of the technical expert reports is found in the Report of Findings, Attachment II. For easy reference, this memo includes the Summary of Key Findings and Recommendations from the Report of Findings. For additional information, a complete copy of each technical expert report is found in Attachment III.

Based on review of similar ordinances from other jurisdictions, the experts made some recommendations for enhancing program monitoring and evaluation, collection site accessibility, and public education and outreach strategies, many of which were already considered by the EPR Working Group. No modifications are being proposed to the Ordinance at this time.

### **Summary of Key Findings and Recommendations from Technical Experts Reports**

The public health impacts of improperly storing and disposing of medicines are well documented. Additionally, many studies report the presence and impacts of pharmaceuticals in the environment. Evidence shows an excess of prescription drugs in consumers' homes. In a recent survey of LA County residents, 59% of respondents reported having medicines that were expired or no longer needed in their homes. Expired and unused medicines in the home can increase the risks of medicine misuse, abuse, poisonings, and overdoses. Drug abuse and initiation of addiction are linked to easy access of medicines kept in homes of family or friends; and surplus drugs have negative impacts on health, crime, and productivity that are measurable as social costs (LaBelle 2017). 70% of those who abuse prescription drugs obtain them from family members or friends, usually for free (National Surveys on Drug Use and Health 2011, 2013). Further, 73% of teens say it is easy to get prescription drugs from parents' medicine cabinets; many teens think prescription medicines are safer than street drugs (Partnership for Drug-Free Kids 2012). In 2015, 87 children in the U.S. died of unintentional opioid intoxication, with thousands more poisoned (Turkewitz 2017); a study of children under the age of six showed 92% of unintentional opioid intoxication cases occurred in the home (Bailey 2009).



Safety impacts from improper disposal of sharps have been documented by California Department of Resources Recycling and Recovery (CalRecycle). Improper disposal of sharps has been found to increase the number of occupational injuries, lost worktime at waste management facilities, and costs to the medical system. Statewide, only 5% of the approximately 936 million needles used by self-injectors are disposed of properly, with the vast majority of home-generated sharps waste either thrown away in trash or recycling bins or flushed down the toilet. This represents a danger for sanitation workers who are responsible for sorting trash, a task frequently done by hand.

The opioid abuse epidemic is a persistent serious public health and safety crisis. Effective substance abuse prevention requires a comprehensive approach to reduce access to the substance and educate the public. Providing secure medicine take-back programs is a key strategy in this comprehensive approach (see Ecoconsult 2017b). EPR laws are effective in addressing the opioid epidemic if: (1) the collection sites are conveniently located and user-friendly; and (2) people are educated about why proper disposal of drugs is important and motivated to clean out their medicine cabinets and drive somewhere to properly dispose of the drugs (LaBelle 2017).

Thousands of scientific studies have reported on the detection of pharmaceuticals in the environment. Additionally, there is a growing concern that municipal drinking water supplies are being contaminated by low levels of a complex mixture of pharmaceuticals. The resulting health risk to humans is likely low; however assessing the environmental impact of pharmaceuticals is complicated and plagued with uncertainties. When this much uncertainty exists, preventing environmental contamination by identifying point sources of contamination pathways is almost always a much more cost effective approach than trying to address problems after they have occurred (Batt, 2017). While more research is needed to create a larger body of evidence to better understand the potentially toxic effects of mixtures and the long-term effect on wildlife, the reduction of the input of pharmaceuticals into receiving waters could prevent or reduce the likelihood of potential impacts. Because one of the obvious pathways of pharmaceuticals into the environment is the disposal of surplus drugs into the sewage system or landfills, drug-take back programs provide a simple solution for reducing the amount of these chemicals that enter the environment at the source (Batt 2017).

Secure medicine take-back is recommended as the most effective medicine disposal method by the U.S. Food and Drug Administration, the Drug Enforcement Administration, and the U.S. Environmental Protection Agency (Ecoconsult 2017a). Despite limited locations and promotion, existing voluntary take-back programs have collected significant amounts of leftover pharmaceuticals and sharps, indicating high levels of consumer demand for safe take-back options (Ecoconsult 2017a). However, a voluntary approach is not sufficient to meet increasing demand, and is costlier to both the County and to the consumer (Ecoconsult 2017a). While Advance Disposal Fees may offer an effective end-of-life management option for certain products, a mandated industry-run stewardship program for collection and disposal of pharmaceuticals is more cost effective, involves less direct government engagement, and provides greater program flexibility (Ecoconsult 2017a).



Requiring manufacturers to manage their products' end-of-life waste through proper disposal has been implemented successfully in other industries, e.g., the paint industry (LaBelle 2017). The services provided by manufacturers under county-level pharmaceutical and sharps ordinances have dramatically increased, with programs now operating in six California counties and two Washington counties. The collection services now available in these counties confirm that well-designed EPR ordinances result in increased drop-off sites at conveniently-located pharmacies (Ecoconsult, 2017b).

Based on review of similar ordinances from other jurisdictions, the experts agreed that the proposed Ordinance was comprehensive and likely to be effective given its similarity to ordinances in other jurisdictions where successful take-back programs have been established. Nonetheless, the experts offered some recommendations to strengthen the proposed Ordinance that included enhancing program monitoring and evaluation, collection site accessibility, and public education and outreach strategies.

The report issued by the California State Auditor in May 2017 found that California consumers do not receive accurate or comprehensive information on how and where to dispose of pharmaceutical or sharps wastes due to a lack of coordination at the state level and provided recommendations to address these issues. However, the experts disagree with many of the recommendations in the State Auditor's Report and found the report too narrow in scope, too short on data, and too limited in analysis of key issues. Instead, one expert proposes that establishing a disposal program at the local agency level in Los Angeles would be area-specific and perhaps more effective than a general, statewide campaign (LaBelle 2017).

In general, experts agreed that more detailed studies would be useful to: (1) quantify the impact of stewardship programs on reducing the amount of drugs that are potentially subject to misuse, abuse, and/or improper disposal; and (2) understand the full scope of ecological effects caused by environmental concentrations of pharmaceuticals.

Overall, the experts concluded that the proposed LA County EPR Ordinance would:

1. Reduce the amount of expired and unused medication and sharps that are currently being stockpiled in homes (Ecoconsult 2017a,b; LaBelle 2017);
2. Reduce the amount of pharmaceuticals that could be misused and even lead to death or hospitalization due to overdose (Ecoconsult 2017a,b; LaBelle 2017);
3. Increase public awareness of hazards associated with pharmaceuticals and sharps used in the home and safe disposal methods through take-back programs (Ecoconsult 2017a,b; LaBelle 2017);
4. Reduce the amount of pharmaceutical and sharps waste entering the environment (Batt 2017; Ecoconsult 2017a,b; SCCWRP 2017); and
5. Reduce the number injuries to waste facility workers and the general public due to improper disposal of sharps (Ecoconsult 2017a,b; LaBelle 2017).

### **Recent Changes to Sheriff's Department Safe Drug Drop-Off Program**

Since 2009, the Sheriff's Department has operated a safe drug drop-off program with self-serve drop off boxes outside 21 Sheriff's stations, allowing residents to safely and anonymously drop-off expired or unused drugs, sharps waste, and controlled substances, 24 hours a day, 7 days a



Each Supervisor  
December 13, 2017  
Page 5

week. Due to challenges with maintaining these bins and the hazards they pose to employees, the Sheriff's Department recently removed drug collection bins from all 21 Sheriff's stations. Instead, effective December 1, 2017, each patrol station will host one drug take-back event per month, which will be supervised by deputy personnel. Existing sharps bins will remain at the Sheriff's stations as these are managed under a contract administered by DPW. At this time, it is unclear how these program changes will affect public usage of the Sheriff's stations as an option to safely and conveniently dispose of unwanted drugs and sharps.

### **Recommendations**

In summary, the experts agreed that the proposed Los Angeles County EPR Ordinance is an intervention that would reduce the impact of pharmaceuticals and sharps waste on public health and the environment, and that it is consistent with existing local stewardship laws that are being successfully implemented in other jurisdictions. It is therefore recommended that your Board consider adoption of Extended Producer Responsibility that takes into account the latest findings and lessons learned from other jurisdictions presented in this report. Such a program would provide residents with safe, convenient, and sustainable disposal options for unwanted pharmaceuticals and sharps thereby protecting public health and reducing the impact of these materials have on the environment.

If you have questions or need additional information, please let me know.

BF:ab

Attachments (3)

c: Chief Executive Officer  
Executive Officer, Board of Supervisors  
County Counsel



## COUNTY OF LOS ANGELES – PHARMA PROJECT

### Status Report – Final Technical Experts

Agency/Group	Experts	Status
Southern California Coastal Water Research Project (SCCWRP)	<p><b>Keith A. Maruya, Ph.D.</b> is a principal scientist with SCCWRP. He received his B.S. in Chemical Engineering and M.S. in Environmental Engineering from the University of Southern California, and Ph.D. in Environmental Engineering Science from U.C. Berkeley. He specializes in the analysis, fate and effects of trace contaminants in aquatic systems.</p> <p><b>Alvina Mehinto, Ph.D.</b> is a molecular toxicologist with SCCWRP. She received her B.S. in marine biology from the University of Portsmouth and Ph.D. in biological sciences from the University of Exeter. She specializes in the environmental impact of natural and man-made contaminants on aquatic organisms especially fish.</p>	Report completed
U.S. Environmental Protection Agency (EPA) Office of Research and Development National Exposure Research Laboratory	<p><b>Angela L. Batt, Ph.D.</b> is a research chemist working in the EPA's National Exposure Research Laboratory. She received her Ph.D. from the University of Buffalo. Her research involves developing analytical methods to determine the occurrence of emerging contaminants in a variety of environmental matrices and has developed methods to analyze over 60 human prescription pharmaceuticals in wastewater and surface water. These methods have applied to several national scale studies to assess the exposure of ecosystems to pharmaceuticals present in wastewater treatment plan discharges.</p>	Report completed
California Conference of Directors of Environmental Health (CCDEH) - Ecoconsult Co.	<p><b>Justin Malan, M.S.</b> is the Executive Director for CCDEH and principal for Ecoconsult, his environmental advocacy and consulting firm. He received his Bachelor's Degree in Law and Administration and a Master's Degree in Environmental Studies from the University of Cape Town, South Africa. He has 30 years of experience in working with local, state and private sectors in resource management, public and environmental health, environmental advocacy, renewable and clean energy development and sustainable development. His team includes a former Secretary to the California Environmental Protection Agency and technical advisors with advanced degrees in Biochemistry, Public Health, and City &amp; Regional Planning.</p>	Report completed
LaBelle Strategies	<p><b>Regina LaBelle, Esq.</b> previously served as Chief of Staff and senior policy advisor at the Office of National Drug Control Policy where she assisted the Director in implementing the Administration's National Drug Control Strategy. She was the co-author and lead of the Administration's prescription drug abuse strategic initiative. She received her B.A. in Political Science from Boston College and her law degree from Georgetown University Law Center. Assisting her are Susan Weinstein, Esq., and Ron Simeone, Ph.D.</p>	Report completed



---

Report of Findings: Technical Expert Reviews of the Proposed Los Angeles County Pharmaceutical and Sharps Collection and Disposal Stewardship Ordinance

---

December 2017

Compiled by:

Department of Public Health

Health Protection - Toxicology and Environmental Assessments Branch

Health Promotion - Substance Abuse Prevention and Control Program



## I. Public Health Findings

### Data and Research

Evidence exists showing an excess of prescription drugs in consumers' homes; in Los Angeles County (LA County), 59% of respondents had medicines in their homes that were expired or no longer needed (LA County Medicines & Sharps Disposal Consumer Survey Results 2016). Leftover and expired medicines in the home can increase risks of medicine misuse, abuse, poisonings, and intentional or unintentional overdoses (Ecoconsult 2017a). Furthermore, public health impacts from improper disposal of prescription drugs and sharps can be devastating, potentially leading to prescription drug addiction, overdose deaths, and needlestick injuries. The amount of evidence directly linking unwanted prescription drugs and sharps waste with public health and safety impacts is limited. However, the available research from consumer surveys, peer-reviewed literature and policy briefings suggests that the proposed LA County Pharmaceutical and Sharps Collection and Disposal Stewardship Ordinance (Ordinance), also referred to as the Extended Producer Responsibility (EPR) Ordinance, would reduce the amount of unwanted prescription drugs and sharps in homes, as well as improve proper disposal, thereby reducing drug misuse and needlestick injuries.

### Public Health and Safety Impacts

Research including surveys of consumers and families, along with peer reviewed scientific literature has found that drug abuse and initiation of addiction are linked to easy access of medicines kept in homes:

- 70% of those who abuse prescription drugs obtain them from family members or friends, usually for free (National Surveys on Drug Use and Health 2011, 2013, as cited by Ecoconsult 2017a).
- 73% of teens say it's easy to get prescription drugs from parents' medicine cabinets; many teens think prescription medicines are safer than street drugs (Partnership for Drug-Free Kids 2012).
- In 2015, 87 children in the U.S. died of unintentional opioid intoxication and with thousands more poisoned (Turkewitz 2017). A study of children under the age of six showed 92% of unintentional opioid intoxication cases occurred in the home (Bailey 2009).
- Among people aged 12 or older, an estimated 18.9 million misused prescription psychotherapeutic drugs in 2015, representing 7.1 percent of the U.S. population (US DHHS 2015).

Safety impacts from improper disposal of sharps have been documented by national studies and the California Department of Resources Recycling and Recovery (CalRecycle), the branch of the California Environmental Protection Agency that oversees the state's waste management, recycling, and waste reduction programs. Improper disposal of sharps or lack of adequate disposal options has been shown to increase the number of occupational injuries and lost worktime, and incurs costs to the medical system. Statewide, only 5% of the approximately 936 million needles used by self-injectors are disposed of properly (Ecoconsult 2017a). The remaining needles are thrown away in trash or recycling bins or flushed down the toilet. This represents a danger for sanitation workers who are responsible for sorting trash, a task that is frequently done by hand. CalRecycle estimates that \$4.6 million is lost every year in California due to accidental needlestick injuries (Ecoconsult 2017a). Nationally, needlestick injuries result in more days of lost work as compared to all other injuries (Leigh et al. 2008).



## Expert Opinion on the Impact of the Proposed Ordinance

The overall policy intent of the proposed LA County EPR Ordinance is consistent with existing local stewardship laws that are being successfully implemented in other counties (LaBelle 2017, Ecoconsult 2017a). With the modifications outlined in its report, Ecoconsult states that the proposed ordinance will:

- Increase public awareness of hazards associated with medicines and sharps used in the home and safe disposal methods through take-back programs.
- Reduce the amount of expired and unused medication and sharps that is currently being stockpiled;
- Reduce the amount of pharmaceuticals that could be misused and even lead to death or hospitalization due to overdose; and
- Reduce the amount of unused/unwanted pharmaceutical and sharps products entering the environment (See Section II for more information);
- Reduce the number injuries to waste facility workers or the general public due to improper disposal of sharps.

LaBelle generally agrees with these positive public health impacts of the LA County EPR Ordinance; however, she identifies the need for more detailed studies to quantify the impact of stewardship programs on reducing the amount of drugs that are in society. In light of available data, experts conclude that stewardship programs can accomplish two key first steps to combat the opioid epidemic: 1) raising awareness about the importance of proper waste disposal, and 2) reducing the amount of unwanted pharmaceuticals and sharps in homes.

## II. Environmental Findings Summary

### Data and Research

Since the landmark survey on the detection of pharmaceuticals and personal care products in U.S. surface waters in 2002 (Kolpin et al. 2002), thousands of scientific studies have reported on the detection of pharmaceutical drugs in the environment. Pharmaceutical drugs have been detected in our waterbodies (i.e. ponds, lakes, rivers, embayments, estuaries, coastal waters, and the ocean; SCCWRP 2017) as well as in landfill leachate according to U.S.G.S. sampling and peer-reviewed research studies. These chemicals in landfill leachate are pumped out of landfills and sent to wastewater treatment facilities, however, pharmaceuticals are not effectively removed or degraded by those facilities and are released into waterways (USEPA 2010; Dougherty et al. 2010). A 2008 Associated Press investigative series found medicines in the drinking water of 24 major metropolitan areas serving 41 million Americans (Donn 2008). In the Los Angeles region, water samples from the Los Angeles, San Gabriel, and Santa Clara river systems showed the presence of 13 pharmaceuticals including acetaminophen, carbamazepine, diazepam, diclofenac, Dilantin, 17 $\alpha$ -ethinylestradiol, fluoxetine, gemfibrozil, ibuprofen, meprobamate, sulfamethoxazole, and trimethoprim (Maruya 2012, 2015; Sengupta et al. 2014; Maruya et al. 2016).

### Environmental Impacts

Although the risks to humans consuming pharmaceuticals at the measured concentrations reported in drinking water and wastewater is very low (Batt 2017), assessing the environmental impact of pharmaceuticals is a complicated issue and it is difficult to assess two key factors:



1. [Effects of complex mixtures:](#)

Complex mixtures of pharmaceuticals can act simultaneously with other bioactive chemicals present in the environment, and the resulting effects are uncertain. (Ecoconsult 2017a; SCCWRP 2017).

2. [Effects of pharmaceutical drugs on aquatic organisms:](#)

Pharmaceuticals have been extensively studied in mammals, and there is considerable information on their dose-response, mode of action, metabolism, and elimination from the human body. That information can be used to estimate risks posed to humans and other parts of the ecosystem, however, exposure and assessing the risks to aquatic organisms, such as fish, invertebrates, etc., is a more complicated issue. Some effect endpoints, such as death, are straight forward to measure, however, different organisms and species can display very different sensitivities to the same chemicals and furthermore, it is more difficult to measure and determine the long-term effects on a community (Batt 2017).

### [Expert Opinion on the Impact of the Proposed Ordinance](#)

According to the experts, secure medicine take-back is recommended as the most effective medicine disposal method by the Food and Drug Administration, the Drug Enforcement Administration, and the U.S. Environmental Protection Administration (Ecoconsult 2017a). Reducing the input of pharmaceuticals into receiving waters, which is one of the goals of the LA County EPR Ordinance, could prevent or reduce the likelihood of potential impacts (SCCWRP 2017). There is still uncertainty in the full scope of ecological effects caused by environmental concentrations of pharmaceuticals and more work is needed to create a larger body of evidence (Batt 2017; Ecoconsult 2017a). Because one of the obvious pathways of pharmaceuticals into the environment is the disposal of surplus drugs into the sewage system or landfills, drug-take back programs do provide a simple solution for reducing the amount of these chemicals that enter the environment at the source (Batt 2017).

### [III. Review of Similar Ordinances](#)

To complement the review of existing scientific data, a policy scan was conducted that focused on challenges, opportunities, and implementation strategies in other jurisdictions to inform the proposed LA County EPR Ordinance.

#### [Effectiveness and Responsiveness](#)

Pharmaceutical and sharps producer programs have been mandated in other counties, states, and abroad. These programs have withstood legal challenge, received broad public support, and have demonstrated success. British Columbia, Canada, and France have well-established drug take-back programs that are provided by manufacturers, per legislative requirements (Ecoconsult 2017b). Some model program examples include:

- In British Columbia, nearly 100% of pharmacies voluntarily participate as collection sites. Increased emphasis on public education by the stewardship program since 2007 has resulted in steadily increasing public awareness and collection amounts.

- In France, all pharmacies participate as collection sites, and in 2014 approximately 0.4 pounds were collected per capita for a total collection amount of more than 26 million pounds of unused medicines.

In the United States, while county-level pharmaceutical stewardship programs are relatively new, the pace of implementation of county EPR laws has increased dramatically during 2017 (Ecoconsult 2017b). MED-Project LLC is a stewardship organization operating take-back programs in six counties in California and two counties in Washington State. Five additional counties that have enacted pharmaceutical EPR ordinances are in the process of reviewing and implementing stewardship plans. Notably, in King County, Washington, Public Health – Seattle & King County enacted its program after reviewing child death data that showed 70% of adolescent deaths were due to drug overdoses, the majority of which involved prescription drugs (King County 2013). Overall, the programs mandated under local stewardship ordinances are achieving expected outcomes, including providing more collection sites, placing collection sites in more convenient locations, and providing enhanced collection services to underserved populations.

Santa Cruz County has the longest-operating sharps collection and disposal program in California and has safely collected and disposed of over 100,000 pounds of sharps over 9 years (Ecoconsult 2017). Overall, accidental needlestick injuries have become infrequent at recycling sorting lines, waste disposal facilities, and wastewater treatment plants. Free, safe, and convenient public sharps disposal has resulted in savings and convenience for residents, as well as safer beaches, parks, and open spaces.

### Implications and Lessons Learned

Existing ordinances and implementation of the related stewardship plans provide insights into barriers and facilitators. Based on their review of existing ordinances, the experts provided the following considerations to optimize the effectiveness of a pharmaceutical and sharps EPR Ordinance, all of which are currently included in the proposed Ordinance:

*Access:* A key aspect of successful programs is to allow any qualified site that volunteers to host receptacles to do so. This results in more participating collection sites, added convenience for consumers, and ultimately a more effective program. Additionally, access through no-cost mailers provide options to homebound residents and others with limited mobility. The goal is to make it as convenient to return unwanted medicines as it is to purchase them (Ecoconsult 2017b).

*Public Awareness:* Successful stewardship programs for other hazardous products demonstrate that convenience, education, and public awareness are essential to equitable and effective program design and implementation. Related assessment measures, as well as “rates and dates” performance metrics, are also key components to successful programs. Ideally, the stewardship program should require that producers promote collection options through clear, standardized signage, public service announcements, advertisements, and a host of other promotional and educational materials (LaBelle 2017). Examples from British Columbia and France show that greater awareness among consumers is closely linked to greater use of collection sites and that centralized data collection supports consistent consumer education efforts (Ecoconsult 2017b).

*Accept Controlled and Uncontrolled Substances:* Accept all prescription and over-the-counter medications, including controlled substances and all sharps and sharps-related products (e.g., epi-pens) (LaBelle 2017).



*Define Eligible Consumers:* Clearly define who can and cannot dispose of medications at the drop-off sites (LaBelle 2017).

*Free Service:* Do not charge consumers a fee for the service (LaBelle 2017).

*Disposal and Safety Methods:* Specify the requirements for collection, handling and disposal of the medications and sharps (LaBelle 2017).

*Local Oversight Fees:* Require that Responsible Stewards pay for the oversight conducted by the Department of Health (LaBelle 2017).

*Monitoring and Reporting:* Require a written, annual report that contains an evaluation and a survey to assess program effectiveness (LaBelle 2017).

### Expert Opinion on the Impact of Similar Ordinances

While similar ordinances in other jurisdictions vary in type, they have similar elements and have been found to be effective in reducing the amount of unwanted drugs and sharps in circulation as long as consumers are properly educated about the programs and the disposal sites are conveniently located (LaBelle 2017). Requiring manufacturers to manage their products' end-of-life waste through proper disposal has been implemented successfully in the United States through the paint industry. Much like the EPR paint laws, a number of EPR ordinances regarding pharmaceutical drugs and sharps have been implemented and are in operation in a handful of jurisdictions in the United States and several throughout the world.

## IV. Review of the State Auditor's 2016-2017 Report

In May 2017, The California State Auditor issued a report entitled "Home-Generated Sharps and Pharmaceutical Waste: By Designating a Lead Agency, the State Could Increase Proper Disposal" The Report was requested by the Joint Legislative Audit Committee of the California State Assembly. It found that California consumers do not receive accurate or comprehensive information on how and where to dispose of pharmaceutical or sharps wastes due to a lack of coordination at the state level. Moreover, the Report found that if one state agency had oversight and played a coordinating role in sharps and pharmaceutical waste disposal, the result would be more accurate and consistent information provided to California consumers.

### Analysis of Strengths of the Auditor's Report

Experts agree that the State Auditor's Report appropriately identified three related conditions that exacerbate the problem of inadequately managed sharps and pharmaceutical waste (Ecoconsult 2017b; LaBelle 2017):

1. Fragmented oversight and inconsistent disposal guidance due to a patchwork of different local programs with variable services;
2. Inadequacy of collection data due to limited resources and no centralized coordination for local programs; and
3. Complexities of federal and state regulation of incineration facilities that restrict access to some types of pharmaceutical waste processing/disposal capacity in California.

The first two conditions could be addressed by the adoption of a producer responsibility program with adequate public education, outreach, and evaluation activities, as proposed by the LA County Ordinance (Ecoconsult 2017b; LaBelle 2017). The third obstacle related to access to incineration facilities, which does not preclude successful operation of medicine take-back programs, would likely require a state legislative remedy, as well as alignment with the EPA's federal regulations on disposal of hazardous waste pharmaceuticals and permitting of disposal facilities (Ecoconsult 2017b).

### *Analysis of Weaknesses of the Auditor's Report*

Experts disagree with a number of the recommendations in the State Auditor's Report. The State Auditor's Report is too narrow in scope, too short on data, too limited in analysis of key issues, and too modest in its recommendations to meaningfully address the public health, public safety, and environmental impacts of unsafely stored, handled, and disposed of home-generated sharps and pharmaceuticals (Ecoconsult 2017b). The findings and recommendations of the report are flawed in five key areas, as described below (Ecoconsult 2017b, LaBelle 2017).

#### *1. Access to Collection Sites:*

The State Auditor's Report concludes that most consumers have reasonable access (within a 20-minute drive) to free collection sites for pharmaceuticals and sharps. However, a 20-minute drive time to a collection site is neither convenient nor an appropriate metric for measuring adequacy of the services needed to address the public health and safety problem (Ecoconsult 2017b). Additionally, although consumers may have reasonable access to free collection sites, the State does not provide reliable information to ensure that consumers are aware of these available collection sites (LaBelle 2017).

#### *2. Public Health and Safety Lens*

One expert noted that the State Auditor's Report's recommendations were weak with little recognition of the public health, safety, and environmental urgency of the issue and inadequate evaluation of pharmaceutical take-back in the context of public health prevention for medicine abuse, poisonings, and overdoses (Ecoconsult 2017b). Notably the auditor's analysis for access to medicine collection sites does not distinguish sites that can accept controlled substances, such as opioids (Ecoconsult 2017b, LaBelle 2017), and does not evaluate sharps take-back in the context of public health prevention for transmission of infectious diseases (Ecoconsult 2017b).

#### *3. Single State Oversight Agency*

The State Auditor's Report found that if one state agency provides oversight, consumers would have more accurate and consistent information regarding pharmaceutical disposal. One expert concluded that this approach is overly simplistic, and overlooks the lack of comprehensive take-back options in all communities, which in turn is the result of the lack of dedicated and sustained funding for these programs (Ecoconsult 2017b). The Report recommends that CalRecycle would be the appropriate oversight agency, but does not address how it would handle managing waste of controlled substances, which have specific disposal requirements and are very different than its current purview (LaBelle 2017).



#### 4. *Cost-Sharing Considerations*

One expert stated that the State Auditor’s Report seems to infer that the Extended Producer Responsibility option is the only option that results in increased costs to consumers, even though little, or no financial analysis, or comparisons of options was offered. All take-back programs pass costs to consumers or taxpayers/ratepayers in one way or another. The Auditor’s Report did not address potential funding mechanisms for its recommendations, glossing over that imposing new requirements on state agencies for oversight and provision of take-back services will ultimately impose costs on consumers (Ecoconsult 2017b).

#### 5. *Policy Analysis of County Policies*

One expert concluded that the State Auditor’s methodology did not include any review of the county-level stewardship law ordinances or their policy requirements. Therefore, the Report failed to recognize that the local ordinances are substantially more similar than they are different. With a lack of state action, counties are taking action to address the public health and safety crisis and serving as model policies. In addition, several of the model programs in other jurisdictions that were recommended by the Auditor’s report are Extended Producer Responsibility programs, but this is not recognized in the Auditor’s analysis (Ecoconsult 2017b).

Finally, the State Auditor’s Report failed to identify the key underlying causes of the inadequate management of pharmaceuticals and sharps wastes in California, where there is a lack of adequate and dedicated resources to support comprehensive take-back systems in all communities (Ecoconsult 2017b).

### Potential Impact of Auditor’s Report

Although, the State Auditor’s Report does not recognize that many of its key recommendations would be addressed by an Extended Producer Responsibility Program (similar to the proposed LA County EPR Ordinance), the proposed LA County EPR Ordinance would accomplish the following recommendations in the State Auditor’s Report (Ecoconsult 2017b):

Key Recommendations in the State Auditor’s Report	Currently addressed in California	Required under proposed LA County EPR Ordinance	Comments
<b><i>Provide consistent messaging to consumers on safe disposal of medicines and sharps</i></b>	No	Yes	Approved stewardship plans would provide uniform messaging county-wide.
<b><i>Single searchable website to provide collection locations</i></b>	No	Yes	See MED-Project website for example of maps and search engine provided by manufacturers.
<b><i>Provide more service to rural areas</i></b>	No	Yes	Prepaid return mailers would be provided by manufacturers.

Key Recommendations in the State Auditor’s Report	Currently addressed in California	Required under proposed LA County EPR Ordinance	Comments
<b><i>Require data collection on proper disposal of pharmaceuticals and sharps</i></b>	No	Yes	Annual reports from manufacturers required on pounds collected, and amount by collection method.

The State Auditor’s Report concluded that inadequately managed sharps and pharmaceutical waste leads to: (1) fragmented oversight and inconsistent disposal guidance; and (2) inadequacy of collection data due to limited resources and no centralized coordination for local problems. These two conditions can be addressed through the adoption of a producer responsibility program by providing more consistent outreach and education, which is consistent with requirements set forth by the LA County EPR Ordinance (Ecoconsult 2017a, LaBelle 2017). In conclusion, establishing a disposal program at the local agency level in Los Angeles would be area-specific and perhaps more effective than a general, statewide campaign (LaBelle 2017).

## V. Technical Expert Recommendations

Effective substance abuse prevention requires a comprehensive approach to reduce access and educate the public; accordingly, providing secure medicine take-back programs is a key strategy in this comprehensive approach (Ecoconsult 2017b). The U.S. Food and Drug Administration, Drug Enforcement Administration, and U.S. Environmental Protection Agency all recommend medicine take-back programs as the most effective methods for disposing of unused medicines (Ecoconsult 2017a). Take-back programs have the potential to reduce the input of pharmaceuticals into waterways (SCCWRP 2017; Batt 2017) and reduce the likelihood of potential impacts (SCCWRP 2017). Additionally, proper disposal through take-back programs is one of the four pillars of the 2011 Prescription Drug Abuse Prevention Plan.

Despite limited locations and promotion, existing voluntary take-back programs have collected significant amounts of leftover pharmaceuticals and sharps, indicating high levels of consumer demand for safe take-back options (Ecoconsult 2017a). However, a voluntary approach is not sufficient to meet increasing demand, and is costlier to both the county and to the consumer (Ecoconsult 2017a). While Advance Disposal Fees may offer an effective end-of-life management option for certain products, a mandated industry-run stewardship program for collection and disposal of pharmaceuticals is more cost effective, involves less direct government engagement, and provides greater program flexibility (Ecoconsult 2017a).

To optimize the effectiveness of a take-back program, the take-back program must have a robust education and outreach strategy to inform residents and healthcare professionals (LaBelle 2017). Through the dedicated funding and coordination of pharmaceutical manufacturers, local stewardship will result in increased collection of leftover and unwanted medicines, which prevents those collected medicines from causing poisonings, addiction, overdoses, or environmental pollution (Ecoconsult 2017a).



## Specific Recommendations to Enhance the Proposed Ordinance

The technical experts recommended the following changes and enhancements be made to strengthen the proposed Ordinance:

*Reevaluate the “Responsible Steward” definition.* The proposed LA County EPR Ordinance exempts repackagers and relabelers of covered drugs from the definition of “responsible stewards.” Such companies in the drug supply chain involved in producing, preparing, processing, repackaging, and relabeling medicines are typically considered to be drug manufacturers. The Federal Food & Drugs Act’s definition of manufacturer and manufacture, includes these companies. Unlike retailers that may have a store label drug product, repackagers and relabelers are solely in the business of pharmaceutical distribution and sales and are “brand owners” with their label on the medicines. One expert advised that it may make compliance and enforcement more straightforward for the County to identify the entities with their brands on the drugs (Ecoconsult 2017a). In contrast, another expert suggests exempting small producers and manufacturers from the definition of “Responsible Steward” (LaBelle 2017).

*Define who are the acceptable users of the program or “covered entities”, “health care community”, and “health care professionals”.* Although it is implied that all residents of LA County may use the collection sites, it would be useful to clarify who is covered by the program. Furthermore, health care community and health care professionals are broad terms that should be defined more specifically when first used in the ordinance (LaBelle 2017).

*Define “compliance”.* Include a paragraph after Subsection B that addresses initial compliance regarding the implementation of the stewardship plan. Define specifically what a Responsible Steward must do to comply with the initial implementation of the program (LaBelle 2017).

*Enhance program monitoring and evaluation.* Require additional monitoring and reporting of collection amounts to provide more timely indicators of whether and how residents are using the program. Quarterly reporting of aggregate amounts or amounts by collection method should be required of the approved stewardship plan(s). Annual reports should summarize amounts by each collection location so that trends in usage of collection sites can be observed and utilized to identify areas where more public education about safe disposal should be targeted (Ecoconsult 2017b). The evaluation could be based on general interviews with participating pharmacists, or specific metrics (e.g. number of needle stick injuries reported by waste management workers; the amount, by weight, of drugs collected and of sharps collected; the types of prescription drugs collected; the number of mail-back envelopes; total costs of the program, etc.), depending on feasibility of various data collection methods (Ecoconsult 2017b, LaBelle 2017). In addition, the frequency of public awareness surveys should be increased to annual and require that manufacturers conduct a baseline survey prior to launch of their program(s) (Ecoconsult 2017b).

*Adjust Timeline.* One expert pointed out that pharmaceutical and sharps manufacturers have organized themselves into a stewardship organization (MED-Project LLC) and are implementing laws similar to the proposed ordinance in a number of local jurisdictions in California and Washington. In the expert’s view, given the manufacturers’ previous experience with the development of stewardship plans, it is reasonable to shorten the timeline for stewardship plan development to six months from the effective date, rather than nine months. The County may extend implementation deadlines for good reason if needed (Ecoconsult 2017a). Another expert advised that the stewardship plan should be submitted in a

shorter amount of time (3 months from effective date instead of 9 months), and the implementation time should be extended (to 9 months from submission of plan instead of 3 months) (LaBelle 2017). In addition, any stewardship plan should work in collaboration with the DEA's semi-annual take-back days (LaBelle 2017).

*Mandate that Manufacturers Must Accept All Qualified Collectors into Program.* Ensure there are as many convenient collection sites for residents as possible by requiring manufacturers to accept all qualified collectors, and clarifying they cannot reject a qualified collector from participating in a Stewardship Plan on the grounds that they have enough collection sites to meet the minimum service convenience goal. In most counties, the pharmaceutical stewardship laws require the stewardship program to include any qualified collector that is a retail pharmacy, hospital/clinic with an on-site pharmacy, or a law enforcement agency. The ordinance could also require that manufacturers include any qualified long-term care facility and/or narcotic treatment program as allowed under the DEA's Rule for Disposal of Controlled Substances (Ecoconsult 2017a).

*Clarify that Manufacturers Must Service Collection Sites Frequently Enough to Avoid Overflow Receptacles.* Pharmacies and other potential collectors who volunteer to host and staff collection receptacles for the manufacturers are responsible for ensuring the collection receptacles do not reach capacity or overflow; however, those collectors are dependent on the stewardship program to service the collection receptacles on a timely schedule. Additional clarification in the proposed ordinance language would aide in defining those responsibilities, and address concerns of potential collectors (Ecoconsult 2017a). Specifically, the County should specify a maximum amount of time that a collection site must be emptied and serviced (e.g. not less than every three to four months to avoid creating hazardous conditions) (LaBelle 2017).

*Disposal Facilities.* Align the disposal facility requirements in Section 11.17.060 with the EPA's recommendation on the most appropriate disposal facilities for collected medicines from residential medicine take-back programs. Current wording largely follows this recommendation, but is unclear about the permit status of cement kilns and it should clarify that these should be limited to cement kilns permitted for disposal of hazardous wastes (Ecoconsult 2017a).

*Program Collection Goals.* Require that manufacturers describe short-term and long-term goals for collection amounts of unwanted pharmaceuticals and sharps in their proposed stewardship plan. Currently, only the proposed frequency of collection from Collection Sites is required in the plan, per Section 11.17.040 of the proposed ordinance. Requiring manufacturers to propose collection goals is consistent with the proposed ordinance's related requirements that the Director may work with each Stewardship Plan to define performance goals, and that each approved stewardship plan must report annually on their goals and efforts to achieve them (Ecoconsult 2017a).

*Clarify Collection Requirements for Any Covered Drugs that May Not Be Suitable for Comingling in Receptacles.* Drug/device combination products that are full or partially full of a covered drug may require special handling and separate disposal, such as inhalers or injectable drug products. These drug products are important to capture for safe disposal. Currently, regulations of the CA Board of Pharmacy do not allow any sharps in medicine collection receptacles, even a retractable or covered sharp attached to a filled drug product; however, the Board of Pharmacy plans to revisit this restriction in the future. A requirement can be added for alternative collection mechanisms for any covered drug products that



might not be suitable for comingling with other covered drugs during collection (Ecoconsult 2017a). Another expert suggests, the ordinance should determine whether collection sites will, or can, accept other medical waste, e.g. epi-pens, inhalers, etc. (LaBelle 2017) as well as fentanyl patches. If collection bins will accept fentanyl patches, they should be listed under “Covered Drugs”, otherwise, they should be listed under “not covered drugs” (LaBelle 2017).

*Require Public Collection Sites for Sharps (e.g. City and County Parks).* In Santa Cruz county, the manufacturers’ MED-Project program is currently reimbursing the county for its costs of operating three public sharps kiosks, and will soon take over direct operations of those kiosks (Ecoconsult 2017b).

*Enhance the Provision of Mail-back Packages for Pharmaceuticals and Sharps.* Requiring manufacturers to provide a supply of mailers upon request to individuals who are providing services to homebound and differentially abled residents. This will allow home health providers, hospice services, and others to help their patients properly dispose of these products via prepaid mailers. In addition to “on request” provision of mailers, the proposed ordinance could require distribution of mailers at convenient community locations such as libraries and fire stations (Ecoconsult 2017b).

*Promotion, Education, and Outreach.* The Stewardship Program should set forth minimum requirements for promotion, education, and outreach, as well as collaborate with dentists, veterinarians, physicians, and other health care prescribers in its education and outreach program. This will ensure a coordinated effort to not only educate everyone on the program but to reduce the amount of potentially harmful substances originally prescribed. Finally, home trash disposal of drugs and sharps should be prohibited, as opposed to discouraged (LaBelle 2017).

## VI. Summary of Key Findings and Recommendations

The public health impacts of improperly storing and disposing of medicines are well documented. As well, many studies report the presence and impacts of pharmaceuticals in the environment. Evidence shows an excess of prescription drugs in consumers’ homes. In a recent survey of LA County residents, 59% of respondents reported having medicines that were expired or no longer needed in their homes. Expired and unused medicines in the home can increase the risks of medicine misuse, abuse, poisonings, and overdoses. Drug abuse and initiation of addiction are linked to easy access of medicines kept in homes of family or friends; and surplus drugs have negative impacts on health, crime, and productivity that are measurable as social costs (LaBelle 2017):

- 70% of those who abuse prescription drugs obtain them from family members or friends, usually for free (National Surveys on Drug Use and Health 2011, 2013, as cited by Ecoconsult 2017a).
- 73% of teens say it is easy to get prescription drugs from parents’ medicine cabinets; many teens think prescription medicines are safer than street drugs (Partnership for Drug-Free Kids 2012).
- In 2015, 87 children in the U.S. died of unintentional opioid intoxication and with thousands more poisoned (Turkewitz 2017). A study of children under the age of six showed 92% of unintentional opioid intoxication cases occurred in the home (Bailey 2009).

Safety impacts from improper disposal of sharps have been documented by California Department of Resources Recycling and Recovery (CalRecycle). Improper disposal of sharps has been found to increase the number of occupational injuries, lost worktime at waste management facilities, and costs to the

medical system. Statewide, only 5% of the approximately 936 million needles used by self-injectors are disposed of properly, with the vast majority of home-generated sharps waste either thrown away in trash or recycling bins or flushed down the toilet. This represents a danger for sanitation workers who are responsible for sorting trash, a task frequently done by hand.

The opioid abuse epidemic is a persistent serious public health and safety crisis. Effective substance abuse prevention requires a comprehensive approach to reduce access to the substance and educate the public. Providing secure medicine take-back programs is a key strategy in this comprehensive approach (see Ecoconsult 2017b). EPR laws are effective in addressing the opioid epidemic if: (1) the collection sites are conveniently located and user-friendly; and (2) people are educated about why proper disposal of drugs is important and motivated to clean out their medicine cabinets and drive somewhere to properly dispose of the drugs (LaBelle 2017).

Thousands of scientific studies have reported on the detection of pharmaceuticals in the environment. Additionally, there is a growing concern that municipal drinking water supplies are being contaminated by low levels of a complex mixture of pharmaceuticals. The resulting health risk to humans is likely low, however assessing the environmental impact of pharmaceuticals is complicated and plagued with uncertainties. When this much uncertainty exists, preventing environmental contamination by identifying point sources of contamination pathways, etc. is almost always a much more cost effective approach than trying to address problems after they have occurred (Batt, 2017). While more research is needed to create a larger body of evidence to better understand the potentially toxic effects of mixtures and the long-term effect on wildlife, the reduction of the input of pharmaceuticals into receiving waters could prevent or reduce the likelihood of potential impacts. Because one of the obvious pathways of pharmaceuticals into the environment is the disposal of surplus drugs into the sewage system or landfills, drug-take back programs do provide a simple solution for reducing the amount of these chemicals that enter the environment at the source (Batt 2017).

Secure medicine take-back is recommended as the most effective medicine disposal method by the U.S. Food and Drug Administration, the Drug Enforcement Administration, and the U.S. Environmental Protection Agency (Ecoconsult 2017a). Despite limited locations and promotion, existing voluntary take-back programs have collected significant amounts of leftover pharmaceuticals and sharps, indicating high levels of consumer demand for safe take-back options (Ecoconsult 2017a). However, a voluntary approach is not sufficient to meet increasing demand, and is costlier to both the County and to the consumer (Ecoconsult 2017a). While Advance Disposal Fees may offer an effective end-of-life management option for certain products, a mandated industry-run stewardship program for collection and disposal of pharmaceuticals is more cost effective, involves less direct government engagement, and provides greater program flexibility (Ecoconsult 2017a).

Requiring manufacturers to manage their products' end-of-life waste through proper disposal has been implemented successfully in other industries, e.g., the paint industry (LaBelle 2017). The services provided by manufacturers under county-level pharmaceutical and sharps ordinances have dramatically increased, with programs now operating in six California counties and two Washington counties. The collection services now available in these counties confirm that well-designed EPR ordinances result in increased drop-off sites, at convenient pharmacy locations. (Ecoconsult, 2017b).

Based on review of similar ordinances from other jurisdictions, the experts agreed that the proposed Ordinance was comprehensive and likely to be effective given its similarity to ordinances in other

jurisdictions where successful take-back programs have been established. Nonetheless, the experts offered some recommendations to strengthen the proposed Ordinance that included enhancing program monitoring and evaluation, collection site accessibility, and public education and outreach strategies.

The report issued by the California State Auditor in May 2017 found that California consumers do not receive accurate or comprehensive information on how and where to dispose of pharmaceutical or sharps wastes due to a lack of coordination at the state level and provided recommendations to address these issues. However, the experts disagree with many of the recommendations in the State Auditor's Report and found the report too narrow in scope, too short on data, and too limited in analysis of key issues. Instead, one expert proposes that establishing a disposal program at the local agency level in Los Angeles would be area-specific and perhaps more effective than a general, statewide campaign (LaBelle 2017).

In general, experts agreed that more detailed studies would be useful to: (1) quantify the impact of stewardship programs on reducing the amount of drugs that are potentially subject to misuse, abuse, and/or improper disposal, and (2) understand the full scope of ecological effects caused by environmental concentrations of pharmaceuticals.

Overall, the experts concluded that the proposed LA County EPR Ordinance would:

1. Reduce the amount of expired and unused medication and sharps that are currently being stockpiled in homes (Ecoconsult 2017a,b; LaBelle 2017);
2. Reduce the amount of pharmaceuticals that could be misused and even lead to death or hospitalization due to overdose (Ecoconsult 2017a,b; LaBelle 2017);
3. Increase public awareness of hazards associated with pharmaceuticals and sharps used in the home and safe disposal methods through take-back programs (Ecoconsult 2017a,b; LaBelle 2017);
4. Reduce the amount of pharmaceutical and sharps waste entering the environment (Batt 2017; Ecoconsult 2017a,b; SCCWRP 2017); and
5. Reduce the number injuries to waste facility workers and the general public due to improper disposal of sharps (Ecoconsult 2017a,b; LaBelle 2017).

In summary, the experts agreed that the proposed LA County EPR Ordinance is an intervention that would reduce the impact of pharmaceuticals and sharps waste on public health and the environment, and that it is consistent with existing local stewardship laws that are being successfully implemented in other jurisdictions.



## VII. References

- Bailey, E. J., Campagna, E. Dart, R. C.R, 2009. The Under Recognized Toll of Prescription Opioid Abuse on Young Children, *Annals of Emergency Medicine*, 53(4):419–424.
- Batt, A. L., 2017. *LA County's Proposed Pharmaceutical and Sharps Takeback Program* (Technical Review).
- CalRecycle, 2015. *Household Hazardous Wastes - Sharps Waste Disposal*. January. Accessible online at: <http://www.calrecycle.ca.gov/HomeHazWaste/Sharps>.
- Donn J, Mendoza M and Pritchard J. 2008. Pharmawater I: Pharmaceuticals found in drinking water, affecting wildlife and maybe humans. Associated Press Investigation. Accessible online at: [http://hosted.ap.org/specials/interactives/pharmawater\\_site/day1\\_01.html](http://hosted.ap.org/specials/interactives/pharmawater_site/day1_01.html).
- Dougherty, J.A., Swarzenski, P.W., Dinicola, R.S., and Reinhard, M. 2010. Occurrence of Herbicides and Pharmaceutical and Personal Care Products in Surface Water and Groundwater around Liberty Bay, Puget Sound, Washington. *J. Environ. Qual.* Vol. 39 No. 4, p. 1173-1180.
- Ecoconsult, 2017a. *Los Angeles County – EPR Ordinance Public Health Policy Technical Analysis*. March, 2017. Sacramento, CA: Ecoconsult in Collaboration with California Conference of Environmental Health.
- Ecoconsult, 2017b. *Los Angeles County – EPR Ordinance California State Auditor Report Analysis*. October, 2017. Sacramento, CA: Ecoconsult.
- King County, 2013. King County Press Release (June 20, 2013). Accessible online at: <http://www.kingcounty.gov/depts/health/board-of-health/regulations/secure-medicine/news-release.aspx>.
- Kolpin, D.W., Furlong, E.T., Meyer, M.T., Thurman, E.M., Zaugg, S.D., Barber, L.B., Buxton, H.T. (2002). Pharmaceuticals, hormones and other organic wastewater contaminants in U.S. streams, 1999-2000: A national reconnaissance. *Environ Sci Technol* 36:1202-1211.
- LaBelle, R. 2017. *A Review of the Proposed Los Angeles County Pharmaceutical and Sharps Collection and Disposal Stewardship Ordinance*. Washington DC: LaBelle Strategies.
- Leigh, J.P., et. al., Characteristics of Persons and Jobs with Needlestick Injuries in a National Data Set, *American J of Infection Control* 36(6):414-420 (August 2008).
- L.A. County Medicines & Sharps Disposal Consumer Survey Results 2016. Published April 8, 2016: <http://publichealth.lacounty.gov/docs/SharpsDisposalSurvey.pdf>
- Maruya, K.A., Vidal-Dorsch, D., Bay, S.M., Kwon, J.W., Xia, K., Armbrust, K.L. 2012. Organic contaminants of emerging concern in sediments and flatfish collected near outfalls discharging treated wastewater effluent to the Southern California Bight. *Environ Toxicol Chem*, 31:2683-2688.
- Maruya, K.A. (2015). Screening study for constituents of emerging concern (CECs) in selected freshwater rivers in the Los Angeles Region – Phase 2. Southern California Coastal Water Research Project. Costa Mesa, CA.

- Maruya KA, Dodder NG, Sengupta A, Smith DJ, Lyons JM, Heil AT, Drewes JE. 2016. Multi-media screening of contaminants of emerging concern (CECs) in coastal urban watersheds in southern California. *Environ Toxicol Chem*. doi: 10.1002/etc3348.
- NSDUH (2011, 2013) National Surveys on Drug Use and Health: Summary of National Findings. As cited in Ecoconsult 2017a.
- Partnership for Drug-Free Kids (2012). Partnership for Drug-Free Kids: 2012 Partnership Attitude Tracking Study, <http://www.drugfree.org/newsroom/pats-2013-full-report-key-findings>
- Sengupta, A., Lyons, J.M., Smith, D.J., Heil, A., Drewes, J.E., Snyder, S. A., Maruya, K.A. 2014. The occurrence and fate of chemicals of emerging concern (CECs) in coastal urban rivers receiving discharge of treated municipal wastewater effluent. *Environ Toxicol Chem*, 33:350-358.
- SCCWRP, Southern California Coastal Water Research Project (2017). Maruya, K. A., Mehinto, A.C. *Pharmaceuticals in the aquatic environment: Occurrence and toxicity*.
- Turkewitz, J., "The Pills are Everywhere: How the Opioid Crisis Claims its Youngest Victims," New York Times, September 20, 2017.
- US DHHS 2015. Prescription Drug Use and Misuse in the United States: Results from the 2015 National Survey on Drug Use and Health, US Department of Health and Human Services, Rockville, MD. Accessible online at: <https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR2-2015/NSDUH-FFR2-2015.pdf> USEPA 2010 Pub. Number 10-03-004: *Control of Toxic Chemicals in Puget Sound Phase 3: Pharmaceuticals and Personal Care Products in Municipal Wastewater and Their Removal by Nutrient Treatment Technologies*. USEPA 2010 Pub. Number 10-03-004. <https://fortress.wa.gov/ecy/publications/documents/1003004.pdf>

**A Review of the Proposed Los Angeles County  
Pharmaceutical and Sharps Collection and  
Disposal Stewardship Ordinance**

By LaBelle Strategies  
Washington, DC



## Executive Summary

Prescription drug misuse and overdose deaths involving prescription opioids are a public health crisis in the United States. Overdose deaths in 2016 topped 60,000, up from 52,000 in 2015, and surpassing deaths due to motor vehicle crashes as the leading cause of unintentional injury deaths. The primary source of prescription opioids for first time misuse by teens and adults is from family and friends, usually from home medicine cabinets.

As many as two-thirds of prescription medications go unused. There is, therefore, a need for a safe, secure, and convenient way to dispose of such medicines. The Drug Enforcement Administration, Office of National Drug Control Policy, Food and Drug Administration, and Environmental Protection Agency all promote medication collection programs as a first choice for disposal, as well as the most secure and environmentally responsible method of drug disposal. Medication collection programs are preferred over discarding medications in the trash or flushing them down the toilet. Similarly, between three and approximately seven and one-half billion needles, syringes, and lancets (sharps) are disposed of in the trash each year across America. A majority of these sharps are improperly discarded in household trash, posing a risk to workers in the sanitation and recycling industries, parks and recreation employees, home health aides, and the general public.

National, on-going medication and sharps take-back programs do not exist for household waste. Therefore, a handful of jurisdictions have created their own programs through product stewardship or extended producer responsibility (EPR) programs. These programs require producers of the hazardous products to pay for the management of the take-back programs as a condition of sale in the jurisdiction.

Los Angeles County mirrors the national scenario, as thousands of people die or end up in emergency rooms due to drug-related overdoses involving prescription or over-the-counter (OTC) drugs. Moreover, many residents who use sharps as part of their home health care usually throw them in the trash, exposing others to injury or potential infection.

In August of 2015, the Los Angeles County Board of Supervisors asked for the creation of a pharmaceutical drug and sharps collection and disposal stewardship ordinance. This ordinance would require manufacturers and producers of prescription and non-prescription drugs and sharps to create and operate take-back programs for the collection and disposal of unused and unwanted drugs and sharps waste. The County Board wanted residents to have access to safe, convenient, and sustainably financed collection and take-back options to properly dispose of unwanted pharmaceuticals and sharps waste.

The purpose of the Los Angeles County Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance (the draft ordinance) is to allow for the safe, convenient, and sustainable collection and disposal of unwanted, covered drugs and unwanted sharps, and protect, maintain, restore, and enhance the environment and its natural resources. It requires the pharmaceutical and sharps industries, with oversight from the Los Angeles County Public Health Department, to design, fund, and operate the program.

The draft ordinance is comprehensive and contains critical elements that: define what covered drugs are included; delineate who has financial responsibility; define the term, “responsible steward;” identify the responsible steward’s responsibilities; and delineate enforcement and penalties for non-compliance.

The amount of research on the potential impact of unwanted pharmaceutical and sharps waste on humans is limited, primarily because the law and subsequent regulation allowing a more comprehensive disposal program for controlled substances was only finalized in 2014. However, the existing data, surveys, and articles that are available demonstrate the devastating impact of unwanted pharmaceuticals and sharps waste on public health. The toll that accidental ingestion of medications takes on children across America is devastating and poorly documented and includes emergency room visits and mortality. Similarly, sharps discarded in household trash, pose a risk to numerous types of workers including those in the sanitation and recycling industries and home health care, subjecting workers to potentially life-threatening infections (*e.g.*, HIV, hepatitis, or tetanus). Exposure to toxic substances and diseases from contaminated sharps continue to be a health risk, and there is a lack of safe and convenient ways to dispose of them. One sharps expert, citing a 2005 literature review, stated that the occurrence of needle sticks is rare when a sharps disposal program exists.

Education about, and exposure to, pharmaceutical and/or sharps disposal programs doubles the probability that a consumer will participate in such a program. Furthermore, people may be more willing to participate in a program if it is conveniently located and does not force them to go out of their way. Any participation, involving events or continuous, on-going disposal processes, results in a reduction in surplus. Surplus drugs have health, crime, and productivity consequences that are measurable as social costs.

EPR laws requiring manufacturers to manage their products’ end-of-life waste have been implemented successfully throughout the United States. One of the most successful programs is that of the paint industry. Much like the EPR paint laws, a number of EPR ordinances regarding pharmaceutical drugs and sharps have been implemented and are in operation in a handful of jurisdictions in the United States and several throughout the world, including European countries South America, and Mexico. The longest existing, and greatest number of, product stewardship programs are in Canada. Of all of the Canadian programs, the British Columbia Medications Return Program is the oldest, in operation since 1996. Pharmaceutical companies, many of which supply drugs to consumers in the United States, fund the Canadian programs from its collection and disposal systems to education and promotion about the programs. Pharmacy participation is voluntary, and 94 percent participate in the program.

Because there is no coordinated, ongoing, national take-back program in the United States, some counties have adopted pharmaceutical stewardship ordinances, requiring the pharmaceutical industry to operate drug (and in one county, sharps) disposal programs for residents. A number of programs exist, and several more are in development. The Alameda County (CA) Safe Drug Disposal Ordinance created the first manufacturer-funded pharmaceutical take-back program in America and is reviewed in this report. Other programs reviewed in this report include: the King County (WA) Secure Medicine Return Program; the San Francisco City and County (CA) Safe

Drug Disposal Program; the Santa Cruz County (CA) Safe Disposal of Drugs and Sharps Program; and the Snohomish County (WA) Secure Medical Return Program.

Based on the small amount of information available from international programs, the five programs reviewed, and interviews with program administrators, it can be concluded that pharmaceutical and sharps disposal programs result in better public health protections. Many users of drugs and sharps are not aware that flushing unwanted drugs down a toilet or disposing of drugs and/or sharps in the household trash is not advisable due to public health and environmental concerns. When a disposal program is available, and once residents are better informed, consumers are then more apt to properly dispose of such waste. The reviewed programs are effective in allowing for the safe, convenient, and sustainable collection and disposal of unwanted prescription and OTC drugs and unwanted sharps.

In May 2017, The California State Auditor issued a report entitled “Home-Generated Sharps and Pharmaceutical Waste: By Designating a Lead Agency, the State Could Increase Proper Disposal.” The report found that California consumers do not receive accurate or comprehensive information on how and where to dispose of pharmaceutical or sharps waste due to a lack of coordination at the state level. It also recommended that one state agency should provide oversight and play a coordinating role in sharps and pharmaceutical waste disposal. This recommendation was made because of the belief that this would provide more accurate and consistent information to California consumers. This report reviews the auditor’s findings, identifies the strengths and weaknesses of those findings, and reviews the impact the findings would have on the Los Angeles County draft ordinance.

Based on general information on EPR programs, a review of existing research, a sampling of a handful of existing stewardship programs, and interviews with experts in the field of drug take-back, the Los Angeles County draft ordinance appears to be an appropriate and reasonable way to reduce the impact of pharmaceuticals and sharps waste on public health. (Please note that this paper is limited to a review of the public health aspects of the proposed ordinance.) An official at the Drug Enforcement Administration stated that educating the community on the importance of getting prescription drugs out of the house alone would make a stewardship program worthwhile. A drug take-back expert from a large not-for-profit stated that EPR laws are effective in addressing the opioid epidemic if the collection sites are conveniently located and user-friendly and people are educated about why proper disposal of drugs are important. Both stressed the importance of education and outreach for any stewardship program. Lack of information about programs is the main reason why individuals do not use collection sites. Additionally, effective education campaigns must coincide with thorough collection strategies.

Limited information on waste disposal programs suggest that pharmaceutical disposal programs increase collection and proper disposal of unwanted prescription drugs and are a useful strategy in reducing illicit drug use and unintentional poisonings. Bin-based drug and sharps collection is more cost-effective than mail-back programs or one-day events. Furthermore, the cost of operating a program is minimal to producers and manufacturers, amounting to just pennies per container of prescription or OTC medicine sold.



As long as the Los Angeles stewardship program produces and promotes an effective education and outreach strategy to inform residents and health care professionals about the program, the county can reasonably expect to decrease: (1) the number of unwanted pharmaceuticals and sharps entering society; (2) the amount of unwanted and unused medications and sharps being stockpiled in homes; (3) the number of pharmaceuticals that may be misused, abused, or diverted and lead to death or hospitalization because of an overdose; and (4) the number of injuries to waste facility workers and the public because of improper sharps disposal.

LaBelle Strategies makes eight recommendations for the Los Angeles County draft ordinance: (1) define the acceptable users of the program or “covered entities; (2) define health care community or health care professionals; (3) list fentanyl patches in the list of “Covered Drugs” if they will be accepted at the disposal site; (4) revise the allotted time for the stewardship plan’s submission and implementation; (5) provide a maximum amount of time within which a collection site must be emptied and serviced; (6) require an annual or biennial evaluation of the program’s effectiveness; (7) define “compliance;” and (8) the stewardship program should collaborate with dentists, veterinarians, physicians, and other health care prescribers in its education and outreach efforts.

Other considerations for the draft ordinance include: (1) exempting small producers and manufacturers from the definition of “Responsible Steward;” (2) determining if collection sites will, or can, accept other medical waste; (3) set forth minimum requirements for promotion, education and outreach of the program; (4) prohibit, rather than discourage, home trash disposal of drugs and sharps; and (5) ensure that the stewardship plan works in collaboration with the Drug Enforcement Administration’s scheduled Take-Back Days.

Based on the experience of, and surveys conducted in, other jurisdictions, there is a strong likelihood of the public using the disposal options proposed in the draft ordinance.

## I. Overview

### A. General Background

According to the Centers for Disease Control and Prevention (CDC), prescription drug misuse and abuse, particularly involving opioids, is a public health crisis in the United States.<sup>1</sup> Drug overdose rates are rapidly on the rise, surpassing deaths due to motor vehicle crashes as the leading cause of unintentional injury deaths.<sup>2</sup> A majority of teens and adults report obtaining opioid drugs for non-medical use from the medicine cabinets of friends and family, and in 2012, 15.3 million people used prescription drugs for a non-medical reason.<sup>3</sup> This home-based source of medications used for non-medical purposes is particularly pronounced for those who are first beginning to misuse prescription drugs. Improperly sharing and disposing of unused medications contributes to diversion and illegal possession and to poisonings by unintentional consumption by children, vulnerable adults, and animals.

In 2010, Congress passed the Secure and Responsible Drug Disposal Act of 2010,<sup>4</sup> allowing consumers to return unused pharmaceutical, controlled substances in a safe, secure, and convenient manner that decreases the supply of drugs, therefore preventing their misuse, abuse, diversion, and poisonings. The U.S. Drug Enforcement Administration (DEA), in its September 9, 2014 final rule,<sup>5</sup> established regulations related to the “transfer, delivery, collection, destruction, return, and recall” of controlled substances, expanding the options for collection of controlled substances to include permanent drop boxes at, among other places, retail pharmacies and law enforcement agencies; mail-back programs; and take-back events operated by law enforcement.<sup>6</sup>

A 2015 study found that up to two-thirds of prescription medications went unused, concluding that a safe, secure, and convenient place to dispose of such medications is crucial to a comprehensive drug strategy that increases public safety.<sup>7</sup> In addition to the DEA, the Office of National Drug Control Policy (ONDCP), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA) all promote medication collection programs over discarding medications in the trash or flushing them down the toilet as the most secure and environmentally safe method of drug disposal. Flushing harms our waterways, and disposing of

---

<sup>1</sup> Drug Overdose Deaths in the United States Continue to Increase in 2015, Centers for Disease Control and Prevention, Atlanta, GA, Found at: <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

<sup>2</sup> The Facts Hurt: A State-By-State Injury Prevention Policy Report, *Trust for America's Health*, Washington, D.C (2015), Found at: <http://healthyamericans.org/reports/injuryprevention15/>.

<sup>3</sup> 2013 National Survey on Drug Use and Health, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, Rockville, MD, Found at: <https://nsduhweb.rti.org/respweb/homepage.cfm>.

<sup>4</sup> Secure and Responsible Drug Disposal Act of 2010, P.L. 111-273 (October 12, 2010).

<sup>5</sup> Disposal of Controlled Substances, Final Rule, Drug Enforcement Administration, U.S. Department of Justice, Washington, D.C., 79 Fed. Reg. 174 (September 9, 2014).

<sup>6</sup> *Id.*

<sup>7</sup> Law, Anandi V., et. al., Taking Stock of Medication Wastage: Unused Medications in U.S. Households, *Research in Social and Administrative Pharmacy*, 11:571-578 (2015), Found at: <http://calpsc.org/mobius/cpsc-content/uploads/2015/08/Study-Taking-Stock-of-Medication-Wastage-Unused-Medicines-in-US-Households-2015.pdf>.

drugs in the trash, even if mixed with undesirable products like coffee grounds or kitty litter, does not deter individuals from retrieving the substances and misusing or diverting them.

It is estimated that between three and seven and one-half billion needles, syringes, and lancets (sharps) are disposed of in the trash each year across America.<sup>8</sup> A majority of these sharps are improperly discarded in household trash, posing a risk to workers in the sanitation and recycling industries, parks and recreation employees, home health aides, and the general public.

There are no national, on-going medication and sharps take-back programs. Therefore, a handful of jurisdictions have created their own disposal programs through product stewardship or extended producer responsibility (EPR) programs. These programs require producers of the hazardous products to pay for the management of the disposal programs as a condition of sale in the jurisdiction. In addition to cost shifting, the programs require stakeholders to collaborate with one another and assume clearly defined goals.<sup>9</sup>

## B. Los Angeles County

In Los Angeles County, thousands of people die drug-related deaths each year. Sixty-one percent of those deaths involve prescription or over-the-counter (OTC) drugs, and nearly 75 percent who misuse prescription drugs get them from friends and relatives.<sup>10</sup>

A 2016 Los Angeles County survey revealed that 59 percent of the over 1,000 residents who responded had expired or unwanted medicines in their homes.<sup>11</sup> Forty-five percent of those surveyed do not know where to dispose of unused and unwanted drugs.<sup>12</sup> Similarly, since there is no regulation for sharps, residents usually throw them in the trash, exposing sanitation and recycling workers and others to injury or infection. A recent CalRecycle survey found that 35 percent of residents did not know how or where to properly dispose of sharps.<sup>13</sup>

In August of 2015, the Los Angeles County Board of Supervisors asked that a pharmaceutical drug and sharps collection and disposal stewardship ordinance be created that requires manufacturers and producers of prescription and non-prescription drugs and sharps to create and operate take-back programs to collect and dispose of unused and unwanted drugs and sharps waste. The County Board wanted county residents to have access to “safe, convenient, and sustainably financed collection and take-back options for properly disposing unwanted

---

<sup>8</sup> Gold, Kathleen, Analysis: The Impact of Needle, Syringe, and Lancet Disposal on the Community, *J Diabetes Sci Technol*, 5(4):848–850 (July 2011); and Community Options for Safe Needle Disposal, U.S. Environmental Protection Agency, Washington, D.C., October 2004, Found at: [https://www.epa.gov/sites/production/files/2016-02/documents/med-govt\\_0.pdf](https://www.epa.gov/sites/production/files/2016-02/documents/med-govt_0.pdf). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3192588/>.

<sup>9</sup> Protecting our Health and the Environment: The Need for Sustainably Financed Drug Take-Back Programs, Briefing Document by the Product Stewardship Institute for the University of Wisconsin Extension (July 27, 2012).

<sup>10</sup> Pharmaceutical Take-back: A Dosage for Change, Message from Interim Health Officer of Los Angeles County, Jeffrey Gunzenhauser, MD, <http://www.publichealth.lacounty.gov/pharma.htm>.

<sup>11</sup> *Id.*

<sup>12</sup> LA County Medicines and Sharps Disposal and Consumer Survey Results, LA County Department of Health, April 8, 2016, <http://publichealth.lacounty.gov/docs/SharpsDisposalSurvey.pdf>.

<sup>13</sup> Graphs of Responses to the Sharps Personal Use Survey on Sharps Use and Disposal, <http://www.calrecycle.ca.gov/homehazwaste/sharps/Survey/PersonalRslt.pdf>.



pharmaceuticals and sharps waste.”<sup>14</sup> It identified the two program goals: (1) to promote EPR principles that include: (a) ensuring the proper collection and disposal of waste, including potentially harmful products; (b) creating shared logistical and financial responsibility for such a program; (c) establishing no-cost convenience for the public; and (d) providing effective outreach and education of such programs; and (2) ensuring that all program elements are consistent with the Secure and Responsible Drug Disposal Act of 2010<sup>15</sup> and other applicable laws and regulations. The Board also created a Technical Advisory Group (TAG) to engage in constructive dialogue about the ordinance and provide information about other EPR programs currently in existence.<sup>16</sup> The TAG, comprised of a number of stakeholders, drafted an ordinance and fellow working group members commented and made changes, resulting in the current draft ordinance.

## II. Los Angeles County Ordinance

As stated in the draft Los Angeles County Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance (the draft ordinance), the purpose of the stewardship program is to: (1) allow for the safe, convenient, and sustainable collection and disposal of unwanted, covered drugs and unwanted sharps; and (2) protect, maintain, restore, and/or enhance the environment and its natural resources.<sup>17</sup> It requires that the program be designed, operated, and funded by the pharmaceutical and sharps industries, with oversight from the Los Angeles County Public Health Department.

The draft ordinance is comprehensive. The following table contains an overview of its critical elements.

Policy Component	LA County Draft Ordinance – Key Elements
Covered Drugs (medicines accepted for return)	<ul style="list-style-type: none"> <li>• Prescription and non-prescription drugs</li> <li>• Includes injectables and controlled substances</li> <li>• Offered for sale to, or otherwise distributed for use by, one or more consumers in the County</li> </ul>
Financial responsibility	<p>Each Responsible Steward (a manufacturer of a covered drug or sharp), group of Responsible Stewards, or Stewardship Organization that participates in a stewardship plan must</p> <ul style="list-style-type: none"> <li>• Develop and implement its stewardship plan at its own cost</li> <li>• Pay the Department of Public Health’s fees for the performance and review of its oversight functions</li> </ul> <p>No fees may be charged to the consumers</p>
Responsibilities of Responsible Stewards	<p><b>Timing</b> - Within six months of the effective date of the ordinance or six months after the covered drug or sharp is first sold to, offered for sale to, or otherwise distributed for use by, one or more consumers in the County, the Responsible Steward must</p> <ul style="list-style-type: none"> <li>• Notify the Department Director of its intent to operate or participate in a stewardship plan</li> </ul>

<sup>14</sup> Los Angeles County EPR Pharmaceuticals and Sharps Ordinance: Objective, Program Goals, and TAG Purpose, (October 22, 2015), Found at: <http://publichealth.lacounty.gov/docs/EPRSharpOrdinance.pdf>.

<sup>15</sup> Secure and Responsible Drug Disposal Act of 2010.

<sup>16</sup> Los Angeles County EPR, Objective, Program Goals, and TAG Purpose.

<sup>17</sup> This report only addresses the public health and safety aspects of the ordinance and does not address its environmental impact.

- Notify the Department Director, in writing, of the official contact for the stewardship plan and
- Submit an annual report to the Department Director that must include several items such as
  - the amount, by weight, of Covered Drugs and Sharps collected from each collection method used
  - the number of mailers and sharps containers provided to county residents and the method and location of distribution
  - the dates and locations of collection events held and
  - a summary of the stewardship plan's goals, the degree of success in meeting those goals in the past year, and, if any goals have not been met, what effort will be made to achieve the goals in the coming year

Within nine months of the effective date, submit to the Department Director for review a proposed stewardship plan for each Covered Drug and type of sharps it manufactures

Within three months of the Department Director's approval of the stewardship plan, the plan must be implemented

At least three years after the start of the stewardship plan, the Responsible Steward must submit to the Department Director an updated stewardship plan explaining any changes to it

**Collection** - Provide ongoing, reasonably convenient, and equitable access for all County residents in the service area

- In each unincorporated community and participating city, each stewardship plan must provide
  - at least one collection site for unwanted Covered Drugs and at least one for unwanted sharps
  - at least one additional collection site for unwanted Covered Drugs and
  - at least one additional site for unwanted sharps for every 30,000 County residents
- If such requirements cannot be met, the Responsible Steward must set forth the reason and provide monthly collection events and/or distribute mailers in those areas
- Ensure safe and secure handling and disposal of the unwanted Covered Drugs and sharps
- Have a mechanism for distributing free, FDA-compliant sharps containers to consumers/residents and Hosts with sharps collection sites
- Engage in good faith negotiations with potential authorized collectors who have an interest in serving as a Host
- Provide free mailers and mail-back services to residents in the service area via its toll-free number and website

All collection sites must

- Accept all Covered Drugs and sharps
- Be accessible to city residents
- Be emptied to avoid creating hazardous conditions
- Utilize secure collection receptacles and
- Prominently display a 24-hour toll-free number and website

Commercial and institutional entities, like hospitals and pharmacies, must be responsible for their own collection and disposal of drugs and sharps

**Disposal** – All Covered Drugs must be disposed of by combustion at a permitted hazardous waste incinerator (or one that meets EPA standards and ensures all materials are non-retrievable as defined by the DEA) or cement kiln

All sharps must be disposed of in accordance with current California legislation

	<p>Alternate disposal techniques may be used if they provide superior protections at a lower cost</p> <p><b><u>Reporting and Evaluation</u></b> – Within six months after the end of the first 12-month period of operation and annually thereafter, each Responsible Steward, group of Responsible Stewards, and Stewardship Organizations must submit a report to the Department Director that must include 12 items, to include</p> <ul style="list-style-type: none"> <li>• A list of the Responsible Stewards in the stewardship plan</li> <li>• The weight of unwanted, Covered Drugs collected each month</li> <li>• The number of unwanted sharps containers provided to County residents</li> <li>• Any safety or security issues that arose and</li> <li>• How the collected packaging was recycled</li> </ul> <p>The Department Director may work with each Responsible Steward, group of Responsible Stewards, and Stewardship Organizations to define the goals and evaluation performance of the stewardship plan</p> <p>Every two years, each Responsible Steward, group of Responsible Stewards, and Stewardship Organizations must conduct a survey of residents, pharmacists, veterinarians, retailers and health professionals who interact with patients on the use of drugs and sharps.</p> <p>The survey must be done by a person or entity with no financial interest and must include questions designed to assess</p> <ul style="list-style-type: none"> <li>• Awareness of the stewardship program</li> <li>• To what extent the collection sites and methods are safe, convenient, easy to use, and utilized by residents and</li> <li>• Knowledge and attitudes about abuse, poisoning, and overdoses from prescription and OTC medications in the home</li> </ul> <p><b><u>Promotion and Outreach</u></b> – Each Responsible Steward, group of Responsible Stewards, and Stewardship Organizations must</p> <ul style="list-style-type: none"> <li>• Promote collection sites that support safe storage of drugs and sharps</li> <li>• Describe where and how to return unwanted Covered Drugs and unwanted sharps under the stewardship plan</li> <li>• Expressly discourage stockpiling of drugs and sharps</li> <li>• Expressly discourage disposal of drugs and sharps in the trash or down the toilet</li> <li>• Distribute material to the health care community for dissemination to residents</li> <li>• Work with Hosts to develop clear, standard instructions, signage, and promotional materials for residents concerning collection receptacles</li> <li>• Establish a 24-hour toll-free number and website for information regarding collection options</li> <li>• Conduct a yearly survey of residents and the health care community regarding the effectiveness of the stewardship plan, awareness of the collection sites, and the dangers of drugs and sharps in the home and</li> <li>• Ensure that all materials regarding the stewardship plan is in English, Spanish, and other languages as determined by the Department</li> </ul>
Enforcement and Penalties	<p>The Department Director will determine if any Responsible Steward, group of Responsible Stewards, or Stewardship Organizations has violated the ordinance and if so, issues a violation notice</p> <p>The violator has 30 days after the date of the written notice to correct the violations, and if compliance is not achieved within that time period, the Director may impose administrative fines</p> <p>The County Counsel, District Attorney, and any City Attorney may bring a civil suit against the Responsible Steward group of Responsible Stewards, or Stewardship Organizations</p>

	<p>Knowingly and willfully violating the ordinance (or rule or regulation regarding it) is a misdemeanor and subject to a fine of between \$50-\$100 per day, per violation or imprisonment not great than six months, or both</p> <p>Anyone violating the ordinance (or rule or regulation regarding it) is liable to the County not to exceed \$1,000 per day, per violation</p> <p>The Department Director and a court may use their discretion in assessing punishment.</p>
Noteworthy omissions	<p>The draft ordinance does not</p> <ul style="list-style-type: none"> <li>• Define “covered entities.” While implied as all county residents who return unwanted or unused drugs and used sharps, there is no specific definition of who are the legitimate users of the program</li> <li>• Require, in the annual report, an evaluation of the effectiveness of the plan but rather a summary of the plan’s goals and the degree of success. This cannot be achieved without an evaluation or formal assessment</li> </ul>

*“Unused prescription drugs thrown in the trash can be retrieved and abused or illegally sold.” DEA*

### **III. Existing Extended Producer Responsibility Ordinances**

#### **A. Research on the Potential Impact of Unwanted Pharmaceutical and Sharps Waste on Humans**

##### **1. Overview**

The amount of research on the potential impact of unwanted pharmaceutical and sharps waste on humans is limited, primarily because the law and subsequent regulation allowing a more comprehensive disposal program for controlled substances was only finalized in 2014. However, the existing data, surveys, and articles that are available demonstrate the devastating impact of unwanted pharmaceuticals and sharps’ waste on public health. The toll that accidental ingestion of medications takes on children across America is devastating and poorly documented and includes emergency room visits and mortality.

In 2015 alone, 87 children died of unintentional opioid intoxication, with thousands more poisoned.<sup>18</sup> Forty-three percent of children hospitalized after an accidental poisoning ended up in intensive care.<sup>19</sup>

One 2009 study looked at children, under the age of six, in a three-year period, who ingested buprenorphine, fentanyl, hydrocodone, hydromorphone, methadone, morphine and oxycodone. In those three years, nearly 10,000 children had accidentally ingested a prescription opioid.<sup>20</sup> Ninety-nine percent of the exposures involved ingestion, and 92 percent occurred in the home.<sup>21</sup> Because of these alarming statistics, the American College of Emergency Physicians sponsored

<sup>18</sup> Turkewitz, J., “The Pills are Everywhere: How the Opioid Crisis Claims its Youngest Victims,” *New York Times*, September 20, 2017; and Dart, R., et. al., The Underrecognized Toll of Prescription Opioid Abuse on Young Children, *Annals of Emergency Medicine*, 53(4):419–424 (April 2009).

<sup>19</sup> Protecting our Health and the Environment: The Need for Sustainably Financed Drug Take-Back Programs, Product Stewardship Institute.

<sup>20</sup> Dart, The Underrecognized Toll of Prescription Opioid Abuse on Young Children.

<sup>21</sup> *Id.*



the American Medicine Chest Challenge, a program that attempts to educate the public on the safe storage and disposal of unwanted prescription drugs. A recent *New York Times* article stated, “Increasingly, parents and the police are encountering toddlers and young children unconscious or dead after consuming an adult’s opioids.”<sup>22</sup> The FDA warns that even medication in a child-resistant container cannot prevent a child from accidentally ingesting the medicine. In one study, 45 percent of child poisonings involved medicines that were stored in child resistant containers.<sup>23</sup>

There has been an increasing recognition of, and concerns raised about, accidental exposure to fentanyl. An FDA pharmacist stated that “Even after a patch is used, a lot of the medicine remains in the patch, so you don’t want to throw something in the trash that contains a powerful and potentially dangerous narcotic . . . .”<sup>24</sup> One recent, multi-state study found that fentanyl had the highest waste rate in its sample.<sup>25</sup> Exposure to fentanyl can cause breathing problems that lead to death in babies, children, pets, and adults (*e.g.*, sanitation workers). It is important, therefore, that mechanisms to dispose of fentanyl be safe and readily available. Without readily available disposal, fentanyl patches are at risk for diversion, illicit use, and accidental poisoning. Programs in Canada address the disposal of patches, and the EPR program in British Columbia distributes a guide on proper disposal. (*See* Appendix B for a copy of the guide.) The FDA recognizes the lethality of fentanyl patches and issued updated guidance in 2013 on proper disposal of fentanyl.<sup>26</sup> This guidance predates the finalization of the DEA rules on disposal.

Sharps discarded in household trash, pose a risk to numerous types of workers including those in the sanitation and recycling industries and home health care. The Bureau of Labor Statistics has identified waste collection as one of the most dangerous jobs in America. Needle sticks subject workers to injuries and potentially life-threatening infections (*e.g.*, HIV, hepatitis, or tetanus). Accidental injury from a sharp can subject an individual to months of medical testing for infection and health-related concerns.<sup>27</sup> A 2008 study found that throughout the nation, 25 percent, or between 150,000 to 200,000, of needle sticks annually occurred outside of the health services industry, at a cost of \$38 million.<sup>28</sup>

---

<sup>22</sup> Turkewitz, *The Pills are Everywhere: How the Opioid Crisis Claims its Youngest Victims*.

<sup>23</sup> How Big of a Problem is Accidental Exposure to Medicine in the United States? U.S. Food and Drug Administration, Washington, D.C., Found at: <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186188.htm#3>.

<sup>24</sup> How to Dispose of Unused Medicines, U.S. Food and Drug Administration, Washington, D.C., Found at: <https://www.fda.gov/forconsumers/consumerupdates/ucm101653.htm>.

<sup>25</sup> Jaramillo-Stametz, J.E., et. al., Multi-state Medication Take Back Initiative: Controlled Substances from 2011-2015, *J of Substance Abuse* (August 2017).

<sup>26</sup> Fentanyl Patch Can Be Deadly to Children, U.S. Food and Drug Administration, Washington, D.C., Found at: <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm>.

<sup>27</sup> Quann, P., “Sanitation Workers Stuck by Loose Needles,” *Bucks County Courier Times*, September 2, 2014; and *see* Nagle, R., *Picking Up: On the Streets and Behind Trucks with the Sanitation Workers of New York City*, Macmillan Press, 2013.

<sup>28</sup> Leigh, J.P., et. al., Characteristics of Persons and Jobs with Needlestick Injuries in a National Data Set, *American J of Infection Control* 36(6):414-420 (August 2008).

Seven percent of needle sticks result in 31 or more days of lost work as compared to 20 percent for all other injuries.<sup>29</sup> As a matter of fact, waste facility workers are injured at a rate of 80 injuries per 100 collectors.<sup>30</sup> Wearing gloves does not protect workers, as even small sharps can penetrate the material. Even those sharps that have been disposed of in a sharps container in the trash are not safe, as these and other plastic containers can burst open when compressed in a garbage truck.<sup>31</sup>

A publication from the National Institute for Occupational Safety and Health noted that home health aides, who are responsible for the use and disposal of sharps in the home, may not have access to appropriate or adequate disposal facilities, putting the health aide and family members at risk for needle stick injuries.<sup>32</sup> Federal Occupational Safety and Health Administration bloodborne pathogens standards also apply to proper collection of syringes.<sup>33</sup>

A California Department of Resources Recycling and Recovery (CalRecycle) survey indicated that 31 percent of respondents identified not knowing where to take their sharps as a barrier to proper disposal.<sup>34</sup> Of those who tried to dispose of them at pharmacies, 47 percent of them were turned away. Moreover, a majority of respondents felt that the most effective way to inform sharps users about proper disposal was to provide them with a brochure at the purchase point.<sup>35</sup>

One sharps expert found that the occurrence of needle sticks is “rare in communities that have introduced sharps disposal programs.”<sup>36</sup>

---

<sup>29</sup> *Id.*

<sup>30</sup> Lederer, C., To the Point: The Risk Home Sharps Disposal Poses to Waste Workers, *Waste 360* (2011).

<sup>31</sup> *Id.*

<sup>32</sup> “Occupational Hazards in Home Health Care,” U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health, Rockville, MD, Publication Number 2010-125 (2010).

<sup>33</sup> Occupational Safety and Health Standards, 56 Fed. Reg. † 2 64004 (2001).

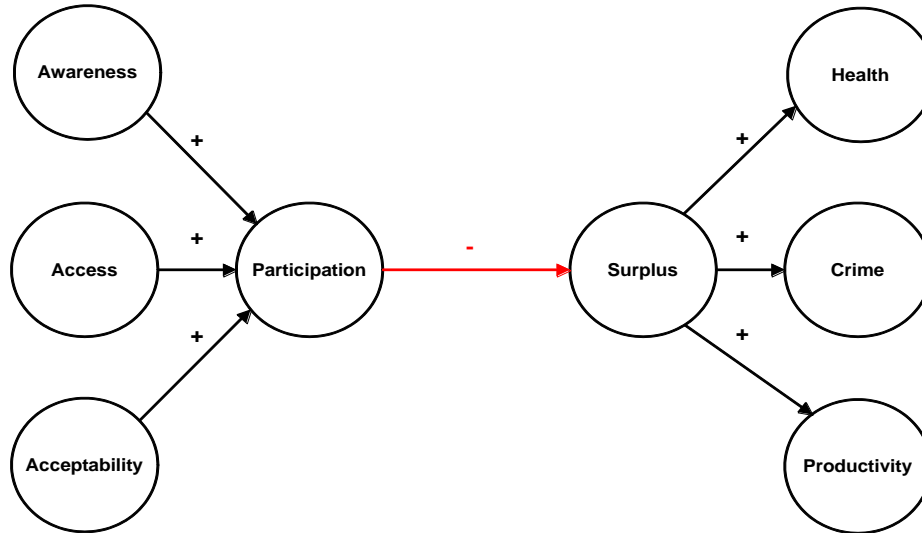
<sup>34</sup> Graphs of Responses to the Sharps Personal Use Survey on Sharps Use and Disposal.

<sup>35</sup> *Id.*

<sup>36</sup> Lederer, To the Point: The Risk Home Sharps Disposal Poses to Waste Workers.

## 2. Data Findings

### The Logic of Prescription Take-back Programs<sup>37</sup>



The meaning of “awareness” is self-evident; people must know that an event will occur, or that a continuous process exists, in order to participate. For example, the American Medicine Chest Challenge is intended to increase awareness regarding the dangers of nonmedical prescription drug use, among other things. Its impact was evaluated in New Jersey, where telephone surveys were conducted in order to estimate the effect of awareness on participation.<sup>38</sup> Exposure to media content describing the program doubles the probability of participation. Research on take-back events conducted in Hawaii indicates that most individuals who returned drugs heard about take-back events via newspaper and television ads.<sup>39</sup>

Access pertains to things like proximity (which is measurable indirectly by the number of events or sites in operation). Research conducted on take-back events held in six states over the period 2011-2015 demonstrates that the number of events is positively associated with the quantity of drugs that are returned.<sup>40</sup>

Acceptability pertains to venue - people may be more willing to participate in a program if it is located in a medical, rather than a law enforcement, setting. There is a body of recent research

---

<sup>37</sup> This illustrates the logic associated with prescription take-back programs: Awareness, access, and acceptability increase the probability of program participation; participation decreases the probability of surplus; and surplus increases the probability of adverse health consequences, criminal activity, and lost productivity.

<sup>38</sup> Yanovitzky I., The American Medicine Chest Challenge: Evaluation of a Drug Take-back and Disposal Campaign, *J Stud Alcohol Drugs*, 77:549-555 (2016).

<sup>39</sup> Ma C, et. al., Take back in Hawaii: Partnership between the University of Hawaii Hilo College of Pharmacy and the Narcotics Enforcement Division, *Hawaii J Med Public Health*, 73(1):26-31 (January 2014).

<sup>40</sup> Jaramillo-Stametz J.E., Multi-state Medication Take Back Initiative: Controlled Substances Collected from 2011 to 2015.

indicating that any participation, involving events or continuous processes, results in some reduction in surplus.<sup>41</sup>

One study conducted in Ohio reported that in the absence of take-back events, approximately 50 percent of participants would have kept their drugs or flushed them down the toilet.<sup>42</sup> The majority of medication returned are not controlled substances (with the balance that are controlled, constituting approximately two percent in Kentucky,<sup>43</sup> five percent in Tennessee,<sup>44</sup> and 10 percent in Hawaii,<sup>45</sup> Ohio,<sup>46</sup> and Maine).<sup>47</sup> When quantities prescribed are compared to quantities returned, and where the prescription is the unit of analysis, average “waste rates” of approximately 60 percent are reported for controlled substances.<sup>48</sup> However, these waste rates cannot be interpreted as estimates of surplus that exist in the population because they are *conditional upon the return of a prescription*. And any program effect must be measured by the proportion of all dispensed drugs that are removed from the population as a result of participation. There is only one recently published study that reports on an analysis of this kind and examines both events and continuous processes. Based on data collected in Kentucky, it suggests that continuous processes may be more effective than events.<sup>49</sup> The effects are small in either case – about .30 percent when combined – but so are the number of events and sites involved. This confirms the role of access as a determinant of participation, and ultimately, surplus.

Other findings from Kentucky indicate that a relatively long period of time may elapse between when a prescription is dispensed and when it is returned (approximately 60 months on average for prescription opioids).<sup>50</sup> This means that it may be more appropriate to estimate the rate of removal for a given period of time by first estimating the *accumulated* quantity of drugs that exists in the population during the same period time (this is the denominator). Moreover, since a large body of literature exists on opioid equianalgesia, it would be ideal to express the rate of removal in terms of morphine-equivalence when dealing with this class of drugs.<sup>51</sup>

---

<sup>41</sup> *Id.*; and *see*, Fleming E., et. al., North Carolina's Operation Medicine Drop: Results from one of the Nation's Largest Drug Disposal Programs. *NC Med J*, 77(1):59-62 (January 2016); Gray J., et. al., Prescription Disposal Practices: a 2-year Ecological Study of Drug Drop Box Donations in Appalachia, *Am J Public Health*. 105(9):e89-e94 (September 2015); and *see* other sources in Bibliography in Appendix.

<sup>42</sup> Perry L., et. al., Quantification of Ongoing Community-based Medication Take-back Program, *J Am Pharm Assoc*, 54:275-279 (May/June 2014).

<sup>43</sup> Egan K., et. al., From Dispensed to Disposed: Evaluating the Effectiveness of Disposal Programs Through a Comparison with Prescription Drug Monitoring Program Data, *Am J Drug Alcohol Abuse*, 43(1):69-77 (2017).

<sup>44</sup> Gray, Prescription Disposal Practices: a 2-year Ecological Study of Drug Drop Box Donations in Appalachia.

<sup>45</sup> Ma, Take back in Hawaii: Partnership between the University of Hawaii Hilo College of Pharmacy and the Narcotics Enforcement Division.

<sup>46</sup> Perry, Quantification of Ongoing Community-based Medication Take-back Program.

<sup>47</sup> Stewart H., Inside Maine's Medicine Cabinet: Findings from the Drug Enforcement Administration's Medication Take-back Events, *Am J Public Health*, 105(1):e65-e71 (2015).

<sup>48</sup> Jaramillo-Stametz, Multi-state Medication Take Back Initiative: Controlled Substances Collected from 2011 to 2015.

<sup>49</sup> Egan, From Dispensed to Disposed: Evaluating the Effectiveness of Disposal Programs Through a Comparison with Prescription Drug Monitoring Program Data.

<sup>50</sup> Gray, Prescription Disposal Practices: a 2-year Ecological Study of Drug Drop Box Donations in Appalachia.

<sup>51</sup> Anderson, R., et. al., Accuracy in Equianalgesic Dosing: Conversation Dilemmas, *J Pain Symptom Management*, 21(5):397-406 (May 2001); and Beaver, W.T., et. al., Analgesic Studies of Codeine and Oxycodone in Patients with



If the primary objective of take-back programs is to reduce surplus, then its role should be assessed relative to other initiatives intended to achieve the same end. Prescription drug monitoring programs (PDMPs), for example, demonstrably reduce the availability of prescription opioids (as measured by morphine-equivalent milligrams per capita) which in turn reduces the per capita rate of drug treatment admissions attributable to drugs in this class.<sup>52</sup> It is also possible—although speculative at this point—that these same programs have had a negative effect on drug seeking behavior (a mechanism of diversion that contributes to surplus).<sup>53</sup> Viewed in this way, the evaluation issue becomes one of assessing marginal utility.

Surplus drugs have health, crime, and productivity consequences that are measurable as social costs.<sup>54</sup>

Research on the effectiveness of a comprehensive disposal program for sharps waste is limited. A May 2012 article in *The American Journal of Infection Control*, found that implementation of sharps disposal programs, combined with use of safety-engineered sharps devices, reduced sharps disposal-related injuries by 53 percent.<sup>55</sup> Another study raised concerns about improper disposal among patients with diabetes in India and the potential for infection with blood-borne diseases due to improper disposal.<sup>56</sup> A third study concluded, from examining the number of community acquired needle stick injuries from 2001-2008, that the costs of a community-based sharps disposal program was not justified by the costs of emergency department-related visits due to needle sticks.<sup>57</sup>

However, due to the risks inherent in needle stick injury, the number of sharps generated in household waste each year, and how common improper disposal of sharps is, providing easy access to proper sharps disposal appears to be a basic public health precaution. California state law prohibits the disposal of sharps in household trash or recycling containers.<sup>58</sup> To address concerns about sharps in household waste, some jurisdictions in California and across the nation have established household sharps disposal programs. For example, the city of San Bernadino, California noted an increase in sharps in household waste after local hospitals stopped accepting

---

Cancer II: Comparisons of Intramuscular Oxycodone with Intramuscular Morphine and Codeine, *J Pharmacol Exp Ther*, 207(1):101-108 (October 1978); and see other sources in Bibliography in Appendix.

<sup>52</sup> Simeone R., *An Evaluation of Prescription Drug Monitoring Programs*, U.S. Department of Justice, Washington, D.C. (2006), NCJ217269.

<sup>53</sup> Inciardi, J.A., et. al., Mechanisms of Prescription Drug Diversion Among Drug-involved Club and Street-based Populations, *Pain Med*, 8(2):171-183 (March 2007); Rigg, K.K., et. al., Prescription Drug Abuse & Diversion: Role of the Pain Clinic, *J Drug Issues*, 40(3):681-702 (March 2010); and see other sources in Bibliography in Appendix.

<sup>54</sup> Simeone R., *The Economic Impact of Illicit Drug Use on American Society*, U.S. Department of Justice, Washington, D.C. (2011), Q0317-002.

<sup>55</sup> Perry, J., et. al., Disposal of Sharps Medical Waste in the United States: Impact of Recommendations and Regulations, 1987-2007, *Am J of Infect Control*, 40:4, 354-358 (May 2012).

<sup>56</sup> Majumdar, Anindo, et. al., Improper Sharp Disposal Practices Among Diabetes Patients in Home Care Settings: Need for Concern? *Indian J of Endo and Metab*, 19(3):420-425 (May-June 2015).

<sup>57</sup> It is important to note that the source of funding for this study was Becton Dickinson Medical Diabetes Care, manufacturers and providers of safety needles and syringes.

<sup>58</sup> Cal. Health and Safety Code Div. 104, Pt 14, Ch 9 § 118286.

used sharps.<sup>59</sup> Therefore, San Bernardino instituted a program of more accessible household collection and disposal to address the issue.<sup>60</sup>

Ongoing drug disposal programs and EPR ordinances have been implemented in various jurisdictions to reduce prescription drugs that can be a source of misuse in the home. These programs also play a key role in decreasing the environmental impact of improper drug disposal.<sup>61</sup> The U.S. Geological Survey sampled American waterways for the first time in 1999-2000 and found significant concentrations of chemicals, including pharmaceuticals in these waterways, particularly pronounced in areas downstream from urban and agricultural areas.<sup>62</sup> Environmental concerns in waterways and leaching from landfills due to concentrations of medications have been documented.<sup>63</sup> In addition, the [World Health Organization](#) recommended implementation of proper disposal programs in an effort to reduce pharmaceuticals in drinking water.

Proper drug disposal has taken on added importance with the increasing rates of opioid prescribing in the U.S, as prescribing rates quadrupled between 1999 and 2014.<sup>64</sup> Therefore, providing for proper, and ongoing, disposal of these prescription drugs, as well as OTC medications, is reasonably expected to result in better environmental outcomes. An article exploring the environmental implications of drug disposal programs in the U.S. cited the need for comprehensive programs, especially in light of increased amounts of pharmaceutical waste in the environment.<sup>65</sup> According to the Canadian EPR Report, Prince Edward Island, Canada, which has an established EPR program for various products, including pharmaceuticals, leads Canada in waste diversion.<sup>66</sup> This demonstrates that EPR programs that include pharmaceutical disposal, are part of a broad-based system and can be reasonably expected to result in better environmental protection.

## B. Successes and Challenges with Existing Extended Producer Responsibility Ordinances

EPR laws requiring manufacturers to manage their products' end-of-life waste have been implemented successfully throughout the United States. One of the most successful programs is that of the paint industry, where EPR laws have been found to be “an effective solution for providing consumers with a responsible and convenient way to dispose of unused paint, while

---

<sup>59</sup> Community Options for Safe Needle Disposal, EPA.

<sup>60</sup> City of San Bernardino, California, Medical Sharps Recycling, Found at: [https://www.ci.san-bernardino.ca.us/cityhall/publicworks/integrated\\_waste\\_management\\_division/environmental\\_projects/recycling\\_programs/residential\\_recycling/medical\\_sharps\\_recycling.asp](https://www.ci.san-bernardino.ca.us/cityhall/publicworks/integrated_waste_management_division/environmental_projects/recycling_programs/residential_recycling/medical_sharps_recycling.asp)

<sup>61</sup> Glassmeyer, S.T., et. al, Disposal Practices for Unwanted Residential Medications in the United States, *Environment International*, 35:566-572 (December 2008).

<sup>62</sup> Kolpin, D.W., et. al., Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance, *Environ Sci Technol*, 36:1202-1211 (2002).

<sup>63</sup> Becker, J., Minding the Gap: Research Priorities to Address Pharmaceuticals in the Environment, *Health Care Research Collaborative* (February 2010).

<sup>64</sup> Prescribing Data, Centers for Disease Control and Prevention, Atlanta, GA, Found at: <https://www.cdc.gov/drugoverdose/data/prescribing.html>.

<sup>65</sup> Lubick, N., Drugs in the Environment: Do Pharmaceutical Take-Back Programs Make a Difference? *Environ Health Perspect*, 118(5):A210–A214 (May 2010).

<sup>66</sup> Extended Producer Responsibility (EPR) Summary Report, *EPR Canada* (September 2017), Found at: <http://www.eprcanada.ca/reports/2016/EPR-Report-Card-2016.pdf>.

reducing the financial burden on local government” and is supported by the American Coatings Association which represents American paint manufacturers.<sup>67</sup> Under paint EPR laws, an industry-run not-for-profit organization named PaintCare is responsible for all of the costs associated with managing leftover latex and oil-based paint, including transportation, recycling, and processing. PaintCare establishes retail collection sites in each jurisdiction that has an EPR law and ensures that the sites are convenient for consumers.<sup>68</sup>

Much like the EPR paint laws, a number of EPR ordinances regarding medicines and sharps have been implemented and are in operation in a handful of jurisdictions in the United States and several throughout the world.

### 1. International Programs

Take-back programs have been operating successfully in various European countries (*e.g.*, France and Spain), in South America (*e.g.*, Brazil and Columbia), and in Mexico. However, the longest existing and greatest number of product stewardship programs exist in Canada. Of all the Canadian programs, the British Columbia Medications Return Program (BCMRP) is the longest-running, having been in operation since 1996.<sup>69</sup> Administered by the Health Products Stewardship Association (HPSA),<sup>70</sup> the program collects prescription drugs, including fentanyl patches, over-the-counter drugs, and natural health products. It does not collect sharps.

Pharmaceutical companies, many of which supply drugs to consumers in the United States, fund the BCMRP. Pharmacy participation is voluntary, and 94 percent (over 1,000) participate in the program. The most recent annual program costs, from 2011, were \$516,000, equaling approximately \$3.40 per pound collected. These costs are shared by the prescription and non-prescription drug health product industries. With increased consumer awareness of the program, the amount of the pharmaceutical waste collected increases. The HPSA measures the success of the program in two ways: (1) consumer knowledge and awareness about the BCMRP; and (2) consumer behavior and usage. By its own measures, the program is effective. The executive director<sup>71</sup> of the HPSA said that one regulation governs all of the programs in Canada, providing uniformity in the way that the programs operate, which assists the funders in knowing what the costs of each program will be. She said that the key to any successful program is that collection sites must be accessible for residents. HPSA conducts telephone surveys biennially, and the latest indicates that usage of a program increases as awareness increases. The required annual reports from each program are compared to those of the previous year to assess awareness, accessibility, and amounts, in weight, of waste collected. The comparisons inform the following year’s education and outreach efforts. Two of the Canadian EPR programs have recently added sharps collection to their programs, and epi-pens are included for disposal.

---

<sup>67</sup> Paint, The Product Stewardship Institute, Found at: [http://www.productstewardship.us/?page=PSI\\_and\\_Paint](http://www.productstewardship.us/?page=PSI_and_Paint).

<sup>68</sup> *Id.*

<sup>69</sup> British Columbia, Canada, International Pharmaceutical EPR Program Fact Sheet, Found at: [http://calpsc.org/mobius/cpsc-content/uploads/2015/02/BC\\_Fact\\_Sheet\\_2\\_9\\_15.pdf](http://calpsc.org/mobius/cpsc-content/uploads/2015/02/BC_Fact_Sheet_2_9_15.pdf).

<sup>70</sup> The Health Products Stewardship Association is a not-for-profit association that is operated by the health products industry.

<sup>71</sup> Telephone interview with Ginette Vanasse, Executive Director, Health Products Steward Association, Ottawa, Ontario, Canada, October 19, 2017.

## 2. National Programs

There are numerous take-back programs in the United States. Because there is no coordinated, ongoing, national take-back program, some counties have adopted pharmaceutical stewardship ordinances, requiring the pharmaceutical industry to operate drug (and in one county, sharps) disposal programs for residents. There are a number of programs in existence, with several more in development. The first program in the United States was in Alameda County, California. A pharmaceutical trade association attempted to challenge the ordinance, but the challenge was rejected by the Ninth Circuit Court of Appeals. LaBelle Strategies selected the following five EPR ordinances to examine in order to conduct a thorough review of, and comparison to, the Los Angeles draft ordinance.

### i. Alameda County, California

Based on EPR programs abroad, the Alameda County Safe Drug Disposal Ordinance created the first manufacturer-funded pharmaceutical take-back program in America. Continuously reviewing and revising the ordinance, as it is now, the stewardship program is managed and funded by Med-Project, a conglomerate of more than 400 pharmaceutical manufacturers.

The Alameda County ordinance accepts prescription and OTC drugs. However, not all locations accept controlled substances. Thirty of the 49 collection sites in the county accept them.<sup>72</sup> In addition, highlights of the ordinance<sup>73</sup> include:

- A definition of those who can and cannot dispose of medications at the drop-off sites, identifying them as “Residential Generators;”
- No consumer fee for the service – drug manufacturers must pay for all administrative and operational costs;
- Specific requirements for collection, handling, and disposal of the medications;
- A requirement that the producers pay for the oversight that the Alameda County Department of Environmental Health conducts of the program;
- A requirement that producers promote the product stewardship program through education and outreach by:
  - Developing and updating educational and other outreach materials that include:
    - Prominently displayed signage;
    - Written materials and templates for reproduction by retailers;
    - Advertising and other promotional material;
  - Publicizing the location and operation of collection locations in the county;
  - Disseminating educational materials to interested parties;
  - Establishing a toll-free number and website
- A requirement of a written, annual report that includes:
  - The amount, by weight, of all returned medications;
  - An evaluation of the success of the outreach efforts; and
  - Overall program activities.

---

<sup>72</sup> Alameda County Website, Found at: <http://www.acgov.org/aceh/safedisposal/>.

<sup>73</sup> Alameda County Safe Drug Disposal Ordinance, Title 6, Alameda County Health and Safety Code, (July 24, 2012, amended February 2, 2016).

The program does not specify where and how the collection sites should be located. The only requirement is that the sites be “reasonably convenient” to the public and allows a mail-back system to be used.

In early 2017, a sharps stewardship plan was submitted to the Department of Environmental Health, and it is under review.

## ii. King County, Washington

After the King County Department of Health reviewed child death data which showed that seven out of 10 deaths of children between the ages of 10-17 were due to drug overdoses, 86 percent of which involved prescription drugs,<sup>74</sup> it enacted the Secure Medicine Return Regulation.<sup>75</sup> Funded by Med-Project, the goal of the program is to protect public health and the environment by, among other things, reducing the amount of medications available for misuse.<sup>76</sup>

The King County program accepts all prescription and OTC medications, including controlled substances. In addition, highlights of the regulation include:

- A definition of those who can and cannot dispose of medications at the drop-off sites, identifying them as “Covered Entities;”
- No consumer fee for the service – drug manufacturers must pay for all administrative and operational costs;
- A requirement that the collection sites be convenient and equitably distributed in every city, town, or unincorporated community service area, with at least one drop-off site for every 30 thousand residents. If this convenience goal cannot be achieved, then the areas must be served by periodic collection events and mail-back services;
- Specific requirements for collection, handling, and disposal of the medications;
- A requirement that producers promote collection options by:
  - Developing clear, standardized, and recognizable signage;
  - Developing and disseminating educational materials; and
  - Establishing a toll-free number and website;
- A requirement that the producers pay for the oversight that the King County Department of Public Health conducts of the program;
- A requirement of a written, annual report that includes:
  - An annual evaluation of:
    - Outreach activities; and
    - The program;
  - A survey, every four years, of residents, pharmacists, and health care professionals in the county regarding program awareness and site convenience.

---

<sup>74</sup> King County Press Release (June 20, 2013), Found at: <http://www.kingcounty.gov/depts/health/board-of-health/regulations/secure-medicine/news-release.aspx>.

<sup>75</sup> King Secure Medicine Return Regulation, Board of Health Rule and Regulation, Title 11 (July 2013), Found at: [https://kingcountysecuremedicinereturn.files.wordpress.com/2013/11/bohcodetitle\\_section1150.pdf](https://kingcountysecuremedicinereturn.files.wordpress.com/2013/11/bohcodetitle_section1150.pdf).

<sup>76</sup> King County Website, Found at: <https://kingcountysecuremedicinereturn.org/>.



### iii. San Francisco City and County, California

In 2012, San Francisco City and County launched a pilot Safe Drug Disposal Program which ultimately tested whether residents would separate their unwanted medicines and drop them off at a pharmacy that was willing to collect the drugs.<sup>77</sup> Simultaneously, in 2011, the San Francisco Board of Supervisors passed the Safe Drug Disposal Stewardship Ordinance.<sup>78</sup> Amended in 2015, the ordinance implemented an EPR model that continues to be in operation.

The San Francisco ordinance covers prescription and OTC drugs, including controlled substances. In addition, highlights of the ordinance include:

- No consumer fee for the service – drug manufacturers must pay for all administrative and operational costs;
- A requirement that the collection sites be convenient and equitably distributed to all residents. It must provide at least five collection sites in every Supervisorial District, and there must be one drop-off site within every city-owned pharmacy. If this convenience goal cannot be achieved, then the areas must be served by periodic collection events and mail-back services in English, Spanish, Chinese, Russian, and Tagalog;
- Specific requirements for collection, handling, and disposal of the medications;
- A requirement that producers promote to residents;
  - Educational materials about the program; and
  - Safe storage of medicines in the home;
- A requirement that the producers pay for the oversight that the San Francisco Department of the Environment conducts of the program;
- A requirement of a written, annual report that includes:
  - The amount, by weight, of all returned medications, from each method used;
  - The number of mailers provided;
  - The dates and locations of collection events;
  - A summary of the plan's goals and successes; and
  - A biennial survey of residents and health care providers to measure program outreach and effectiveness.

### iv. Santa Cruz County, California

Based on a pharmaceutical pilot program that the Santa Cruz County Department of Public Works had been operating, in late 2015, its Safe Disposal of Drugs Ordinance passed. Approximately eight months later, in mid-2016, it added sharps disposal to the ordinance.<sup>79</sup> The

---

<sup>77</sup> San Francisco Website, Found at: <https://sfenvironment.org/safe-medicine-disposal>.

<sup>78</sup> San Francisco Safe Drug Disposal Stewardship Ordinance (2012, amended 2015), Found at: <http://www.sfbos.org/ftp/uploadedfiles/bdsupvrs/ordinances15/o0031-15.pdf>.

<sup>79</sup> Santa Cruz Website, Found at: <http://www.cityofsantacruz.com/government/city-departments/public-works/resource-recovery-garbage-recycling-sweeping/hazardous-waste/pharmaceuticals-and-sharps-disposal-program>.

renamed Santa Cruz County Safe Disposal of Drugs and Sharps Ordinance<sup>80</sup> is one of the few existing local ordinances that addresses sharps disposal in addition to drug disposal.

The Santa Cruz ordinance covers prescription and OTC drugs, including controlled substances and sharps which it defines as “hypodermic needles, pen needles, intravenous needles, lancets, and other devices used to penetrate the skin . . . .” In addition, highlights of the ordinance include:

- A mandate that all producers and retailers whose covered drug or sharps are sold or distributed in the county must participate. However, if a retailer does not sell or provide sharps, it is not required to collect them. Similarly, if a retailer does not sell or provide drugs, it is not required to collect them;
- A definition of those who can and cannot dispose of medications at the drop-off sites, identifying them as “Consumer Generators;”
- No consumer fee for the service – drug manufacturers must pay for all administrative and operational costs;
- A general requirement that the drugs and sharps be safely and securely tracked once dropped off, and provides specific information in the requirement about disposal;
  - Sharps must be destroyed by “high heat sterilization;” and
  - Drugs must be destroyed by “incineration” at a medical or hazardous waste facility;

In either case, if other methods are superior and more cost-effective, a producer may petition to use that method;

- A requirement that the program be promoted to consumer generators, health care professionals, and retailers through;
  - Easily visible signs and permanently displayed signage;
  - Written materials about the program and about location and operation; and
  - A toll-free number and website;
- A requirement that the producers pay for the oversight that the Santa Cruz County Department of Public Works conducts of the program;
- A requirement of a written, annual report that includes:
  - The amount, by type and weight, of all returned medications and sharps;
  - The names and locations of all disposal facilities;
  - The degree of success in meeting the program goals; and
  - A “detailed characterization study.”

#### v. Snohomish County, Washington

In July of 2016, the Board of Health of the Snohomish County Health District enacted the Snohomish Secure Medical Return Regulation.<sup>81</sup> This EPR ordinance is modeled after the regulation in King County.

---

<sup>80</sup> Santa Cruz County Safe Drugs and Sharps Ordinance, Ch. 7.95 (2015), Found at: <http://www.codepublishing.com/CA/SantaCruzCounty/html/SantaCruzCounty07/SantaCruzCounty0795.html>.

<sup>81</sup> Snohomish Secure Medical Return Regulation, Health District Board of Health, Ch. 15, (2016), Found at: <http://www.snohd.org/Portals/0/Snohd/Waste/files/Ord%20No%2016-001%20-%20Secure%20Medicine%20Return.pdf>.

The Snohomish County regulation covers prescription and OTC drugs, including controlled substances. In addition, highlights of the regulation include:

- A definition of those who can and cannot dispose of medications at the drop-off sites, identifying them as “Covered Entities;”
- No consumer fee for the service – drug manufacturers must pay for all administrative and operational costs;
- A requirement that the collection sites be convenient and designed equitably and operate on an on-going, year-round basis. In every city and town in the county, there must be at least one collection location and an additional site for every 30 thousand residents. If this convenience goal cannot be achieved, then the areas must be served by periodic collection events and mail-back services;
- Specific requirements for collection, handling, and disposal of the medications;
- A requirement that producers ensure that residents and health care professionals are aware of the program and must:
  - Discourage disposal of unwanted drugs in the trash;
  - Promote safe storage of medicines in the home;
  - Provide uniform signage for all collections sites;
  - Provide educational materials; and
  - Set up a toll-free number and website;
- A requirement that the producers pay for the oversight that the Snohomish Health District conducts of the program;
- A requirement of a written, annual report that includes:
  - The amount, by weight, of all returned medications;
  - An evaluation of how the plan’s goals were met;
  - Program expenditures; and
  - A biennial survey of residents and health care professionals to assess whether the program outreach is effective.

All of the above-referenced ordinances are similar, with small differences:

- The five U.S. ordinances and the one from British Columbia accept prescription and OTC drugs, but:
  - Not all collection sites in Alameda County accept controlled substances; and
  - Only Santa Cruz County accepts sharps.
- All are free to consumers.
- All refer to collection, handling, and disposal but each varies in specificity.
- All are voluntary, except the one in Santa Cruz County is mandatory.
- The number, type, and proximity of collection sites range from convenient to specifying how many per a certain number of residents and location.
- All but one defines users or those who can and cannot dispose of waste at the collection sites.
- The specificity of the types of promotion, outreach, and education of the programs varies, with all requiring a toll-free number and website for consumer access. The materials to be produced and to whom they are to be disseminated varies.

- Annual reporting requirements vary, with some only requiring information on the total weight of the waste collected, while others require an evaluation of program effectiveness and/or a survey of users' knowledge and awareness of the program.
- All provide details about what to do when a producer does not comply with the ordinance, but none define "compliance," particularly for when a program first begins.

With the specific sections of each ordinance and the similarities and differences among them listed above, Los Angeles County will be able to select the most effective options for it to address its public health and safety and environmental concerns. Depending on the County's priorities, it will likely want to: (1) accept all prescription and OTC medications, including controlled substances and all sharps and sharps-related products (*e.g.*, epi-pens); (2) define those who can and cannot dispose of medications at the drop-off sites; (3) not charge consumers a fee for the service; (4) ensure that the collection sites be convenient and equitably distributed, setting forth that there must be at least one drop-off site for every X number of residents; (5) specify the requirements for collection, handling, and disposal of the medications and sharp; (6) require that producers promote collection options through clear, standardized signage, public service announcements, advertisements, and a host of other promotional and educational materials, and establish a toll-free number and website; (7) require that Responsible Stewards pay for the oversight conducted by the Department of Health; and (8) require a written, annual report that contains an evaluation and a survey to assess program effectiveness. For specific recommendations and considerations, *see* Section V.2. and 3.

#### C. Determination of Whether the Other Extended Producer Responsibility Ordinances Will Result, or Have Resulted, In Increased Public Health and Environmental Protections

There is limited research assessing the effectiveness of pharmaceutical and/or sharps disposal EPR laws, from either a public health, public safety, or environmental perspective. A study should be conducted to determine how disposal programs reduce drug misuse, by reducing the supply of drugs that could be misused and raise awareness of the dangers inherent in prescription drug misuse, and whether they, with sharps programs, increase public health and safety. However, based on the small amount of information from international programs and the five programs reviewed above and interviews with program administrators, it can be concluded that these programs result in, or can be expected to result in, better public health protections, as well as positive effects on the amount of drug and sharps waste in landfills and waterways.

Many users of drugs and sharps are not aware that flushing unwanted drugs down a toilet or disposing of drugs and/or sharps in the household trash is potentially dangerous. Only after they are educated on the subject are they more apt to properly dispose of such waste.<sup>82</sup> In one California survey, 86 percent of respondents said that if there was an ongoing type of disposal program, they would likely use it to dispose of leftover medications or sharps.<sup>83</sup> As a product stewardship program grows and has more convenient collection sites and awareness of its

---

<sup>82</sup> Yanovitzky I., The American Medicine Chest Challenge: Evaluation of a Drug Take-back and Disposal Campaign.

<sup>83</sup> City of Rosedale – Environmental Utilities Residential Customer Telephone Tracking Survey, January 2014, Found at: [http://calpsc.org/mobius/cpsc-content/uploads/2015/03/CityOfRoseville\\_EnviroUtilities\\_-\\_ResidentialCustomerSurvey\\_PharmaceuticalResults\\_Jan2014.pdf](http://calpsc.org/mobius/cpsc-content/uploads/2015/03/CityOfRoseville_EnviroUtilities_-_ResidentialCustomerSurvey_PharmaceuticalResults_Jan2014.pdf).

existence, the amount of properly disposed waste increases.<sup>84</sup> This removes unwanted and potentially dangerous drugs and sharps from society, reducing the number of injuries from needle sticks and the amount of drugs that can cause accidental poisoning, contribute to overdoses and deaths, be diverted for illegal use, be stockpiled, or make their way into landfills and waterways. The cost to the pharmaceutical industry is minimal, particularly as compared to the number of potential injuries an EPR program can prevent and lives it can save.

A public health expert estimated that based on an annual cost of approximately \$1.2 million for the Alameda County Safe Drug Disposal Program, the cost to the pharmaceutical industry amounts to approximately 0.1 percent of annual medication sales in the county. This equals approximately .02 cents per container of prescription or OTC drugs sold there.<sup>85</sup>

In King County, prior to its Secure Medication Return Regulation, there were a limited number of voluntary take-back programs which were collecting large amounts of medicines.<sup>86</sup> There were 24 pharmacies that collected medications, but none collected controlled substances. Only the 11 law enforcement agencies that participated in the program were legally able to take controlled substances, and none of them existed in the largest cities. Based on the large amount of unwanted medications that had been collected on DEA take-back days, it was clear that county residents would welcome an on-going solution to safely dispose of their leftover medicines.

After the King County regulation went into effect, the number of sites increased to 99, with all now able to accept controlled substances. While the results of King County's efforts have not yet been determined, this increased availability of disposal options has the potential to dramatically decrease the amount of potentially dangerous drugs in households across the county.

Similar to Alameda County, the cost of the King County regulation, compared to the sales made by the drug producers in the county equals approximately 0.1 percent of annual medicine sales. This amounts to between approximately two and four cents per container of prescription or OTC drugs sold in the county.<sup>87</sup> Representatives of the King County program indicate their program is operating well and has been well-received in the community. Previously, King County had a long-standing program that collected only non-controlled medications. Consumers in the area, therefore, had grown accustomed to disposing of medications (although only non-controlled) so the transition to a more comprehensive program has been smooth from the consumer standpoint. The County does not collect sharps in its program.

A 2013 study evaluated San Francisco's pilot program during its first year of operation.<sup>88</sup> The study found the total weight of medications collected in that year to be a little over ten tons (or over 20,000 pounds). The average monthly weight of medication collected at pharmacies was

---

<sup>84</sup> Yanovitzky, The American Medicine Chest Challenge: Evaluation of a Drug Take-Back and Disposal Campaign.

<sup>85</sup> Shields, Margaret, Ph.D., Presentation to the Oregon House Interim Committee on Health Care, , Community Environmental Health Strategies, (September 22, 2016); and *see* King County Department of Health Report (June 20, 2013), Found at: <http://www.kingcounty.gov/depts/health/board-of-health/regulations/secure-medicine.aspx>.

<sup>86</sup> *Id.* (King County Department of Health Report).

<sup>87</sup> Shields, Presentation to the Oregon House Interim Committee on Health Care.

<sup>88</sup> Teleosis Institute, 2013 Medicine Waste Characterization Study (August 2, 2013).



1,176 pounds, while police stations collected 88 pounds per month.<sup>89</sup> This information is valuable, since product stewardship programs not only allow for on-going collection which is more convenient for residents, but at convenient locations, like pharmacies rather than only at police stations. Once pharmacies began to act as collection sites, the amount of unwanted medications increased. Researchers found that of the total sample taken from the ten tons, 95 percent were pharmaceutical products. Of that 95 percent, 71.9 percent were prescription medications. Controlled substances comprised 11.6 percent of the drugs.<sup>90</sup> As of March of 2015, the program has increased its collection to 26 tons of medication per year.

Today, with the San Francisco Safe Drug Disposal Stewardship Program in effect, there are over 35 collection bins in place, and the program is more than halfway to its minimum goal of 55. According to the Senior Residential Toxics Reduction Coordinator at the San Francisco Department of the Environment, the ordinance will not reach all of the 135 licensed pharmacies in the county because half of them are a chain pharmacy that has declined to participate in the Med-Project program and instead, has started its own. The program makes it a point to let residents know that it accepts fentanyl patches.

The program has begun to reach a number of residents, and it appears that it is collecting more medications than ever. The Senior Residential Toxics Reduction Coordinator<sup>91</sup> believes that the two most important keys to success for any program is to ensure that: (1) the collection sites are placed in convenient, easily accessible locations; and (2) the education and outreach component is comprehensive. She believes that the San Francisco program is effective based on the amount of pharmaceuticals collected and that getting drugs out of the home is always preferable to stockpiling. She also said that she believes that emergency room overdose visits appear to have declined, but she was hesitant to attribute the decline to the stewardship program.

Based on her experience, she would amend San Francisco's current ordinance to: (1) include sharps in the ordinance; (2) provide a three-month timeframe for a producer to submit a stewardship plan and a six to nine-month timeframe to implement the plan; (3) exempt small producers from having to share in the costs of the stewardship program; (4) prohibit, not just discourage, home disposal in the ordinance; and (5) include in the plan medical devices that contain both sharps and medicine in them (*e.g.*, epi-pens) and other items like inhalers, auto-injectors, and iodine-containing drugs.

Santa Cruz County based its current ordinance on its pilot program that had been in operation since 2008. Because the county had difficulty persuading pharmacies to participate as collection sites, the ordinance mandates participation in the stewardship program. The Santa Cruz County Safe Disposal of Drugs and Sharps Program has not yet launched its outreach and education program. However, the Santa Cruz County Planner<sup>92</sup> who oversees the program already believes that the program is a success. While the program would like to evaluate whether prescription drugs on the streets are declining, whether the county coroner has seen the causes of fatal

---

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> Telephone interview with Margaret Johnson, Senior Residential Toxics Reduction Coordinator, San Francisco Department of the Environment, October 3, 2017.

<sup>92</sup> Telephone interview with Tim Goncharoff, Santa Cruz County Planner, September 27, 2017.

overdoses due to drugs diminishing, and whether waste management workers are experiencing fewer needle sticks, the program currently measures success by the amount of materials collected and properly disposed. The County Planner reported that thus far this year, the program has collected 17 thousand pounds of medicine and 11 thousand pounds of sharps in the 43 collection sites that are in the county. However, he believes that only 15 percent of the unused medications in households are being properly discarded, but once the education and outreach program begins, more residents will dispose of the waste at the collection sites. The education campaign will include: (1) newsletters sent to every county resident; (2) public service announcements on television and radio; (3) local events; (4) brochures at all health care facilities and pharmacies; and (5) direct education about the program to all health care providers in the county.

While he has not yet seen a decrease in prescription opioid misuse and overdoses, anecdotally, he has heard of fewer accidental needle sticks from waste management workers. Late in 2016, the ordinance was awarded the 2016 Outstanding Policy/Legislative Advancement Award by CalRecycle.

The Snohomish Secure Medical Return Regulation is very new. It was fashioned after the King County regulation. An interview with representatives of the Snohomish County program revealed that their program has been well-received in the community, and they have been working to establish accessible disposal options throughout the county.

#### **IV. Analysis of the California State Auditor’s 2016-2017 Home-generated Sharps and Pharmaceutical Waste Report**

In May 2017, The California State Auditor issued a report entitled “Home-Generated Sharps and Pharmaceutical Waste: By Designating a Lead Agency, the State Could Increase Proper Disposal” (the Report). The Report was requested by the Joint Legislative Audit Committee of the California State Assembly. It found that California consumers do not receive accurate or comprehensive information on how and where to dispose of pharmaceutical or sharps wastes due to a lack of coordination at the state level. Moreover, the Report found that if one state agency had oversight and played a coordinating role in sharps and pharmaceutical waste disposal, the result would be more accurate and consistent information provided to California consumers.

The Los Angeles County Department of Public Health asked LaBelle Strategies to conduct an analysis of the Report and has requested an evaluation of how its data, findings, and recommendations may impact the Los Angeles County draft ordinance. In addition, LaBelle Strategies has been asked to identify strengths and weaknesses in the data, findings, and recommendations found in the Report from a public health perspective. Below are its findings and recommendations.

##### **A. The State Provides Fragmented Oversight and Inconsistent Guidance Related to the Disposal of Home-Generated Sharps and Pharmaceutical Waste**

The Report stated that conflicting guidance regarding sharps and pharmaceutical waste disposal “is in part the result of the fact that the state has not assigned oversight of this issue to a specific

state agency.” It then listed the agencies that have some responsibility for disposal, to include CalRecycle, the California Department of Public Health (Public Health), the California State Board of Pharmacy, and the County Department of Toxic Substances Control. Each of these agencies play a legislative or regulatory role in proper disposal of sharps or pharmaceutical waste. The Report then recommended that CalRecycle be given statutory oversight responsibility of pharmaceutical and sharps disposal and should be provided additional resources “to the extent it can justify the need.” The Report made this recommendation because of CalRecycle’s existing responsibility in overseeing state-managed solid waste-handling programs. It also recommended that CalRecycle coordinate a public education campaign about home-generated sharps and pharmaceutical waste; maintain an up-to-date, well publicized, and accessible statewide list of sharps and pharmaceutical waste collection sites; and maintain increased access to proper disposal sites in underserved areas.

*Impact on Los Angeles County Draft Ordinance:* If this recommendation is accepted, the state would adopt standard requirements for counties wishing to establish EPR programs. To the extent, therefore, that these requirements conflicted with the draft ordinance and reflect local preferences, it would supersede the local authority. Moreover, the state could pass on additional requirements to Los Angeles County which may require additional county expenditures.

*Strengths/Weaknesses:* While CalRecycle would appear to be a logical choice to oversee a state managed solid waste program, pharmaceutical waste, and to some extent sharps, are different than the other products CalRecycle oversees. Pharmaceutical waste can be divided into two products – controlled and non-controlled substances. Controlled substances are governed by the Controlled Substances Act (CSA), and the DEA is responsible for its enforcement. Non-controlled substances include OTC medications and some prescription medications and are not subject to the CSA. Throughout the Report, the auditor does not distinguish between these two groups of substances. This is a significant oversight since the CSA has specific requirements for the disposal of controlled substances that can be collected for disposal without the specific regulatory requirements of the Safe and Responsible Drug Disposal Act. The products ordinarily under CalRecycle’s purview are not substances that fall under the purview of the CSA or require law enforcement involvement. Therefore, while CalRecycle may play a coordinating role in their disposal, other agencies, including the Board of Pharmacy must be involved in any statewide disposal system involving controlled substances.

- B. Although Most Consumers Have Reasonable Access to Free Collection Sites for Sharps and Pharmaceutical Waste, They May Not Be Aware of Site Locations
  - 1. Most Consumers in Urban Areas Have Access to Disposal Sites for Home-Generated Sharps and Pharmaceutical Waste
  - 2. The State Does Not Provide Reliable Information to Ensure that Consumers are Aware of Available Collection Sites

### 3. The State Could Implement Alternative Disposal Methods in Rural Areas

The Report found that “89 percent of Californians – almost 34 million people – live within a 20-minute drive of free collection sites for both home-generated sharps and pharmaceutical waste.” These collection sites are concentrated around urban centers. However, because there is no main source of information about collection sites, this information is not properly disseminated to consumers. The Report also stated that lack of access to disposal sites is particularly pronounced in rural or “isolated” parts of the state. Various state agencies, to include CalRecycle, maintain a list of collection sites, but they are not well-maintained and therefore, not reliable.

The Report makes the following recommendations: CalRecycle should develop and implement a public education campaign on sharps and pharmaceutical waste disposal and coordinate this campaign with other levels of government and should maintain an up-to-date, well-publicized, and accessible statewide list of free sharps and pharmaceutical waste collection sites. The list should be created by improving upon its existing list or by establishing a new more user-friendly database. It also recommended that the state finance specific programs for rural areas of the state, such as distributing prepaid mail-back envelopes to these areas. It further recommended that the state use its bulk buying power to reduce the costs of prepaid mail-back envelopes which retail for \$30 and up. To expand access to disposal in rural or more isolated areas, the Report recommended that local government waste management contracts include sharps and non-controlled pharmaceutical waste disposal.

*Impact on the Los Angeles County Draft Ordinance:* These findings do not directly affect the draft ordinance. The draft ordinance requires public education, outreach, and evaluation activities. The Los Angeles outreach activities would be specific to the area and arguably better-suited to the area than a more general, statewide campaign. Establishing a Los Angeles disposal program would provide more accurate information on collection sites, thereby allowing information from the area to be fed into any state database. The draft ordinance would enhance, rather than diminish, any statewide database. Furthermore, since the proposed Los Angeles County draft ordinance applies to unincorporated counties with an opt-in provision by cities within the county area, this would address the issues of accessibility raised in the Report. The proposed Los Angeles County draft ordinance requires that there be a collection site within two and one-half miles of every resident in the designated “Service Area.” In addition, the draft ordinance ensures that disposal options will remain available and will not depend upon the vicissitudes of local government budgets.

*Strengths/Weaknesses:* The overall findings in this section are reasonable. California residents should be able to find accurate information on where to dispose of sharps and all pharmaceutical waste in their area. Further, individuals in rural or more isolated regions should have ready access to appropriate disposal of sharps and pharmaceutical waste.

The finding that most California consumers already have reasonable access to free collection sites for sharps and pharmaceutical waste is contradicted by the Report’s additional finding that

there is a lack of accurate information on collection sites. If the database is inaccurate, it is difficult to see how the auditor can conclude that most consumers have reasonable access to free collection sites. The document acknowledged that there is no distinction between sites that collect controlled substances and those that collect non-controlled substances, further undermining the finding that 89 percent of Californians live within a 20-minute drive to a collection site. Controlled substances, such as prescription opioids and stimulants, are often diverted and subject to misuse. Conflating disposal sites that can legally collect controlled substances with those that can only take sharps or other non-controlled pharmaceutical waste makes the Report's findings regarding accessibility to collection sites confusing.

C. The State Lacks Data on the Volume of Sharps and Pharmaceutical Waste that Consumers Generate and the Ways in Which They Dispose of This Waste

1. Most Collection Sites Dispose of Sharps Waste in the State but Ship Pharmaceutical Waste to Out-of-State Incinerators
2. Both In-State and Out-of-State Facilities Have Sufficient Capacity to Process Significant Increases in California's Sharps or Pharmaceutical Waste
3. Exempting Pharmaceutical Waste from the State's Definition of Hazardous Waste Would Allow for More In-State Incineration

The Report found that accurate information regarding the volume of sharps and pharmaceutical waste is lacking partly because CalRecycle does not have funding to enforce the regulatory requirement that local agencies report the amount of waste they collect. Therefore, state data are incomplete and inaccurate. In addition, other organizations, such as syringe exchange programs that collect and dispose of sharps, do not track or retain information on sharps disposal. The DEA's Take-Back Days weigh the amount of drugs collected at their scheduled events. The Report included this information in its estimate.

The Report states that household pharmaceutical waste is defined as "hazardous waste," requiring it to be shipped out-of-state to be destroyed. In addition, controlled substances are governed by the CSA, and under rules set forth by the DEA, any waste containing controlled substances must be "irretrievable." The Report recommended, therefore, that pharmaceutical waste be exempted from the state's definition of hazardous waste. This would allow for more in-state incineration and avoid the cost of sending waste out-of-state.

*Impact on the Los Angeles County Draft Ordinance:* The draft ordinance establishes a mechanism for collection of pharmaceutical waste and sharps. Any disposal of pharmaceutical waste and sharps must comply with applicable federal and state laws. Therefore, the extent to which the state legislature revises the definition of hazardous waste would affect the draft ordinance.



*Strengths/Weaknesses:* It is important to note that one of the goals of Take-Back or drug disposal programs is to provide a safe, “no questions asked” way to remove potentially dangerous prescription drugs from the home. As stated earlier in the report in Section III.A., the majority of individuals who begin misusing prescription drugs, obtain them from family and friends. Therefore, a goal of drug disposal programs is to provide a place where people can dispose of these drugs without being subject to questioning or undue scrutiny. Unfortunately, this may make it more difficult to determine with exactitude what is disposed. However, the value of removing prescription drugs from the home was one of the main drivers of the Secure and Responsible Drug Disposal Act, with the other being reducing the introduction of harmful substances into the environment. These dual purposes remain paramount.

#### D. Other States and Countries Follow Collection and Disposal Practices That Could Serve as Models for California

1. California Could Employ Elements of Programs from Other States and Countries
2. In 2010 CalRecycle Provided the State with Options for Pharmaceutical Waste Collection Programs

The Report contains an overview of other disposal programs, including those in New York, Minnesota, Sweden, and Canada and suggested that California could benefit from adopting some of the practices found in other models. Specifically, the Report pointed to the EPR programs for sharps and pharmaceutical waste found in four Canadian provinces. In its 2016 report, the Ontario EPR program indicated that collection of sharps waste had increased by 19 percent since 2015 and that its collection of pharmaceutical waste increased by 16 percent in the same time period. In addition, the report looks to the New York model where pharmacies and other retail establishments that sell pharmaceuticals must display information on New York’s pharmaceutical waste disposal program. The New York program does not, however, have metrics by which to judge its success. Moreover, the Report noted that these programs have different goals. Some (*e.g.*, Minnesota) have the goal of reducing pharmaceuticals that can be misused or cause accidental poisoning, while others, including Sweden, have the goal of reducing environmental harms.

CalRecycle issued a report in 2010 that provided recommendations on establishing model pharmaceutical waste collection programs in California. That report was the result of a state legislative mandate and made four recommendations: (1) Leave the current system in place; (2) Establish state regulations; (3) Implement a statewide EPR program; or (4) Develop a state-managed program paid for by consumers. The auditors recommended the second option, designating one lead agency with enforcement authority and converting model guidelines for disposal into a state regulatory scheme. While recommending a statewide program, the auditors stated that provisions could be made for counties choosing to have EPR programs. The Report suggests that guidelines developed by the state legislature could determine whether county programs include collection of nonprescription medications and whether to include a mail-back

component. The Report reiterated its concern that a state EPR system would result in cost shifting to consumers and that legislation establishing a statewide EPR system would be difficult to pass. The Report further found that the second option, a lead state agency and statewide guidelines, would not create “additional costs for consumers.” However, it recognized that the lead state agency would require additional resources to develop and implement regulations.

*Impact on Los Angeles County Draft Ordinance:* The first recommendation, that other government programs be reviewed to determine what might benefit California, would not greatly impact the draft ordinance. In fact, the draft ordinance has been informed by ordinances in other jurisdictions, including disposal ordinances passed in Washington state. In addition, the draft ordinance contains a provision requiring consumer education which likely goes further than New York’s. Consumer education of disposal programs goes hand in hand with establishing more disposal options for consumers.

The impact of the second recommendation, whereby a lead state agency would be established and guidelines would be formulated, could have a significant impact on the draft ordinance, depending upon what is in the guidelines. For example, the Los Angeles County draft ordinance contains a provision in which consumers cannot be charged fees at the time of collection or upon sale of the medication to recover costs associated with the EPR. This provision could be prohibited by the state legislature, thereby allowing cost shifting to consumers. In addition, guidelines could be written in such a manner that county EPR programs would either be cost prohibitive or would not have the intended effect of addressing pharmaceutical waste from either the public health or environmental perspective.

*Strengths/Weaknesses:* The Report includes an assertion that the state could establish policies for county run EPR programs. One of the examples used was a state determination of whether county EPR programs could include nonprescription medications. Using this as an example misses a major policy imperative of drug take-back programs. The public health imperative behind these programs is to remove unused or unwanted controlled substances from the home so they will be less available to misuse, abuse, or accidentally ingest. Controlled substances are controlled because of the harms associated with their misuse. Take-back and disposal programs distinguish between controlled and non-controlled medications, not merely prescription and non-prescription medications. Controlled medications are subject to the CSA and have different collection and disposal requirements. Further, the purpose of providing for secure and convenient collection and disposal of controlled substances includes both public health and environmental concerns. Contrary to what the Report stated, both policy goals must be included in any program and neither the state, nor county policymakers should be forced to decide between these two equally important policy goals.

While other state public education campaigns, such as New York’s, should be reviewed, it is difficult to judge the effectiveness of a program if disposal options are not expanded concurrently. Increasing the awareness of the importance of drug disposal, without providing a

means of disposal either by increased access to prescription drug drop boxes or postage paid mailers, may result in an aware, but frustrated, populace.

State guidelines that provide minimum standards by which local disposal programs should adhere and increased accuracy of statewide databases are important policy goals. However, state guidelines that establish restrictions and result in counties unable to establish comprehensive disposal programs without shifting costs to consumers, should be avoided. The Report noted that the state database is inaccurate and enforcement is not done because resources are lacking. It is doubtful therefore, that CalRecycle can take on additional duties, including drafting and overseeing the rule-making process and upgrading the existing disposal database and enforcing these rules, without additional budget authority.

## **V. Analysis of, and Recommendations for, the Los Angeles County Ordinance**

### **A. Is the Los Angeles County Draft Ordinance an Appropriate and Reasonable Approach to Addressing Public Health Concerns Related to the Disposal of Unwanted Controlled Substances and Sharps?**

#### **1. Analysis**

Based on general information on EPR programs, a sampling of a handful of existing stewardship programs, and interviews with experts in the field of drug take-back, the Los Angeles County draft ordinance appears to be an appropriate and reasonable way to address the public health and safety and environmental concerns related to the disposal of both drugs and sharps. A Section Chief in the Office of Diversion Control at the DEA stated that educating the community on the importance of getting prescription drugs out of the house alone, makes it worth having a stewardship program.<sup>93</sup> Moreover, by raising awareness about the importance of disposing prescription drugs, stewardship programs force patients to question doctors about the quantity of pain medication they prescribe. Fewer doses in prescriptions means fewer drugs in the house, which makes medications less accessible for children, animals, and vulnerable adults to accidentally ingest and for teens and adults to misuse or divert. Limiting quantities is the first step in a comprehensive plan. Educating individuals on how to store drugs safely in the home and promoting their proper disposal can be effective in addressing various public health concerns.

A drug take-back expert from the Partnership for Drug-free Kids<sup>94</sup> (The Partnership) stated that EPR laws are effective in addressing the opioid epidemic if: (1) the collection sites are conveniently located and user-friendly; and (2) people are educated about why proper disposal of drugs are important and motivated to want to clean out their medicine cabinets and drive somewhere to properly dispose of the drugs.

---

<sup>93</sup> Telephone interview with Office of Diversion Control, Drug Enforcement Administration, October 5, 2017.

<sup>94</sup> Telephone interview with Marcia Lee Taylor, Chief Policy Officer, Partnership for Drug-free Kids, October 5, 2017.

She also stated that the most important part of any stewardship plan is education and outreach. Pamphlets, public service announcements, phone apps, social media, op eds (particularly written by someone who lost a child to an overdose), and other types of educational materials are very helpful in demonstrating why proper drug storage and disposal are so important. A study of international drug stewardship programs found that lack of information about programs was the main reason why individuals did not use collection sites. Effective education campaigns also must coincide with thorough collection strategies.<sup>95</sup> The success of the program in British Columbia is measured by consumer knowledge and awareness of the EPR program and by consumer behavior.<sup>96</sup>

While programs throughout the country differ, the message, the representative from The Partnership said, should be uniform across municipalities. The campaign to reduce the amount of waste in America (*e.g.*, cardboard, plastic, and electronics) is associated with the three words, “reduce, reuse, recycle.” Drug and sharps disposal should develop its own “catch phrase” that becomes a part of the American lexicon. The State of Tennessee has collected 54 tons of drugs in the last year and has been using the phrase, “Count It! Lock It! Drop It!” This statewide campaign has increased the number of residents to 72 percent who think that pills should be properly discarded at a drop off location.<sup>97</sup> Reducing access to unwanted or unused drugs is definitely a step in the right direction.

Finally, a principal research scientist from the University of Washington<sup>98</sup> believes that stewardship programs are useful in: (1) raising awareness about the importance of proper waste disposal; (2) reducing access to opioids; and (3) suggesting that people to talk to their doctors about prescribing too many doses of a medication that they may not even need.

Limited information on waste disposal programs suggest that pharmaceutical disposal programs increase collection and proper disposal of unwanted prescription drugs and are a useful strategy in reducing illicit drug use and unintentional poisonings.<sup>99</sup> A cost benefit analysis done in one study suggests that drug disposal programs produce positive, net social benefits.<sup>100</sup> Moreover, bin-based drug collection is more cost-effective than mail-back programs or one-day events.<sup>101</sup> As stated in section III.C., the cost of operating a program is minimal to producers and manufacturers, amounting to just pennies per container of prescription or OTC medicine sold.<sup>102</sup>

---

<sup>95</sup> Health Care without Harm, Found at: [https://noharm-europe.org/sites/default/files/documents-files/2616/Pharm%20Report\\_WEB.pdf](https://noharm-europe.org/sites/default/files/documents-files/2616/Pharm%20Report_WEB.pdf).

<sup>96</sup> Houskeeper, Brandon, “Drug Take-back Programs: What Will They Solve?” Washington Policy Center, Seattle, WA, January 2009.

<sup>97</sup> Fletcher, Holly, “Tennesseans Turn in Mountains of Pills, but Fight Against Opioids Rages,” *USA Today*, October 15, 2017.

<sup>98</sup> Email from Caleb Banta Green, Ph.D., Principal Research Scientist, University of Washington, October 9, 2017.

<sup>99</sup> Levi, J., et. al., “Prescription Drug Abuse: Strategies to Stop the Epidemic,” *Trust for America’s Health*, Washington, D.C., October 2013.

<sup>100</sup> Kotchen, Matthew J., et. al., Pharmaceuticals in Wastewater: Behavior, Preferences, and Willingness to Pay for a Disposal Program, *J of Environmental Management*, 90(3):1476-1482 (2009).

<sup>101</sup> Carnevale Associates, “Prescription Drug Takeback Programs & Substance Abuse Prevention,” Policy Brief, February 2012.

<sup>102</sup> Shields, Community Environmental Health Strategies.

While more detailed studies are needed to demonstrate that EPR programs reduce the amount of drugs in society and are, therefore, effective in reducing drug misuse, overdoses, diversion, and deaths, anecdotes reveal, and experts agree, that decreasing access to potentially harmful medications and sharps is a positive step toward addressing the opioid problem plaguing America. Disposal programs also provide an opportunity to educate consumers about the dangers inherent in misusing prescription medications.

## 2. Recommendations

As long as the Los Angeles County stewardship program produces and promotes an effective education and outreach strategy to inform residents and health care professionals about the program, the county can reasonably expect to decrease: (1) the number of unwanted pharmaceuticals and sharps entering society; (2) the amount of unwanted and unused medications and sharps being stockpiled in homes; (3) the number of pharmaceuticals that may be misused, abused, or diverted and lead to death or hospitalization because of an overdose; and (4) the number of injuries to waste facility workers and the public because of improper sharps disposal.

The 2016 Los Angeles County Medicines and Sharps Disposal Consumer Survey<sup>103</sup> found that 59 percent of the Los Angeles County residents surveyed had expired or unwanted medications in their homes, 45 percent of them did not know what to do with them, 23 percent were saving them, and 12 percent were waiting for a drug take-back day but said that the periodic collections days were either too rare or not accessible. Twenty-four percent of respondents indicated that someone in their household used medical sharps, but 33 percent said that they sometimes or never used a sharps container. Eleven percent admitted not knowing how to dispose of sharps. This 44 percent reported that they dispose of sharps in the trash. Lastly, 87 percent said that on-going, drop-off bins for disposal of medicines and sharps were a good option, and 69 percent selected pharmacies as the most convenient place for these bins. Based on these responses, existing programs, expert opinions, and a thorough analysis of the Los Angeles County draft ordinance, LaBelle Strategies makes the following recommendations:

- i. In § 11.17.020, define who are the acceptable users of the program or “covered entities”<sup>104</sup> – While it is implied that residents of Los Angeles County may use the collection sites to dispose of waste, it would be useful to define who is (and is not) covered.
- ii. In § 11.17.020, define health care community or health care professionals – These broad terms can incorporate a number of individuals and entities that were not intended. The phrases should be defined in the definition section but can be defined when they are first used (*e.g.*, in § 11.17.160),

---

<sup>103</sup> 2016 Los Angeles County Medicines and Sharps Disposal Consumer Survey, April 8, 2016, Found at: <http://publichealth.lacounty.gov/docs/SharpsDisposalSurvey.pdf>.

<sup>104</sup> The Alameda County Safe Drug Disposal Ordinance calls users “Residential Generators,” while the King County Secure Medication Return Regulation names them, “Covered Entities.”



and the draft ordinance should choose only one phrase to use, rather than interchange the two.

- iii. If the collection bins will accept fentanyl patches, they should be listed under “Covered Drugs” in § 11.17.020 F – If the program does not want to, or cannot, include these patches, they should be on the list of what are not Covered Drugs.
- iv. In § 11.17.030 C 4, change the allotted time for plan submission and implementation – The amount of time for a Responsible Steward to submit its stewardship plan should be reduced from nine months to three, and extend the amount of time from three months to nine for the implementation of the stewardship plan.
- v. In § 11.17.050 C, provide a maximum amount of time within which a collection site must be emptied and serviced – The third sentence now would read, “Collection sites shall be emptied and otherwise serviced as often as necessary, but not less than every X months [*e.g.*, three or four, based on experience] to avoid creating hazardous conditions, including reaching capacity.”
- vi. In addition to requiring a biennial survey, in § 11.17.030B, require an annual or biennial evaluation of the program’s effectiveness – The evaluation could review whether there was a decrease in the number of needle sticks reported by waste management workers, the amount, by weight, of drugs collected and of sharps collected, the types of prescription drugs collected, the number of mail-back envelopes used, and the total costs of the program. Just as required for the survey, the evaluation should be conducted by a person or entity without financial ties to the Responsible Steward.
- vii. In § 11.17.120, define “Compliance” – Include a paragraph after subsection B that addresses initial compliance regarding the implementation of the stewardship plan. A Responsible Steward may believe that a program is in operation once its website is active, but the county may believe that it is in operation once collection boxes are placed in all of the designated locations. In other words, define what a Responsible Steward must do to comply with the initial implementation of a program.
- viii. The stewardship program should collaborate with dentists, veterinarians, physicians, and other health care prescribers in its education and outreach program – This will ensure a coordinated effort to not only educate everyone on how to properly dispose of potentially harmful substances but to reduce the amount of potentially harmful substances originally prescribed.

### 3. Other Considerations

Before Los Angeles County finalizes its draft ordinance, it may want to consider the following:

- i. Exempting small producers and manufacturers from the definition of “Responsible Steward” – If a manufacturer makes one product and annually distributes 300 of those products in the county, it might put a strain on the company to be deemed a “Responsible Steward.” If an exemption from the definition is appropriate, the county must define what constitutes a “small producer.” The definition might rest on the fact that the manufacturer earns less than a certain dollar amount per year in sales or something similar.
- ii. Determine if collection sites will, or can, accept other medical waste – Items such as auto-injectors (*e.g.*, epi-pens with expired medication remaining in the device), inhalers, and iodine-containing drugs should be considered. If so, they should be mentioned specifically as “Covered Drugs,” and if not, they should be listed as non-covered.
- iii. In § 11.17.160, set forth minimum requirements for promotion, education and outreach – Delineate what “materials” must be included for the design, effectiveness, and coordination of the promotion, education and outreach activities. These could include clearly understood and uniform signage at each collection site, public service announcements, social media campaigns, and pamphlets.
- iv. Prohibiting, rather than discouraging, home trash disposal of drugs and sharps
- v. Ensuring that any stewardship plan works in collaboration with the DEA’s semi-annual Take-Back Days

Based on the experience of, and surveys conducted in, other jurisdictions, there is a strong likelihood of the public using the disposal options proposed in the draft ordinance.

## **VI. Conclusion**

A safe, secure, and convenient place to dispose of unwanted medications and used sharps is important to a comprehensive drug strategy that increases public health and safety. With no national, on-going medication and sharps take-back program, jurisdictions are forced to create their own disposal programs through product stewardship or EPR programs, which is why the County of Los Angeles created its draft Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance.

With only a small amount of information on the effectiveness of drug and sharps disposal programs, it appears that properly getting rid of unwanted pharmaceuticals and sharps waste can have a positive impact on the devastating public health problem. Getting drugs and sharps out of circulation reduces surplus which diminishes the chance that they can cause harm in society.

Requiring manufacturers to manage their products' end-of-life waste through proper disposal has been implemented successfully in the paint industry in the United States. Much like the EPR paint laws, a number of EPR ordinances regarding pharmaceutical drugs and sharps have been implemented, and are in operation, in a handful of jurisdictions in the United States and throughout the world. While these programs vary in type, they have similar elements and have been found to be effective in reducing the amount of unwanted drugs and sharps in circulation, as long as consumers are properly educated about the programs and the disposal sites are conveniently located.

With some recommended changes to its draft ordinance and through a comprehensive and targeted education and outreach program, the public will likely use the disposal options, and the draft ordinance will be able to decrease access to potentially harmful medications and sharps and address the opioid problem plaguing Los Angeles County.

# **APPENDIX A**

## Bibliography

## Bibliography

### Research Studies and Surveys

Anderson, R., et. al., Accuracy in Equianalgesic Dosing: Conversation Dilemmas, *J Pain Symptom Management*, 21(5):397-406 (May 2001).

Beaver, W.T., et. al., Analgesic Studies of Codeine and Oxycodone in Patients with Cancer II: Comparisons of Intramuscular Oxycodone with Intramuscular Morphine and Codeine, *J Pharmacol Exp Ther*, 207(1):101-108 (October 1978).

Becker, J., Minding the Gap: Research Priorities to Address Pharmaceuticals in the Environment, *Health Care Research Collaborative* (February 2010).

Bruera E., et al. Randomized, Double Blind, Cross-over Trial Comparing Safety and Efficacy of Oral Controlled-release Oxycodone with Controlled Release Morphine in Patients with Cancer Pain, *J Clin Oncol*, 16(10):3222-3229 (October 1998).

Bruera E., Opioid Rotation in Patients with Cancer Pain, *Cancer*, 78(4):852-857 (August 1996).

CalRecycle, Graphs of Responses to the Sharps Personal Use Survey on Sharps Use and Disposal, <http://www.calrecycle.ca.gov/homehazwaste/sharps/Survey/PersonalRslt.pdf>.

Carnevale Associates, "Prescription Drug Takeback Programs & Substance Abuse Prevention, Policy Brief (February 2012).

Caulkins J.P., Models Pertaining to How Drug Policy Should Vary Over the Course of an Epidemic Cycle, In: Lindgren B, Grossman M, eds. *Substance Use: Individual Behavior, Social Interactions, Markets, and Politics, Advances in Health Economics and Health Services Research*, Vol 16: Elsevier, (2005).

Caulkins J.P., *The Need for Dynamic Drug Policy*, Heinz Research Paper, 23 (2006).

Cepeda M.S., et. al., Assessing Opioid Shopping Behavior: A Large Cohort Study from a Medication Dispensing Database, *Drug Saf*, 35(4):325-334 (May 2012).

Cepeda M.S., et. al., Opioid Shopping Behavior: How Often, How Soon, Which Drugs, and What Payment Method, *J Clin Pharmacol*, 53(1):112-117 (January 2012).

Cicero T.J., et. al., Multiple Determinants of Specific Modes of Prescription Opioid Diversion, *J Drug Issues*, 41(2):283-304 (Spring 2011).

City of Rosedale, Environmental Utilities Residential Customer Telephone Tracking Survey, [http://calpsc.org/mobius/cpsc-content/uploads/2015/03/CityOfRoseville\\_EnviroUtilities\\_-\\_ResidentialCustomerSurvey\\_PharmaceuticalResults\\_Jan2014.pdf](http://calpsc.org/mobius/cpsc-content/uploads/2015/03/CityOfRoseville_EnviroUtilities_-_ResidentialCustomerSurvey_PharmaceuticalResults_Jan2014.pdf).

Coalition Against Insurance Fraud, *Prescription for Peril: How Insurance Finances Theft and Abuse of Addictive Prescription Drugs*, Washington, D.C. (2007).

Dart, R., et. al., The Underrecognized Toll of Prescription Opioid Abuse on Young Children, *Annals of Emergency Medicine*, 53(4):419–424 (April 2009).

Dunbar P.J., et. al., Clinical Analgesic Equivalence for Morphine and Hydromorphone with Prolonged PCA, *Pain*, 68(2-3):265-270 (December 1996).

Egan K., et. al., From Dispensed to Disposed: Evaluating the Effectiveness of Disposal Programs Through a Comparison with Prescription Drug Monitoring Program Data, *Am J Drug Alcohol Abuse*, 43(1):69-77 (2017).

Executive Office of the President of the United States, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011).

Extended Producer Responsibility (EPR) Summary Report, *EPR Canada* (September 2017), <http://www.eprcanada.ca/reports/2016/EPR-Report-Card-2016.pdf>.

Fleming E., et. al., North Carolina's Operation Medicine Drop: Results from one of the Nation's Largest Drug Disposal Programs. *N C Med J*, 77(1):59-62 (January 2016).

Glassmeyer, S.T., et. al, Disposal Practices for Unwanted Residential Medications in the United States, *Environment International*, 35:566-572 (December 2008).

Gold, Kathleen, Analysis: The Impact of Needle, Syringe, and Lancet Disposal on the Community, *J Diabetes Sci Technol*, 5(4):848–850 (July 2011).

Golub A., et. al., *Monitoring Drug Epidemics and the Markets That Sustain Them, Arrestee Drug Abuse Monitoring (ADAM) and ADAM II Data, 2000-2003 and 2007-2010*, Ann Arbor, MI: Inter-university Consortium for Political and Social Research, ICPSR33201.v1 (2012).

Gray J., et. al., Prescription Disposal Practices: a 2-year Ecological Study of Drug Drop Box Donations in Appalachia, *Am J Public Health*, 105(9):e89-e94 (September 2015).

Health Care without Harm, [https://noharm-europe.org/sites/default/files/documents-files/2616/Pharm%20Report\\_WEB.pdf](https://noharm-europe.org/sites/default/files/documents-files/2616/Pharm%20Report_WEB.pdf).

Houskeeper, Brandon, “Drug Take-back Programs: What Will They Solve?” Washington Policy Center, Seattle, WA, January 2009.



- Hunt R., et. al., A Comparison of Subcutaneous Morphine and Fentanyl in Hospice Cancer Patients, *J Pain Symptom Manage*, 18(2):111-119 (August 1999).
- Inciardi, J.A., et. al., Mechanisms of Prescription Drug Diversion Among Drug-involved Club and Street-based Populations, *Pain Med*, 8(2):171-183 (March 2007).
- Inciardi, J.A., et. al., The “Black Box” of Prescription Drug Diversion, *J Addict Dis*, 28(4):332-347 (October 2009).
- Inciardi, J.A., et. al., The Diversion of Prescription Drugs by Health Care Workers in Cincinnati, Ohio, *Subst Use Misuse*, 41(2):255-264 (2006).
- Inturrisi C.E., Clinical Pharmacology of Opioids for Pain, *Clin J Pain*, 18(4):S1-S11 (July-August 2002).
- Jaramillo-Stametz, J.E., et. al. Multi-state Medication Take Back Initiative: Controlled Substances from 2011-2015, *J of Substance Use*, 1-7 (August 2017).
- Kalso E, et. al., Morphine and Oxycodone Hydrochloride in the Management of Cancer Pain, *J Clin Pharm Ther*, 47(5):639-646 (May 1990).
- Kolpin, D.W., et. al., Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance, *Environ Sci Technol*, 36:1202-1211 (2002).
- Kotchen, Matthew J., et. al., Pharmaceuticals in Wastewater: Behavior, Preferences, and Willingness to Pay for a Disposal Program, *J of Environmental Management*, 90(3):1476-1482 (2009).
- Law, Anandi V., et. al., Taking Stock of Medication Wastage: Unused Medications in U.S. Households, *Research in Social and Administrative Pharmacy*, 11:571-578 (2015).
- Lederer, C., To the Point: The Risk Home Sharps Disposal Poses to Waste Workers, *Waste 360* (2011).
- Leigh, J.P., et. al., Characteristics of Persons and Jobs with Needlestick Injuries in a National Data Set, *American Journal of Infection Control* 36(6):414-420 (August 2008).
- Levi, Jeffrey, PhD., et. al., Prescription Drug Abuse: Strategies to Stop the Epidemic, Trust for America’s Health, Washington, D.C., October 2013.
- Lipari R. and Hughes A., *How People Obtain the Prescription Pain Relievers They Misuse*, Substance Abuse and Mental Health Services Administration, Rockville, MD, NBK424785 (2017).

Los Angeles County Department of Health, LA County Medicines and Sharps Disposal and Consumer Survey Results, <http://publichealth.lacounty.gov/docs/SharpsDisposalSurvey.pdf>.

Lubick, N., Drugs in the Environment: Do Pharmaceutical Take-Back Programs Make a Difference? *Environ Health Perspect*, 118(5):A210–A214 (May 2010).

Ma C, et. al., Take back in Hawaii: Partnership between the University of Hawaii Hilo College of Pharmacy and the Narcotics Enforcement Division, *Hawaii J Med Public Health*, 73(1):26-31 (January 2014).

Majumdar, Anindo, et. al., Improper Sharp Disposal Practices Among Diabetes Patients in Home Care Settings: Need for Concern? *Indian J of Endo and Metabolism*, 19(3):420–425 (May-June 2015).

Martins S.S., et. al., Worldwide Prevalence and Trends in Unintentional Drug Overdose: A Systematic Review of the Literature, *Am J Public Health*, 105(11):2373-2373 (November 2015).

Maughan B., et. al., Unused Opioid Analgesics and Drug Disposal Following Outpatient Dental Surgery: A Randomized Controlled Trial, *Drug Alcohol Depend*, 168:328-334 (2016).

National Center for Health Statistics, *Multiple Cause of Death 1999-2014 on CDC WONDER Online Database*, Centers for Disease Control and Prevention, Atlanta, GA (2015).

Pereira J., et. al., Equianalgesic Dose Ratios for Opioids: A Critical Review and Proposals for Long-term Dosing, *J Pain Symptom Manage*, 22(2):672-687 (August 2001).

Perry, J., et. al., Disposal of Sharps Medical Waste in the United States: Impact of Recommendations and Regulations, 1987-2007, *Am J of Infection Control*, 40(4):354-358 (May 2012).

Perry L., et. al., Quantification of Ongoing Community-based Medication Take-back Program, *J Am Pharm Assoc*, 54:275-279 (May/June 2014).

Pradel V., et. al., Impact of a Prescription Monitoring Program on Doctor-shopping for High Dosage Buprenorphine, *Pharmacoepidemiol Drug Saf*, 18(1):36-43 (January 2009).

Rigg, K.K., et. al., Prescription Drug Abuse & Diversion: Role of the Pain Clinic, *J Drug Issues*, 40(3):681-702 (March 2010).

Rigg, K.K., et. al., Patterns of Prescription Medication Diversion among Drug Dealers, *Drugs (Abingdon Engl)*, 19(2):144-155 (2012).

Ripamonti C., et. al., Switching from Morphine to Oral Methadone in Treating Cancer Pain: What is the Equianalgesic Dose Ratio, *J Clin Oncol*, 16(10):3216-3221 (October 1998).

Schwartz R.P., et. al., Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995-2009, *Am J Public Health*, 10(5):917-922 (May 2013).

Sherman S.G., et. al., Efforts to Reduce Overdose Deaths, *Am J Public Health*, 103(8):e1-2 (August 2013).

Shields, Margaret, Ph.D., Presentation to the Oregon House Interim Committee on Health Care, Community Environmental Health Strategies, (September 22, 2016).

Simeone R., *The Economic Impact of Illicit Drug Use on American Society*, U.S. Department of Justice, Washington, D.C. (2011), Q0317-002.

Simeone R., *An Evaluation of Prescription Drug Monitoring Programs*, U.S. Department of Justice, Washington, D.C. (2006), NCJ217269.

Simeone R., *Doctor Shopping Behavior and the Diversion of Opioid Analgesics: 2008-2012*, Office of National Drug Control Policy, Executive Office of the President, Washington, D.C. (2014).

Simeone R., Doctor Shopping Behavior and the Diversion of Prescription Opioids, *Subst Abuse*, 11:1-10 (April 2017).

Stewart H., Inside Maine's Medicine Cabinet: Findings from the Drug Enforcement Administration's Medication Take-back Events, *Am J Public Health*, 105(1):e65-e71 (2015).

Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, *Treatment Episode Data Set – Admissions (TEDS-A) – Concatenated, 1992 to 2012*, Rockville, MD, Ann Arbor MI: Inter-university Consortium for Political and Social Research, ICPSR 25221 (2015).

Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, *Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health*, Rockville, MD, HHS Publication No. (SMA) 15-4927, NSDUH Series H-50 (2015).

Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits*, Rockville, MD, HHS Publication No. (SMA) 13-4760, DAWN Series D-39 (2013).

Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, *National Admissions to Substance Abuse Treatment Services*, Rockville, MD, BHSIS Series S-71, HHS Publication No. (SMA) 14-4850 (2015).

Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings (Detailed Tables)*, Rockville, MD, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795 (2015).

Teleosis Institute, 2013 Medicine Waste Characterization Study (August 2, 2013).

United States General Accounting Office, *Prescription Drugs: Oxycontin Abuse and Diversion and Efforts to Address the Problem*, Washington D.C., GAO-04-110 (2003).

Volkow N.D., America's Addiction to Opioids: Heroin and Prescription Drug Abuse, Paper presented at the Senate Caucus on International Narcotics Control (2014).

Welham G., et. al., Type and Frequency of Opioid Pain Medications Returned for Disposal, *Drugs - Real World Outcomes*, 2(2):129-135 (2015).

World Health Organization, *Pharmaceuticals in Drinking-water*, WHO Press, Geneva Switzerland (2011).

Yang C., et. al., Analysis of Medications Returned During a Medication Take-back Event, *Pharmacy*, 3:79-88 (2015).

Yanovitzky I., The American Medicine Chest Challenge: Evaluation of a Drug Take-back and Disposal Campaign, *J Stud Alcohol Drugs*, 77:549-555 (2016).

#### Legislation/Legal Citations

Cal. Health and Safety Code, Div. 104, Pt 14, Ch 9 § 118286.

Disposal of Controlled Substances, Final Rule, Drug Enforcement Administration, U.S. Department of Justice, 79 Fed. Reg. 174 (September 9, 2014).

Secure and Responsible Drug Disposal Act of 2010, P.L. 111-273 (October 12, 2010).

#### News Articles and Books

Fletcher, H., "Tennesseans Turn in Mountains of Pills, but Fight Against Opioids Rages," *USA Today*, October 15, 2017.

Nagle, R., *Picking Up: On the Streets and Behind Trucks with the Sanitation Workers of New York City*, Macmillan Press, 2013.

Ryan H., et. al., “OxyContin Goes Global — We’re Only Just Getting Started,” *Los Angeles Times*, December 18, 2016.

Turkewitz, J., “The Pills are Everywhere: How the Opioid Crisis Claims its Youngest Victims,” *New York Times*, September 20, 2017.

Quann, P., “Sanitation Workers Stuck by loose Needles,” *Bucks County Courier Times*, September 2, 2014.

#### Federal and Other Web Resources

Centers for Disease Control and Prevention, Drug Overdose Deaths in the United States Continue to Increase in 2015, <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

Centers for Disease Control and Prevention, Prescribing Data, Found at: <https://www.cdc.gov/drugoverdose/data/prescribing.html>.

Environmental Protection Agency, Community Options for Safe Needle Disposal, [https://www.epa.gov/sites/production/files/2016-02/documents/med-govt\\_0.pdf](https://www.epa.gov/sites/production/files/2016-02/documents/med-govt_0.pdf).

Environmental Protection Agency, Medical Waste, <https://www.epa.gov/rcra/medical-waste>.

Food and Drug Administration, How Big of a Problem is Accidental Exposure to Medicine in the United States? <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186188.htm#3>.

Food and Drug Administration, How to Dispose of Unused Medicines, <https://www.fda.gov/forconsumers/consumerupdates/ucm101653.htm>.

Food and Drug Administration, Fentanyl Patch Can be Deadly to Children, <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm>.

Paint, The Product Stewardship Institute, Found at: [http://www.productstewardship.us/?page=PSI\\_and\\_Paint](http://www.productstewardship.us/?page=PSI_and_Paint).

Product Stewardship Institute, Protecting our Health and the Environment: The Need for Sustainably Financed Drug Take-Back Programs, <http://c.ymcdn.com/sites/www.productstewardship.us/resource/collection/FFDF28A1-9926-46E7-87F9-70C7BBD95491/TheNeedforSustainably.pdf>.

Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, 2013 National Survey on Drug Use and Health, <https://nsduhweb.rti.org/respweb/homepage.cfm>.

Trust for America's Health, The Facts Hurt: A State-By-State Injury Prevention Policy Report, <http://healthyamericans.org/reports/injuryprevention15/>.

## **APPENDIX B**

Fentanyl Disposal Sheet from the British Columbia  
(Canada) Medications Return Program



# SAFE DISPOSAL OF FENTANYL PATCHES

A fentanyl patch is a medicated adhesive patch that is placed on the skin to deliver a specific dose of fentanyl through the skin.

Improper disposal of these patches is a risk for illicit use and overdose and can also cause serious harm to members of the public including children, pets, and sanitation workers, as well as our water supply.

A used fentanyl patch may still contain more than 50% of the labelled amount of fentanyl – enough to cause serious harm or even death.

Placing used fentanyl patches in the garbage or flushing them down the toilet can cause serious harm to children, pets, sanitation workers, and our water supply.



## How to Safely Dispose of Fentanyl Patches

In order to prevent accidental exposure or diversion, please use the following steps to dispose of used fentanyl patches:



Wear protective gloves to prevent accidental exposure to the drug



Fold the patch in half so that the adhesive side is stuck together



Dispose of patch in a tamperproof, childproof storage container (or sharps container)



Bring the container holding the patch to your pharmacy or other medications return location for safe disposal



## How NOT to Dispose of Fentanyl Patches

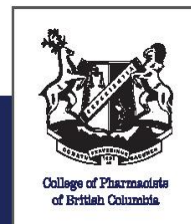


Placing them in the garbage



Flushing them down the toilet

For more information visit:  
[www.bcpharmacists.org/fentanyl-patches](http://www.bcpharmacists.org/fentanyl-patches)



# Ecoconsult Report

Los Angeles County – EPR Ordinance Review

Part A – March 10, 2017

Part B – October 19, 2017

# **Part A – March 10, 2017**

**Los Angeles County - EPR Ordinance  
Public Health Policy Technical Analysis  
March 10, 2017**

**Project Title: Pharmaceutical and Sharps Collection and Disposal  
Stewardship Ordinance**

**Department: Department of Public Health – Environmental Health Division**

**Prepared by Ecoconsult**

**In collaboration with**

**California Conference of Directors of Environmental Health**

**910 K Street, Suite 300**

**Sacramento, CA 95814**

## Table of Contents

- 1. Executive Summary & Methodology**
- 2. Analysis**
  - 2.1 Identification of success and/or obstacles with existing ordinances and implementation of the related stewardship plans.**
    - a) County Pharmaceutical Stewardship Ordinances: Timeline of Passage**
    - b) Implementation**
    - c) Overview of unsuccessful pharmaceutical industry lawsuits**
    - d) Counties Assisting Pharmaceutical Industry in Stewardship Learning Curve**
  - 2.2 Interviews**
  - 2.3 Effectiveness of Extended Producer Responsibility (EPR)**
    - a) Pharmaceutical EPR**
    - b) Cost Analysis**
    - c) Medical Sharps**
  - 2.4 Review of existing research and findings on the potential impact of unwanted pharmaceutical and sharps waste on humans due to improper disposal or lack of adequate disposable options.**
    - a) Unused Medicine**
    - b) Medicine Disposal**
    - c) Pharmaceutical Pollution in the Environment**
    - d) Analysis of studies commonly cited by the Pharmaceutical Industry**
  - 2.5 and 2.6 Evaluation of whether or not implemented ordinances have resulted in, or are expected to, result in better public health and environmental protections**
    - a) Challenges of Voluntary Programs**
    - b) About Evaluation of Effectiveness of Medicine Take-back Programs**
    - c) Prevention Strategy**
  - 2.7 The most effective options available for Los Angeles County to address the public health and safety, and environmental impacts related to the disposal of unwanted pharmaceuticals and sharps waste**
- 3. Opinion**
  - 3.1 Recommendations for proposed ordinance**
  - 3.2 Ordinance Determinations**

**APPENDIX A: Ecoconsult Team Qualifications**

**APPENDIX B: Support from human health, environmental, and industry perspective – King County, WA**

**APPENDIX C: Status of Implementation of County Laws in California and Washington**

**APPENDIX D: DEA Rule for Disposal of Controlled Substances**

**APPENDIX E: Interview Tables; Table of Responses and Table of References and Data Sources**

## Executive Summary

This Public Health Policy Technical Analysis of the Los Angeles County Pharmaceutical and Sharps Collection and Disposal Stewardship Ordinance (Pharma EPR Ordinance) been conducted by Ecoconsult in conjunction with the California Conference of Directors of Environmental Health.

The Ecoconsult team includes its Principal and internal staff as well as external advisors with extensive experience in public environmental health. (See team biographies in Appendix A). The conclusions reached are based on the team's professional experience, academic training, analysis of Los Angeles County public records, literature review and interviews of existing pharmaceutical take-back program managers.

Consistent with the application of a Public Health Logic Model we drew two key assumptions in this analysis without independent verification:

1. It is in the interest of Los Angeles County and its residents to reduce:
  - the amount of expired and unused medication and sharps that are currently being stockpiled unsafely in private homes;
  - the amount of pharmaceuticals that could be misused, and lead to addiction, or even death or hospitalization due to overdose;
  - the amount of pharmaceuticals that could be misused and even lead to death or hospitalization due to unintentional poisoning;
  - the number of injuries to waste facility workers or the general public due to improper disposal of sharps; and
  - the amount of unused/unwanted pharmaceuticals and sharps products entering the environment whether into landfills, wastewater (flushing) or litter.
2. Reducing access to potentially dangerous medications and sharps through proper management is the most efficient and effective option for reducing or eliminating the public health and safety impacts of unsafe storage or improper disposal of unwanted medications and sharps.

In the process of evaluating the likely efficacy of the proposed ordinance, our analysis drew the following related conclusions about the overall approach being considered by the County:

1. There is compelling evidence that links drug abuse and initiation of addiction to easy access to medicines kept in homes.
2. Significant amounts of pharmaceuticals go unused by consumers or expire before use for a variety of reasons, including for appropriate and legitimate healthcare reasons, and need proper disposal. Medical sharps by design must be disposed of after use.
3. Despite limited locations and promotion, existing voluntary take-back programs have collected significant amounts of leftover pharmaceuticals and sharps. Consumer demand for safe take-back options has been confirmed by a variety of consumer surveys and by their use of voluntary take-back programs, despite their lack of convenience.
5. Voluntary take-back programs have failed to provide adequate access and convenience, and lack sufficient resources for promotion or for management of larger amounts of return medicines, to ensure that unwanted or unused drugs are adequately collected and safely managed to prevent stockpiling or improper disposal of these medicines.

6. Absent a comprehensive and effective national or statewide program that ensures the safe end-of-life management of these medicines and sharps, the public health and environmental protection obligation falls on the local jurisdictions.
7. Centralized data collection will assist with program evaluation and consistent consumer education.
8. While Advance Disposal Fees may offer an effective end-of-life management option for certain products, our research found that a mandated shared product stewardship for collection and disposal of pharmaceuticals was more cost effective for local government, consumers and retail outlets and involved less direct government engagement and greater program flexibility.
9. Notwithstanding the assertions from pharmaceutical producers that the take-back mandates in the proposed ordinance will place the primary financial burden on the manufacturers/producers, we found that the existing EPR programs do share responsibility and cost and will most likely place a minimal financial burden on an industry that is receiving large revenue returns.
10. Despite pharmaceutical industry resistance within USA and their own countries, Canada has already initiated and Mexico has recently started to implement national producer responsibility plans.
11. Successful stewardship programs in California and beyond for other hazardous or hard-to-handle products such as electronics, thermostat, paint, and batteries, demonstrate that carefully established convenience standards, education and public awareness assessment measures, as well as “rates and dates” performance metrics are not only desirable, but are essential to the equitable and effective program design and implementation.
12. Substantially similar pharmaceutical and sharps producer programs mandated and implemented in other counties, states and abroad have withstood legal challenge, enjoy broad public support and have demonstrated early success.

The overall policy intent of the proposed LA county ordinance is sound, and is similar to the policy of local stewardship laws that are being successfully implemented in other counties. The following recommendations that are described in greater detail in Section 3 of this analysis are refinements to the existing policy that further clarify the intent or reflect learnings from other jurisdictions.

- Adjust Implementation Timeline;
- Mandate that Manufacturers Must Accept All Qualified Collectors into Program;
- Narrow the Exemptions in the “Responsible Steward” Definition to Better Mirror the FDA’s Definition of Manufacturer;
- Clarify that Manufacturers Must Service Collection Sites Frequently Enough to Avoid Overfull Collection Receptacles;
- Align the disposal facility requirements in Section 11.17.060 with the EPA;
- Require manufacturer description of Program Collection Goals; and
- Clarify Collection Requirement for Any Covered Drugs that May Not Be Suitable for Comingling in Collection Receptacles.

## **Methodology**

Our conclusions respond to the issues raised in the solicitation for the analysis without necessarily conforming exactly to the format prescribed in the workscope proposed by the County.



## 2. Analysis

### 2.1 - Identify success and/or obstacles with existing ordinances and implementation of the related stewardship plans.

#### a) Select County Pharmaceutical Stewardship Ordinances: Timeline of Passage

The nation's first product stewardship law for prescription medicines was passed by the Board of Supervisors of Alameda County, CA in July 2012. The Board of Health of King County, WA passed the second law in July 2013 for secure return of prescription and over-the-counter medicines. Each county conducted extensive stakeholder processes lasting more than one year to develop the policy. Each law requires that pharmaceutical companies that manufacture the medicines must finance and provide a convenient and safe system for secure collection and environmentally sound disposal of expired and unneeded medicines used in the home. Medicine manufacturers are required to develop a stewardship plan(s) explaining how they propose to meet the performance requirements defined in the ordinance. The local oversight agency reviews and approves the stewardship plan(s) and oversees the approved program for safety and compliance with the ordinance. King County's regulation was very similar in policy approach to the Alameda ordinance, but more specific on the performance standards for the stewardship program, including requiring that producers meet a minimum convenience standard for providing secure drop boxes throughout the county.

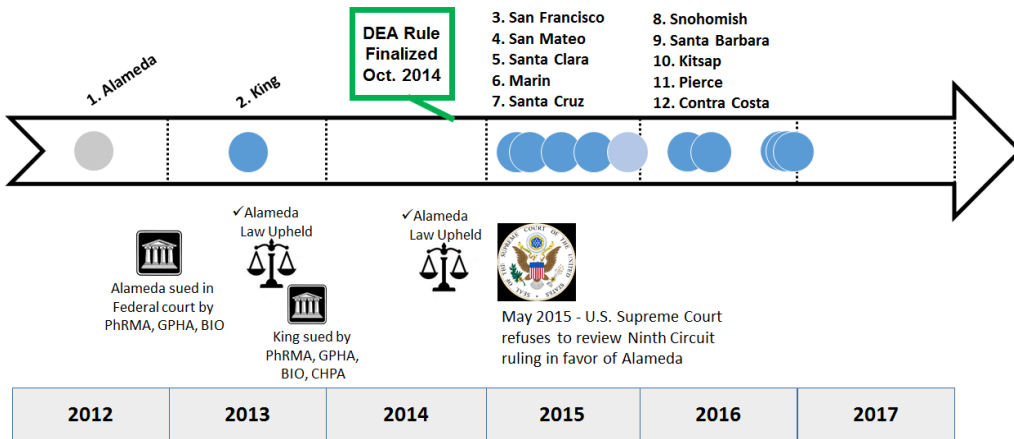
Alameda County and King County were each sued in federal court, unsuccessfully, by pharmaceutical industry associations, which created one of two significant areas of delay in implementation of the first two county laws. While the Alameda lawsuit worked its way through the courts, both counties voluntarily extended their deadlines for stewardship plan submission, which were originally one year after passage. The [Northern California District Court](#) and the [Ninth U.S. Circuit Court of Appeals](#) each upheld Alameda County's ordinance, dismissing the industry's claim of a violation of the dormant Commerce Clause. (see section 2.1(c))

After the Ninth Circuit ruling in September 2014, both counties resumed implementation deadlines. Shortly thereafter, the DEA issued its final Rule on disposal of controlled substances which defined protocols and authorizations for operation of medicine take-back programs collecting medicines that are controlled substances. (see Appendix B)

In 2015, five more CA counties passed laws modeled on King County's regulations, with some modifications. Alameda County amended their ordinance in February 2016, making it more similar to the others (see discussion on this under Program Implementation in Alameda County).

In 2016, local pharmaceutical stewardship laws were enacted in seven additional local jurisdictions: three counties in WA, two counties in CA, as well as in the cities of Capitola and Santa Cruz in Santa Cruz County, CA.

## Timeline of Passage of County Pharmaceutical Stewardship Laws & Resolution of Pharmaceutical Association Federal Lawsuits



### b) Implementation

#### Alameda County, CA

After resolution of the pharmaceutical industry associations' lawsuit in September 2014, implementation deadlines were resumed and manufacturers developed stewardship plans.

February 2015 – Alameda County approved the [Alameda MED-Project](#) stewardship [Plan](#) representing about 320 producers. The Plan proposed one collection event per month and a roll-out of services for law enforcement drop boxes during year 1, then expansion to drop boxes in pharmacy and healthcare locations during year 2.

Implementation of the Plan was slower than expected during 2015 as the Plan operators learned about forming contracts with public and private entities. The county and local agencies have continued to coordinate medicine collection events and operate 30 secure collection sites until the Alameda MED-Project can take over that role.

August 2015 – First take-back event held, with greater than 360 pounds of medicines collected. After this event, MED-Project stopped participating in collection events to consider how to address the over-the-counter medicines returned by residents because the ordinance only required collection of prescription drugs.

February 2016 – Alameda Board of Supervisors amended the 2012 ordinance to align with similar laws in King County and other CA counties by requiring stewardship of over-the-counter medicines, requiring collection of controlled substances pursuant to DEA's regulation, requiring that any qualified collector is included as a drop-off location, and other adjustments. The [Amendment](#) took effect on March 3, 2016. In March, the Alameda MED-Project Plan amended its agreement with Sheriff's Office, and clarified how controlled substances and over-the-counter medicines would be collected.

2016 collection events: MED-Project Plan held more than 20 collection events in 2016, and plans to conduct a total of 24 take-back events around the county during 2016. Communication with county staff indicates that while amount collected has increased, they remain concerned that marketing of these events has fallen short.

Secure drop box installations: Beginning in December 2016, MED-Project began installing ongoing secure drop boxes in pharmacies in Alameda County. Currently there are 12 secure drop boxes: 10 at independent pharmacies and 2 at police stations.

**Table of MED-Project Events in Alameda County & Collection Amounts**

Event #	Event Type	Event Date	Location	Persons/Cars	Volume (gallons)	Weight (pounds)	Lbs/Hr	Lbs/Car
1	Fair/Festival/Event	03/03/2016	Oakland		55	50.5	7.8	N/A
2	Fair/Festival/Event	03/12/2016	San Leandro		85	123.5	30.9	N/A
3	Fair/Festival/Event	04/23/2016	San Lorenzo		150	299.9	50.0	N/A
4	HHW	05/01/2016	Pleasanton		150	278.65	69.7	N/A
5	HHW	05/15/2016	San Leandro		120	212.2	53.1	N/A
6	HHW	06/19/2016	Albany		180	337	84.3	N/A
7	Fair/Festival/Event	06/21/2016	Pleasanton		15	31	10.3	N/A
8	Fair/Festival/Event	06/22/2016	Pleasanton		15	26.5	8.8	N/A
9	Fair/Festival/Event	06/23/2016	Pleasanton		15	25	8.3	N/A
10	Fair/Festival/Event	06/24/2016	Pleasanton		15	28	9.3	N/A
11	Fair/Festival/Event	06/25/2016	Pleasanton		15	27.5	6.9	N/A
12	Fair/Festival/Event	06/26/2016	Pleasanton		15	19	4.8	N/A
13	HHW	07/17/2016	Alameda	68	90	159	39.8	2.3
14	Fair/Festival/Event	07/23/2016	Castro Valley		125	265.5	88.5	N/A
15	HHW	07/31/2016	Emeryville	54	90	187.5	46.9	3.5
16	HHW	08/13/2016	Castro Valley	250	850	1298	216.3	5.2
17	HHW	08/28/2016	Oakland	49	90	196	49.0	4.0
18	Fair/Festival/Event	09/15/2016	Oakland	33	60	131	21.8	4.0
19	HHW	09/24/2016	Union City	71	150	317.5	79.4	4.5
20	HHW	10/02/2016	Albany	135	270	572.5	143.1	4.2

### **King County, WA**

After resolution of the pharmaceutical industry associations' lawsuit in September 2014, the county resumed the regulation's implementation deadlines.

February 2015 – Two stewardship organizations submitted plans: ReturnMeds ([Call2Recycle](#)) and [King County MED-Project \(PPSWG\)](#). Both plans were rejected on initial review as not meeting all requirements of the regulations, and producers were required to create revised plans. The ReturnMeds plan was accepted after one round of revision. The King County MED-Project plan was accepted after two rounds of revision.

October 2015 – Revised plan from ReturnMeds was accepted and designated the Standard Plan, representing 12 producers.

March 2016 – Revised plan from King County MED-Project was accepted as an Independent Plan, representing > 370 producers.

April 2016 – The King County MED-Project plan was designated the approved [Standard Plan](#) after ReturnMeds withdrew its participation as an approved stewardship plan due to lack of sufficient participating producers.

Required Collection Services to be Provided to Residents: Secure drop boxes must be distributed throughout the county to meet a minimum geographic and population based standard. Producers are also required to partner with any pharmacy or law enforcement site that offers to host a drop box. In any areas lacking drop boxes, periodic collection events or pre-paid return mailers must be provided. Pre-paid return mailers must also be available for home-bound or differentially-abled residents.

Implementation of MED-Project's Standard Plan: MED-Project began implementing its approved plan in March 2016, and requested and received approval for a revised timeline to have the required collection system fully operational in January 2017.

Under the local Board of Health Regulation in King County, WA's, a system of secure medicine drop boxes was rolled out during November and December 2016, with an official launch on January 17, 2017.<sup>1</sup>

Prior to the launch of the stewardship program, secure medicine take-back options in the county were limited due to lack of resources for voluntary programs:

- 10 drop boxes at law enforcement offices in Auburn, Bothell, Burien, Kenmore, Lake Forest Park, Issaquah, Maple Valley, Sammamish, Snoqualmie, Woodinville.
- 3 drop boxes at Walgreens stores in Burien, Kent, Kirkland. Walgreens has more than 30 stores in the county, but is only providing medicine take-back services at certain stores.
- No ongoing drop boxes in the county's two largest cities of Seattle, Bellevue, or in the large cities of Federal Way and Renton.

MED-Project, representing 410 drug manufacturers, launched a system of 87 secure drop boxes for safe disposal of prescription and over-the-counter medicines in January 2017. All locations collect prescription and over-the-counter medicines, including controlled substances.

- 70 drop boxes at pharmacies: 17 drug stores; 21 grocery stores; 30 clinics; 2 hospitals.
- 17 drop boxes at law enforcement offices.
- Pre-paid return mailers are also available for homebound or differentially-abled residents.
- MED-Project is required to provide a minimum number of drop-off sites in towns/cities and unincorporated areas. Collection events or prepaid return mailers fill in any service gaps.



More pharmacies and law enforcement can join the manufacturers' program. King County's law is an "opt-in" system for pharmacies and law enforcement agencies. A February 16, 2017 media release by King County WA stated that 99 drop boxes were in operation.<sup>2</sup> The three drop boxes at Walgreens stores continue to operate independently. If it chooses to, Walgreens can join the MED-Project program at any of its 30 stores in the county.

The focus on the pharm stewardship ordinances in WA has been on public health & safety, while still providing some focus on the environmental benefits.

**Appendix B provides support from human health, environmental, and industry perspective – King County, WA**

**Appendix C provides a summary of the status of county ordinances in California and Washington State.**

<sup>1</sup> King County Secure Medicine Return website. <https://kingcountysecuremedicinereturn.org/>

<sup>2</sup> King County, WA media release. Feb. 16, 2017. "King County Brings Secure Medicine Return Program to the Region" <https://kingcountysecuremedicinereturn.org/press-release-february-16-2017/>

### c) Overview of unsuccessful pharmaceutical industry lawsuits

Three pharmaceutical industry associations - PhRMA, GPhA, and BIO - sued Alameda County in federal court in Dec. 2012 over the Safe Drug Disposal Ordinance. King County was sued in Nov. 2013 over its Secure Medicine Return Regulations and the suit included the Consumer Healthcare Products Association (CHPA) because King County's regulation included over-the-counter medicines.

#### Timeline of Legal Proceedings in Federal Courts

July	2012	Alameda County, CA passes a Safe Drug Disposal Ordinance, first-in-nation pharmaceutical stewardship law requiring manufacturers to provide a secure medicine take-back system.
Dec	2012	Three pharmaceutical associations (PhRMA, GPhA, BIO) file a federal lawsuit against Alameda County claiming violation of the dormant Commerce Clause.
June	2013	King County, WA passes a Secure Medicine Return Regulation.
Aug.	2013	U.S. Northern California District Court upholds Alameda County's law.
Sept.	2013	Pharmaceutical associations appeal the verdict to the U.S. Ninth Circuit Court.
Nov.	2013	Four pharmaceutical industry associations (PhRMA, GPhA, BIO, CHPA) file a similar federal lawsuit against King County. There are some differences in details between the two county laws but the two federal lawsuits were legally identical.
Sept.	2014	U.S. Ninth Circuit Court upholds Alameda's law.
Dec.	2014	Pharmaceutical associations file petition for review to U.S. Supreme Court.
<b>May</b>	<b>2015</b>	<b>U.S. Supreme Court dismisses pharmaceutical associations' petition against Alameda County. County Pharmaceutical Stewardship Laws Upheld.</b>
June	2015	Pharmaceutical associations end their lawsuit against King County. No hearings were held on the King suit because the Alameda suit was working through federal courts.

In these federal lawsuits, the pharmaceutical associations argued that the county laws violate the "dormant Commerce Clause" by placing unfair burdens on pharmaceutical manufacturers, who are essentially all outside the county, to pay for a local medicine take-back program. The Commerce Clause of the U.S. Constitution empowers Congress to regulate interstate commerce. The "dormant Commerce Clause" is a corollary under which state and local governments may not unduly interfere with interstate commerce. Two levels of federal courts rejected this dormant Commerce Clause argument. A petition from the pharmaceutical associations to the U.S. Supreme Court to review the Ninth Circuit ruling was denied in May 2015.

The U.S. Northern California District Court ruled:

- Alameda County's ordinance does not discriminate against out-of state entities in the manner prohibited by the dormant Commerce Clause. The law does not favor companies in the county over companies outside of the county.
- Alameda County's ordinance does not directly regulate interstate commerce in the manner prohibited by the dormant Commerce Clause. The ordinance applies to drug producers who sell their products in Alameda County, which the court said means it does not target producers on the basis of their location.
- Alameda County has "adequately shown that the Ordinance serves a legitimate public health and safety interest, and that the relatively modest compliance costs producers will incur should they choose to sell their products in the county do not unduly burden interstate commerce."

The U.S. Ninth Circuit Court upheld the lower court ruling, and stated in its verdict:

- “...there is nothing unusual or unconstitutional per se about a state or county regulating the in-state conduct of an out-of-state entity when the out-of-state entity chooses to engage the state or county through interstate commerce.”
- “The fact that the county could run a similar program does not nullify the program’s benefits...Moreover, even if the Ordinance did nothing other than save the county money, that is not equivalent to “no public benefits.”

Since the resolution of these lawsuits, there have been no further legal filings from the pharmaceutical industry on the county pharmaceutical stewardship programs.

#### **d) Counties Assisting Pharmaceutical Industry in Stewardship Learning Curve**

Medicine producers finance and operate medicine take-back programs in other countries, but these stewardship laws were new to the U.S. offices of these companies. Additionally, in October 2014, the DEA finalized regulations governing protocols for secure take-back of controlled substances by pharmacies, hospitals, and other authorized collectors. (See Appendix B for the DEA’s Rule for Disposal of Controlled Substances) This “learning curve” on stewardship and adjustment to the new DEA Rule was the second significant delay in implementing the county stewardship laws. Alameda County and King County conducted extensive outreach to pharmaceutical companies to explain the laws and assist the industry in developing successful stewardship plans. Alameda County also held public meetings and conducted outreach to pharmaceutical manufacturers to encourage them to form a stewardship organization. During this time period, voluntary medicine take-back programs continued operations and other entities, including for-profit companies like Sharps Compliance, started up new programs compliant with the DEA’s Rule. MED-Project LLC required several iterative attempts to develop a successful stewardship plan in Alameda County and in King County. It is notable that subsequent plan development and approval processes during 2015 and 2016 have proceeded more rapidly in San Francisco and other counties.

#### **APPENDIX D provides DEA Rule for Disposal of Controlled Substances**

## **2.2 Interviews**

Ecoconsult conducted eight telephonic interviews with pharmaceutical take-back program managers in California and Canada.

The respondents shared similar experiences on their program implementation in seven key areas:

1. Public health and safety issues were the most compelling arguments in supporting their ordinances. Environmental issues were important, but generally viewed as secondary to the public health and safety arguments.
2. Increasing opioid use/abuse rates and increasing rates of overdoses were offered as the leading drivers for local government intervention.
3. A few of the jurisdictions have seen dramatic collection increases in their voluntary take back programs. The amounts of medicines collected in Snohomish and Sonoma counties have doubled and tripled, respectively, in recent years, and both of them indicated that the increase is becoming unsustainable due to a lack of funding and resources to be able to handle existing loads, much less handle expanding the programs in the future as public demand increases.
4. Each jurisdiction recognized the lack of public support for continued and expanded public funding for the necessary continuation and expansion of these services. All indicated the need for financial support from the producers.
5. Most jurisdictions are in the early stages of implementation, so pre and post data analyses are not available. The manufacturer's MED-Project program is operating in several counties, but have not yet completed a full year of operation and submitted a required annual report.
6. Most jurisdictions are measuring standard outputs for the program (pounds collected, public awareness surveys, convenience goals). These local agencies have not attempted to quantify outcomes (improved water quality or reduced number of drug overdoses) particularly due to the cost of proving a causal relationship for a complex and multifactorial impact.

**APPENDIX E provides Interview Questions; Table of Responses and Table of References and Data Sources.**



## **2.3 Effectiveness of Extended Producer Responsibility (EPR)**

### **a) Pharmaceutical EPR**

#### **Medicine collection amounts are expected to be higher under pharmaceutical stewardship programs**

Our analysis has found that through the dedicated funding and coordination of pharmaceutical manufacturers, the local stewardship ordinances will provide more collection sites, will place collection sites in more convenient locations, and will provide enhanced collection services to underserved populations. Therefore, the mandated stewardship programs will result in increased collection of leftover and unwanted medicines, which prevents those collected medicines from causing poisonings, addiction, overdoses, or environmental pollution. Removing more unwanted medicines from homes reduces access which reduces the public health and safety risks.

Implementation of the pharmaceutical stewardship ordinance in King County, WA is proof of concept. The number and convenience of collection options has dramatically increased throughout the county with the launch of the MED-Project program in January 2017 (see details in section on implementation status of the county laws).

#### **1. More collection locations**

Under the pharmaceutical stewardship ordinances, manufacturers are required to provide a system of secure drop boxes, collection events, and mailers that will greatly increase the number of collection locations and options for county residents. Key to ensuring more collection sites is the provision in most of the county pharmaceutical laws that any qualified pharmacy location or law enforcement location that volunteers to host a secure collection receptacle must be included in the manufacturers' program. Some local ordinances also mandate inclusion of any qualified hospital/clinic with an on-site pharmacy. These policy provisions are key to moving towards a take-back system that makes it as convenient for residents to return leftover and expired medications as it is for them to purchase them.

#### **2. More convenient locations**

The local pharmaceutical stewardship ordinances make full utilization of the convenience of employing retail pharmacies and hospitals and clinics with on-site pharmacies as collection sites, as now possible under the protocols of the DEA's Rule for Disposal of Controlled Substances feasible. While law enforcement agencies have done an admirable job of providing secure drop boxes and collection events, it's undeniable that it will be much easier for residents to take leftover medicines to their local pharmacy, than to their police station. Retail pharmacies are often able to be open for the public to drop-off medicines for longer hours and on weekends than police stations. And residents can incorporate medicine take-back into their regular shopping at pharmacies or visits to their doctors. More convenience will clearly result in greater collection of potentially dangerous drugs, as demonstrated by comparing collection rates at pharmacies to law enforcement agencies.

#### **3. Alternate return options for underserved populations.**

The local pharmaceutical ordinances address the needs of homebound or differentially-abled residents by requiring prepaid return mailers upon request through the manufacturers' program. The mail-back service should be of particular value for homebound seniors, who use many medications and often have changes in medications that result in leftovers. Areas of the counties that lack pharmacies, hospitals, or police stations can also be served by periodic collection events and/or prepaid mailers.

#### **Per Capita Collection Amounts in Established EPR Programs with Pharmacy Collection Sites**

While the county-level pharmaceutical stewardship programs are quite new, British Columbia, Canada

and France have well-established drug take-back programs that are provided by manufacturers, per legislative requirement. Essentially all pharmacies participate voluntarily as collection sites. These programs have also conducted periodic public surveys to understand public awareness of the take-back programs and how many people use the program.

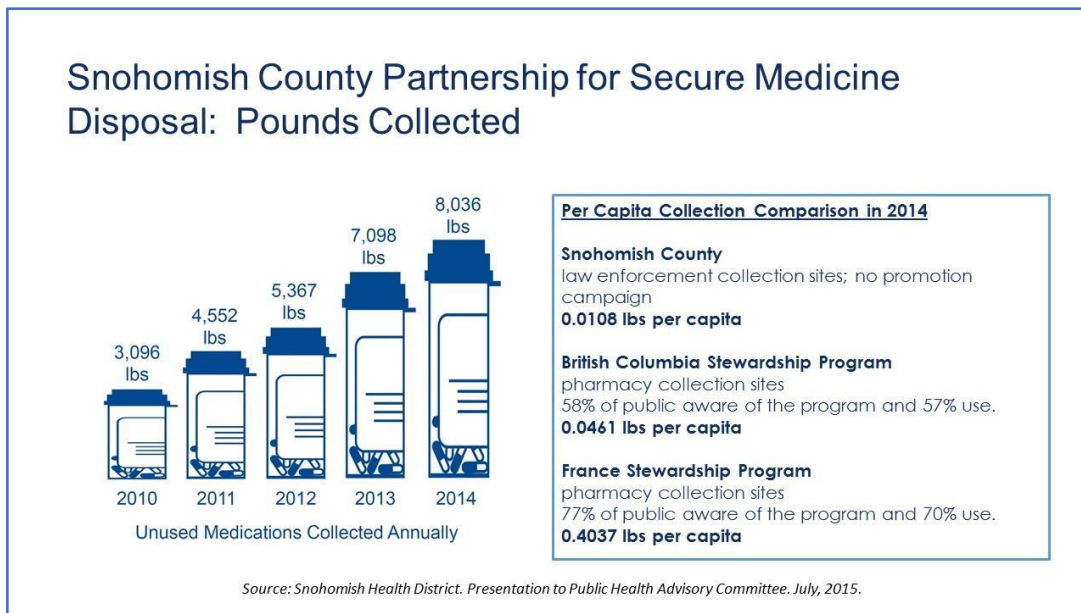
British Columbia Product Stewardship Program

- Established EPR program with almost 100% of pharmacies voluntarily participating as collection sites.
- 213,136 pounds of medicines collected from a population of 4,621,349 in 2014. Or 0.0461 pounds per capita.
- Survey found that 58% of the public are aware of the program and 57% use it for medicine disposal.<sup>3</sup> Increased emphasis on public education by the stewardship program since 2007 has resulted in steadily increasing public awareness and collection amounts.

France Cyclamed Program

- Established EPR program with all pharmacies participating as collection sites.
- 26,578,930 pounds of medicines collected in 2014, from a population of 65,835,579 in 2014. Or 0.4037 pounds of medicine per capita.
- Survey found that 77% of the public were aware of the program and 70% always use for medicine disposal.<sup>4</sup>

These per capita collection amounts are much higher than those at less convenient law enforcement collection programs that lack concerted promotion campaigns. The law enforcement collection program in Snohomish County, WA has seen rapidly increasing collection amounts each year since the program was started in 2010, but 2014 collections were about 0.0108 pounds per capita.



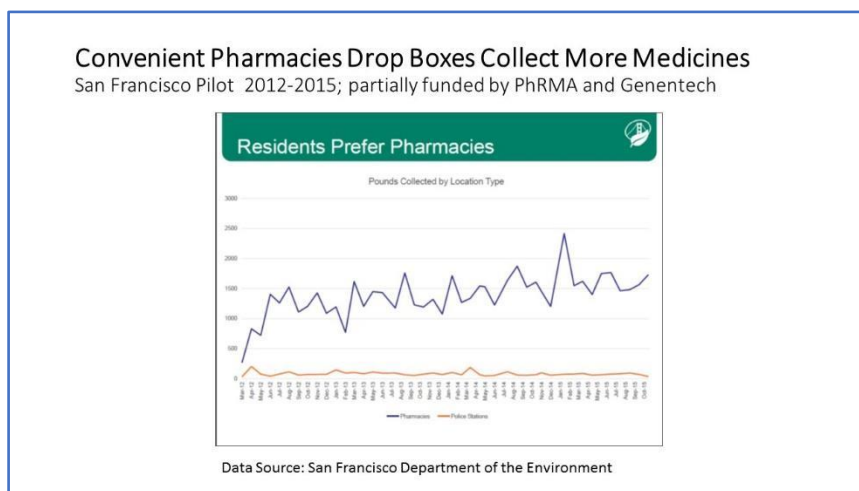
**Higher Collection Amounts at Pharmacy Drop Boxes Than Law Enforcement Drop Boxes in San**

<sup>3</sup> <http://www.healthsteward.ca/collection/british-Columbia>

<sup>4</sup> 2014 annual report for Cylamed program, <http://www.cyclamed.org/rubrique/documents/rapport-annuel>

## Francisco Pilot Program

Data from the San Francisco Safe Medicine Disposal Pilot Program from March 2012 to October 2015 at 13 independent pharmacy drop boxes than at 10 law enforcement drop boxes. Collection amounts at pharmacies were routinely significantly larger than at police stations, due to convenience and resident access. This voluntary pilot program was partially funded by a grant from PhRMA and Genentech. The fluctuations in amounts in the pharmacy collections are largely due to how the collection service periodically reported its amounts, rather than actual seasonal fluctuations.



A sample sort of returned medicines found that 72% were prescription and 23% were over-the-counter. 11% were controlled substances (which roughly mirrors the percentage of prescription drugs sold that are controlled substances). DEA's security regulations no longer allow drug sorts. The fluctuations in pharmacy collection are due to how the collection service periodically reported amounts, rather than actual seasonal fluctuations.<sup>5</sup>

### b) Cost Analysis

Contract scope and time limitations preclude a detailed financial analysis of all end-of-life management options, but available program expenditures for existing EPR programs demonstrate that the cost of these producer-funded programs represent a very small fraction of medicine sales and revenues.

### Medicine Sales in L.A. County

Estimates of the amounts of prescription and over-the-counter medicines sold in Los Angeles County can be pieced together from several publicly available sources for national and state pharmaceutical sales. This data can be extrapolated by population to provide an estimate of sales in Los Angeles County. The pharmaceutical industry will have accurate information of sales patterns, but it is not all publicly available.

<sup>5</sup> San Francisco Department of the Environment & Teleosis Institute 's San Francisco Medicine Waste Characterization Study. 2013.  
[https://sfenvironment.org/sites/default/files/fliers/files/sfe\\_th\\_sf\\_medicine\\_waste\\_characterization\\_study.pdf](https://sfenvironment.org/sites/default/files/fliers/files/sfe_th_sf_medicine_waste_characterization_study.pdf)

<b>Estimated Medicine Sales In 2015</b>	<b>Sales in CA State</b>	<b>Sales in LA County (uninc)</b>	<b>Sales in LA County (uninc) per capita</b>	<b>Sales in LA County (incorp &amp; unincorp)</b>	<b>Sales in LA County (incorp &amp; unincorp) per capita</b>
Prescription Medicines <sup>6</sup>	\$35,260,741,888	\$ 948,513,956.8	\$904.17	\$ 9,167,792,891	\$902.78
Over-the-Counter Medicines <sup>7</sup>	\$3,900,150,000	\$ 104,914,035	\$100.01	\$ 1,014,039,000	\$99.86
<b>Total</b>	<b>\$39,160,891,888</b> <b>or \$39.16 billion</b>	<b>\$ 1,053,427,992</b> <b>Or \$1.05 billion</b>	<b>\$1,004.18</b> <b>per capita</b>	<b>\$ 10,181,831,891</b> <b>Or \$10.18 billion</b>	<b>\$1,002.64</b> <b>per capita</b>

LA County Unincorporated Population 1/1/2015: 1,049,046 = 2.69% of CA

LA County Entire Population 1/1/2015: 10,155,069 = 26% of CA

CA Population 1/1/2015: 38,907,642<sup>8</sup>

In 2015, CA was 12.15% of the US Population.<sup>9</sup>

Pharmaceutical Industry Advertising & Marketing Spending:

- **\$758,400,000 on total pharmaceutical marketing in Los Angeles County in 2014.** This is extrapolated per capita from total pharmaceutical marketing spending of \$24 billion in the U.S. Los Angeles County entire population was 3.16% of U.S. population in 2015.<sup>10</sup>
- **\$164,320,000 on direct-to-consumer ads in Los Angeles County in 2015.** This is extrapolated per capita from total direct-to-consumer ad spending of \$5.2 billion in the U.S. Los Angeles County entire population was 3.16% of U.S. population in 2015.<sup>11</sup>

### **Estimated Costs of a Pharmaceutical Stewardship Program to Drug Manufacturers**

Pharmaceutical EPR ordinances in the other counties require drug manufacturers to pay for costs of drug take-back program operation and administration, including: collection supplies, medicine pick-up, transportation, disposal, and education about safe medicine storage and disposal for residents and healthcare providers. Actual costs of medicine take-back programs are dependent on program design and

<sup>6</sup> Prescription medicine data based on retail pharmacy sales in CA State in 2015. Does not include mail-order prescriptions which represent about 11% of total prescriptions dispensed in U.S. Source: Kaiser Family Foundation

<sup>7</sup> Over-the-counter medicine data based on sales at all outlets in U.S. in 2015, extrapolated for CA State which was 12.15% of U.S. population in 2015. Source: Consumer Healthcare Products Association

<sup>8</sup> <http://www.dof.ca.gov/Forecasting/Demographics/Estimates/E-1/>

<sup>9</sup> <https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=>

<sup>10</sup> The Pew Charitable Trusts. "Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients" Nov. 2013. <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients>

<sup>11</sup> STAT (Boston Globe Media). "Drug makers now spend \$5 billion a year on advertising. Here's what that buys." March 9, 2016. <https://www.statnews.com/2016/03/09/drug-industry-advertising/>

the amounts of medicines collected.

The following are two estimates of the costs of pharmaceutical EPR program for Los Angeles County:

~ **\$1.2 million per year for Alameda County pharmaceutical stewardship program** (pop. ~ 1.6 million in 2013) was the program cost estimate stated by PhRMA, BIO and GPhA in 2013 in their unsuccessful [legal motion](#) against Alameda County's Safe Drug Disposal ordinance.

~**\$1 million per year for King County pharmaceutical stewardship program** (pop. ~ 2 million in 2013) was program cost estimate from a [Board of Health Staff Report](#) in June 2013 for costs to drug producers collectively (> 350 companies)

~\$1 million per year is the rough average of a low and a high estimate:

Estimate 1: ~ \$600,000 annually, assuming 85 drop-off sites and 50,000 pounds medicines per year (0.0255 pounds per capita).

Estimate 2: ~ \$1.3 million annually, assuming 400 drop-off sites and 300,000 pounds medicines per year (0.1533 pounds per capita).

*Note: Both county estimates assume pharmacy drop-off sites participate voluntarily without staff time compensation.*

Using the higher cost estimate from the pharmaceutical associations for Alameda County, and extrapolating to Los Angeles County's population, a program cost estimate for the entire population of L.A. is \$7.6 million per year.

Compared to estimated annual sales of prescription and over-the-counter medicines in L.A. of about \$10.18 billion, the estimated program cost is roughly 0.075% of medicine sales.

### **Cost Effectiveness of EPR programs**

An EPR pharmaceutical stewardship program allows drug manufacturers to design their own program within the law's criteria, manage their own funds, and negotiate contracts with service providers. A county-run program would very likely be more expensive than the manufacturer-financed MED-Project program due to government overheads and public agency requirements to send most service contracts out to bid. A county-run program will probably have to assign more staff to operate the program than MED-Project has. The more cost-effective EPR program should have a smaller economic impact on consumers than a government-run program.

### **c) Medical Sharps**

#### **The Issues**

Used needles, syringes and lancets, collectively known as "sharps" from individuals are termed "home-generated" medical waste by California law, and are not regulated as "medical waste," which is generated on site by medical providers. State law (H&SC §118286) makes it illegal to dispose of home-generated sharps waste in the trash or recycling containers, and requires that all sharps waste be transported to a collection center in a sharps container approved by the local enforcement agency.

As with many products banned from both the trash and recycling, safe and proper disposal options are limited. Consumers can take used medical sharps to local Household Hazardous Waste (HHW) Facilities or save them up for the occasional HHW takeback events hosted by many jurisdictions including Los

Angeles County. The lack of convenient disposal options leads many consumers to take inappropriate steps to get rid of their used sharps. They throw them in the trash or the recycling bin despite the bans or even flush them down the toilet. Complicating the issue are the many needles used by homeless individuals, either for medical purposes or recreational use. People who are illegal drug users are unlikely to use the limited disposal options offered especially if it brings them into contact with law enforcement as is the case in Los Angeles County where the sheriff hosts the needle collection bins. Needle disposal from illegal drug use is one problem with needles in public spaces but another is improper management by the legal needle users as well, both commercial and residential uses.

In Los Angeles County there are many stories of improperly disposed needles. For example, on Tuesday 11/24/15 Burrtec workers stopped and started the sorting line for nearly two hours to remove some 5,000 needles (see image 064338). The needles may have come in on Monday 11/23 from a Burbank commercial recycling load. Workers weighed samples to determine that one pound contains approximately 190 syringes. The total weight was 27.4 pounds, the largest daily quantity on record for the Burbank Recycle Center (BRC). No workers were stuck, but needles are found regularly in the Burbank recycling loads; many loose, some packaged in plastic bottles, fewer in sharps containers. Burrtec's Regional Manager, Victor Urena reports that more needles are found at Burbank Recycle Center (BRC) than at other facilities operated by Burrtec. He estimates needles are found 2-3 days per week (40-60% of work days) at the Burbank site.

In 2013, 238 pounds of sharps (photo below) were pulled from the Burbank recycling line and two workers were stuck.



### **Safe Sharps Disposal Containers**

Containers for the safe storage and disposal of sharps are available for sale at almost all pharmacies. They are generally made of injection-molded plastic, come in many different sizes, and feature secure lids for safety. Despite laws and regulations encouraging the use of such safe disposal containers however, existing programs have found that their use is more the exception than the rule. Consumers will often purchase one container to keep at home, but then return the used sharps in improvised containers ranging from soda cans to bleach bottles and even plastic or paper bags, clearly less than safe options. One approach has been to require that pharmacies offer safe sharps disposal containers at no cost with each sharps sale. These containers typically cost about 80 cents wholesale, and the cost is generally born by the stewardship organization, not by the pharmacy. There are many shapes and sizes of containers sold on-line and in pharmacies and they are often red although that is not a regulated color (Canada uses yellow).

They generally are sold for approximately \$5.00 each for a container that does not have a mail-back disposal option included, and approximately \$30 for a 1-1.5 quart size that includes the mail-back disposal option with pre-paid shipping.

As with many products banned from both the trash and recycling, safe and proper disposal options are limited. Consumers can take used medical sharps to local Household Hazardous Waste Facilities or save them up for the occasional HHW takeback events hosted by many (but not all) jurisdictions. The lack of convenient disposal options leads many consumers to take inappropriate steps to get rid of their used



sharps. They throw them in the trash or the recycling bin despite the bans or even flush them down the toilet. Complicating the issue are the many needles used by homeless individuals, either for medical purposes or recreational use. These individuals are even less likely to avail themselves of the limited disposal options offered in most communities.

Millions of Americans self-inject medications for ailments such as diabetes and hepatitis, often several times a day. Many of these must frequently use lancets to test their blood. And these numbers are growing. Current best estimates are that about 936 million needles are used by self-injectors in California each year. Only about 5% of these are properly disposed of. The rest end up in the trash, in our wastewater, on recycling sorting lines, and even in our parks and on our beaches. Surveys have found that 43% of self-injectors just throw their needles in the trash. In California, almost half of all waste disposal facilities still hand-sort municipal trash, leading to painful, costly and dangerous needle sticks. A single needle stick can cost thousands of dollars in treatment, disease testing, and lost productivity.



CalRecycle estimates that \$4.6 million is lost every year in California due to accidental needle sticks.

Why don't people do a better job of safely disposing of their home-generated sharps? Surveys have found that the majority of users don't know where to go. Many report that the stores where they buy their sharps won't take them back. Cost of proper disposal containers is also cited as an obstacle.<sup>12</sup>

### **California Law on Sharps Disposal**

California law does not require pharmacies to take back sharps waste from individuals, although Business and Professions (B&P) Code Section 4146 permits pharmacies to accept the return of needles and syringes from the public if contained in a sharps container, which is defined in H&S Code Section 117750 as “a rigid puncture-resistant container that, when sealed, is leak resistant and cannot be reopened without great difficulty.”

B&P Code 4145.5 requires syringe exchange programs and pharmacies that sell or provide nonprescription syringes to also provide consumers with one or more of three disposal options: 1) onsite disposal, 2) provision of sharps containers that meet applicable state and federal standards, and/or 3) provision of mail-back sharps containers.

Health and Safety (H&S) Code Section 118286 prohibits individuals from discarding home-generated sharps waste in home or business recycling or waste containers.

H&S Code Section 118286 also requires that home-generated sharps waste be transported only in a sharps container or other container approved by the applicable enforcement agency, which may be either the state (CalRecycle program) or a local government agency. Home-generated sharps waste may be

---

<sup>12</sup> Above statistics from: <http://www.calrecycle.ca.gov/HomeHazWaste/Sharps/>



managed at household hazardous waste facilities, at “home-generated sharps consolidation points,” at the facilities of medical waste generators, or by the use of medical waste mail-back containers approved by the state.

Senate Bill 486 requires pharmaceutical manufacturers that sell or distribute a medication in California that is usually intended to be self-injected at home through the use of a hypodermic needle, pen needle, intravenous needle, or any other similar device, to submit a plan to CalRecycle on or before July 1, 2010, and annually thereafter, that describes how the manufacturer supports the safe collection and proper disposal of the waste devices. The latest pharmaceutical manufacturers' sharps collection and disposal plans are available on the CalRecycle web site. Most rely on expensive mailback options.

The California Department of Public Health (CDPH) has the authority to approve locations as points of consolidation for the collection of home-generated sharps waste, which, after collection, are transported and treated as medical waste. CDPH's Medical Waste Management Program provides support and oversight to home-generated sharps consolidation points located in 25 counties and two cities.

Recently the California State Board of Pharmacy considered whether to regulate sharps collection and disposal, and decided to refer the issue to the Department of Toxic Substances Control. The DTSC has not taken any action as of this date.

In 2015, Alameda County amended the EPR ordinance for drug disposal to include sharps. Other cities and counties are considering similar steps.

### **Local Solutions**

In the absence of any comprehensive action at the state or federal level, a number of local jurisdictions have adopted innovative approaches of their own.

San Luis Obispo County Integrated Waste Management Authority's (IWMA) Ordinance No. 2008-2 took effect in Sept. 2008, requiring retailers that sell sharps to accept home-generated sharps waste for proper disposal. The program was initially funded with seed money from a CalRecycle grant, but now retailers fund the program with the IWMA's Household Hazardous Waste (HHW) contractor collecting and consolidating the sharps waste. Prior to the ordinance, the only locations to accept home-generated sharps were the five IWMA HHW facilities. 40 retail locations accept sharps from the public.

The City of Sacramento's Ordinance No. 2010-018 took effect in August 2010 and requires all retailers, medical offices, hospitals and veterinarian clinics, and other providers that dispense sharps to the general public in the City of Sacramento to provide a sharps collection and disposal program at their locations at no additional cost to the general public. Prior to the ordinance, the only locations to accept home-generated sharps were three Household Hazardous Waste facilities. 35 retail locations accept sharps from the public.

Santa Cruz County began a voluntary program for drug and sharps takeback in 2008 that eventually spread to over 40 locations, including most pharmacies. In 2014 the county passed an ordinance requiring all sellers of sharps to participate in sharps takeback programs. In 2015 Santa Cruz County followed the lead of Alameda County and San Francisco in adopting an extended producer responsibility ordinance for the collection of leftover medications. Unlike the previous ordinances, this one also required the manufacturers to fund sharps collection and disposal. Participating locations had the option of hosting collection bins, which were regularly emptied by a licensed contractor, or of providing no-cost mailback containers to their customers. The Santa Cruz County ordinance also requires pharmacies to provide safe disposal containers to their customers at no cost. This expense is borne by the stewardship organization and funded by the manufacturers. There is no cost to pharmacies. The Santa Cruz County program is

also unusual in that it provides several public sharps disposal options, which have proven very popular. Countywide, the program collects more than 10,000 pounds of sharps per year.



In 2016-17, all of the cities in Santa Cruz County passed ordinances similar to the County's. They are now working on the transition from their current program to one operated by the stewardship organization and funded by the manufacturers.

In 2015, Alameda County amended the EPR ordinance for drug disposal to include sharps. Other cities and counties are considering similar steps.

### **International Approaches**

Outside the United States, producers playing a role in the ultimate disposal of difficult products is routine. This approach is used for a wide range of products, including drugs and sharps. In Canada, for example, provinces from Saskatchewan to Nova Scotia have sharps collection programs funded by the manufacturers. Note that these are for the most part the same large, global firms which dominate the business in the United States.

### **Why is EPR for sharps the best approach?**

In response to EPR ordinances for unused medications, the pharmaceutical industry formed the Pharmaceutical Product Stewardship Working Group (PPSWG), a membership organization which now includes over 400 of the world's largest drug manufacturers. As local ordinances began to include sharps, sharps manufacturers also joined the group. PPSWG now represents the manufacturers of more than 90% of all medical sharps sold in the US, and new members are being added frequently.

The sharps manufacturing industry is prepared for EPR for sharps. They expect it, they have an approach to collection and treatment that works for them, is safe and follows all laws. Most importantly, they are ready and willing to pay for it.

We know from experience that this approach works. Not only is this a practice of long-standing abroad, but experience among early adopters here in California shows why EPR for sharps is appropriate and reasonable, and the best approach for providing safe and effective sharps disposal. In the longest-operating California program, Santa Cruz County has safely collected and disposed of over 100,000 pounds of sharps over 9 years. Accidental sticks have become infrequent at recycling sorting lines, waste disposal facilities and wastewater treatment plants. Free, safe and convenient public sharps disposal has resulted in savings and convenience for residents, and safer beaches, parks and open spaces for everyone.

## **2.4 Review of existing research and findings on the potential impact of unwanted pharmaceutical and sharps waste on humans due to improper disposal or lack of adequate disposable options.**

### **a) Unused Medicine**

#### **How much medicine goes unused?**

A commonly used estimate is that 30% of medicines sold to consumers go unused for various reasons. This is based on studies using different methodologies to estimate or measure the amount of medicines that go unused.

Examples of Survey Results:

A recently published survey of 238 residents in California found that 2 out of 3 prescription medicines were reported unused. Common reasons were: disease/condition improved (40.4%), forgetfulness (10.6%), and side effects (8.0%).<sup>13</sup>

The Los Angeles County Department of Public Health conducted a survey of 1,062 residents from December 2015 to January 2016, and found:

- 59% of respondents had medicines in their homes that were expired or no longer needed. 45% of these people said they did not know what to do with them.
- When asked about drop-off or mail-back options for medicine disposal, 87% said pharmacy drop-off is a “good approach” and 69% chose a pharmacy drop-off bin as the preferred method.<sup>14</sup>

A 2009 survey of WA residents found similar results:

- Over half of respondents had six or more medication containers in the home, and 39% of those people had at least one container that had expired or would not be used for some other reason.
- 25% of respondents said there were unused narcotics or other medications following a death or major illness of somebody they knew.
- 72% of respondents said that they or a household member would either drop-off unused or expired medicines at a free, convenient location or use a free mailer.<sup>15</sup>

#### **Why are there unused medicines?**

There are many reasons why our prescription and over-the-counter medicines go unused. Some waste can be reduced by changes in prescribing practices, dispensing practices, and changes in consumer demand. Even when the health care system and patients do everything right, some medicines are leftover and need secure disposal. Reasons for leftover medicines include:

- Lots of medicines are needed during a serious illness, but when the individual recovers there are leftovers.
- Lots of medicines, including strong pain relievers, are needed for end-of-life care and are leftover for family members to deal with when the patient dies.
- Medicine is not finished if the patient has an allergic reaction, can't tolerate the drug, or other side effects develop.

---

<sup>13</sup> [Law et al. “Taking stock of medication wastage: Unused medications in US household”. 2015. Research in Social and Administrative Pharmacy 11; 571-578.](#)

<sup>14</sup> <http://publichealth.lacounty.gov/docs/SharpsDisposalSurvey.pdf>.

<sup>15</sup> “Medication Disposal: 2009 Survey of Attitudes and Preferences Among Oregon and Washington State Residents”. The Gilmore Research Group. December 2009.

- Different medications are prescribed in the search for the right treatment. This is particularly common in treatment for depression and other common psychological conditions.
- Medicines expire before they are fully used. This is common with prescription drugs that patients take only “as needed” for a recurring condition, and with over-the-counter medicines that consumers purchase to have on hand if needed.
- Drugs are overprescribed in some situations. There is increasing awareness in the medical community about the problem of overprescribing, especially for pain pills. This is a complex issue. Responsible practitioners must balance limiting the size of a prescription with a patient’s legitimate need for appropriate pain management, or other treatment.
- Consumers buy more over-the-counter medicines than they will need. This is encouraged by advertising that prompts consumers to “stock up” their medicine cabinets.
- Sometimes people stop taking their prescription medicines before they should, sometimes because they feel better. While physicians stress the importance of medication adherence to patients, this is an ongoing area of emphasis to ensure patients complete drug treatments.

Survey responses from 2,041 Maine residents who returned unwanted medicines in a pilot mail-back program found the following reasons why medicines were returned:

- 47.4 % medicine expired
- 31.1% doctor said to stop taking it
- 27.3% doctor ordered a new medicine
- 24.2% other reason
- 18.0% felt better
- 12.2% side effects
- 11.9% negative reaction or allergy
- 7.2% didn’t want to take it

*Respondents could select multiple reasons.*<sup>16</sup>

A small survey\* of individuals returning unwanted medicines to Alameda County’s drug drop box program found:

- 56% were returning their own medicines
- 44% were returning medicines for more than just themselves (others in household)
- 23% were returning drugs for a deceased person

\* Data was collected using a voluntary written survey on location set in a visibly convenient place on the take-back bin at nine of the 31 sites. 62 responses were collected in a three month period.

Analysis of a 1,418 pound sample of unwanted medicines collected in Bay Area take-back events in 2009 found 65% prescription and 25% over-the-counter (also 10% were nutritional supplements which were accepted in the events). Medication classes included respiratory agents, central nervous system agents, pain relievers, antipsychotics, antidepressants, cardiovascular agents, antibiotics, hormones, topical drugs, and others.<sup>17</sup>

### **Public health concerns with medicines in the homes**

Leftover and expired medicines that linger in the home medicine cabinet increase risks of medicine misuse, abuse, poisonings, and intentional or unintentional overdoses.

<sup>16</sup> Kaye, Crittenden, Gressitt, Sorg, LaBrie and Chase. Safe Medicine Disposal for ME: A Handbook and Summary Report April 2010. Page 47, <http://umaine.edu/safemeddisposal/resource-library/>

<sup>17</sup> Bay Area Medication Disposal Study 2009. Teleosis Institute; National Unused and Expired Medicines Registry (in operation from 2005-2014).

- 73% of teens say it's easy to get prescription drugs from parents' medicine cabinets.
- Many teens think prescription medicines are safer to abuse than street drugs.<sup>18</sup>
- 70% of those who abuse prescription medicines obtain the drugs from family members or friends, usually for free. Surveys of sources of prescription drugs from the 2011 and 2013 SAMHSA/NSDUH National Surveys on Drug Use and Health: Summary of National Findings. The "about 70%" amount is a combination of those who get their prescription drugs for free from a friend or relative (54.2%) and those that bought/took the drugs from a friend or relative (16.6%) in 2011.<sup>19</sup>
- 45% of heroin users are also addicted to prescription opioid painkillers.<sup>20</sup>
- Over half people injecting heroin have also abused prescription drugs like opioids or amphetamines. Of those 91% abused the prescription drugs first, before switching to heroin.<sup>21</sup>
- Nonmedical use of Adderall, a medication used to treat attention deficit hyperactivity disorder (ADHD), rose 67% among young adults between 2006 and 2011. The number of emergency room visits involving misuse of the drug among 18- to 25-year-olds also rose from 862 visits in 2006 to 1,489 in 2011. During this period the number of Adderall prescriptions remained unchanged among young adults.<sup>22</sup>
- About 165 young kids — or roughly four school busloads of children — are seen in emergency rooms every day in the US after getting into medications (both over-the-counter and prescription).<sup>23</sup>
- In 2009 national data, 71,224 emergency department visits made annually for medication overdoses by children under age 18. 82% involved children under age 5. 34% of these ER visits involved commonly available over-the-counter medications. Acetaminophen, cold and cough products, NSAIDs and antihistamines were the most frequently reported.<sup>24</sup>

### **Collection of over-the-counter medicines by secure take-back programs**

Some over-the-counter medicines are commonly abused, especially by teens. And over-the-counter medicines are a common cause of preventable poisonings in the home. Improper disposal of over-the-counter medicines through flushing or trash disposal contributes to pharmaceutical pollution in our environment. The regulatory distinction between prescription and over-the-counter drugs reflects whether the FDA deems the drug safe for self-medication when used as instructed, not whether the drug poses a

---

<sup>18</sup> Partnership for Drug-Free Kids. 2012 PARTNERSHIP ATTITUDE TRACKING STUDY

<http://www.drugfree.org/newsroom/pats-2013-full-report-key-findings>

<sup>19</sup> <http://www.icpsr.umich.edu/icpsrweb/ICPSR/series/64>

<sup>20</sup> "Today's Heroin Epidemic. More people at risk, multiple drugs abused" CDC VitalSigns. July 2015.

<http://www.cdc.gov/vitalsigns/heroin/>

<sup>21</sup> Kathy Perkins, Snohomish Health District in October 2015 based on 2014 health surveys of people accessing needle exchange and/or naloxone distribution programs.

<sup>22</sup> Lian-Yu Chen et al. "Prescriptions, Nonmedical Use, and Emergency Department Visits Involving Prescription Stimulants" J Clin Psychiatry. Feb. 2016 doi:10.4088/JCP.14m09291

<http://www.psychiatrist.com/jcp/article/Pages/2016/aheadofprint/14m09291.aspx>

<sup>23</sup> Centers for Disease Control and Prevention. Put Your Medicines Up and Away and Out of Sight. CDC Website. Available from: <http://www.cdc.gov/features/medicationstorage/>. Accessed February 9, 2012.

<sup>24</sup> Schillie, S.F., et al. 2009. Medication overdoses leading to emergency department visits among children. Am J Prev Med 2009. Available online at: [http://www.ajpm-online.net/webfiles/images/journals/amepre/AMEPRE\\_2545.pdf](http://www.ajpm-online.net/webfiles/images/journals/amepre/AMEPRE_2545.pdf)

risk of poisoning or abuse if accidentally or intentionally misused. And not whether the drug is safe in our environment. Sometimes the same medicine that is available in over-the-counter form, is also prescribed in a higher dosage or are purchased as a prescription under certain health plans.

Also, as a practical matter, most consumers do not know the difference between prescription medicines and over-the-counter medicines, so it is unrealistic to expect consumers to separate the types of drugs. It would burden authorized collectors to have to try to exclude over-the-counter medicines from being deposited in a secure drop box. The effective and convenient approach is to encourage consumers to return any unused or expired medicine used in the home to a secure and safe medicine take-back program.

Some examples of concerns with over-the-counter medicines:

- OTC cough medicines, antihistamines, decongestants, and diet pills are often abused, especially by teenagers.<sup>25</sup>
- Loperamide – an anti-diarrhea medicine sold under the brand name Imodium – is being abused by opioid addicts. Loperamide is now available over-the-counter, but it used to be regulated as a prescription drug and a controlled substance.<sup>26</sup>
- Drugs are often shifted from prescription status to over-the-counter. The pharmaceutical industry is working to convert a large number of drugs currently sold as prescription to over-the-counter status, including drugs for chronic conditions like hypertension, lipid-lowering, osteoporosis, arthritis.<sup>27</sup>
  - An example is nicotine patches for smoking cessation. These patches were initially prescription only, but are now available over-the-counter. Nicotine is toxic, and exposure to even small amounts can be fatal to children. Nicotine patches designate as federal hazardous waste for disposal.
- Several over-the-counter medicines, e.g., ibuprofen, Tylenol, and antihistamines, are among the top ten causes of poisonings in Washington homes, especially for children.<sup>28</sup>
- One study found that 34% of ER visits for children poisoned by medicines in the home were a result of over-the-counter medicines.<sup>29</sup>
- 26% of child poisoning deaths in Washington were caused by someone else’s over-the-counter medications and 32% were caused by someone else’s prescription medications.<sup>30</sup>

## **b) Medicine Disposal**

### **Flushing of Waste Medicines**

Wastewater treatment plants cannot effectively remove pharmaceuticals that are flushed or that come from landfill leachate through garbage disposal.

- A 2010 report by the US EPA and Washington State Ecology concluded that a “2008 screening study detected pharmaceuticals and personal care products in every influent, effluent, and biosolids sample analyzed from five Pacific Northwest wastewater treatment plants.”<sup>31</sup>

---

<sup>25</sup> <https://www.drugabuse.gov/publications/drugfacts/cough-cold-medicine-abuse> and

<http://abovetheinfluence.com/drugs/over-the-counter/>

<sup>26</sup> <http://nyti.ms/1UR8BTo>

<sup>27</sup> [www.chpa.org/Switch.aspx](http://www.chpa.org/Switch.aspx)

<sup>28</sup> [WA Poison Center’s 2014 Top Ten List](#)

<sup>29</sup> [Schillie et al. “Medication overdoses leading to emergency department visits among children” 2009. Am J Prev Med 37: 181-187.](#)

<sup>30</sup> [Sabel, J. \(2004\). Washington State Childhood Injury Report – Poisoning Chapter. WA DOH.](#)

<sup>31</sup> Control of Toxic Chemicals in Puget Sound Phase 3: Pharmaceuticals and Personal Care Products in Municipal

- Pharmaceutical are released by septic systems. A USGS study of Liberty Bay near Poulsbo, Washington found a range of pharmaceuticals, personal care products, and pesticides in a sensitive estuary where there are no nearby point sources, such as wastewater treatment facilities. The study, designed to determine whether a coastal community served primarily by septic systems could release PPCPs, herbicides and plasticizers into their surface and groundwaters, was conducted where 70% of nearby residents use septic systems. Pharmaceutical compounds were detected that include Carbamazepine (anticonvulsant) , Gemfibrozil (lipid reduction), Ibuprofen (anti-inflammatory), Ketoprofen (anti-inflammatory), Propranolol (hypertension medication) and Trimethoprim (antibiotic)<sup>32</sup>

## Trash Disposal of Waste Medicines

Disposing of potentially dangerous unused medicines in the household garbage is not secure, not recommended for controlled substances by the DEA.

- The FDA, DEA, and EPA all recommend medicine take-back programs as the best method for safe disposal of unused medicines, and only suggest putting medicines in the trash if there is no drug take-back program available.<sup>33</sup>
- The DEA wants leftover medicines that are controlled substances collected and destroyed so that they are non-retrievable by those who are addicted. DEA has stated “sewering (disposal by flushing down a toilet or drain) and landfill disposal (mixing controlled substances with undesirable items such as kitty litter or coffee grounds and depositing them in a garbage collection) are examples of current methods of disposal that do not meet the non-retrievable standard.”<sup>34</sup>
- To attempt to reduce risks of diversion from the trash, “in home disposal” methods ask residents to mix leftover pills with kitty litter or coffee grounds. This can be messy, and puts residents at risk of exposure to pill dust and residues, especially if residents crush up the pills or dissolve them in liquids. These methods can be difficult for large volumes of pills. There is no evidence that residents are willing to follow these procedures to hide medicines in the trash. Secure medicine take-back is safer.

Disposing of pharmaceuticals in the trash does not ensure that pharmaceuticals won’t be released into the environment.

- Pharmaceuticals are commonly found in landfill leachate according to [U.S.G.S. sampling](#) and peer-reviewed research studies. These chemicals are released into waterways when leachate is pumped out of a landfill and sent to wastewater treatment facilities because pharmaceuticals are not effectively removed or degraded by those facilities.
- Some local governments in WA State prohibit disposal of household medicines, and other household hazardous wastes, in the garbage because of these problems. In WA, this includes Kitsap County, Snohomish County, and the City of Tacoma. They recommend using a secure medicine take-back program.
- Analysis of three landfills in Maine by the Maine Department of Environmental Protection (DEP) collected and analyzed leachate (sludge) samples from three municipal solid waste landfills to assess the types and concentrations of pharmaceuticals that may be present. None of the landfill

---

Wastewater and Their Removal by Nutrient Treatment Technologies, USEPA 2010 Pub. Number 10-03-004  
<https://fortress.wa.gov/ecy/publications/documents/1003004.pdf>

<sup>32</sup> [Dougherty, J.A., Swarzenski, P.W., Dinicola, R.S., and Reinhard, M. 2010. Occurrence of Herbicides and Pharmaceutical and Personal Care Products in Surface Water and Groundwater around Liberty Bay, Puget Sound, Washington. J. Environ. Qual. Vol. 39 No. 4, p. 1173-1180.](#)

<sup>33</sup> [FDA’s How To Dispose of Unused Medicines](#)

<sup>34</sup> [Federal Register 79 \(174\): page 53547.](#) September, 2014.



sites studied had been exposed to sludge from municipal wastewater treatment plants, which ensured that any pharmaceuticals present were linked to household trash disposal. The results of the study showed that compounds from over 40 pharmaceutical and personal care products (PPCPs) were found in landfill leachate. The study also concluded that the detected PPCP concentrations indicate the potential discharge of hundreds of pounds of PPCPs per year.”<sup>35</sup>

Peer-reviewed research reports have measured an array of pharmaceuticals in landfill leachate samples. Examples of these studies are:

- Maine Department of Environmental Protection collected and analyzed leachate samples from three municipal solid waste landfills in Maine to assess the types and concentrations of pharmaceuticals that may be present. Forty-seven compounds were detected in at least one of the three landfills. Twenty of these compounds were commonly found in all three leachate samples and include Albuterol, Atenolol, Carbamazepine, Cimetidine, Enalapril, Estrone, Gemfibrozil, Penicillin G and Valsartan. Results from this initial evaluation clearly demonstrate that a large variety of both prescription and over-the-counter drugs are discarded in household waste and can appear in landfill leachate.<sup>36</sup>
- While modern landfills are lined per EPA regulations, studies of older landfills demonstrate the presence of pharmaceuticals in the leachate and the potential for environmental contamination:
  - Four wells downgradient from a landfill near Elkhart, Indiana were sampled during 2000-2002 to evaluate the presence of waste-indicator and pharmaceutical compounds in landfill-leachate-affected ground water. Compounds detected in leachate-affected ground water included an antioxidant (5-methyl-1H-benzotriazole), and several pharmaceuticals and metabolites (acetaminophen, cotinine, 1,7-dimethylxanthine, fluoxetine, and ibuprofen).<sup>37</sup>
  - Ground water samples from a municipal landfill site in Norman, Oklahoma were analyzed by USGS for pharmaceuticals and other organic waste water contaminants (OWCs). The landfill was closed in and covered with a clay cap in 1985. In 2000, five sites near the landfill, four of which are located downgradient, were sampled and analyzed for 76 OWCs including eighteen human prescription and non-prescription medicines. OWCs were detected in water samples from all of the sites sampled, with 22 of the 76 OWCs being detected at least once, including an antibiotic (lincomycin) and a metabolite of a nonprescription drug. The sites closest to the landfill had more detections and greater concentrations of each of the detected compounds than sites located farther away. Detection of multiple OWCs occurred in the four sites located within the leachate plume, with a minimum of four and a maximum of 17 OWCs detected. Because the landfill was established in the 1920s and closed in 1985, many compounds detected in the leachate plume were likely disposed of decades ago. These results indicate the potential

---

<sup>35</sup> Behr, R., Stahler, D., and Pistell, A. (2009). "Preliminary Characterization of the Pharmaceutical Content of Municipal Solid Waste Landfill Leachate from three landfills in Maine." Maine Department of Environmental Protection.

<sup>36</sup> Behr, R., Stahler, D., Pistell, A. (2010). *Preliminary Characterization of the Pharmaceutical Content of Municipal Solid Waste Landfill Leachate from three landfills in Maine*. Maine Department of Environmental Protection. <http://productstewardship.us/associations/6596/files/Landfill%20leachate%20testing%20study%201%2010.pdf>, accessed 9/3/2010.

<sup>37</sup> Buszka, P. M., Yeskis, D. J., Kolpin, D. W., Furlong, E. T., Zaugg, S. D., & Meyer, M. T. (2009). *Waste-indicator and pharmaceutical compounds in landfill-leachate-affected ground water near Elkhart, Indiana, 2000-2002*. (2009) Bulletin of Environmental Contamination and Toxicology, 82(6), 653-659.

- for long-term persistence and transport of some OWCs in ground water.<sup>38</sup>
- A Florida landfill received waste in 1968 and 1969 from two large naval aviation bases. Although permitted to accept only solid waste, physical evidence suggested it could have received waste from a local hospital. Samples taken from groundwater and drinking water wells located 300 meters from the landfill in 1991 confirmed pentobarbital contamination at 1 ppb. Finding trace amounts of pentobarbital 21 years after the landfill closed and 300 meters from the landfill site, demonstrates the persistence of the pharmaceutical.<sup>39</sup>

### c) Pharmaceutical Pollution in the Environment

Pharmaceutical pollution is the result of many sources including human excretion, agricultural sources, manufacturing releases, and improper disposal of unused medicines. Scientific analyses that measure drugs in our waterways cannot distinguish between these sources; therefore, the relative contribution of each source is unknown. Human excretion is a problematic source that cannot be eliminated at this time without telling people to stop taking medicines. However, it's estimated that 30% of medicines sold to consumers go unused, and proper disposal is a source reduction strategy to keep those leftover medicines out of waterways and water supplies.

Scientists and credible environmental and health organizations are concerned, even about these low concentrations of pharmaceutical pollution. Research is demonstrating harm to fish and other aquatic species from exposure to the low levels of pharmaceuticals commonly found in the environment.<sup>40</sup> Even some members of the pharmaceutical industry admit there's a problem, like this scientist at Merck: "There's no doubt about it, pharmaceuticals are being detected in the environment and there is genuine concern that these compounds, in the small concentrations that they're at, could be causing impacts to human health or to aquatic organisms."<sup>41</sup>

### Drinking water concerns

Levels of pharmaceutical compounds detected in some drinking water supplies are low, below therapeutic doses, and potential health effects are not known. However, the presence of a mixture of drugs in some drinking water supplies suggests the need to reduce environmental contamination through safer disposal of waste medicines. Some drinking water supplies have tested negative for pharmaceuticals because their water sources are from pristine watersheds. This result is expected for any water supply which is protected from human activities. Municipalities that use water sources downstream of wastewater treatment facilities are those which might detect pharmaceuticals.

Contamination of municipal drinking water supplies by low levels of a complex mixture of pharmaceuticals is a growing concern. A 2008 Associated Press investigative series found medicines in the drinking water of 24 major metropolitan areas serving 41 million Americans. Some frequently detected compounds were atenolol (heart medication), carbamazepine (mood-stabilizer), gemfibrozil

---

<sup>38</sup> Barnes, K.K., Christenson, S.C., Kolpin, D.W., Focazio, M.J., Furlong, E.T., Zaugg, S.D., Meyer, M.T., and Barber, L.B. (2004). "Pharmaceuticals and other organic waste water contaminants within a leachate plume downgradient of a municipal landfill." *Groundwater Monitoring & Remediation* 24(2): 119-126.

<sup>39</sup> Eckel, William, et al. (1993) Pentobarbital found in Ground Water, *Ground Water*, Vol. 31, Issue 5, pp 801-804.

<sup>40</sup> CA's Dept of Toxic Substances Control - <https://dtsc.ca.gov/AssessingRisk/PPCP/PPCPTox.cfm>

<sup>41</sup> Mary Buzby, director of environmental technology for Merck & Co. Inc, in USA Today, March 10, 2008. "AP: Drugs found in drinking water". Online at: [http://www.usatoday.com/news/nation/2008-03-10-drugs-tap-water\\_N.htm](http://www.usatoday.com/news/nation/2008-03-10-drugs-tap-water_N.htm)

(anti-cholesterol), meprobamate (tranquilizer), naproxen (pain-killer), phenytoin (anti-seizure medication), sulfamethoxazole and trimethoprim (antibiotics).<sup>42</sup>

The World Health Organization's July 2011 report "Pharmaceuticals in Drinking-water" recommends the use of medicine take-back programs and finds that "Inappropriate disposal practices, such as flushing unwanted or excess drugs down toilets and sinks and discarding them into household waste, are common and may be the main contributors to pharmaceuticals in wastewater and other environmental media, such as surface waters and landfill leachate."<sup>43</sup>

#### **d) Analysis of studies commonly cited by the Pharmaceutical Industry**

##### **Pharmaceutical industry trade groups rely on a theoretical modeling study to dismiss contributions of landfill leachate to environmental pollution**

Pharmaceutical associations point to a modeling analysis financed by PhRMA and conducted by Tischler and Kocurek, who are engineering consultants who estimated leaching of pharmaceutical compounds from a landfill. No actual measurements of pharmaceuticals in landfill leachate were made, and the assumptions used in the modeling are debatable, such as their low estimates of the amount household medicines that go to waste (no more than 15%) and low volumes of leachate generated by landfills in rainy areas. Tischler and Kocurek's modeling analysis was conducted in 2006, but could not find a journal to publish the paper until 2012 when it appeared in a minor technical journal. Their co-authors are employees from the pharmaceutical giants Merck, GlaxoSmithKline, and Eli Lilly.<sup>44</sup>

##### **Pharmaceutical industry associations claim that medicine take-back is worse for the environment, has a larger carbon footprint, than throwing leftover drugs in the trash**

That claim is based on a University of Michigan life cycle modelling analysis funded by Merck & Co. Life cycle analysis depends on the factors selected for consideration in the model, on assumptions used, and on available data. The U. Michigan model made several debatable assumptions about how medicine take-back programs would operate, ignored some factors, and defined other factors that don't seem realistic.

For example:

- The model considered the environmental impact of just 10 pharmaceuticals when there are thousands on the market.
- The model assumed that 50% of personal vehicle trips to a medicine take-back location would be for the sole purpose of taking back medicines. That seems unlikely. People would combine trips to return medicines with the purchase of other items from the pharmacy, or with other nearby errands. Pollution from car trips heavily biased the model's outcome.  
Zero Waste Washington recently collected real data from Washington residents about whether they run other errands when using an electronics take-back program. That study found 72% of the people combined the recycling trip with another errand. On average, people were doing 2.7 errands per trip to a take-back location.<sup>45</sup>
- The model did not include all sources of vehicle pollution with trash disposal, for example it failed to consider that many U.S. residents self-haul their garbage to dump sites.
- The model assumed that participation rates for medicine take-back programs were unlikely to

<sup>42</sup> [http://hosted.ap.org/specials/interactives/pharmawater\\_site/day1\\_01.html](http://hosted.ap.org/specials/interactives/pharmawater_site/day1_01.html)

<sup>43</sup> World Health Organization. (2011) "Pharmaceuticals in Drinking-Water". Technical Report WHO/HSE/WSH/11.05. [http://www.who.int/water\\_sanitation\\_health/publications/2011/pharmaceuticals/en/](http://www.who.int/water_sanitation_health/publications/2011/pharmaceuticals/en/)

<sup>44</sup> <http://onlinelibrary.wiley.com/doi/10.1002/ieam.1311/abstract>

<sup>45</sup> <http://www.zerowastewashington.org/index.php/trip-assessment-recycling-study>

exceed 50%, without providing any justification. In France, 70% of the population uses an established medicine take-back program and in Sweden, 70% use it.

Most importantly, the theoretical study was flawed because it focused only on environmental impacts of leftover medicines without accounting for the acute hazards to human health and safety from leftover medicines. The study did not consider security and safety of medicine disposal at all. The model didn't consider that trash cans are not secure and did not estimate the impact of potential exposures to humans or animals of medicines thrown into household trash.

The model assumed that 100% of people throwing medicines in the trash would take steps to disguise the pills in kitty litter or some other substance and hide them in the trash, but provided no data to support 100% compliance.

The human impacts of tragedies associated with medicines in the home were not considered. What's the impact of an ambulance trip to the emergency room when a teenager overdoses on leftover pain pills? Or when a toddler pulls a fentanyl patch out of the garbage can?

When the U. Michigan study was published in *Environmental Science & Technology* in 2012, an EPA scientist responded with concerns similar to those stated above. Since 2012, federal agencies including the DEA, as well as local agencies, have continued to recommend the use of secure medicine take-back programs as the best method for medicine disposal.

### **Pharmaceutical industry representatives claim studies show lack of impact of medicine take-back on pharmaceuticals in wastewater.**

In past statements, representatives of the pharmaceutical industry have claimed that medicine take-back programs in Europe have been shown to be ineffective in reducing pharmaceuticals in wastewater, e.g. from the CA Life Sciences Association: "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)."

The three European studies cited as sources – Ternes 1998, Wick *et al.* 2009, and Coetsier *et al.* 2009 - did not assess whether concentrations of pharmaceuticals have been reduced by national take-back programs for unused medicines. There is no mention in any of the three papers of medicine take-back programs, nor any analysis of impacts of unused pharmaceuticals from households on the amount of pharmaceuticals measured in surface waters. The three studies examined pharmaceutical compounds in the effluent of municipal sewage treatment plants and in rivers in Germany to increase understanding of how pharmaceuticals pass through sewage treatment plants. These studies were not designed to compare levels of pharmaceuticals in European surface waters over time, or comment on the relative levels of pharmaceuticals in the environment over time. Study goals as stated in the articles were:

- Ternes 1998. "Occurrence of Drugs in German Sewage Treatment Plants and Rivers." *Water Research* Vol. 32, No. 11, pp. 3245±3260: "The aim of this work was to survey the exposure of German STP (sewage treatment plant) effluents and German rivers to drugs and some selected metabolites."
- Wick *et al.* 2009. "Fate of beta blockers and psycho-active drugs in conventional wastewater treatment" *Water Research* Vol. 43, pages 1060 –1074: "The objective of this study was to

- obtain more comprehensive knowledge about the fate (sorption, biotransformation) of several beta blockers and psycho-active drugs in a conventional activated sludge treatment by comparing a modeling approach with long-term full-scale measurement campaigns.”
- Coetsier *et al.* 2009. “Discharge of pharmaceutical products (PPs) through a conventional biological sewage treatment plant: MECs vs PECs?” *Environment International* Vol. 35 , pages 787–792: “The main objective of this study was to compare PEC (predicted environmental concentration) and MEC (measured environmental concentration) values in order to assess their relevance in STP (sewage treatment plant) effluent and surface water at a local scale in Alès, a city in Languedoc Roussillon region.”

## **2.5 and 2.6 Evaluation of whether or not implemented ordinances have resulted in, or are expected to, result in better public health and environmental protections.**

### **a) Challenges of Voluntary Programs**

Our analysis of voluntary programs found that sheriffs, police, local governments, and some pharmacies are operating a limited number of take-back programs, but are struggling for funding. Many communities cannot afford to start a program. The DEA and local law enforcement provide twice-a-year collection events in many communities; however, collection events are not as convenient and accessible as ongoing secure drop boxes. These voluntary local medicine take-back programs do not have secure funding, and have very few resources for program promotion. Therefore, they are collecting only a fraction of the leftover medicines in residents' homes.

### **b) About Evaluation of Effectiveness of Medicine Take-back Programs**

Effectiveness of medicine take-back programs is typically measured through outputs of the pounds of leftover medicines collected and safely destroyed. Surveys are also conducted to measure public awareness, assess convenience of take-back options, and measure how many residents are using the program.

Established pharmaceutical take-back programs – in Canadian provinces, most European Union countries and Australia - view the benefits of securely collecting and properly disposing of excess medicines as evident, and have not required further research on the outcomes of these programs. Public participation and satisfaction with the medicine take-back programs is viewed as high (see examples for Canada and France above). Pharmaceutical manufacturers who fund and operate medicine take-back programs in many countries have also not conducted research to directly measure their impacts.

Voluntary take-back programs operated by law enforcement, pharmacies, and local governments are relatively new in the U.S.. They are not comprehensive or widely promoted due to limited funding, and do not have any funds for program evaluation beyond tracking collection amounts. Such programs cannot be fairly evaluated for outcomes; however, they have demonstrated the feasibility of secure protocols and confirmed that residents will utilize take-back programs. Mandated pharmaceutical stewardship ordinances are even newer, and can be evaluated for collection amounts, public participation, and for societal impacts once they have established operations.

Analysis of outcomes in preventing substance abuse and poisonings, or reducing environmental pollution, would require complex longitudinal analysis of multiple factors contributing to these complicated problems, and such research would be costly.

### **c) Prevention Strategy**

Public health leaders, substance abuse professionals, health professionals and law enforcement agencies support medicine take-back as part of a comprehensive prevention strategy for medicine abuse, addiction, and overdoses. The home medicine cabinet is the most common source of medicines that are abused. Safe storage of medicines in the home and secure disposal of medicines when they are no longer needed reduces the supply of medicines that could be misused.

In the 2015 National Drug Control Strategy, and in earlier versions of that national strategy, the Four Pillars for Preventing and Addressing Prescription Drug Misuse and Heroin Use were identified as

Pillar 1: Education - Educate Health Care Providers About Opioid Pain Medicine Prescribing

Pillar 2: Monitoring - Enhance Prescription Drug Monitoring Programs and Expand Information Sharing among State Systems and to Electronic Health Records

Pillar 3: Disposal - Increase Prescription Return/Take-Back and Disposal Programs

Pillar 4: Enforcement - Assist States to Address Diversion and Pill Mills<sup>50</sup>

---

<sup>50</sup> National Drug Control Strategy. 2015. White House Office of National Drug Control Policy. Pages 87-101. <https://www.whitehouse.gov/ondcp/national-drug-control-strategy> (removed from White House pages since Trump took office)



## **2.7 The most effective options available for Los Angeles County to address the public health and safety, and environmental impacts related to the disposal of unwanted pharmaceuticals and sharps waste**

Secure medicine take-back is recommended as the safest medicine disposal method by the FDA, the DEA, the EPA, and many local agencies.

- [FDA – How To Dispose of Unused Medicines](#) “Is your medicine cabinet full of expired drugs or medications you no longer use? How should you dispose of them? Many community-based drug “take-back” programs offer the best option.”
- [DEA Drug Disposal Information](#) provides resources on the DEA’s Rule for take-back of controlled substances and locations of Authorized Collectors for take-back of controlled substances.
- Flyers for the DEA’s National Drug Take-back Initiative state: “Unused prescription drugs thrown in the trash can be retrieved and abused or illegally sold. Unused drugs that are flushed contaminate the water supply. Proper disposal of unused drugs saves lives and protects the environment. Take-back programs are the best way to dispose of old drugs.”
- [EPA - Collecting and Disposing of Unwanted Medicines](#) “EPA encourages the public to take advantage of pharmaceutical take-back collection programs that accept prescription or over-the-counter drugs, as these programs offer a safe and environmentally-conscious way to dispose of unwanted medicines.”

In areas where there are no drug take-back programs, federal and local agencies are having to advise people to throw medicines in the trash as an interim, or last resort measure. However, some local governments prohibit disposal of waste household medicines down the sewer or in the solid waste stream.

### **3. Opinion**

#### **3.1 Recommendations for proposed ordinance**

##### **Recommended Policy Adjustments for the proposed LA County ordinance “Stewardship Program for Collection and Disposal of Unwanted Covered Drugs and Unwanted Sharps”**

The overall policy intent of the proposed LA county ordinance is sound, and is similar to the policy of local stewardship laws that are being successfully implemented in other counties. The following recommendations are refinements to the existing policy that further clarify the intent or reflect learnings from other jurisdictions.

##### **Adjust Implementation Timeline**

Pharmaceutical and sharps manufacturers have organized themselves into a stewardship organization – MED-Project LLC – and are implementing laws similar to the L.A. County proposed ordinance in a number of local jurisdictions in California and Washington. Given the manufacturers’ experience with the development of stewardship plans, it is reasonable to shorten the implementation timeline by allowing six months for stewardship plan development, rather than one year. The county may extend implementation deadlines for good reason if needed.

For example, county laws in Washington state adopted after the initial King County ordinance generally follow this timing after the date of ordinance adoption:

- *2 months:* each medicine producer must notify local agency of their intent to participate in a stewardship plan; retailers with a store label drug must notify the local agency that their manufacturer intends to participate.
- *4 months:* producers must notify local agency of name/contact for their stewardship plan operator.
- *4 months:* producers/stewardship organizations must notify all authorized collectors of opportunity to participate as collector.
- *6 months:* producers must submit a proposed stewardship plan to the local agency;
- *3 months after plan approval:* stewardship plan(s) must begin operations.

##### **Mandate that Manufacturers Must Accept All Qualified Collectors Into Program**

Ensure as many convenient Collection Sites for residents as possible by requiring manufacturers to accept all qualified collectors, and clarifying they cannot reject a qualified Collector from participating in their Stewardship Plan on the grounds that they have enough collection sites to meet the minimum service convenience goal. In most counties, the pharmaceutical stewardship laws require manufacturers to include in their stewardship program any qualified collector that is a retail pharmacy, hospital/clinic with an on-site pharmacy, or a law enforcement agency (i.e. see ordinances in Snohomish County, WA and Pierce County, WA). The ordinance could also require that manufacturers include as a collector any qualified long-term care facility and/or narcotic treatment program as allowed under the DEA’s Rule for Disposal of Controlled Substances.

##### **Narrow the Exemptions in the “Responsible Steward” Definition to Better Mirror the FDA’s Definition of Manufacturer**

The proposed L.A. County ordinance exempts repackagers and relabelers of covered drugs from the definition of “responsible stewards”. Such companies in the drug supply chain involved in producing, preparing, processing, repackaging, and relabeling medicines are typically considered to be drug manufacturers. The federal Food & Drugs Act’s definition of manufacturer and manufacture, includes

these companies:

**Manufacturer** means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

**Manufacture** means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his/her administration or dispensing such substance in the course of his/her professional practice, prepares, compounds, packages or labels such substance.

Unlike retailers that may have a store label drug product, repackagers and relabelers are solely in the business of pharmaceutical distribution and sales and are “brand owners” with their label on the medicines. It may make compliance and enforcement more straightforward for the county to identify the entities with their brands on the drugs. The county pharmaceutical stewardship ordinances in Washington state include repackagers and relabelers in their “producer” definitions, while other local ordinances in California currently exempt them.

### **Clarify that Manufacturers Must Service Collection Sites Frequently Enough to Avoid Overfull Collection Receptacles**

Pharmacies and other potential collectors who volunteer to host and staff collection receptacles for the manufacturers are responsible for ensuring the collection receptacles do not reach capacity or overflow; however, those collectors are dependent on the stewardship program to service the collection receptacles on a timely schedule. Additional clarification in the proposed ordinance language would aide in defining those responsibilities, and address concerns of potential collectors. For example, this language is an adaptation of a provision in Section 7 of the Pierce County, WA ordinance:

A stewardship organization shall provide a service schedule that meets the needs of each collection site to ensure that collection receptacles do not reach capacity and collected covered drugs or sharps are transported to final disposal in a timely manner, including a process for additional prompt collection service upon notification from the collection site.

### **Disposal Facilities**

Align the disposal facility requirements in Section 11.17.060 with the EPA’s recommendation on the most appropriate disposal facilities for collected medicines from residential medicine take-back programs. Current wording largely follows this recommendation, but is unclear about the permit status of cement kilns and it should clarify that these should be limited to cement kilns permitted for disposal of hazardous wastes.

Background: In 2008, EPA issued a recommendation to Regional RCRA Division Directors on the types of incineration facilities that should be utilized for residential medicine take-back programs, saying: “Our preference is that they be sent to a permitted hazardous waste combustor, but when that is not feasible, at a minimum, they should be sent to a large or small municipal waste combustor.”

EPA provides examples of such recommended facilities by state, that includes two RCRA permitted facilities that are readily accessible in Texas and two municipal waste combustion facilities within LA county borders.<sup>51</sup>

While this 2008 memo was a recommendation, EPA has shown its intent to require the use of

---

<sup>51</sup> EPA’s “Recommendation on the Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs”  
[https://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/FCB11DD6F61D4B1685257AFE005EB5CE/\\$file/14833.pdf](https://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/FCB11DD6F61D4B1685257AFE005EB5CE/$file/14833.pdf)

these disposal facilities in its proposed rule for Management of Hazardous Waste Pharmaceuticals.<sup>52</sup>

### **Program Collection Goals**

Require that manufacturers describe short-term and long-term goals for collection amounts of unwanted pharmaceuticals and sharps in their proposed stewardship plan. Currently, only the proposed frequency of collection from Collection Sites must be provided in the plan, per Section 11.17.040 of the proposed ordinance. Requiring manufacturers to propose collection goals is consistent with the proposed ordinance's related requirements that the Director may work with each Stewardship Plan to define performance goals, and that each approved stewardship plan must report annually on their goals and efforts to achieve them.

### **Clarify Collection Requirement for Any Covered Drugs that May Not Be Suitable for Comingling in Collection Receptacles**

Drug/device combination products that are full or partially full of a covered drug may require special handling and separate disposal, such as inhalers or injectable drug products. These drug products are important to capture for safe disposal. Currently, regulations of the CA Board of Pharmacy do not allow any sharps in medicine collection receptacles, even a retractable or covered sharp attached to a filled drug product; however, the Board of Pharmacy plans to revisit this restriction in the future. A requirement can be added for alternative collection mechanisms for any covered drug products that might not be suitable for comingling with other covered drugs during collection.

Example language from Pierce County, WA ordinance; Section 7 – Collection of Covered Drugs  
I. Alternative collection methods shall be provided for any covered drugs that cannot be accepted or comingled with other covered drugs in secure drop boxes, in mailers, or at collection events. Such collection methods shall be reviewed and approved by the Health Department and shall operate in compliance with applicable regulations.

### **3.2 Ordinance Determinations**

From the team's collective professional experience, academic training, analysis of Los Angeles County public records, literature review and interviews of existing pharmaceutical take-back program managers, we are confident in our determination that with the modifications outlined above, the proposed ordinance will:

- Increase public awareness of hazards associated with medicines and sharps used in the home and safe disposal methods through take-back programs.
- Reduce the amount of unused/unwanted pharmaceutical and sharps products entering the environment;
- Reduce the amount of expired and unused medication and sharps that is currently being stockpiled;
- Reduce the amount of pharmaceuticals that could be misused and even lead to death or hospitalization due to overdose; and
- Reduce the number injuries to waste facility workers or the general public due to improper disposal of sharps

---

<sup>52</sup> EPA Proposed Rule for Management of Hazardous Waste Pharmaceuticals, released on September 25, 2015. See section § 266.506 in the proposed rule: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-25/pdf/2015-23167.pdf>

## **APPENDIX A: Ecoconsult Team Qualifications**

**Justin Malan, Principal/Owner of Ecoconsult:** Thirty plus years experience in environmental and public health management. Served as Executive Director of California Conference of Directors of Environmental Health (CCDEH) for 22 years. Has served as Executive Director for numerous other resource-based organizations including Ocean Science Trust and California Aquaculture Association and has worked with many environmental organizations and agencies, including StopWaste, CA Stormwater Quality Association, Heal The Bay and Sustainable Conservation. Holds Masters Degree in Environmental Studies and undergraduate degrees in public administration and law. Full resume is available at: [www.ecoconsult.biz](http://www.ecoconsult.biz)

**Linda Adams, Senior Advisor:** Linda has served in cabinet-level positions with three governors during her distinguished career with State of California. Ms. Adams held key positions in both the Executive and Legislative branches during her many years in public service. In 2006, Ms. Adams was appointed by Governor Arnold Schwarzenegger as secretary of the California Environmental Protection Agency (Cal/EPA), the first woman to serve in that position. Immediately upon her appointment, she was designated the governor's lead negotiator on AB 32, the ground-braking climate change and clean energy measure. When Governor Jerry Brown was elected in 2010, Linda was asked to continue as secretary of Cal/EPA and to assist in the transition, including relevant administration appointments until August of 2011. Prior to her appointment to Cal/EPA, Ms. Adams served as chief of staff to State Controller Steve Westley and as Legislative Secretary to Governor Gray Davis. Ms. Adams negotiated key pieces of legislation on behalf of Governor Davis, including the first-in-the-nation laws to reduce greenhouse gas emissions from automobiles and for the promotion of environmental justice. During the Davis administration, she was appointed as the first woman director of the California Department of Water Resources. Ms. Adams also served as a key staff member in the Legislature, including lead staff for both the Senate Committee on Agriculture and Water Resources and the Assembly Committee on Water, Parks and Wildlife, where she drafted the state's first comprehensive groundwater management law. Ms. Adams holds the position of the chair of the Climate Action Reserve, North America's premier carbon registry. She also serves on the boards of the Pacific Forest Trust, the Delta Vision Foundation, the California Council for Environmental and Economic Balance, and is the founding President of R 20-Regions of Climate Action. Full resume is available at: [www.ecoconsult.biz](http://www.ecoconsult.biz)

**Margaret Shield, PhD:** Dr. Margaret Shield is an environmental and public health policy consultant with a background in the biological sciences. She has worked for the past eleven years for local governments and non-profits on product stewardship and reducing use of and exposures to hazardous chemicals. She has been policy and legislative staff for local government agencies in Washington state, working on federal, state and local regulatory and legislative issues.

Margaret is recognized as a national expert on health and environmental problems associated with waste pharmaceuticals, medicine take-back program operations, related regulations, and pharmaceutical stewardship policies. Her experience includes working with

pharmaceutical take-back programs operated by pharmacies and by law enforcement, development of pharmaceutical stewardship policies, and extensive review of scientific studies pertaining to medication abuse, poisonings, overdoses, and pharmaceutical pollution. She has collaborated extensively with California agencies and organizations on medicine disposal and take-back since 2008. Full resume is available at: [https://www.cehstrategies.com/wp-content/uploads/2016/05/MargaretShield\\_CEHS\\_Resume.pdf](https://www.cehstrategies.com/wp-content/uploads/2016/05/MargaretShield_CEHS_Resume.pdf)

**John Rogers, Technical Advisor:** John has over 30 years experience working in the Environmental Health sector. He is a California Registered Environmental Health Specialist #4883 and holds a Bachelor of Science in Biology, Masters in Biology, and Masters in Public Health. John has worked as an Environmental Health Specialist, a Supervising Environmental Health Specialist, and the Director of Environmental Health for Mendocino County. He most recently served as the Environmental Health Division Chief for Sacramento County Environmental Management Department and retired in October 2015. John now works part-time as a Temporary Environmental Health Consultant for Yolo County. John has facilitated working groups to develop statewide guidelines for new laws relating to disclosure of nutritional information (SB 1420), trans fat ban in food (AB 97), and food handlers' cards (SB 303). The working groups were comprised of representatives from local environmental health agencies, state agencies, industry, and other interested parties. John is also the recipient of "The Gary Erbeck Food Safety Leadership Award" in recognition of outstanding service in promoting food safety in California. John was the Chairperson for the 2015 Symposium on Food Safety and Public Health. The symposium brought in government, agriculture, academia, food industry and other interested parties to explore emerging issues around public health, health of the environment, and safely feeding the population.

**Tim Goncharoff, Technical Advisor:** Tim is a well-known figure in the world of waste reduction and environmental protection. A veteran of years in the field, he speaks and writes widely about waste diversion and related topics. Tim has won numerous awards for his work, including for a groundbreaking drug and sharps ordinance which has provided the model for many of those which followed. Tim has consulted with numerous cities, counties and states about drug takeback laws, and would bring very useful expertise to this project. Tim holds a Bachelor degree from UC Santa Cruz and a Masters degree from Cornell University.

**Final Draft Review by Christine Sosko, REHS, Sonoma County Environmental Health Director & CCDEH Solid Waste Policy Committee Chair**

**APPENDIX B: Support from both the human health and environmental perspectives, and industry perspective from King County, WA.**

June 19, 2013

King County Board of Health

ATTN: Maria Wood

Public Health – Seattle & King County

401 Fifth Avenue, Suite 1300

Seattle, WA 98104

Dear Chair McDermott and King County Board of Health Members:

Thank you for your leadership in developing a thoughtful and effective solution for the safe disposal of unused and expired medicines. As health care providers, substance abuse prevention groups, environmental and civic organizations, faith-based groups, and community public health and safety networks, we support the passage of the proposed Secure Medicine Return Regulation.

Residents of King County benefit from the use of prescription and non-prescription medication. However, about one-third of medicines sold to households goes unused every year – an estimated 11 million containers annually in King County. In recent years, abuse, fatal overdoses, and poisonings from medicines used in homes have emerged as an epidemic. In addition, medicines such as antibiotics, hormones and antidepressants have been found in many streams and waterways.

There is no one magic bullet that will fully solve these complex problems. Like all substance abuse and poisoning prevention programs, multiple sectors of the community need to conduct a variety of activities side-by-side to be most effective. However, a safe medicine return program will reduce harm and is an essential component of a comprehensive approach. We know that the medicines disposed in a secure take-back program will not be abused by a teenager, will not contribute to an accidental poisoning of a child or senior, and will not pollute the Puget Sound.

We support the product stewardship approach used in the Regulation because it will provide sustainable funding to ensure a sustainable program. It also appropriately allocates responsibility, with producers that profit from medicine sales predominantly financing the program. Drug producers should step forward to provide a secure, convenient and environmentally-sound take-back program for residents throughout King County.

Thank you for this opportunity to provide comments. Please pass this smart Medicine Return Regulation, and help protect the health of our families, our communities and our environment.



Sincerely,

Inga Manskopf, DFC Coordinator  
Adolescent Substance Abuse Program,  
Seattle Children's Hospital  
206-987-7612

[inga.manskopf@seattlechildrens.org](mailto:inga.manskopf@seattlechildrens.org)

Michael Garrity,  
Washington State Conservation Director

American Rivers

Randy Beaulieu

Central Seattle Drug Free Communities Coalition

Jon Gould, Deputy Director

Children's Alliance

Rudy Garza, Coordinator

Coalition for Drug-Free Youth

Robb Miller, Executive Director

Compassion & Choices of Washington

LeeAnne Beres, Executive Director

Earth Ministry

Paula Matthyse, Outreach Director

And the Board of Directors

Eastside Community Network

Melinda Papen, RN, CHPN, Director

EvergreenHealth Hospice and Palliative Care  
Steven G. Gilbert, PhD, DABT  
INND - Institute of Neurotoxicology &  
Neurological Disorders  
Judy Brewer, Chair  
Issaquah Community Network  
Vicki Hoffman, Chair  
Issaquah Drug Free Community Coalition  
Laura Kramer, LMHCA, CDPT,  
Addiction Counselor and Educator  
Alternatives to Addiction  
Jewish Family Service Seattle  
Liz Wilhelm and Constance Perenyi, Co-Chairs  
King County Community Organizing Program  
Advisory Board (KCCOP)  
Sue Vermeulen, Executive Director  
King County Nurses Association  
Judy Bevington, President  
League of Women Voters of Seattle-King County  
Alana Morris, Outreach Chair  
Mercer Island Communities That Care  
Carol Hannum, Executive Committee Treasurer  
OWL - Older Women's League, Seattle/King

County Chapter

Gary Hothi, Chair

Prevention WINS Coalition

Scott and Charlene DePuy

The Ryan's Solution Foundation

Deb Spiger, President

School Nurse Organization of Washington

Frank Couch, Executive Director

Science and Management of Addictions (SAMA)

Laura Smith, Executive Director

Snoqualmie Valley Community Network

Board of Directors

Snoqualmie Valley Healthy Community Coalition

Harla Tumbleson, Director

SOAR

Luke McQuillin, Project Coordinator

Vashon Alliance to Reduce Substance Abuse

(VARSA)

Maggie Hood, President

Washington Chapter American Academy of

Pediatrics

Brendon Cechovic, Executive Director

Washington Conservation Voters

Josh Osborne-Klein, Conservation Chair  
Washington State Chapter of the Sierra Club  
Lisa Butler, Director of Public Policy  
Washington State Hospice & Palliative Care  
Organization  
Karen Bowman, MN, RN, COHN-S,  
Environmental Health Specialist  
Washington State Nurses Association  
Suellen Mele, Program Director  
Zero Waste Washington

**King County Board of Health – Secure Medicine Return Rule & Regulation**  
**Adopted 6/20/14; Effective 7/20/13**

This overview is for explanatory purposes only. For more information on the King County Board of Health’s Subcommittee on Secure Medicine Return, see [www.kingcounty.gov/healthservices/health/BOH/MedicineTakeback.aspx](http://www.kingcounty.gov/healthservices/health/BOH/MedicineTakeback.aspx), or contact Administrator Maria Wood at [maria.wood@kingcounty.gov](mailto:maria.wood@kingcounty.gov) or 206-263-8791.

**Overview of Proposed Secure Medicine Return Rule & Regulation.**

The King County Board of Health’s Subcommittee on Secure Medicine Return has recommended a Rule and Regulation (R&R) establishing an industry-funded product stewardship model to collect and safely dispose of unwanted household medicines from residents of the county.

**Overview of the proposed secure medicine return system**

Residents will be encouraged to bring leftover, expired, and unneeded medicines to secure drop boxes in retail pharmacies or law enforcement offices throughout the county. These collection sites will participate voluntarily, and if a medicine drop-off site is not

available in a specific area then periodic collection events or pre-paid return mailers will be provided. Pre-paid return mailers can be requested for residents who are home bound or disabled. Drop-off site locations and other collection services will be promoted to the community through a toll-free telephone line, a website, and print materials.

Collected medicines will be securely handled, transported and disposed of according to federal and state laws, including policies of the Drug Enforcement Administration and the Washington State Board of Pharmacy. The drugs will be destroyed at properly permitted high temperature incineration facilities.

Drug producers selling medicines for residential use in or into King County are required to finance and provide the secure medicine return system. Residents cannot be required to pay a fee for secure medicine return when they purchase medicines or return them. Public Health - Seattle & King County (Public Health) will oversee the drug producers' medicine return system to ensure safety and compliance with the R&R.

### **Medicines accepted for return**

- Prescription and non-prescription (over-the-counter) medicines that residents use in their homes, or in other residential settings. Includes medicines in any form: pills, liquids, creams; and includes legally prescribed controlled substances, such as OxyContin, Vicodin, Valium, Ritalin, and stimulants.
- Current DEA regulations restrict return of controlled substances to law enforcement drop-off sites or collection events; however, new regulations the DEA is developing will authorize drug manufacturers, retail pharmacies and others to operate drop-off and mail-back programs.
- Not accepted for return: over-the-counter drugs that are regulated as cosmetics, e.g. toothpaste, sunscreen, medicated shampoos; vitamins and supplements; and pharmaceutical waste from businesses.

### **Operation of the system by drug producers**

- The proposed R&R defines requirements and standards, but allows drug producers to develop their own stewardship plan for providing an efficient medicine return system.
- Every drug producer selling medicines for residential use in or into the county must participate in the “standard” stewardship plan. If a producer or group of producers prefers to form a different partnership, they may propose an “independent” plan. Both the standard plan and the independent plan must meet system requirements and standards, and be approved by Public Health before initiating operations.
- If multiple stewardship plans are approved, the plans must coordinate their promotional activities to ensure residents can easily understand and use the collection services of any plan.

- Timing of program implementation: drug producers must submit a proposed stewardship plan no later than 12 months after the R&R is enacted; and must begin operation of the stewardship plan no later than 3 months after plan approval by Public Health.

### **System requirements & standards**

- The primary collection method will be secure drop boxes at retail pharmacies and law enforcement offices.
- The R&R defines a “service convenience goal” to ensure convenient and equitable access for all residents. Any retail pharmacy or law enforcement agency that volunteers to be a drop-off site must be included in the collection system to ensure as many drop-off sites as possible. Any areas lacking a minimum number of drop-off sites will be served through periodic collection events and/or through mail-back programs.

This overview is for explanatory purposes only. For more information on the King County Board of Health’s Subcommittee on Secure Medicine Return, see [www.kingcounty.gov/healthservices/health/BOH/MedicineTakeback.aspx](http://www.kingcounty.gov/healthservices/health/BOH/MedicineTakeback.aspx), or contact Administrator Maria Wood at [maria.wood@kingcounty.gov](mailto:maria.wood@kingcounty.gov) or 206-263-8791.

### **System requirements & standards (continued)**

- Prepaid, preaddressed mailers can be requested for home bound or disabled residents.
- Collectors may offer to serve as a collector voluntarily, or may agree to serve in exchange for incentives or payment offered by the drug producers.
- Handling of all drugs must conform to all applicable federal and state laws and regulations, including those of the Drug Enforcement Administration and the Washington State Board of Pharmacy.
- Collected medicines must be disposed of at a properly permitted hazardous waste facility, unless permission is granted to use a large municipal waste combustion facility (e.g. Waste-to-Energy facilities) because of cost or logistical barriers. Use of alternative disposal technologies that provide superior environmental and human health protection may also be approved.

### **Promotion and evaluation requirements**

Promotion: drug producers are required to promote safe storage of medicines and how to use the medicine return system to residents, pharmacists, retailers, and health professionals; provide materials to pharmacies, health care facilities, and others; and provide a website and a toll-free number. Drug producers must work with collectors to develop clear instructions on use of secure drop boxes and a readily

recognizable, consistent drop box design.

Evaluation: drug producers must report annually on the pounds of medicines collected, annually evaluate the effectiveness of program promotion, and conduct a survey of residents to measure awareness and program convenience after the first program year, and again at years five and nine.

LHWMP will develop template educational materials for use by pharmacies, law enforcement, health care providers and local governments, and provide targeted education to key populations.

### **Costs responsibilities**

Drug producers are responsible for:

- Costs of collection supplies for drop-off sites, prepaid mailers, and any collection events.
- Costs of transporting collected medicines (including law enforcement escort if required), and final disposal at approved high temperature incineration facilities.
- Costs of program promotion and evaluation, as well as administrative costs.
- Payment of fees to Public Health to reimburse costs of plan review and annual oversight.

Collectors participate voluntarily and provide in-kind staff time at drop-off sites.

The Local Hazardous Waste Management Program in King County is responsible for costs of:

- Providing up to 400 secure drop boxes for the standard stewardship plan. Drug producers participating in the standard plan are responsible for any additional drop boxes or maintenance costs, and producers operating an approved independent plan must provide all drop boxes.
- Assisting with program promotion (see description above).

### **Oversight and enforcement**

- Public Health will oversee the program to ensure compliance and safety.
- Public Health oversight authority includes: review and approval of the stewardship plan(s) from drug producers, monitoring of plan operations, inspections as needed, review and approval of substantive changes to the approved stewardship plan(s), and review of annual reports.

- Drug producers who are not in compliance with the R&R are subject to written warnings and civil penalties of up to \$2,000 per day.
- Public Health oversight costs will be recovered through plan review and annual operating fees from producers.

**Link to PhRMA's Position on Safe Disposal of Unused Medicines For the King County Board of Health – February 21, 2013:**

<http://www.kingcounty.gov/depts/health/board-of-health/regulations/secure-medicine/~media/depts/health/board-of-health/documents/securemed/PhRMAstatement21Feb2013.ashx>



## APPENDIX C: Status of Implementation of County Laws in California and Washington

<p><b>Status of Implementation of County Laws in CA</b></p>	<p><b>Alameda County, CA</b>  <a href="#">Safe Drug Disposal Ordinance</a>                  Passed July 24, 2012; Effective August 24, 2012.</p> <p>Manufacturers’ MED-Project program held 1 collection event in 2015, 23 events around the county in 2016, and plans for 12 events in 2017. Installation of secure drop boxes began in December 2016, with 12 drop boxes in operation as of early March 2017.</p>	<p>First pharmaceutical stewardship ordinance enacted in U.S.</p> <p>Ordinance was amended in February, 2016 and now more closely aligns with regulations in King County (WA), San Francisco, and other CA counties.</p>
	<p><b>City &amp; County of San Francisco, CA.</b>  <a href="#">Safe Drug Disposal Stewardship Ordinance</a>                  Passed March 26, 2015; Effective April 25, 2015.                  Stewardship plan deadline: April 2016</p> <p>MED-Project <a href="#">stewardship plan</a> accepted conditionally on July 25, 2016. County adopted a <a href="#">regulation</a> on producers’ outreach activities on July 25, 2016.</p>	<p>The San Francisco ordinance is modeled after the King County regulation, with some modifications.</p> <p>Ordinances in the three other counties were modeled after San Francisco’s, with some modifications.</p>
	<p><b>San Mateo County, CA.</b>  <a href="#">Safe Medicine Disposal Ordinance</a>                  Passed April 28, 2015; Effective May 28, 2015.                  Stewardship plan deadline: May 28, 2016</p> <p>County accepted a <a href="#">MED-Project plan</a> on <a href="#">September 13, 2016</a>.</p>	<p><i>Implementation Status:</i></p> <p>In progress and being coordinated across the 4 CA counties with similar laws (San Francisco, San Mateo, Santa Clara, Marin).</p> <p>Each ordinance has compliance deadlines leading up to the 1 year deadline for submission of a stewardship plan.</p>
	<p><b>Santa Clara County, CA.</b>  <a href="#">Safe Drug Disposal Ordinance</a></p>	

	<p>Passed June 23, 2015; Effective June 23, 2015. Stewardship plan deadline: July 2016</p> <p>County received a MED-Project plan on October 21, 2016, that was returned with comments. A revised plan was received in late December 2016 and a public comment period was held until Jan. 13, 2017. County decision on the plan is pending.</p>	
	<p><b>Marin County, CA.</b> <a href="#">Safe Drug Disposal Ordinance</a></p> <p>Passed Aug. 11, 2015; Effective Sept. 11, 2015. Stewardship plan deadline: September 12, 2016</p> <p>County is reviewing MED-Project plan received Sept. 12, 2016.</p>	
	<p><b>Santa Cruz County, CA.</b> <a href="#">Safe Drug and Sharps Disposal Ordinance</a></p> <p>Passed Dec. 8, 2015; Effective Jan. 8, 2016. Stewardship plan deadline: March 1, 2016.</p> <p>MED-Project plan submitted. County reviewed and rejected the plan several times. A revised MED-Project plan accepted in September 2016.</p>	<p>Similar to King County and subsequent CA county laws, but also includes medical sharps and mandates retailer participation as collectors, as well as other modifications.</p> <p>If stewardship program not implemented by June 30, 2016, producers must reimburse county for costs of its existing medicine take-back program</p>
	<p><b>Santa Barbara County, CA</b> <a href="#">Extended Producer Responsibility Stewardship for the Collection and Disposal of Unwanted Covered Drugs</a></p> <p>Passed June 21, 2016; Effective July 21, 2016. Stewardship plan deadline: July 21, 2017.</p>	<p>Similar to San Mateo and other CA county laws.</p>
	<p><b>Contra Costa County, CA</b> <a href="#">Safe Drug Disposal</a></p> <p>Passed December 20, 2016; Effective January 20, 2017. Stewardship plan deadline: January 2018.</p>	

<p><b>Status of Implementation of County Laws in WA</b></p> <p>County laws in WA have been enacted by local Boards of Health through their authority under state statute to protect public health and safety. These local Boards include some or all of the county's councilmembers, and may include additional elected or appointed members.</p>	<p><b>King County, WA.</b>  <a href="#">Secure Medicine Return Regulations</a>  Passed July 24, 2012; Effective August 24, 2012.</p> <p>MED-Project stewardship plan approved in April 2016. County-wide system of more than 87 secure drop boxes launched in January 2017.</p>	
	<p><b>Snohomish County, WA</b>  <a href="#">Secure Medicine Return Regulations</a>  Passed June 14, 2016; Effective July 15, 2016.  Stewardship plan deadline: December 15, 2016.  Stewardship plan received from MED-Project; initial plan rejected; revised plan due by March 12, 2016.</p>	<p>Similar to King County law with some modifications, including: refinements to further align with the DEA Rule, an enhanced service convenience goal, shortened implementation timelines, and expanded promotion requirements.</p>
	<p><b>Kitsap County, WA</b>  <a href="#">Secure Medicine Return Ordinance</a>  Passed December 6, 2016; Effective immediately.  Stewardship plan deadline: June 2017</p>	<p>Very similar to Snohomish County regulation.</p>
	<p><b>Pierce County, WA</b>  <a href="#">Secure Medicine Return Regulations</a>  Passed December 7, 2016; Effective December 8, 2016.  Stewardship plan deadline: June 2017</p>	<p>Very similar to Snohomish County regulation with some modifications, including: clarifications around service schedules for emptying secure drop boxes, requirements for alternative collection mechanisms for any drugs that cannot be commingled during collection, and specific language requirements for promotion materials.</p>

## APPENDIX D: DEA Rule for Disposal of Controlled Substances

The Drug Enforcement Administration (DEA)'s [Rule for Disposal of Controlled Substances](#) went into effect on October 9, 2014 to implement the federal [Secure and Responsible Drug Disposal Act](#) of 2010. The Rule defines protocols for take-back of leftover controlled substances from any person the drug is prescribed to, any member of that person's household, and from individuals lawfully entitled to dispose of a deceased person's property. Controlled drugs for pets can also be disposed of by household members.

### Allowed Collection Methods:

- Secure collection receptacle locations (i.e., permanent drop-off boxes) – operated by authorized drug manufacturers, distributors, reverse distributors, retail pharmacies, hospitals/clinics with an on-site pharmacy, narcotic treatment centers, or law enforcement agencies. Certain types of long-term care facilities may also have a secure drop box operated by an authorized retail pharmacy or by an authorized hospital/clinic with an on-site pharmacy.
- Take-back events – conducted by law enforcement agencies only, but other entities may partner with law enforcement to promote and coordinate the take-back event.
- Mail-back programs – operated by authorized drug manufacturers, distributors, reverse distributors, retail pharmacies, hospitals/clinics with an on-site pharmacy, narcotic treatment centers, or law enforcement agencies that can meet specific requirements of the Rule.

Comingling of medicines allowed: By any of the approved collection methods, controlled substances may be co-mingled with other consumer medications. Consumers can place all leftover medicines into one collection box or one mail-back envelope without having to attempt to identify and separate different medications.

Transportation and final destruction options: The proposed rule makes it simpler for authorized collectors to send drugs away to final destruction through existing providers of pharmaceutical waste disposal. Reverse distributors, drug distributors, and common carriers may be used. The Rule does not limit the specific destruction method, but requires that drugs must be rendered non-retrievable and the disposal method must comply with federal, tribal, state, local laws. DEA specifically says flushing and trash disposal do not meet the non-retrievable standard for collected medicines. See the Rule and the [DEA Drug Disposal Information](#) webpage for additional information.

Prior to this Rule, leftover prescribed controlled substances - such as prescription narcotics and stimulants - could only be legally collected from residents by law enforcement, at take-back events or drop-off programs. The Secure and Responsible Drug Disposal Act, effective October 2010, amended the Controlled Substances Act and authorized the DEA to develop the Rule, but the federal law does not mandate the creation of any medicine take-back programs, nor does it provide any funding for those programs.

**APPENDIX E – Interview Questions; Table of Responses and Table of References and Data Sources.**

<b>Table 1. Pharmaceutical and Sharps Take Back Program Survey – Basics of Program</b>						
<b>Jurisdiction</b>	<b>Ordinance Adoption and Start Dates</b>	<b>Program Basics</b>	<b>Drug Types and Sharps</b>	<b>Support/ Opposition</b>	<b>Funding</b>	<b>Voluntary Program Details</b>
<i>National Environment al Health Association (NEHA)</i>	NEHA does not run a program	N/A	Unused/unwanted pharmaceuticals and sharps products	EPR program, such as that proposed by LA County is highly effective in reducing the amount of unused/unwanted pharmaceuticals and sharps entering the environment, reducing the amount of expired and unused medication and sharps that are currently being stockpiled, reducing the amount of pharmaceuticals that could be misused and lead to death or hospitalization due to overdose, reducing the number of injuries to waste facility workers or the general public die to improper disposal of sharps. EPR is the most reasonable, appropriate, and effective approach. See March 2017, JEH Executive Directors Column/ Duke University Blog.	N/A	N/A
<i>Alameda County</i>	Alameda Co Board of Supervisors adopted an Ordinance in July 2012 and an amended ordinance in Feb 2016. Ordinance requires drug	The mandated program is run by MED-Project (MP) for the drug manufacturers through the Pharmaceutical Product Stewardship Working Group (PPSWG). Another entity	Prescription and non-prescription drugs are approved for collection and disposal. Legally prescribed controlled substances (e.g.	The ordinance had support from waste water treatment facilities, cities, public health and environmental advocacy groups, law enforcement, and alcohol and drug abuse	Ordinance requires drug manufacturers to be responsible for the costs relating to collection,	A voluntary program exists and is run by different agencies (cities and waste water agencies). Some of the 30 locations will become

	<p>manufacturers to implement a drug collection, transport, and disposal plan. First event was held in Aug 2015. Drop boxes started Dec 2016. The ordinance applies in the cities, except Berkeley.</p>	<p>(Exelixis) has been approved for a single product. Alameda's Dept of Environmental Health is the lead agency to review plans, provide oversight, and ensure program compliance. There are approx. 14 voluntary collection sites at pharmacies and law enforcement offices. The goal is 100 drop boxes by the end of 2017 to be well distributed and convenient for residents.</p>	<p>OxyContin) are also covered. Sharps are covered by a separate ordinance adopted in Nov 2015. The sharps ordinance requires each producer to participate in a product stewardship plan. Regulations for the sharps ordinance are currently in development.</p>	<p>prevention organizations, including a Senior community group. Opposition came from drug manufacturers.</p>	<p>transport, disposal, program monitoring, and administration. Dept of Environmental Health costs are recovered from annual fees and charges for services (e.g. reviewing stewardship plans) paid by product stewardship groups.</p>	<p>part of MED-Project. The current system is not well coordinated due to different entities running them. There are not enough locations and they are not well distributed.</p>
<p><i>King County, WA</i></p>	<p>King Co (KC) Board of Health adopted Rules/ Regulations (RR) in June 2013. RR requires drug manufacturers to implement a drug collection and disposal plan. Drop-offs for residents started Jan. 2017. The Board of Health's RR apply in the incorporated cities.</p>	<p>The mandated program is run by MED-Project (MP) for the drug manufacturers. The county's Local Hazardous Waste Management Program of King County (a five agency consortium) provides oversight and is responsible for securing drop boxes and program promotion. The KC Public Health Department oversees the program to ensure compliance and safety. There are approx. 90 voluntary collection sites at pharmacies and law enforcement offices (regulation requires a minimum of 1 in every city plus 1 for every 30,000 population, otherwise collection events or mailers must be provided).</p>	<p>Prescription and non-prescription drugs are approved for collection and disposal. Legally prescribed controlled substances (e.g. OxyContin) are also covered. Sharps are not included but are recovered through a robust needle exchange program.</p>	<p>Support came mostly for public health benefits related to opiate crisis - public testimonials from family members impacted by accidental/intentional use and abuse of prescription drugs. Other support came from schools, law enforcement, and alcohol and drug abuse prevention organizations. Pharmaceutical industry opposed. Environmental benefits recognized but not a principal driver.</p>	<p>The law requires drug manufacturers to be responsible for the costs relating to collection, transport, disposal, program monitoring, and administration. Local Haz Waste Management Program recovers costs through tipping fees and waste water service fees. Public Health Dept costs are recovered from annual fees and charges for services (e.g. reviewing</p>	<p>N/A – suggestion that voluntary programs not as effective or convenient due to limited resources and limited number of drop boxes.</p>

					stewardship plans) paid by MED-Project.	
<i>Pierce County, WA</i>	Tacoma-Pierce County Board of Health adopted regulations in Dec 2016. The regulations require drug manufacturers to implement a drug collection and disposal plan. Drop boxes or kiosks for residents are anticipated to start by the end of 2017. The regulations apply in the cities.	The mandated program is to be run by MED-Project (MP) for the drug manufacturers through the Pharmaceutical Product Stewardship Working Group (PPSWG). The Tacoma-Pierce County Health Dept is the lead agency to review stewardship plans, provide oversight, and ensure program compliance. There will be 40-50 voluntary collection sites at select locations (1 in every city plus 1 for every 30,000 population).	Prescription and non-prescription drugs are approved for collection and disposal. Legally prescribed controlled substances (e.g. OxyContin) are also covered. Sharps are not included in the regs. The primary focus was on medicines. Sharps are currently collected in drop boxes located at solid waste sites.	The regulations had support from government agencies (Solid Waste Advisory Group, waste treatment facilities, law enforcement), environmental advocacy organizations, public health advocacy groups, Zero Waste Washington and environmental advocacy groups, and alcohol and drug abuse prevention organizations. There was a letter of opposition from drug manufacturers.	The law requires drug manufacturers to be responsible for the costs relating to collection, transport, disposal, program monitoring, and administration. T-P Co Health Dept costs are recovered from annual fees and charges for services (e.g. reviewing stewardship plans) paid by MED-Project.	Law enforcement agencies operate a small voluntary program with no separate funding. Not as effective due to limited number of locations. Not likely law enforcement would be able to economically or effectively manage a larger system, given their primary role of law enforcement in the county.
<i>San Francisco City/County</i>	SF City/County Board of Supervisors adopted an Ordinance in March 2015. Ordinance requires drug manufacturers to implement a drug collection, transport, and disposal plan. Drop-offs for residents started Feb. 2017.	Similar to King County, WA, the mandated program is run by MED-Project (MP) for the drug manufacturers through the Pharmaceutical Product Stewardship Working Group (PPSWG). SF's Dept of the Environment (separate agency from Environmental Health) is the lead agency to review plans, provide oversight, and ensure program compliance. There are approx. 23 voluntary collection sites at pharmacies and law enforcement offices. The goal is 55 drop boxes (5 for each 11 supervisorial districts).	Prescription and non-prescription drugs are approved for collection and disposal. Legally prescribed controlled substances (e.g. OxyContin) are also covered. Sharps are not included but are recovered through an existing Household Hazardous Waste Program.	The ordinance had broad support including pharmacies that participated in a pilot study, environmental and public health advocacy groups, public safety groups, schools, law enforcement, and alcohol and drug abuse prevention organizations. The Ca Retail Association provided support for voluntary role of pharmacies. Early opposition from pharmaceutical industry which resulted in a pilot study. SF residents like the program, they appreciate that	Ordinance requires drug manufacturers to be responsible for the costs relating to collection, transport, disposal, program monitoring, and administration. Dept of Environment costs are recovered from annual fees and charges for services (e.g. reviewing	Not as effective due to limited number of participating businesses and drop boxes.

				they are doing the right thing.	stewardship plans) paid by MED-Project. A small portion of costs are recovered from garbage/refuse collection fees.	
<i>Santa Barbara County</i>	SB Co Board of Supervisors adopted an ordinance in March 2015. Ordinance required drug manufacturers to implement a drug collection, transport, and disposal plan. Drop-offs for residents are expected to start in Jan 2018. The ordinance applies in the cities.	The mandated program is run by MED-Project (MP) for the drug manufacturers through the Pharmaceutical Product Stewardship Working Group (PPSWG). SB's Division of Environmental Health is the lead agency to review plans, provide oversight, and ensure program compliance. The goal is to have 25 voluntary collection sites at pharmacies and law enforcement offices (5 boxes for each 5 supervisorial districts).	Prescription and non-prescription drugs are approved for collection and disposal. Legally prescribed controlled substances (e.g. OxyContin) are also covered. Sharps are not included but are collected through an existing program run by the county's Public Works Dept.	The ordinance had support from the cities, public health advocacy groups, public works, law enforcement, and alcohol and drug abuse prevention organizations. An opposition letter was provided by the California Life Sciences Association.	Ordinance requires drug manufacturers to be responsible for the costs relating to collection, transport, disposal, program monitoring, and administration. The Division of Environmental Health costs are recovered from annual fees and charges for services (e.g. reviewing stewardship plans) paid by MED-Project.	Sheriff operates a small voluntary program with no separate funding source. Not as effective due to limited number of locations and some residents may avoid sheriff's offices.
<i>Santa Clara County</i>	SC Co Board of Supervisors adopted an ordinance in June 2015. Ordinance required drug manufacturers to implement a drug collection, transport, and disposal plan. The county is working to amend the ordinance, no date on when they will start drop	The mandated program will be run by MED-Project (MP) for the drug manufacturers through the Pharmaceutical Product Stewardship Working Group (PPSWG). SC Co's Consumer and Environmental Protection Agency will be the lead agency to provide oversight and ensure program compliance. Currently, stewardship plans are being	Prescription and non-prescription drugs are approved for collection and disposal. Legally prescribed controlled substances (e.g. OxyContin) are also covered. Sharps are not included in the ordinance. SC Co is considering a separate	The ordinance had support from the cities, environmental organizations, public health advocacy groups, law enforcement, and alcohol and drug abuse prevention organizations. There was no formal opposition for the ordinance.	Ordinance requires drug manufacturers to be responsible for the costs relating to collection, transport, disposal, program monitoring, and administration. SC Co costs are	Voluntary programs are currently offered at approx 12 clinics and independent pharmacies. The public seems to like the program, as do the independent pharmacies. The program is managed by the Sheriff's Office with no specific funding source. There are not



	boxes. The ordinance applies in the cities.	reviewed out of the County Executive's Office. The goal is to have approx. 90 voluntary collection sites at pharmacies and law enforcement offices (1 box per 20,000 population).	ordinance for sharps.		recovered from annual fees and charges for services (e.g. reviewing stewardship plans) paid by MED-Project.	enough locations to conveniently service the entire population.
<i>Snohomish County, WA</i>	The Board of Health of the Snohomish Health District adopted an ordinance in June 2016. The regulations require drug manufacturers to implement a drug collection and disposal plan. Drop boxes or kiosks for residents are anticipated to start by the end of 2017. The ordinance applies in the cities.	The mandated program will be run by MED-Project (MP) for the drug manufacturers through the Pharmaceutical Product Stewardship Working Group (PPSWG). The Division of Environmental Health of the Snohomish Health District is the lead agency to review stewardship plans, provide oversight, and ensure program compliance. There will be approx 40 voluntary collection sites at select locations (1 in every city/town plus 1 for every 30,000 population).	Prescription and non-prescription drugs are approved for collection and disposal. Legally prescribed controlled substances (e.g. OxyContin) are also covered. Sharps are not included in the regs. The primary focus was on medicines. The only current option for sharps disposal is through pharmacies.	The ordinance had support from the cities, public health advocacy groups, product stewardship organizations, environmental advocacy groups (e.g. Zero Waste Washington), and law enforcement.	The law requires drug manufacturers to be responsible for the costs relating to collection, transport, disposal, program monitoring, and administration. The Snohomish Health District, Division of Environmental Health costs are recovered from annual fees and charges for services (e.g. reviewing stewardship plans) paid by MED-Project	Law enforcement agencies in cooperation with the Snohomish Health District operate a significant voluntary program with no separate funding source. There are 25-30 locations where unwanted drugs can be collected. Collection of medicines has more than doubled in 5 years (see Table 2). There is not enough funding or staff resources to sustain or expand the program.
<i>Sonoma County</i>	Sonoma County (SC) is in the process of developing an ordinance for safe medicine and sharps collection and disposal. The Board of Supervisors has provided conceptual support for an ordinance.	If adopted, the mandated program will likely be run by MED-Project (MP) for the drug manufacturers through the Pharmaceutical Product Stewardship Working Group (PPSWG). The Division of Environmental	Prescription and non-prescription drugs will be approved for collection and disposal. Legally prescribed controlled substances (e.g. OxyContin) will also be covered. Sharps	At this point, the ordinance has support from the cities, water agencies, the county waste management agency, health advocacy groups, community advocacy groups, and law enforcement. Opposition has come from	Once the ordinance is adopted, it will require drug manufacturers to be responsible for the costs relating to collection,	A current voluntary take back program is run by several agencies in the county with no separate funding source. Collection of medicines has tripled from 2008 to 2015 (see Table 2). There

	<p>They plan to adopt an ordinance in Spring 2017 with a start date of late 2017 or early 2018 for drop boxes. SC is working with the 9 cities and will eventually bring them into the program by resolution.</p>	<p>Health of the Sonoma County Dept of Health Services will be the lead agency to review stewardship plans, provide oversight, and ensure program compliance. There will be approx 25-30 voluntary collection sites at select locations (1 in every Board of Supervisor District plus 1 for every 30,000 population).</p>	<p>collection and disposal will also be included in the ordinance.</p>	<p>the pharmaceutical industry.</p>	<p>transport, disposal, program monitoring, and administration. The Division of Environmental Health costs will be recovered from annual fees and charges for services (e.g. reviewing stewardship plans) paid by MED-Project.</p>	<p>is not enough funding or staff resources to sustain or expand the program. Collection of sharps is currently handled by the Solid Waste Management Agency.</p>
--	---	---	--	-------------------------------------	--	---

**Table 2. Pharmaceutical and Sharps Take Back Program Survey – Supporting Information**

Jurisdiction	Issues and References	Benchmarks and Goals	EH Role	Other Models	Comments
<i>Alameda County</i>	<p>Public health and safety impacts were of greatest concern, particularly overdose rates for seniors and youth. Drug abuse rates are increasing. The public, particularly children and the elderly, are at significant and unnecessary risk of poisoning due to improper disposal of prescription and non-prescription drugs and the illegal re-sale of prescription drugs. See “Findings” section in drugs and sharps ordinances in link for more information:  <a href="https://www.acgov.org/aceh/safedisposal/documents/SDDRevisedOrdinance_Final_02-02-2016.pdf">https://www.acgov.org/aceh/safedisposal/documents/SDDRevisedOrdinance_Final_02-02-2016.pdf</a>   <a href="https://www.acgov.org/aceh/safedisposal/documents/SafeConsumer-GeneratedSharpsDisposalOrdinance.pdf">https://www.acgov.org/aceh/safedisposal/documents/SafeConsumer-GeneratedSharpsDisposalOrdinance.pdf</a></p>	<p>Benchmarks and goals are not specifically addressed in the ordinance. A 2015 annual report included collection goals (increasing the number of kiosks and collection events), education and public outreach goals (call volume, number of press advisories, website hits, percentage of community centers reached), regulatory outreach goals (contacting potential collection entities and identifying type of entity), take back events (one event collected 336 pounds of products), and collection system (improve access for all county residents)</p>	Lead Agency	<p>Alameda Co used a San Francisco proposed ordinance that was not adopted by SF. Alameda Co was the first local government in the US to pass legislation requiring pharmaceutical companies to operate a program to collect and dispose of unwanted drugs.</p>	<p>Alameda Co coordinates with other Bay Area counties to be as consistent with each other as possible.</p>
<i>King County, WA</i>	<p>Public health and safety impacts were of greatest concern. In 2010 Medical Examiner reported 209 fatal overdoses with 130 involving prescription-type opiates and 79 involving prescription sedatives. From 2008-2010, 7 in 10 deaths of children ages 10-17 were due to drugs or multiple drugs with 86% involving prescription drugs. See “Findings” in link for more information:  <a href="http://www.kingcounty.gov/depts/health/board-of-health/~media/depts/health/board-of-health/documents/regulations/BOHRegulation1303.aspx">http://www.kingcounty.gov/depts/health/board-of-health/~media/depts/health/board-of-health/documents/regulations/BOHRegulation1303.aspx</a></p>	<p>Additional benchmarks include # deaths (from Morbidity and Mortality Data); # pharmacies participating; amount collected; # locations; working with U. Washington researchers. Not looking directly at environmental benchmarks.</p>	Limited	<p>Vancouver, British Columbia; Alameda County</p>	<p>Areas lacking a minimum number of collection sites can be mitigated by holding periodic collections or mail-back programs</p>

<p><i>Pierce County, WA</i></p>	<p>Public health and safety impacts were of greatest concern. See link for additional references on those impacts:  <a href="http://www.tpchd.org/files/library/6adf87ac0c3b4049.pdf">http://www.tpchd.org/files/library/6adf87ac0c3b4049.pdf</a>  The regulations also contained findings. For example, 70% of those who abuse prescription medicines obtain them from family members or friends. See link for additional findings:  <a href="http://www.tpchd.org/files/library/ae24bd1181f77b4f.pdf">http://www.tpchd.org/files/library/ae24bd1181f77b4f.pdf</a></p>	<p>Benchmarks and goals are not specifically addressed in the ordinance. Will likely include information in annual report (e.g. collection weights). Other goals include convenience goals and public awareness through surveys. Environmental impacts are more difficult to quantify and to establish a clear correlation between the program and its effect on the environment.</p>	<p>The Tacoma-Pierce Co Health Dept is the lead agency. As one of the branches of the dept, Environmental Health will likely have a key role in reviewing plans and ensuring compliance.</p>	<p>Regulations were modeled from King County (WA) and Snohomish County (WA) to effect consistent expectations and standards.</p>	<p>State legislation has been introduced and passed through a couple of committees. Concern expressed about pre-emption and less effective statewide standards.</p>
<p><i>San Francisco City/County</i></p>	<p>Described in “Findings” section of ordinance, which cite references related to environmental effects, public health and safety effects, and zero waste goals. Nine of ten poisoning deaths are caused by drugs. EPA study found at least one pharmaceutical compound in all samples collected at waste treatment plants. See link for more details:  <a href="https://sfgov.legistar.com/View.ashx?M=F&amp;ID=3683502&amp;GUID=BDD1E6B8-1779-4277-8913-592F009AC299">https://sfgov.legistar.com/View.ashx?M=F&amp;ID=3683502&amp;GUID=BDD1E6B8-1779-4277-8913-592F009AC299</a></p>	<p>Convenience goals (boxes per district); outreach awareness goals from biennial surveys (see link for more detail); annual report - weight collected. Hard to prove correlations between outputs (e.g. improved awareness) and public health outcomes (e.g. reduction in poisonings).  <a href="https://sfenvironment.org/sites/default/files/editor-uploads/toxics/pdf/sfe_th_regulations_safe_drug_disposal_stewardship_ordinance_july_25.pdf">https://sfenvironment.org/sites/default/files/editor-uploads/toxics/pdf/sfe_th_regulations_safe_drug_disposal_stewardship_ordinance_july_25.pdf</a></p>	<p>Limited</p>	<p>Alameda County, King County, British Columbia (effective - # drop boxes in King County).</p>	<p>Mail back programs and events to supplement boxes. Pilot Study  <a href="https://sfenvironment.org/sites/default/files/fliers/files/sfe_th_safe_medicine_disposal_pilot_program_update_dec2012.pdf">https://sfenvironment.org/sites/default/files/fliers/files/sfe_th_safe_medicine_disposal_pilot_program_update_dec2012.pdf</a>   Drug Waste Characterization Study  <a href="https://sfenvironment.org/sites/default/files/fliers/files/sfe_th_sf_medicine_waste_characterization_study.pdf">https://sfenvironment.org/sites/default/files/fliers/files/sfe_th_sf_medicine_waste_characterization_study.pdf</a></p>

<p><i>Santa Barbara County</i></p>	<p>Public health and safety impacts were of greatest concern. For example, prescription drugs increased in SB County from 2008-2010 with a rising level of addiction and overdoses due to prescription drug abuse. See “Background” section in Board Letter in link for more information:  <a href="https://santabarbara.legistar.com/LegislationDetail.aspx?ID=2283904&amp;GUID=85BE1FFF-EA4F-48BE-A011-E03685D1BA50">https://santabarbara.legistar.com/LegislationDetail.aspx?ID=2283904&amp;GUID=85BE1FFF-EA4F-48BE-A011-E03685D1BA50</a></p>	<p>Benchmarks and goals are not specifically addressed in the ordinance. They will be developed as part of developing program specifics. Will likely include information in annual report (collection weights). May look at morbidity and mortality data related to drug overdose as well as incidence of addiction in the county. Environmental impacts are not routinely monitored directly.</p>	<p>Lead Agency</p>	<p>Modeled after 2016 draft Los Angeles County ordinance. King County, WA regulations were also useful.</p>	
<p><i>Santa Clara County</i></p>	<p>Public health and safety impacts were of greatest concern. Described in the “Findings” section of ordinance, which cite references related to public health, public safety and environmental impacts. For example, each year more than 9,000 young children are hospitalized after accidentally ingesting prescription drugs. And drug overdoses have been rising steadily over the past two decades. In 2011, 80% of the 41,340 drug overdose deaths in the U.S. were unintentional. In another example, a 2013 EPA report found at least one pharmaceutical compound in all samples collected from 50 waste treatment plants. See “Findings” in link for more details:  <a href="https://www.sccgov.org/sites/rwr/Documents/SafeDrugDisposalOrdinance.pdf">https://www.sccgov.org/sites/rwr/Documents/SafeDrugDisposalOrdinance.pdf</a></p>	<p>Benchmarks and goals are not specifically addressed in the ordinance. Will likely include information in annual report (e.g. weights of collection). Other goals include convenience goals and public awareness through surveys. There is no plan to document or test for local water quality issues.</p>	<p>To be determined - The Consumer and Environmental Protection Agency is the lead. The Department of Environmental Health is a branch in the agency.</p>	<p>SC Co ordinance was modeled after SF and San Mateo Co ordinances. King Co (WA), Santa Barbara, Co and Marin Co ordinances were also useful.</p>	<p>SC Co Is amending its ordinance, in part to be more prescriptive. As far as public health outcomes, SC Co representative felt that more collection of unwanted drugs will result in fewer poisonings.</p>
<p><i>Snohomish County, WA</i></p>	<p>The current voluntary collection program is not sustainable without more funding and more staff. Collection of unwanted medicines increased from 3,000 pounds in 2010 to 8,000 pounds in 2014. The successful voluntary program points to an increasing public demand and need for more collection locations. The “Findings” section of the ordinance included references to support a program. For example, drug</p>	<p>Benchmarks and goals are not specifically addressed in the ordinance. Goals will likely include information in annual report (e.g. collection weights). Other goals include convenience goals and public awareness through surveys. The Snohomish</p>	<p>Lead Agency</p>	<p>The ordinance was modeled after King County (WA) and is very similar. In addition to Pierce County</p>	<p>Adoption of the ordinance was facilitated by an ad hoc committee that took input from stakeholders and drafted the ordinance. The ad hoc committee was comprised of reps from the cities, law enforcement, health district,</p>

	<p>overdoses in Snohomish County have surpassed car crashes as the leading cause of unintentional injury deaths. See link for more information:</p> <p><a href="http://www.snohd.org/Portals/0/Snohd/Waste/files/Ord%20No%2016-001%20-%20Secure%20Medicine%20Return.pdf">http://www.snohd.org/Portals/0/Snohd/Waste/files/Ord%20No%2016-001%20-%20Secure%20Medicine%20Return.pdf</a></p>	<p>Health District will likely compare changes in unintentional injuries or deaths before and after implementation of the ordinance.</p>		<p>(WA), the different ordinances are very similar to promote consistent expectations and standards in Washington.</p>	<p>solid waste and other interested parties.</p>
<p><i>Sonoma County</i></p>	<p>Initial interest in an ordinance came from water agencies seeking to improve water quality. Public health and safety issues have increased due to rising concerns of opioid use and abuse. According to a 2016 report to the Board of Supervisors, prescription drug abuse is a critical problem in Sonoma County where emergency room visits from opioid overdoses have increased nearly 75% over the past 5 years (see link below).</p> <p>The current voluntary collection program is not sustainable without more funding and more staff. Collection of unwanted medicines increased from 3,165 pounds in 2008 to 19,500 pounds in 2015. The successful voluntary program points to an increasing public demand and need for more collection locations.</p> <p>Summary report:  <a href="http://sonoma-county.granicus.com/Viewer.php?view_id=2&amp;event_id=662&amp;meta_id=203471">http://sonoma-county.granicus.com/Viewer.php?view_id=2&amp;event_id=662&amp;meta_id=203471</a></p>	<p>Benchmarks and goals will not be specifically addressed in the ordinance. Goals will likely be addressed in the annual report (e.g. collection weights). Other goals will include convenience goals and public awareness through surveys. Sonoma County indicated difficulty identifying a causal relationship to environmental and health outcomes (e.g reduction in opioid abuse as a result of increased medicine collection). They indicated they can track public knowledge on the importance of take back to improving environmental and public health and safety outcomes.</p>	<p>Lead Agency</p>	<p>The ordinance was modeled after Santa Cruz County and SF ordinances. They also used the draft LA County ordinance.</p>	<p>Development of the ordinance has been a collaborative effort of several agencies including the Russian River Watershed Assoc, Sonoma County (SC) Water Agency, SC Department of Health Services, SC Waste Management Agency, and cities of Santa Rosa, Petaluma, and Sebastopol.</p>

## **Part B – October 19, 2017**

# **Los Angeles County - EPR Ordinance**

## **California State Auditor Report Analysis**

**October 16, 2017**

### **Project Title**

*Conduct a review of the California State Auditor's 2016-2017 Home-Generated Sharps and Pharmaceutical Waste report, determine its impact on the proposed Los Angeles County Pharmaceutical and Sharps Collection and Disposal Stewardship Ordinance, and identify any strengths and weaknesses in the Report findings.*

**Prepared for  
Los Angeles County  
Department of Public Health – Environmental Health Division**

**Prepared by  
Ecoconsult  
910 K Street, Suite 300  
Sacramento, CA 95814**



## **Table of Contents**

### **Part 1: Summary of Strengths & Weaknesses of State Auditor's Report**

### **Part 2: Comparison of State Auditor's Report Findings to Key Findings from EcoConsult's Initial Review**

- Measuring Efficacy of Access to Collection Sites
- Weak recommendations for a serious public health concern
- State oversight and more education alone is no guaranteed fix
- Cost sharing analysis missing
- No policy analysis of county stewardship laws or recognition that some of the report's recommended model programs in other countries are Extended Producer Responsibility

### **Part 3: Review of Consumer Surveys**

### **Part 4: Implementation Status of County EPR Ordinances for Pharmaceuticals or Pharmaceuticals and Sharps**

### **Part 5: Evaluation of Potential Impacts of Proposed EPR Ordinance**

- Recommended policy refinements

### **APPENDIX I: Examples of MED-Project website search functions for collection sites and mailer distribution sites**

### **APPENDIX II: Federal Agency Disposal Guidance for Pharmaceuticals Provide a Disposal Hierarchy**

## Executive Summary

This Executive Summary provides an overview of the principal findings of two analyses: the *Public Health Policy Technical Analysis of the Los Angeles County Pharmaceutical and Sharps Collection and Disposal Stewardship Ordinance* (Analysis #1) and the analysis of the *California State Auditor's 2016-2017 Home Generated Sharps and Pharmaceutical Waste Report* (Analysis #2) conducted by Ecoconsult in conjunction with the California Conference of Directors of Environmental Health.

The Ecoconsult team includes its Principal and internal staff as well as external advisors with extensive experience in public environmental health. (See team biographies in Appendix A in Analysis #1). The conclusions reached are based on the team's professional experience, academic training, analysis of the State Auditor's Report and Los Angeles County public records, literature review and interviews of existing pharmaceutical take-back program managers.

Consistent with the application of a Public Health Logic Model we have drawn two key assumptions in these analysis without independent verification:

1. *It is in the interest of Los Angeles County and its residents to reduce:*
  - the amount of expired and unused medication and sharps that are currently being stockpiled unsafely in private homes;
  - the amount of pharmaceuticals that could be misused, and lead to addiction, or even death or hospitalization due to overdose;
  - the amount of pharmaceuticals that could be misused and even lead to death or hospitalization due to unintentional poisoning;
  - the number of injuries to waste facility workers or the general public due to improper disposal of sharps; and
  - the amount of unused/unwanted pharmaceuticals and sharps products entering the environment whether into landfills, wastewater (flushing) or litter.
  
2. *Reducing access to potentially dangerous medications and sharps through proper management is the most efficient and effective option for reducing or eliminating the public health and safety impacts of unsafe storage or improper disposal of unwanted medications and sharps.*

Our review found the State Auditor's Report to be too narrow in scope, too short on data, too limited in analysis of key issues, and too modest in its recommendations to meaningfully address the urgent public health, public safety and environmental impacts of unsafely stored, handled and disposed of home-generated sharps and pharmaceuticals.

Furthermore, the State Auditor's Report failed to identify the key underlying causes of the inadequate management of pharmaceuticals and sharps wastes in California - the lack of adequate and dedicated resources to support comprehensive take-back systems in all communities.

Specifically, in contrast to the objectives of and the rationalization for the County's proposed EPR program, the State Auditor's recommendations were flawed in several respects:

- **Poor Measurement of Efficacy of Access to Collection Sites:** A 20-minute drive time to a collection site is neither convenient nor an appropriate metric for measuring adequacy of the services needed to address the public health and safety problem.
- **Inadequate response to a serious public health concern:** The report's recommendations would likely continue the status quo, despite the public health imperative of taking actions to help break the cycle of the opioid abuse epidemic.
- **State oversight and more education alone is no guaranteed fix:** Focusing primarily on state oversight by a single agency and consistent disposal education as a remedy to the problem is overly simplistic. It overlooks that the fundamental causes for inconsistent disposal guidance: The lack of comprehensive take-back options in all communities, which results in a lack of dedicated and sustained funding for these programs.
- **Cost sharing analysis missing:** With little or no financial analysis or comparisons of funding options offered, the report fails to quantify the cost to consumers or the societal costs of inadequate response to the public health problem, as identified. Funding sources were not identified for recommended actions.
- **Scant or no analysis of existing stewardship programs in CA, U.S. and abroad that have demonstrated early successes.** The auditor's analysis did not include review of the local EPR ordinances for pharmaceuticals and sharps in California, and therefore did not recognize the scope of services provided by these programs or the commonalities and efficiencies of the EPR policy approaches.

We found that the State Auditor had correctly identify three related conditions that exacerbate the problem of inadequately managed sharps and pharmaceutical waste:

- **Fragmented oversight and inconsistent disposal guidance due to a patchwork of different local programs with variable services;**
- **Inadequacy of collection data due to limited resources and no centralized coordination for local programs; and**
- **Complexities of federal and state regulation of incineration facilities that restrict access to some types of pharmaceutical waste processing/disposal capacity in California.**

Based on our analysis of the County's proposed ordinance, the first two of these conditions could be addressed by the adoption of a producer responsibility program that would be driven by data and predicated on consistent practices and singular oversight. The third obstacle related to access to incineration facilities, which does not preclude successful operation of medicine take-back programs, would likely require a state legislative remedy, as well as alignment with the EPA's federal regulations on disposal of hazardous waste pharmaceuticals and permitting of disposal facilities.

In the process of evaluating the likely efficacy of the proposed ordinance, our analysis drew the following related conclusions about the overall approach being considered by the County:

- There is compelling evidence that links drug abuse and initiation of addiction to easy access to medicines kept in homes.
- Significant amounts of pharmaceuticals go unused by consumers or expire before use for a variety of reasons, including for appropriate and legitimate healthcare reasons, and need proper disposal. Medical sharps by design must be disposed of after use.
- Despite limited locations and promotion, existing voluntary take-back programs have collected significant amounts of leftover pharmaceuticals and sharps. Consumer demand for safe take-back options has been confirmed by a variety of consumer surveys and by their use of voluntary take-back programs, despite their lack of convenience.
- Voluntary take-back programs have failed to provide adequate access and convenience, and lack sufficient resources for promotion or for management of larger amounts of return medicines, to ensure that unwanted or unused drugs are adequately collected and safely managed to prevent stockpiling or improper disposal of these medicines.
- Absent a comprehensive and effective national or statewide program that ensures the safe end-of-life management of these medicines and sharps, the public health and environmental protection obligation falls on the local jurisdictions.
- While Advance Disposal Fees may offer an effective end-of-life management option for certain products, our research finds that a mandated shared product stewardship for collection and disposal of pharmaceuticals was more cost effective for local government, consumers and retail outlets and involved less direct government engagement and greater program flexibility.
- Notwithstanding the assertions from pharmaceutical producers that the take-back mandates in the proposed ordinance will place the primary financial burden on the manufacturers/producers, we found that the existing EPR programs do share responsibility and cost and will most likely place a minimal financial burden on an industry that is receiving large revenue returns.
- Despite pharmaceutical industry resistance within USA and their own countries, Canada has already initiated and Mexico has recently started to implement national producer responsibility plans.
- Successful stewardship programs in California and beyond for other hazardous or hard-to-handle products such as electronics, thermostat, paint, and batteries, demonstrate that carefully established convenience standards, education and public awareness assessment measures, as well as “rates and dates” performance metrics are not only desirable, but are essential to the equitable and effective program design and implementation.
- Substantially similar pharmaceutical and sharps producer programs mandated and implemented in other counties, states and abroad have withstood legal challenge, enjoy broad public support and have demonstrated early success.

- During 2017, the services provided by manufacturers under the county-level pharmaceutical and sharps ordinances has dramatically increased, with programs now operating in 6 California counties and 2 Washington counties. The collection services now available in these counties confirm that well-designed EPR ordinances result in increased drop-off sites at convenient pharmacy locations as well as provision of mail-back services.

The overall policy intent of the proposed LA county ordinance is sound, and is similar to the policy of local stewardship laws that are being successfully implemented in other counties. The following recommendations that are described in greater detail in Section 3 of this analysis are refinements to the existing policy that further clarify the intent or reflect learnings from other jurisdictions.

- Adjust Implementation Timeline;
- Mandate that Manufacturers Must Accept All Qualified Collectors into Program;
- Narrow the Exemptions in the “Responsible Steward” Definition to Better Mirror the FDA’s Definition of Manufacturer;
- Clarify that Manufacturers Must Service Collection Sites Frequently Enough to Avoid Overfull Collection Receptacles;
- Align the disposal facility requirements in Section 11.17.060 with the EPA;
- Require manufacturer description of Program Collection Goals; and
- Clarify Collection Requirement for Any Covered Drugs that May Not Be Suitable for Comingling in Collection Receptacles.

## Part 1: Summary of Strengths & Weaknesses of State Auditor's Report

Overall, our analysis found the report to be weak. It is too narrow in scope, too short on data, too limited in analysis of key issues, and too modest in its recommendations to meaningfully address the urgent public health, public safety and environmental impacts of unsafely stored, handled and disposed of home-generated sharps and pharmaceuticals.

The report failed to identify the key underlying causes of the inadequate management of pharmaceuticals and sharps wastes in California - the lack of adequate and dedicated resources to support comprehensive take-back systems in all communities. The report does correctly identify three related conditions that exacerbate the problem of inadequately managed sharps and pharmaceutical waste:

- Fragmented oversight and inconsistent disposal guidance due to a patchwork of different local programs with variable services;
- Inadequacy of data due to limited resources and no centralization coordination for local programs; and
- complexities of federal and state regulation of incineration facilities that restrict access to some types of processing/disposal capacity in California.

However, we consider the findings and recommendations of the report to be flawed in five key areas, which are summarized here and further discussed in Part 2:

1. **Poor Measurement of Efficacy of Access to Collection Sites:** A 20-minute drive time to a collection site is neither convenient nor an appropriate metric for measuring adequacy of the services needed to address the public health and safety problem;
2. **Weak recommendations for a serious public health concern.** The report's recommendations are weak and largely continue the status quo, despite the public health imperative of taking actions to help break the cycle of the opioid abuse epidemic. Little recognition of the public health, safety and environmental urgency of the issue and inadequate evaluation of pharmaceutical take-back in the context of public health prevention for medicine abuse, poisonings, overdoses. Notably the auditor's analysis for access to medicine collection sites does not distinguish sites that can accept prescription opioids, which lead among the most important medicines to collect to reduce the supply fueling the opioid/heroin epidemic. Similarly, the report does not evaluate sharps take-back in the context of public health prevention for transmission of infectious diseases.
3. **State oversight and more education alone is no guaranteed fix:** Focusing primarily on state oversight by a single agency and consistent disposal education as a remedy to the problem is overly simplistic. It overlooks that the fundamental causes for inconsistent disposal guidance is the lack of comprehensive take-back options in all communities, which in turn is the result of the lack of dedicated and sustained funding for these programs.
4. **Cost sharing analysis missing:** With little or no financial analysis or comparisons of options offered, the report can be read to infer that the Extended Producer Responsibility option is the only option to impose costs on consumer.

All take-back programs pass costs along to consumers or taxpayers/ratepayers in one way or another. The auditor's report did not address potential funding mechanisms for its recommendations, glossing over that imposing new requirements on state agencies for oversight and provision of take-back services will ultimately impose costs on consumers.

5. **No policy analysis of county stewardship laws or recognition that some of the report's recommended model programs in other countries are Extended Producer Responsibility** The auditor's methodology did not include any review of the county-level stewardship law ordinances or their policy requirements. Therefore, it failed to recognize that the local ordinances are substantially more similar than they are different. Absent state action, counties are taking action to address the public health and safety crisis and serving as model policies incubators. In addition, several of the model programs in other jurisdictions that were recommended by the auditor's report are Extended Producer Responsibility programs, but this is not recognized in the auditor's analysis.

The auditor's report does not recognize that many of their key recommendations would be addressed by an EPR program such as the program required under the proposed Los Angeles County pharmaceutical and sharps stewardship ordinance. Our analysis of the proposed LA ordinance is that it would provide a comprehensive take-back system throughout the county and accomplish the following recommendations in the auditor's report.

- Provide consistent messaging to consumers on safe disposal of medicines and sharps and monitor their awareness of proper disposal methods.
- Establish a single searchable website to provide collection locations.
- Provide more service to rural areas.
- Require data collection on proper disposal of pharms and sharps through the stewardship system.

## **Part 2: Comparison of State Auditor's Report Findings to Key Findings from Ecoconsult's Initial Review**

### **1. Measuring Efficacy of Access to Collection Sites**

A. 20-minute drive time is a poor metric for access to collection sites: The auditor's report concludes that there is "reasonable access" to sharps and pharmaceutical waste collection sites because 89% of Californians live within a 20-minute drive of a collection site. This analysis is flawed in its core assumptions and its methodology:

- A 20-minute drive time, i.e. a 40-minute round trip, is not convenient access. This drive time, a 40-minute round trip, is longer than would be considered convenient by most urban and suburban residents.
- Drive time in a personal vehicle is an inaccurate metric because it is variable contingent on traffic conditions. In urban areas, even short distances can result in long drive times during congested times. Los Angeles traffic

congestion continues to be among the worst in the nation.<sup>1</sup> The auditor's analysis did not address this variability.

- Drive time is a poor metric because it assumes residents have access to a private vehicle. The auditor's report acknowledges this but does not otherwise address it. Transit times would be much longer for bus riders or people who walk.
- Drive time is an inappropriate metric for homebound residents who cannot utilize collection sites at all. The auditor's report focuses on recommending provision of mail-back services to residents living more than 20 minutes from a collection site, but fails to address that mail-back services are needed by homebound and differentially abled residents.
- The auditor's analysis of collection sites available to residents was flawed because it (1) relied on information about collection sites that the report viewed as inaccurate and incomplete, and (2) failed to differentiate between medicine collection sites that accept medications that are controlled substances (narcotics and stimulants) and those that cannot. The auditor found that available information about collection sites for pharmaceutical and sharps – from CalRecycle, CA Public Health, CA Pharmacy Board, DEA, and Walgreens – was “not sufficiently reliable for the purpose of this audit”, see Table 2. On page 25, the report states public information about collection sites is “sometimes inaccurate”, and describes inaccuracies and inconsistencies it found in the lists, including sites that had closed. As one source of medicine collection sites, the auditor's analysis utilized DEA's list of authorized collectors; however, this is not a list of active medicine collection sites, rather it is a list of registrants that have amended their registration with DEA to become an authorized collector. It is well-known, and readily apparent from spot checks, that the DEA's list of authorized collectors includes pharmacies that are not operating a drop box, either because their medicine take-back program has not launched or has been terminated. Although the auditor's report acknowledged that the collection site lists are “not sufficiently reliable”, these lists were nonetheless used for the analysis without explanation of why they were adequate for that purpose. Those with expertise on pharmaceuticals and sharps collection know that these programs are largely organized at the local level (city and county), and must also be verified at the local level. The auditor's failure to assess which collection sites can accept controlled substances is a serious flaw in the state auditor's analysis and demonstrates a lack of understanding of the public health imperative for collecting prescription opioids and other controlled substances. Residents may be less likely to utilize collection sites that cannot accept controlled substances because of confusion over which medicines are accepted and which are not. *See more on this flaw in subpart D.*

---

<sup>1</sup> Los Angeles Times. March 2016 “Los Angeles area can claim the worst traffic in America. Again”  
<http://www.latimes.com/local/lanow/la-me-ln-la-worst-traffic-20160314-story.html>



- The auditor’s report does not distinguish between the type of drop-off site, e.g. pharmacy, hospital or clinic, law enforcement, or waste transfer station, in their drive time analysis. This treats all of these types of collection sites as equally accessible for residents, when they are not. Collection sites at retail pharmacies, medical centers, or hospitals are inherently more convenient and accessible for all residents than collection sites at police stations or waste transfer sites. Pharmacy and clinical collection sites are:
  - Usually more conveniently located and well-known to local residents.
  - Residents go to these places more regularly, especially for retail pharmacies.
  - More comfortable for residents to lack and do not have the social barriers to access that may occur with collection sites at police stations.

Residents clearly prefer pharmacy drop-off (per LA consumer survey results, see Section 3). The amounts of medicines collected by pharmacy take-back programs are routinely higher than amounts collected by law enforcement take-back programs. (See pages 8-10 of our initial analysis.)

- The auditor’s drive time analysis likely counted the drop-off locations provided in response to local EPR ordinances in several counties, including Alameda, San Francisco. The manufacturers’ MED-Project programs operating under these local ordinances are establishing new collection sites, providing greater access and services. The state auditor’s report is critical of the county laws in many respects, but the success of these laws contributes to the auditor’s conclusion that existing programs provide sufficient services.

Given these flaws, the auditor’s conclusion on page 22 that “the clear majority of Los Angeles County residents live within a 20- minute drive of pharmaceutical collection sites” is not informative from a public health and safety perspective.

The proposed LA pharmaceuticals and sharps stewardship ordinance would result in a more convenient collection system, with much greater access than a 20-minute drive time. The ordinance requires convenient and equitable access to collection sites for unwanted pharmaceuticals and unwanted sharps for all residents (Section 11.17.050). It defines a minimum number of collection sites that must be provided in each city and in unincorporated areas. It requires that the collection sites are distributed to ensure that every resident is within 2.5 miles of a collection site. In any areas of the county lacking the minimum required access to collection sites, collection events must be provided and/or mailers must be distributed to consumers upon request. Additionally, residents throughout the county will be able to request mailers and mail-back services through a website or a 24-hour toll-free telephone number.

B. Mail-back services are provided under local EPR ordinances: The auditor’s analysis finds that 4 million Californians are live more than 20-minute drive of collection sites. This is not acceptable access for those individuals. To improve service to rural areas, the state auditor’s report recommends use of mail-back

containers for pharmaceuticals and sharps. The local EPR ordinances already meet this recommendation by requiring manufacturers to provide prepaid return mailers or packages to residents upon request (in all county ordinances except Alameda County's). Mailers or collection events must also be provided in areas lacking access to the required minimum number of collection sites. The manufacturers' MED-Project program provides pre-paid return mailers for medicines at libraries, YMCAs, city halls etc. In Santa Cruz county, MED-Project is also required to provide sharps mail-back packages to residents, in addition to prepaid mailers for medicine return, at various locations. See table X in Part 4 that summarizes the collection services provided by drug manufacturers under the local EPR ordinances.

C. Flawed analysis of collection amounts and volumes improperly disposed: The auditor attempted the difficult task of estimating the amounts of pharmaceuticals and sharps that were safely collected and the amounts that were improperly disposed across the state. We find some flaws in the methodology used:

- The auditor relied heavily on collection amounts from San Francisco's programs for safe medicine disposal and safe needle collection to develop an annual statewide collection amount. San Francisco's collection programs are more robust than in many other areas of the state, and they are more accessible to residents because of the high population density and small geography of San Francisco. We think extrapolating San Francisco's data to the entire state produces an overestimate of collection amounts.
- The auditor's analysis did not attempt to estimate sales of sharps into California as part of its estimates on the number of sharps that were improperly disposed. This estimate could have been attempted from sales data. This would have been key to examining the adequacy of sharps collection programs and amounts.

The auditor's analysis of pharmaceutical collection amounts did not seem to include drug take-back collection events held by law enforcement. The DEA provides total collection amounts from the twice yearly National Drug Take-back Days that it organizes with local law enforcement. These amounts should have been considered in the statewide collection estimate. Overall, the auditor's analysis seemed to overlook the role of law enforcement medicine collection events and failed to understand that sheriffs and police are burdened with conducting these events because there are not enough ongoing drop-off sites for medications. See more on this omission in the analysis in Part 2.B.

References to Initial Ecoconsult report:

- Section 2.1 b) Implementation: we provided early analysis of improved collection services available in Alameda and King County under their EPR ordinances. Please also see Part 4 of this analysis for status of implementation of the county EPR ordinances.
- Section 2.3 a) Effectiveness of Extended Producer Responsibility (EPR): this section included analysis of improved collection services under pharmaceutical EPR ordinances, as well as examples of higher per capita

collection from pharmacy-based take-back programs than law enforcement collection sites.

- Appendix E: this appendix summarized our interviews with stakeholders and local jurisdictions that included frequent analysis that existing voluntary collection programs are insufficient, and more convenient pharmacy-based take-back systems are needed for pharmaceuticals and sharps.

## 2. Weak recommendations for a serious public health concern.

The state auditor's report lacks an appropriate sense of urgency in addressing the public health crises of the epidemic of abuse of opioids and other medicines, as well as the serious public safety risks posed by sharps sticks.

- A. The lens of the auditor's report was solely focused on waste management, instead of public health prevention and protection. The auditor's report did not evaluate pharmaceutical take-back in the context of public health prevention for medicine abuse, poisonings, overdoses and did not evaluate sharps take-back in the context of public health prevention for transmission of infectious diseases. The report focuses only on public health risks from improper disposal of pharmaceutical and sharps, without acknowledging the substantial public health risks from stockpiling and storing unneeded medications and used sharps in the home. Providing convenient and safe disposal options to residents is critical to reducing that risk.

The auditor's poor metrics for convenience, such as the 20-minute drive time, show a lack of awareness of these public health prevention goals. The report's recommendations focus on administrative changes to the status quo rather than bold system-change to increase services and change consumer behaviors.

The local actions taken by the eight counties that have adopted stewardship ordinances, like the legislation proposed in LA county, are bold system change initiatives that have risen out of local recognition that the status quo is not good enough. The stewardship policies strive to back safe take-back of pharmaceuticals and sharps as convenient and as common-place as purchasing these products. Although these programs mandated under these laws are still young, the manufacturers MED-Project program is already providing more collection sites and more consistent disposal messaging in these counties. *Further description of the MED-Project programs is in Part 4.*

- B. Ensuring convenient take-back of highly addictive controlled substances is a public health imperative: Failure to assess how many medicine take-back locations in California can accept controlled substances (narcotics and stimulants) is a serious flaw in the state auditor's analysis (see page 43 of state auditor's report). By not differentiating between collection sites that accept controlled substances and those that do not, the auditor's report does not provide any assessment on the adequacy

or potential impact of the existing collection system on reducing opioid abuse. It also fails to recognize a key reason why additional, dedicated resources are needed to improve the efficacy of medicine take-back programs through convenient collection of all leftover medicines, including legally prescribed controlled substances.

Collection of leftover prescription opioids and other controlled substances is part of a comprehensive strategy to prevent abuse, addiction, and overdose deaths. Overdose deaths from opioids It is well-established through a variety of studies, that the majority of individuals addicted to heroin started with prescription opioids first. Opioid abuse typically occurs from a patient using their own pills for purposes other than pain management or from experimentation with pills obtained from family or friends, usually for free. Providing secure methods for residents to dispose of excess prescription opioids as soon as they no longer need them reduces the supply of drugs for misuse.

Medicine take-back programs that accept controlled substances continue to be more limited, and continue to be predominantly at less accessible law enforcement agencies or through occasional collection events. Collection and disposal of medicines that are controlled substances is more expensive than take-back of non-controlled substances due to security protocols mandated by the DEA's Rule for Disposal of Controlled Substances. These additional costs create a barrier for medicine take-back programs operating under limited public funds. The costs also create barriers for participation by retail pharmacies and hospitals as now allowed under the DEA Rule. Local programs often rely solely on law enforcement collection programs which are inherently less convenient than pharmacy-based take-back programs.

The state auditor's report does not address pharmaceutical disposal through law enforcement collection events, and this is a flaw in its analysis both in terms of collection amounts and in terms of costs that are being passed along to residents.

- The auditor's examination of collected amounts (pages 27- 30 of state auditor's report). did not include the substantial amounts of medicine being collected in California at the DEA's semi-annual National Drug Take-back Days that are staffed by law enforcement.

For the April 29, 2017 take-back event, the DEA reported that 204 law enforcement agencies in CA provided a total of 346 collection locations. A total of 74,864 pounds of medicines was collected during the Saturday collection event, held 10 AM to 2 PM. For the October 28, 2017 take-back day, there are 48 collection events sites in LA County as of October 18.<sup>2</sup> Participating agencies include the Los Angeles County Sheriff's Office, the

---

<sup>2</sup> DEA search engine for National Drug Take-back Day Collection Sites

[https://apps.dea.diversion.usdoj.gov/NTBI/NTBI-PUB.pub;jsessionid=2BEA9F46DB96EE4548426E3F4E77F0FB?\\_flowExecutionKey=c0461355E-AB31-7D8C-07C4-55179388104E\\_k158367F7-0576-8A3A-32F3-4CEC53BE29C8](https://apps.dea.diversion.usdoj.gov/NTBI/NTBI-PUB.pub;jsessionid=2BEA9F46DB96EE4548426E3F4E77F0FB?_flowExecutionKey=c0461355E-AB31-7D8C-07C4-55179388104E_k158367F7-0576-8A3A-32F3-4CEC53BE29C8)

Los Angeles Police Department, Long Beach Police Department, Santa Monica Police Department, and 19 other local law enforcement agencies.

Collection events burden the budgets and the staffing of local law enforcement agencies who have no dedicated funding source for medicine take-back services. Local law enforcement agencies often save the costs of disposal of collected medicines by transporting boxes of drugs to DEA consolidation points after each semi-annual drug take-back day. The DEA then transports the drugs to incinerators. Even with DEA assistance, these events burden local law enforcement agencies and divert officers from other duties. The local agency has to store boxes of collected medicines in their evidence rooms from the Saturday collection event until the boxes are transported to the DEA. Typically, two uniformed officers are required for secure transport of the collected medicines to a DEA site or to an incineration facility.

The need for more resources to support secure drop boxes for controlled substances at pharmacies and medical centers is a common rationale for the adoption of local stewardship ordinances. The auditor's failure to recognize the importance of take-back of controlled substances demonstrates a fundamental lack of understanding of these challenges and barriers at the local level.

- C. Providing resources for public sharps collection is a critical public safety need. As we described in our initial analysis, used sharps that are discarded in public areas are a significant threat to public health and safety. Providing safe drop boxes, or kiosks, for disposal of used needles in public places may prevent some improper disposal by people injecting drugs, and assists community efforts to clean up needles. In Santa Cruz county, the manufacturers' MED-Project program is currently reimbursing the county for its costs of operating three public sharps kiosks in parks and other public areas. MED-Project will soon take over direct operations of those kiosks.
- D. Critical to understand the DEA's requirements and allowed options for take-back of controlled substances. The state auditor's report does not seem to fully acknowledge that the DEA's federal authority supersedes on handling and disposal of controlled substances. More specifically, the report does not adequately consider the requirements or the opportunities for secure disposal of pharmaceuticals under the DEA's 2014 Rule for Disposal of Controlled Substances<sup>3</sup>, This results in flawed analysis in some of the report's findings and recommendations.

The state auditor's report attempts to simply describe how home-generated pharmaceutical wastes are processed but it oversimplifies and omits some options.

---

<sup>3</sup> Department of Justice. Drug Enforcement Administration. Disposal of Controlled Substances; Final Rule. Federal Register 79 (174) September, 2014. [https://www.deadiversion.usdoj.gov/fed\\_regs/rules/2014/2014-20926.pdf](https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf).

The reports description, summarized in Figure 2 on page 9, has the following errors or omissions:

- Disposal of any prescription drug that is a controlled substance, e.g. OxyContin, Percocet, or Adderall, through a mail-back container or a take-back program must be treated as a controlled substance, and procedures must comply with the DEA's Rule for Disposal of Controlled Substances. Fig. 2 lists this as a "may" which is potentially confusing. The DEA's rule applies to any medicine collection program that collects controlled substances, even inadvertently<sup>4</sup>.
- Reverse distributors are not the only entities that can service take-back programs at pharmacies or hospitals under the DEA's Regulation for disposal of controlled substances from consumers (i.e. ultimate users). Figure 2 states this and the description suggests the state auditor's analysis is confusing requirements for waste pharmaceuticals generated by the facilities that are regulated as business wastes.

The DEA's regulation clearly requires authorized collectors of residential medicines, such as pharmacies and hospitals, to keep medicines collected from residents separate from their own undispensed inventory and pharmaceuticals wastes. Under the DEA's rule, sealed boxes of residentially-generated medicines collected by authorized collectors can be transferred to in three ways for proper disposal:

- common or contract carrier to the authorized location of a reverse distributor or drug distributor,
- pick-up by a drug distributor,
- pick-up by a reverse distributor.

The common carrier option is important because it allows a convenient, and typically lower cost, option for transport of collected medicines to appropriate disposal facilities. The common carrier option makes the use of more remote or out-of-state disposal facilities less burdensome and more cost effective.

- Law enforcement take-back programs also have options for transport of collected medicines to final disposal that are not described in Figure 2. Under the DEA's Rule, law enforcement agencies may transport collected medicines to final destruction themselves or they can transfer collected medicines to a reverse distributor for disposal.
- Municipalities and local waste haulers cannot enter contracts for collection of waste medicines from residents due to the restrictions of the DEA's Rule for Disposal of Controlled Substances. The auditor's report made this recommendation on page 27, and it is not appropriate because it would be impossible to ensure that controlled substances were not in the waste mix. The DEA mandates that medicine disposal programs follow its Rule for Disposal of Controlled Substances if any controlled substance is collected

---

<sup>4</sup> =See page 53529 of the Federal Register document for the DEA's Final Rule for Disposal of Controlled Substances. [https://www.deadiversion.usdoj.gov/fed\\_regs/rules/2014/2014-20926.pdf](https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf)

even inadvertently. The state auditor's report correctly recognizes that it is difficult for consumers to separate legally prescribed controlled substances from other medicines, so controlled substances would be collected. Local waste haulers are not DEA registrants and cannot be authorized collectors under the DEA Rule. The DEA Rule does not allow any authorized collectors to provide door-to-door pick-up of medicines or to host drop boxes at waste transfer stations. A waste hauler could distribute mail-back envelopes to residents upon request that the resident then deposits in the U.S. mail, but this seems like an efficient method of distribution of mail-back packages than mailing them directly to residents and providing them at community distribution sites such as libraries. We agree with CalRecycle's response to this recommendation; and feel that the state auditor's reply continues to miss the regulatory barrier.

#### References to Initial Ecoconsult report

- Section 2.4 a) Unused Medicines: providing information about public health and safety concerns with medicines in the homes, and how keeping unneeded medicines in the home increases risks of medicine misuse, abuse, preventable poisonings and overdoses from household medicines.
- Appendix D: DEA Rule for Disposal of Controlled Substances: provided an overview of key aspects of the DEA rule, with links to language of the complete Rule.

### **3. State oversight and more education alone is no guaranteed fix**

The report concludes that the key actions needed to improve pharmaceutical and sharps take-back programs in the state are to centralize regulatory authority in one state agency and require more education with consistent messaging.

- A. A single lead state agency alone is not a fix, and is probably not feasible. The state auditor's report focused on which state agency should oversee pharmaceutical and sharps take-back programs. To a large degree this is not germane to the evaluation of potential impact of the proposed LA county EPR ordinance. Local stewardship ordinances and the resulting take-back programs must operate in compliance with all applicable state and federal laws and regulations. The proposed LA ordinance is compatible with the current framework of state oversight, and would also be compatible with future changes.

We feel, however, the report's central conclusion that designating a lead state agency is the highest need misses the mark. We do not agree that the lack of a single state-level oversight agency is the root cause of conflicting disposal guidance given to consumers. Rather, differing disposal guidance predominantly result from the lack of comprehensive and consistent take-back options throughout the state, (See subpart B of this section). The lack of comprehensive programs is the result of insufficient dedicated resources to support these programs. The lack of robust education about available take-back options as well as insufficient data collection

are also the result of lack of sufficient dedicated resources. The state auditor's report consistently fails to describe a funding mechanism for providing those resources.

It would require time-consuming legislative and regulatory changes, as well as potentially costly agency restructuring and staffing changes, to place all regulatory authority for management of pharmaceutical and sharps waste within a single state agency. Regulation of pharmaceuticals and sharps wastes logically needs to be shared between multiple state agencies due to the diversity of regulated entities that participate in take-back programs, including: pharmacies, hospitals, law enforcement agencies, household hazardous waste programs, solid waste disposal service providers, pharmaceutical waste disposal service providers, medical waste disposal facilities, solid waste disposal facilities, and hazardous waste disposal facilities. Expertise and regulatory authority is distributed between state agencies because public health and safety and environmental protection components need to be integrated with regard to regulations, consumer education, and performance evaluation.

There are also multiple federal agencies involved in regulating the management of pharmaceuticals and sharps including: DEA (Department of Justice), EPA, and Department of Transportation (DOT). FDA and HHS are also involved. We are aware of coordination between these federal agencies around medicine take-back and efforts have been made to streamline regulatory processes. Similarly, improved communication and coordination between state agencies in their oversight of pharmaceuticals and sharps management would be beneficial, of course. It would be helpful to local programs if California agencies collaborated on a consistent approach.

As the report acknowledges, there are conflicts between California regulations and policies and the FDA's federal guidance for flushing certain particularly dangerous medicines *if no medicine take-back program is available*. This conflict will not be resolved by designation of a single state-agency lead. When secure medicine take-back programs are available at essentially every pharmacy and hospital, the FDA's flushing guidance will not be applicable.

- B. Resolving conflicting guidance to consumers requires a comprehensive take-back system. The auditor's report correctly identifies that there is inconsistent messaging to consumers about proper disposal of leftover pharmaceuticals and used sharps. The report erroneously attributes this problem almost entirely to the lack of a single state-level oversight agency. The auditor's analysis fails to recognize that the conflicting guidance are more fundamentally linked to lack of a comprehensive take-back system due to a lack of dedicated resources. Proper management of household pharmaceuticals and sharps has been left to local jurisdictions without any funding. This has resulted in patchwork of different programs that vary from city to city, and from county to county, across the state. For pharmaceuticals for example, some communities have no take-back services at all, others have occasional collection events provided by law enforcement, other areas have some



secure drop boxes at police stations, other areas have some secure drop boxes at both pharmacies and hospitals.

The lack of consistent and comprehensive take-back programs in all communities creates a chicken-and-egg situation for consumer education. Consumers cannot be directed to use a safe and secure disposal program if the infrastructure for collection and disposal does not exist or is not accessible for all residents. When residents cannot access safe take-back programs, federal, state, and local agencies are forced to suggest trash disposal with cumbersome precautions to attempt to improve safety of this less desirable disposal method. Flushing of certain highly dangerous medications when no secure take-back program is available is still recommended by the FDA because trash disposal of these medicines is too risky.

Furthermore, the auditor's analysis of various agency disposal guidance failed to recognize the disposal hierarchy for medicines in those guidance that first promote the use of secure medicine take-back programs over trash disposal, and even over flushing of certain drugs. In Figure 3, page 10, and in Figure 4, page 17, the auditor report's summary of state and federal agency disposal guidance for home-generated sharps and pharmaceuticals fails to explain that the guidance does not treat all disposal methods as equally good. The report's explanation entirely omits the DEA's guidance which clearly recommends use of secure medicine take-back programs for all medicines that are controlled substances. Federal and state agency guidance have become more aligned in recent years as more take-back programs have been launched, although there is certainly room for further alignment and clarity. (See Appendix II for summary of the disposal hierarchies recommended by federal agencies).

- C. More education is needed but it alone is not a fix. We agree with the auditor's report conclusions that improvements are needed in consumer education for proper disposal of pharmaceuticals and sharps, including greater promotion of available collection sites. We note that the state auditor's report did not include any methodology to assess how consumers currently obtain information about collection sites, or how they would like to receive this information. We view the lack of a robust educational system as a symptom of the lack of adequate and dedicated financing. The state auditor's report overlooks this problem and does not identify a source of funding for its recommendation that a state agency create an online database of collection sites and conduct a more robust public education campaign. Education alone cannot solve the underlying problem that there are not enough convenient take-back locations to make proper disposal methods convenient enough for all residents. The report's conclusion that current available collection locations provide sufficient convenience is flawed, as previously explained in Part 1.

Enacting the LA pharmaceuticals and sharps EPR ordinance would create a consistent disposal message for all LA County residents that is widely promoted and a comprehensive and convenient take-back system that serves all residents. Pharmaceutical manufacturers are required to provide a website listing their

collection locations and provide a toll-free phone number. These services must also provide methods for requesting mail-back packages. Other educational requirements in Section 11.17.160 of the proposed LA ordinance include distribution of educational materials to pharmacies, health care providers and prescribers. The proposed ordinance also requires educational displays at the point-of-sale of pharmaceuticals and sharps (Section 11.17.150). Periodic surveys are required to evaluate the effectiveness of educational activities on public awareness and consumer behaviors.

The auditor's report focuses on the need for a single online database that provides an accurate list of collection locations. In counties that have enacted stewardship ordinances, pharmaceutical manufacturers are providing the [MED-Project.org](https://www.med-project.org) website with county-by-county listings of collection sites and prepaid mailers distribution sites. Locations are displayed on an interactive map and there is a search function by zip code that creates a list of locations. The map and searchable functions are also accessible on mobile devices. See Appendix II for screen shots of the MED-Project website.

Recommended disposal facilities: The state auditor's report focuses evaluating in-state and out-of-state capacity for disposal of household pharmaceutical wastes and altering waste regulations to encourage more use of in-state solid waste incinerators. We agree that the complexities of federal and state regulation of hazardous waste disposal present some challenges to disposal of household-generated pharmaceutical wastes. We do not agree that the current regulatory context presents a barrier that precludes affordable disposal of pharmaceuticals collected by residential medicine take-back programs. Given the public health imperative, there is no reason to delay action on expanding medicine take-back programs while undergoing what is likely to be a lengthy and costly rule-making process involving multiple state agencies, federal agencies, local agencies, and air quality boards.

The auditor's report does not explore the legitimate rationales behind federal and state regulatory requirements for proper end-of-life management of hazardous pharmaceuticals to protect public health and environmental quality. The EPA recommends that pharmaceutical wastes from residential take-back programs are managed as hazardous wastes because of their chemical characteristics, and California has adopted this standard for all household hazardous wastes. A number of medicines commonly used in the household setting meet the characteristics of hazardous wastes under the federal Resource Conservation and Recovery Act (RCRA)<sup>5</sup>, including warfarin (coumadin), unused nicotine patches, topical solutions of erythromycin or hydrocortisone, epinephrine in EpiPens, and a number of chemotherapy drugs. There are a small number of RCRA hazardous waste

---

<sup>5</sup> U.S. EPA. Management of Pharmaceutical Hazardous Waste.  
<https://www.epa.gov/hwgenerators/management-pharmaceutical-hazardous-waste>

pharmaceuticals that are also controlled substances, such as chloral hydrate, fentanyl sublingual spray, and testosterone gels.

The auditor's report recommends regulatory changes to allow solid waste incinerators in California to accept hazardous pharmaceutical wastes "but only after considering environmental impacts". To our knowledge there is no validated data or published studies comparing emissions or other environmental impacts from combustion of pharmaceutical waste in different types of incineration facilities. Proper consideration of environmental impacts by California agencies would require funding for an environmental review, expert analysis, as well as funding for test burns of materials at different types of facilities with emissions analysis.

The debate over which types of incineration facilities are appropriate for disposal of pharmaceutical wastes is long-running and not unique to California. This issue may be decided by future regulatory actions of the EPA. In 2012, the EPA issued recommendations<sup>6</sup> for the types of incineration facilities that should be used for medicines collected by residential take-back programs. Hazardous waste incinerators are preferentially recommended and the closest of these to California are in Utah, Arizona, and Texas. At a minimum, EPA recommended use of large or small municipal waste combustors. In 2015, the EPA released a proposed rule for Management Standards for Hazardous Waste Pharmaceuticals<sup>7</sup>. The timeframe for finalization of this proposal rule is uncertain, however, it contains regulatory streamlining that is favored by many in the healthcare industry. The proposed Rule is focused on pharmaceutical wastes generated by healthcare facilities and the EPA does not intend for the proposed Rule to apply to households or to residential medicine take-back programs, except for one section. Section 266.506 of the proposed rule would formalize EPA's 2012 recommendation on appropriate disposal facilities for medicine take-back programs. The proposed language states that pharmaceuticals collected from ultimate users (i.e. residents and household members) by an authorized collector as defined by the DEA *are exempt* from RCRA requirements for hazardous waste pharmaceuticals *provided that they are:*

- (1) combusted at a municipal solid waste (large or small) or hazardous waste combustor, and
- (2) managed in accordance with all applicable DEA regulations.

While the regulatory landscape for disposal of pharmaceutical wastes may change at some point, we continue to conclude that there is no barrier to proper disposal of pharmaceuticals collected by take-back programs. The disposal requirements in the

---

<sup>6</sup> U.S. EPA Memorandum to RCRA Division Directors. September 26, 2012. "Recommendation on the Disposal of Household Pharmaceuticals Collected By Take-back Events, Mail-Back, and Other Collection Programs" [https://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/FCB11DD6F61D4B1685257AFE005EB5CE/\\$file/14833.pdf](https://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/FCB11DD6F61D4B1685257AFE005EB5CE/$file/14833.pdf)

<sup>7</sup> Proposed Rule issued by the EPA. September 2015. "Management Standards for Hazardous Waste Pharmaceuticals". Federal Register # 2015-23167. Docket ID No. EPA-HQ-RCRA-2007-0932. Docket online at: <https://www.regulations.gov/#!documentDetail;D=EPA-HQ-RCRA-2007-0932-0150>

proposed LA pharm EPR ordinance (Section 11.17.060) are aligned with current disposal recommendations of the EPA and are flexible to consider other disposal technologies in the future.

The manufacturers' MED-Project stewardship organization has developed stewardship plans that have accepted as compliant with local stewardship ordinances in six California counties and two Washington counties. The MED-Project program is using either the Clean Harbors hazardous waste incinerator in Aragonite, Utah or the Veolia hazardous waste incinerator in Port Arthur, Texas for disposal of pharmaceutical collected in secure drop boxes in these counties.

References to Initial Ecoconsult report

- Section 2.7: summarizes medicine disposal recommendations of the FDA, DEA, and EPA that are aligned in recommending medicine take-back as the best disposal method.

**4. Cost sharing analysis missing.**

A. Analysis of costs or funding mechanisms in the report is limited or non-existent.

The auditor's analysis failed to identify that the lack of adequate and dedicated funding sources is the root cause behind many other deficiencies identified in the report, including lack of comprehensive take-back options, robust and consistent education, and data collection. Responsibility for pharmaceuticals and sharps disposal has largely fallen upon local health departments, local law enforcement, and local solid waste agencies. Local agencies attempt to identify funding sources, squeeze funds out of existing budgets, and form public-private partnerships. These efforts do not fully solve the problem. In fact, the need for dedicated and sustained funding to expand take-back options for residents has been a common rationale for adoption of EPR ordinances by local governments.

The auditor's report does not attempt to analyze the adequacy or stability of public funding mechanisms for pharmaceuticals and sharps take-back programs. Any funding from the federal or state level has been limited, and insufficient to cover all costs of local programs. It is also unstable in the form of short-term grants or variable appropriations. In our experience, these funding fluctuations mean that take-back programs often start up, but they struggle to find ongoing funding or resources that allow program expansion.

As an example of unstable public funding: The auditor suggests that Maine's mail-back program is a model program (see Table 4 on page 36 and page 27) without describing that the program was terminated in 2012 due to a lack of dedicated and sufficient funding. The Maine program was funded through a short-term EPA grant, and then through state funds which were not reappropriated. This demonstrates the problem with relying on public grants and appropriations for medicine take-back.

- B. Current costs to consumers of publicly funded programs are over-looked. The auditor's report concludes that EPR programs are likely to pass along costs to consumers, but fails to describe that consumers are currently paying for take-back programs, either through local taxes and fees or through costs passed along by collectors such as pharmacies. The auditor's report consistently fails to acknowledge that consumers also pay for take-back programs provided by government and pharmacies through taxes, waste rates, or higher costs of goods.

In Table 5, the auditor's report lists "Who Would Absorb Costs?" but fails to identify that taxpayers would ultimately pay for government-provided programs under Options 1 and 2. Consumers would pay directly for Option 4, an Advanced Disposal Fee (ADF), and the report's statement that CalRecycle or other state agency would also pay is unclear. This may reference the large agency staffing and overhead needed to administer the collection and distribute of the ADF.

As another example, the report cites the convenience of some municipal programs, such as San Francisco's needle exchange program (page 20), without investigating the costs of this program to the city and taxpayers.

- C. No cost analysis of recommended actions for state or local governments. The auditor's report makes recommendations for activities that a lead state agency or that local governments should take, without estimating the costs of those services, without suggesting funding mechanisms, and without acknowledging that government costs will be borne by California taxpayers.

Unfunded recommendations for state agencies actions include:

- Maintaining a complete and accurate online database of drop-off sites for pharms and sharps that is also user-friendly for residents. This will require staff support to continually verify drop-off locations with all of the local entities providing services, and these programs come and go because of unstable funding. Technology support and funding for website and mobile app development and maintenance will also be needed.
- Providing mail-back services to reach the estimated 4 million Californians without access to collection sites. Mail-back is typically the most expensive collection method. For example, a ballpark cost for a medicine return mailer that holds about 8 ounces is roughly \$7 for an efficient program (~\$1 for the mailer and postage and \$6 for disposal). Providing just 1 prepaid medicine mailer per person per year would cost \$28 million. If agency funds are appropriated, these costs will be passed along to taxpayers, i.e. consumers.

Unfunded recommendations for local governments include consideration of waste management by local waste haulers (page 27). In section 2.D., we explained why this recommendation is not feasible for pharmaceuticals because it does not conform with DEA regulations. It might be feasible and legal for local waste management agencies to pick up filled sharps containers at curbside, or provide a consolidation point at a transfer station. Curbside is clearly convenient, but it may

be a costlier option because the waste hauler would either need to make a separate pick-up or store sharps containers separately on the truck. Drop-off of sharps containers at waste consolidation points is likely to be less convenient for residents that drop-off sites at pharmacies or hospitals. Regardless of logistics, a funding source would be needed. The auditor's recommendation pushes this cost responsibility onto the local government's contract, which in turn will be passed along to all ratepayers and taxpayers in the jurisdiction.

- D. Potential costs of EPR programs. The report provides no analysis or comparison of the potential efficiencies of different financing mechanisms and program designs. The auditor's methodology did not include a policy review of the local ordinances so the report does not analyze these policies or provide any specific justification for singling out EPR programs for passing costs along to consumers. EPR policies are designed to encourage cost effectiveness of program design and operation.

Under the county EPR policies, manufacturers pay for and operate the take-back programs directly, controlling their own funds. Medicine manufacturers design their own program(s) and manage their own finances to meet the bill's criteria for a system of secure medicine drop boxes, as well as prepaid return mailers, and public education about safe medicine storage and secure disposal. Government's role is limited to oversight. Manufacturers can pass costs through the supply chain to purchasers of drugs, which include healthcare providers, insurance companies, and consumers, by various mechanisms. A point-of-sale fee or point-of-return fee is not allowed.

Unfortunately, the actual costs of the manufacturers' MED-Project programs have not yet been provided in annual reports because these programs are still relatively young. The pharmaceutical industry's estimated costs of EPR programs are a small percentage of overall medicine sales (see analysis in our initial report), roughly 0.1% of a conservative estimate of medicine sales. This amounts to 1 penny for every \$10 in medicine sales. This small amount is unlikely to result in discernable increases in the costs of medicines given the huge variability in medicine prices due to other factors.

#### References to Initial Ecoconsult report

- Section 2.3 b): Cost Analysis: we provided estimated costs to manufacturers of a pharmaceutical EPR ordinance and compared these costs to estimated sales of prescription and over-the-counter medicines in L.A. County to demonstrate that anticipated take-back programs costs are less than 0.1% of medicine sales.

**5. No policy analysis of county stewardship laws or recognition that some of the report’s recommended model programs in other countries are Extended Producer Responsibility.**

- A. The auditor’s methodology did not include any review of the county-level stewardship law language or policy. In Table 1 on page 11, the Audit Objectives and Methods do not include review of the county laws. This omission in the auditor’s methodology throws question upon a number of the report’s findings, including that:
- the county policies are inconsistent and therefore burdensome to manufacturers. This finding appears to be solely based on interviews they conducted with unnamed representatives of the pharmaceutical industry, which is on record as being the sole stakeholder group opposing the local ordinances. The local governments and agencies who developed the policies and are collaborating on program implementation do not appear to have been asked for input on this issue.
  - the county EPR laws will result in higher cost burdens to consumers. The EPR policy model has built in drivers for cost efficiencies because the manufacturers manage their own funds, and operate the stewardship program directly as a private sector program, with a limited oversight role for government. This is further described in our cost analysis in Part 4.E.

Our analysis of the proposed LA ordinance is that it would provide a comprehensive take-back system throughout the county and accomplish the following recommendations in the auditor’s report.

Key Recommendations in the State Auditor’s Report	Currently addressed in California	Required under proposed LA County pharm/sharps stewardship ordinance	Comments
Provide consistent messaging to consumers on safe disposal of medicines and sharps	No	Yes	Approved stewardship plans would provide uniform messaging county-wide (see Appendix for MED-Project examples).  Messaging by federal agencies (FDA, DEA, EPA, CDC) is outside control of state or local governments; however MED-Project messaging is consistent.
Single searchable website to provide collection locations	No	Yes	See MED-Project website for example of maps and search engine provided by manufacturers.
More service to rural areas	No	Yes	Prepaid return mailers would be provided by manufacturers.
Data collection on proper disposal of pharms and sharps	No	Yes	Annual reports from manufacturers required on pounds collected, and amount by collection method

- B. Standardizing policy requirements of EPR programs for pharmaceuticals/sharps: The auditor's report recommends that state adopts standards for local EPR policies. On principle, we feel this creates jurisdictional concerns. Given the state's inaction on a statewide solution, it is not appropriate for the state to interfere with local initiatives to protect public health and safety. Local governments are testing and refining the policy model that should eventually be adopted at state level. Moreover, the auditor's limited analysis fails to recognize that the county-level stewardship laws are already substantially more similar than they are different. In fact, most requirements of county EPR ordinances in CA are well-aligned already.

As examples for state-level guidelines, the state auditor's report suggests the guidelines should address whether county EPR programs should include nonprescription medications and whether they should provide a mail-back component. From our inquiries we believe that all the county EPR ordinance do include nonprescription medicines and all except one ordinance requires mail-back.

The most significant differences between the county pharm EPR ordinances are in whether they mandate retailer participation. It appears that Santa Cruz's stewardship ordinance is the only one that mandates retailer participation. San Luis Obispo's retailer take-back ordinance also mandates retailer participation, but this is not a full EPR policy because it does not place responsibilities on producers.

Other differences between the county EPR policies represent important local customization, such as the minimum number of required collection sites based on local population centers.

In practice, MED-Project is submitting substantially similar stewardship plans on behalf of participating manufacturers to each of the counties. Each plan must describe arrangements with local collection sites in the county; however, many other portions of the plan are essentially identical, such as service vendors, disposal facilities, educational materials, branding, and promotional strategies.

- C. Local leadership drives state action. Absent effective state engagement, local jurisdictions have stepped up to protect their residents. While industry resistance has thwarted adoption of a statewide take-back program by the Legislature, eight local governments have already adopted local ordinances to do so. Adoption of an EPR ordinance in LA County is likely to signal state-wide acceptance of this model.

The counties are serving as model policy incubators for pharmaceuticals and sharps stewardship. While adopting and implementing these local laws has been substantial work for local agencies, they are moving forward because the public health and safety crisis posed by leftover medicines and sharps must be addressed. These local counties have determined that existing approaches were insufficient.



D. Auditor's report recommends EPR programs in other countries as models. The auditor's report highlights model programs in other jurisdictions or countries, but fails to identify that several of these programs are in fact the result of EPR regulations. The following programs listed in Table 4 on page 36 are financed and coordinated by pharmaceutical manufacturers under national or provincial laws:

- Spain's Sigre Program for medicine take-back.
- France's Cyclamed Program for medicine take-back at pharmacies which has been funded by pharmaceutical manufacturers since its inception in 1994. In France, 80% of residents use the Cyclamed drop boxes that have been provided by drug manufacturers at pharmacies since 1994. In 2015, more than 26 million pounds collected from population of about 66 million.<sup>8</sup>
- Canada's National Medicine Take-Back Program – the report's description of this program does not make clear that it is solely an educational campaign that directs consumers to return their medicines to pharmacies. The pharmacy take-back programs are financed and provided by manufacturers in all Canadian provinces except one. The take-back programs are coordinated by the manufacturers' stewardship organization the Health Products Stewardship Association, <http://www.healthsteward.ca/about-us>., which also operates collection programs for medical sharps.
- The DASTRI sharps collection program in France is an Extended Producer Responsibility program according to the Global Product Stewardship Council.<sup>9</sup>

E. Model take-back programs are predominantly pharmacy-based. We agree with the state auditor's report conclusions that California could improve its collection and disposal system by adopting programs and practices that other countries use. In other countries, collection sites for pharmaceuticals and sharps are primarily in pharmacies and medical centers. The collection site access analysis provided in the auditor's report consistently fails to adequately recognize the importance of creating a pharmacy-based take-back system. Pharmacies, hospitals and medical clinics, are more convenient collection locations for residents than police stations or limited solid waste/hazardous waste transfer stations for several reasons:

- Many residents regularly shop at a pharmacy, often several times a month. Residents, particularly those with health conditions, regularly visit medical clinics and hospitals and/or know where they are located in their communities.
- Regular business hours are often longer at pharmacies, clinics, and hospitals than at police stations or waste transfer stations which may not be open in evenings, or on weekends, or seven days a week.

---

<sup>8</sup> 2015 Cyclamed Report <http://www.cyclamed.org/>

<sup>9</sup> Product Stewardship for Sharps and Unwanted Medicines – Background and Issues Paper Global PSC Members. October 2016.

[http://www.globalpsc.net/wpcontent/uploads/2017/07/US\\_Sharps\\_UM\\_Background\\_Issues\\_Final\\_Members\\_Only.pdf](http://www.globalpsc.net/wpcontent/uploads/2017/07/US_Sharps_UM_Background_Issues_Final_Members_Only.pdf)

### References to Initial Ecoconsult report

- Our initial analysis provided various examples of local leadership and model programs including in Alameda and King counties for pharmaceuticals (pages 2-6) and San Luis Obispo and Santa Cruz counties for sharps (pages 15-16).

### **Part 3: Review of Consumer Surveys**

The Los Angeles County Pharmaceutical Working Group conducted a survey of residents about their concerns, practices, and preferences for disposal of leftover pharmaceuticals and sharps. We found this survey to be credible and informative for LA County's policy development process and consideration of a pharmaceuticals and sharps EPR ordinance. The survey results were consistent with similar surveys of residents and consumers in other jurisdictions that we are aware of, and we provide some examples for comparison in this section.

The Los Angeles survey results confirm a number of key conclusions in our initial analysis about why EPR policies are needed to improve safe disposal options:

(1) Residents are finding it difficult to dispose of leftover pharmaceuticals and sharps properly and, at the same time, are very supportive of using take-back programs if they are convenient. This supports our conclusion that improving the number of collection sites and providing drop boxes in more convenient locations such as pharmacies will increase collection amounts and better protect public health and safety (initial analysis: Section 2.3 Effectiveness of Extended Producer Responsibility).

- For medicine disposal, only about 9% of participants are currently using a law enforcement drop box, another 12% are using a collection event or HHW facility, and 2.3% are using a mailer. Overall about 23% of residents are willing to use these medicine take-back services, even though they are not very convenient. This is encouraging that a convenient pharmacy take-back program would be well-utilized, as is seen in other countries with established pharmacy take-back programs.

(2) Many residents do not want to dispose of waste medicines in the trash because of concerns about harming the environment. Of those who use trash disposal for their leftover medicines, few are willing or able to follow the cumbersome advice of disguising medicines in kitty litter or coffee grounds as an effort to prevent diversion from unsecured trash cans. This supports our conclusion that trash disposal of medicines is an undesirable and unworkable disposal option that needs to be replaced with safe and secure take-back (initial analysis: page 21 on Trash Disposal of Waste Medicines).

- Disposal recommendations to disguise medicines prior to trash disposal have poor compliance: Just 12% said that they mixed medicines with coffee grounds or kitty litter to disguise them prior to throwing them in the trash, while 35% of participants overall said that they dispose of their medicines in the trash as is. Disguising medicines before trash disposal is the method favored by the pharmaceutical industry. These results suggest poor

consumer compliance with that disposal guidance, resulting in improper and risky disposal.

(3) A significant number of residents are continuing to put used sharps in the trash, supporting our conclusions that legal disposal methods are not yet convenient enough (initial analysis: Medical Sharps section, pages 12-16).

(4) Residents commonly choose pharmacies as a convenient and preferred place to take-back leftover medicines and used sharps for safe disposal, supporting our emphasis on establishing EPR policies to ensure adequate financing to provide safe and secure drop boxes in pharmacies, clinics, and hospitals (initial analysis: Section 2.3 Effectiveness of Extended Producer Responsibility).

We found the following specific findings of the LA County survey suggestive of needed actions to increase awareness about proper management of medicines:

- The survey results clearly demonstrate that there is a need to give residents clear guidance on proper medicine disposal as well as information collection locations.
- 12% of residents were waiting for a medicine collection event. This finding suggests these residents do not have reasonable access to an ongoing drop box and therefore are hanging on to potentially dangerous medicines until the event. Stockpiling of medicines needs to be minimized through providing more ongoing drop boxes. In addition, safe storage of medicines in the home needs to be emphasized.
- 59% of participants had expired or unneeded medicines in their home, showing how common it is that some medicines go unused or expire before use. However, 8.8% of residents said they were unsure, suggesting that they are not monitoring their medicine supplies closely and need education about risks of unsecured medicines in the home.
- 23% of survey participants were saving their expired or leftover medicines, for undisclosed reasons. This suggests the need for educational messages to discourage such hoarding of medicines. These messages should explain the increased risks of misuse, poisonings, overdoses, suicide attempts when unneeded, excess medicines are kept in the home.

### **Methodology of the LA County survey**

We found the methodology of the survey appropriate overall, and a reasonable sample size of 1,062 residents was utilized. Just more than half, 56%, took the survey online and the remainder took the survey in a pharmacy. The selection of pharmacy sites to sample some of the residents may have introduced some bias because these individuals had already chosen to visit an in-store pharmacy. However, surveys using random selection of residents are consistent in finding a preference for pharmacy take-back programs as a convenient option.

The survey did not attempt to specifically sample home-bound residents. Two seniors stated they have trouble getting to the collection sites. A survey of home-bound residents would probably confirm the need for mail-back options for this population.

We noted some demographic details that could be addressed through more comprehensive surveys in the future:

- Survey participants skewed strongly female in the online survey and the DHS pharmacy site sample.
- DHS pharmacy participants were predominantly non-white, and additional survey approaches may be needed to provide a representative sample of non-white county residents.
- The survey was conducted in English and Spanish; and 5.8% of survey takers took the survey in Spanish. Given language diversity in Los Angeles County, it would be valuable to conduct surveys in additional languages.

### **Comparison to other survey results**

The results of LA county consumer survey are consistent with findings of similar surveys in other jurisdictions with regard to findings that a majority of residents have medicines that are expired or unneeded, that many residents do not know how to properly dispose of medicines, and that residents commonly prefer pharmacies as a convenient take-back location.

In our initial analysis, we briefly listed some surveys in Section 2.4 (page 17) as examples of the amounts of leftover medicines that residents say they have in their homes. Some of these surveys also asked residents why they had leftover or expired medicines.

The following surveys provide examples of surveys consistent with the LA County survey findings:

1. In November 2016, the Contra Costa Health Service Public Health Division survey conducted a survey of 1,600 residents that was modeled on the LA County survey and they found consistent results.<sup>10</sup>
  - 73% of respondents have unused or left-over prescription medications in their home.
  - 94% of respondents believe it is inappropriate to flush leftover medications and 84% believe it is inappropriate to put leftover medications in the trash.
  - 83% of residents said they would be likely or very likely to dispose of unwanted medications at a pharmacy. 55% would be likely or very likely to

---

<sup>10</sup> Memo from Contra Costa Human Services to the Family and Human Services Committee of the Contra Costa Board of Supervisors. Nov. 14, 2016. Online at: <http://cchealth.org/hazmat/hmc/pdf/2016-1114-Safe-Drug-Disposal.pdf>

use a prepaid return envelope. These methods were preferred over collection events or drop boxes at law enforcement agencies.

2. A public awareness survey conducted by the Health Department in Whatcom County, WA of 625 residents found:
  - 57% of residents currently have leftover or unwanted medications in the home.
  - 72% of survey participants who do not have a local take-back program in their community said they were “very likely” to use a convenient location for medicine disposal.
  - 81% of survey participants agreed that pharmaceutical companies should be responsible for providing safe medicine disposal options.

Currently, and at the time of the survey, Whatcom County has law enforcement take-back programs for medicines in two cities (Bellingham and Ferndale). These cities also have pharmacy take-back programs for medicines; however, the pharmacies do not accept controlled substances.

3. Law et al published a research brief in Science Direct<sup>11</sup> describing results of surveying a sample of residents in Southern California about unused medicines and disposal methods.
  - Approximately 2 of 3 prescription medicines were unused.
  - “Throwing medicines in the trash” was the most common method of disposal.
  - Pharmacies were the preferred location for medicine disposal.
4. Surveys in countries with established pharmacy take-back programs confirm that residents find pharmacies convenient and utilize the programs.
  - In France, 80% of residents use the Cyclamed drop boxes provided by drug manufacturers at pharmacies since 1994. In 2015, more than 26 million pounds collected from population of about 66 million.  
Source: 2015 Cyclamed Report <http://www.cyclamed.org/>
  - In British Columbia, 73% of B.C. residents in 2016 with medicines in their homes were aware of the drug take-back program provided by drug manufacturers under a provincial EPR regulation. 55% of those had used the program for their leftover medicines in the past year. 2015 collections in B.C. were 220,846 pounds from a population of 4.7 million.  
Source: annual reports and surveys for British Columbia from the Health Products Stewardship Association <http://www.healthsteward.ca/>

---

<sup>11</sup> Law et al. “Taking stock of medication wastage: Unused medications in US household”. 2015. Research in Social and Administrative Pharmacy 11; 571-578.

<http://www.sciencedirect.com/science/article/pii/S1551741114003337>

#### **Part 4: Implementation Status of County EPR Ordinances for Pharmaceuticals or Pharmaceuticals and Sharps**

The pace of implementation of the county EPR laws has increased dramatically during 2017. The implementation delays that we described in our initial analysis (pages 1-6 under Section 2-Analysis) for first two county laws in Alameda and King counties have been overcome. Those delays were due to the pharmaceutical industry's unsuccessful lawsuits and the manufacturers' stewardship organization's learning curve in developing stewardship plans that meet the requirements of the local ordinances.

MED-Project LLC is the stewardship organization operating the take-back programs on behalf of about 400 pharmaceutical manufacturers. MED-Project is now providing stewardship programs in 6 counties in California and 2 counties in Washington State. Santa Cruz and Alameda counties have also enacted EPR ordinances for sharps. Manufacturers are operating a sharps stewardship program in Santa Cruz County, and developing a sharps stewardship plan for Alameda County. Five additional counties that have enacted pharmaceutical EPR ordinances are in the process of reviewing proposed stewardship plans from the manufacturers or are anticipating plan submission.

Table II summarizes the status of implementation of each county's law and lists the number of MED-Project drop boxes in each county as of early October 2017. Additional services may include collection events to fill in gaps in drop box coverage. All the local ordinances, except Alameda's, also require that mail-back services are available. MED-Project has made mailers available upon request and from distribution sites such as libraries. The county-level ordinances allow authorized collectors – such as pharmacies, hospitals, and law enforcement agencies for pharmaceuticals – to join the programs over time. The number of collection sites is therefore expected to continue to increase with time.

Under the regulations, the manufacturers are responsible for servicing the secure drop boxes, including costs of collection supplies, transportation and proper destruction of collected medicines or sharps. Manufacturers are also responsible for costs of collection events, mail-back services, program promotion and administration.

In all of the counties, the MED-Project programs collect prescription drugs, including controlled substances, and over-the-counter medicines (with just a few exceptions). Customers drop all medicines into the secure drop box. No pre-screening by the pharmacist is required. Pharmacy collection sites must amend their DEA registration to be an authorized collector and follow all security requirements of the DEA's regulations, as well as other applicable federal and state laws.

The MED-Project website, <http://www.med-project.org/locations>, was used as a source of information for each county's collection services. In addition, information from contacts with county staff was used to create the summary. It has often been the case that MED-Project works with a collection site to install and open a secure drop box, then waits a few weeks to ensure smooth operations prior to publicizing the collection location on [www.med-project.org](http://www.med-project.org). Therefore, the list of collection sites on the MED-Project website may represent an undercount of the collection sites provided. As previously stated, additional collectors can also "opt in" to the MED-Project programs over time.

**Table II: MED-Project Program Status and Implementation**  
as of October 12, 2017

	<b>County population</b>	<b>Program Status</b>	<b>Drop Boxes Provided</b> <i>Medicine drop boxes all accept controlled substances</i>	<b>Mail-back Services</b>
<b>California</b>	<b>Alameda</b> 1.6 million	MED-Project program operating. Drop box installation began in Dec. 2016.	27 secure medicine drop boxes at 23 pharmacies and 4 law enforcement agencies. Collection events are also scheduled. MED-Project stewardship plan for medical sharps is under review.	Not currently provided for medicines, and not required under local ordinance.
	<b>Contra Costa</b> 1.1 million	Stewardship plan under development; due in January 2018.	Plan must include secure medicine drop boxes.	Plan must include prepaid return mailers for medicines.
	<b>Marin</b> 500,000	MED-Project program operating. Drop box installation began in spring 2017.	13 secure medicine drop boxes at 5 pharmacies and 8 law enforcement agencies.	Prepaid return mailers for medicines provided at 10 locations, all libraries. Mailers available upon request via website or phone to residents and to service providers for homebound residents.
	<b>Santa Barbara</b> 445,000	Stewardship plan deadline was July 2017; plan under review.	Plan must include secure medicine drop boxes.	Plan must include prepaid return mailers for medicines.
	<b>Santa Clara</b> 1.92 million	MED-Project plan approved in March 2017.	County expects to transition existing medicine drop boxes, ~ 40 locations, to MED-Project during 2017. Installation beginning August 2017.	Prepaid mailers available to homebound residents and their service providers upon request via website or phone. Mailer distribution sites also expected, but not yet listed.
	<b>Santa Cruz</b> 275,000	MED-Project program operating, directly providing some collection services and compensating the county for its collection programs. The four incorporated cities within the county have adopted the same ordinance.	MED-Project is directly operating 3 medicine drop boxes at pharmacies and 5 boxes at law enforcement agencies. Every pharmacy must participate in both pharmaceutical and sharps collection, either by hosting a drop box or providing pre-paid mailers. In total, MED-Project is either directly providing or compensating the county for: 24 sites for medicines and sharps; 12 sites for medicines only; 13 sites for sharps only, including 3 public kiosks. All county collection programs are expected to fully transition to MED-Project operations during October 2017.	MED-Project is directly supporting 10 pharmacies distributing prepaid mailers for medicines. MED-Project is compensating the county for its mailer distribution sites for medicines and sharps. Prepaid medicine mailers are available to residents upon request via MED-Project website or phone.



**Table II: MED-Project Program Status and Implementation**  
*as of October 12, 2017*

	<b>County population</b>	<b>Program Status</b>	<b>Drop Boxes Provided</b> <i>Medicine drop boxes all accept controlled substances</i>	<b>Mail-back Services</b>
	<b>San Francisco,</b> City and County 850,000	MED-Project program operating. Drop box installation began in Dec. 2016.	33 secure medicine drop boxes at 21 pharmacies (including clinics and hospitals) and 12 law enforcement agencies. More drop boxes being installed during 2017. Collection events are also scheduled.	Prepaid mailers available at all libraries, and other distribution sites like YMCAs and schools. ~ 25 mailer distribution sites total.
	<b>San Mateo</b> 760,000	MED-Project program operating.	35 secure medicine drop boxes at 13 pharmacies (including clinics and hospitals) and 22 law enforcement agencies. Collection events are also scheduled.	Prepaid mailers available at all libraries. ~ 10 mailer distributions sites total. Mailers available to homebound residents & their service providers upon request via website or phone.
<b>NY</b>	<b>Rockland</b> 327,000	Stewardship plan in development.	Plan must include secure medicine drop boxes or prepaid return mailers are every retail pharmacy chain with 3 or more stores.	Plan must include secure medicine drop boxes or prepaid return mailers are every retail pharmacy chain with three or more stores.
<b>Washington</b>	<b>King</b> 2.2 million	MED-Project program operating. Drop box installation began in Nov. 2016.	99 secure medicine drop boxes at 74 pharmacies (including clinics and hospitals) and 24 law enforcement agencies.	Prepaid mailer distribution sites provided at county library locations and some town halls. ~18 mailer distribution sites total. Mailers available to homebound residents & their service providers upon request via website or phone.
	<b>Snohomish</b> 780,000	MED-Project program operating. Drop box installation began in August 2017.	31 secure medicine drop boxes at 18 pharmacies (including clinics and hospitals) and 13 law enforcement agencies.	Mailers available to homebound residents & their service providers upon request via website or phone.
	<b>Kitsap</b> 260,000	Stewardship plan deadline was June 2017; plan under review.	Plan must include secure medicine drop boxes.	Plan must include prepaid return mailers for medicines.
	<b>Pierce</b> 845,000	Stewardship plan deadline was June 2017; plan under review.	Plan must include secure medicine drop boxes.	Plan must include prepaid return mailers for medicines.



Information Sources for Table x:

MED-Project website: [www.med-project.org](http://www.med-project.org)

Alameda: July 2017 Program Status Update: <https://www.acgov.org/aceh/safedisposal/documents/July2017-SDD-SSD-ProgramUpdate.pdf>

Contra Costa: <https://cchealth.org/safe-drug-disposal/>

King: <https://kingcountysecuremedicinereturn.org/>

Kitsap: [https://www.kitsappublichealth.org/information/medicine\\_return.php](https://www.kitsappublichealth.org/information/medicine_return.php)

Marin: <https://www.marincounty.org/depts/cd/divisions/environmental-health-services/safe-drug-disposal-ordinance>

Pierce: <http://www.tpchd.org/environment/waste-management/medicine-return-program/>

Santa Barbara: <http://cosb.countyofsb.org/phd/environmentalhealth.aspx?id=53031>

Santa Clara: <https://www.sccgov.org/sites/rwr/Pages/safemeds.aspx>

San Francisco: <https://sfenvironment.org/safe-drug-disposal-stewardship-ordinance>

San Mateo: <http://www.smchealth.org/general-information/safe-medicine-disposal-ordinance>

Snohomish: <http://www.snohd.org/Waste/Medicine-Disposal/Pharmaceutical-Stewardship>

Information on the implementation status of some CA county programs was shared by the California Product Stewardship Council. calpsc.org. Information about the Kitsap and Pierce county ordinances in WA was obtained through personal communications with local health department staff. Information about the status of the Santa Cruz County program was obtained through personal communication with county staff.

## County EPR Laws are providing more services to residents

In our initial analysis, we predicted that “through the dedicated funding and coordination of pharmaceutical manufacturers, the local stewardship ordinances will provide more collection sites, will place collection sites in more convenient locations, and will provide enhanced collection services to underserved populations” (page 8). Although the programs mandated under these laws are still young, the manufacturers’ stewardship programs are achieving these expectations.

The MED-Project programs are already providing more collection sites and more consistent disposal messaging in California counties than was previously available in these counties. We believe a thorough county-by-county comparison would confirm that the counties with EPR laws now have more take-back services for medicines than are available in other California counties. The county laws are also accomplishing a shift from secure medicine drop-off locations being located predominantly in police stations to more convenient drop boxes at pharmacies, clinics, and hospitals. It is also notable that all the secure medicine drop boxes operated by MED-Project accept legally prescribed controlled substances, as well as other prescriptions and nonprescription medicines.

Here are a few examples of the Before & After for pharmaceutical take-back services:

### San Francisco, City & County:

*Before MED-Project:* 10 law enforcement collection sites and 13 pharmacy collection sites that could not accept controlled substances.  
*With MED-Project:* 33 secure medicine drop boxes at 21 pharmacies, clinics, or hospitals and 12 law enforcement agencies.

### San Mateo County:

*Before MED-Project:* 14 collection sites at law enforcement agencies  
*With MED-Project:* 35 secure medicine drop boxes at 13 pharmacies, clinics, or hospitals and 22 law enforcement agencies.

### King County:

*Before MED-Project:* 10 collection sites at law enforcement agencies, but none in the county’s largest cities.  
*With MED-Project:* 99 secure medicine drop boxes at 74 pharmacies, clinics, or hospitals and 24 law enforcement agencies.  
Since 2016, Walgreens also provides 3 drop boxes that continue to operate independently.

### Snohomish County:

*Before MED-Project:* 25 law enforcement drop boxes and 2 pharmacy drop boxes.  
*With MED-Project:* 31 secure medicine drop boxes at 18 pharmacies, clinics, or hospitals and 13 law enforcement agencies.

## **Part 5: Evaluation of Potential Impacts of Proposed EPR Ordinance**

The opioid abuse epidemic is persistent and a serious public health and safety crisis in our communities. While many efforts are underway to address this crisis, we continue to view substance abuse prevention strategies as critical to preventing initiation of misuse of prescription opioids and resulting addiction. Effective substance abuse prevention requires a comprehensive approach to reduce access to the substance and educate the public. Providing secure medicine take-back programs is a key strategy in this comprehensive approach.

Secure medicine return programs help reduce the supply of prescription opioids and other prescription controlled substances that are available for misuse. Statistics continue to show that the home medicine cabinet is a large source of prescription drugs that are misused.

The proposed LA county ordinance will provide more collection locations for pharmaceuticals and sharps, and those locations will be more convenient for residents to use through participation of pharmacies, clinics, and hospitals. We believe that the early results of the manufacturers MED-Project programs in other counties show that pharmacy-based take-back locations for medicines and sharps are popular with residents and will be well-utilized. Our support for convenient pharmacy-based drop-off boxes to increase collection of pharmaceuticals and used sharps is also supported by the results of the LA county consumer survey and the popularity of these programs in other countries, including Canada and France. The proposed LA ordinance will also provide return mailers to residents and we view this service as critical for home-bound residents or those in more remote areas.

The proposed LA county EPR ordinance already includes evaluation components by requiring annual reports that include reporting on program services and educational activities, with assessments of how well the program achieved its proposed goals. In addition, periodic public awareness surveys are required. Monitoring of program effectiveness could be further enhanced by the following:

- Require additional monitoring and reporting of collection amounts to provide more timely indicators of whether and how residents are using the program. Quarterly reporting, of aggregate amounts or amounts by collection method, should be required of the approved stewardship plan(s). Annual reports should detail collection amounts by each collection location so that trends in usage of collection sites can be observed and utilized to identify areas where more public education about safe disposal should be targeted.
- Increase frequency of public awareness surveys to annual and require that manufacturers conduct a baseline survey prior to launch of their program(s).

### Recommended policy refinements:

In our initial analysis we commended the overall policy approach of the proposed LA county for stewardship of sharps and pharmaceuticals, and made recommendations for further policy refinements, see pages 30-32 of Ecoconsult's original report. We

continue to support those recommendations. In particular, we encourage that the proposed ordinance is modified to mandate that manufacturers must accept all qualified collectors into the stewardship program. Any qualified collector that volunteers to host a drop box for pharmaceuticals or sharps should be allowed to participate to increase convenience for residents. We believe this requirement has proven successful in other counties such as San Francisco and King County that now have a large number of drop boxes.

In addition to our earlier recommendations, we suggest these additional policy requirements to further improve the policy based on learnings from implementation of the successful stewardship ordinances in other counties:

- Strengthen and clarify language that producers must service collection sites on a schedule that meets the needs of each collection site, to avoid the potential for overfull drop boxes. We have found that many pharmacies are willing to host and staff drop boxes as a part of a stewardship program, but they need assurance that the stewardship organization will service the drop boxes regularly and that collected medicines will be promptly sent for final destruction.
- Require quarterly reporting of collection amounts. Require reporting by collection location in annual reports.
- Require public collection sites for sharps, such as in city and county parks. In Santa Cruz county, the manufacturers' MED-Project program is currently reimbursing the county for its costs of operating three public sharps kiosks, and will soon take over direct operations of those kiosks.
- Enhance the provision of mail-back packages for pharmaceuticals and sharps by requiring manufacturers to provide a supply of mailers upon request to individuals who are providing services to homebound and differentially abled residents. This will allow home health providers, hospice services, and others to help their patients properly dispose of these products via prepaid mailers. In addition to "on request" provision of mailers, the proposed ordinance could require distribution of mailers at convenient community locations such as libraries and fire stations.

# Appendix I: Examples of MED-Project website search functions for collection sites and mailer distribution sites

## Alameda County

**MED-Project™**  
Medication Education & Disposal

County Search MEDInfo MEDfaq Contact

### KIOSKS

Community drug take-back locations allow residents to bring expired or unwanted medicines to a convenient, centralized location for proper disposal.

**ACCEPTED:** Medications in any dosage form, except for those listed below, in their original container or sealed bag.\*

*\*If transferring medications to a sealed bag, please be sure to recycle all remaining packaging.*

**NOT ACCEPTED:** Herbal remedies, vitamins, supplements, cosmetics, other personal care products, compressed cylinders, aerosols, inhalers, medical devices, sharps, illicit drugs, iodine-containing medications.

To find the nearest disposal location, enter your zip code below.

**Starting Point**

**Radius**

**SEARCH**

Unwanted Medicine Kiosks

# San Francisco, City & County

**Starting Point**

Zipcode

**Radius**

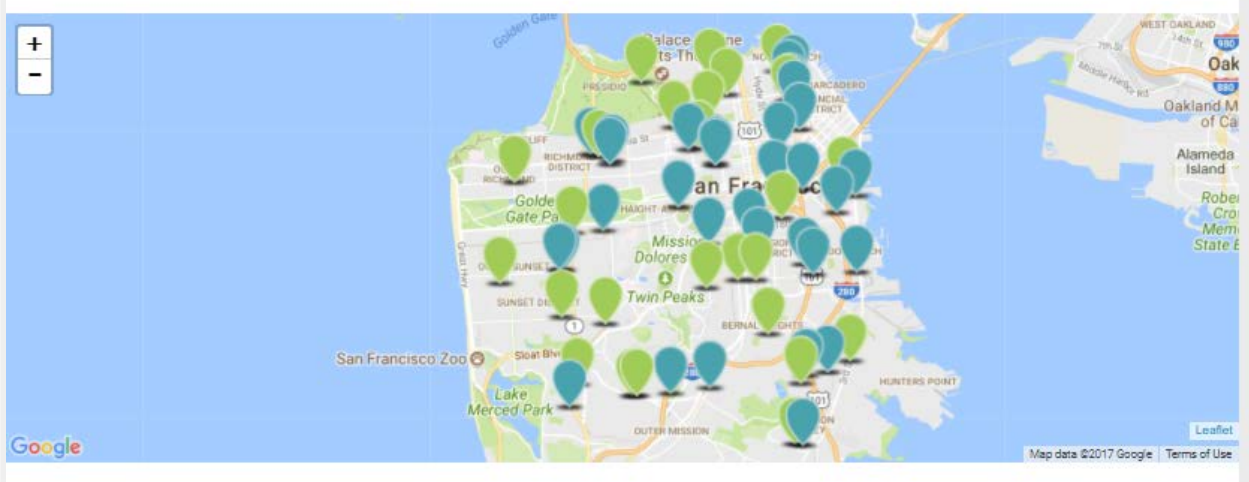
5 miles

**SEARCH**

Unwanted Medicine Kiosks

Mail-Back Package Distribution Sites

**CLEAR FILTERS**



Map data ©2017 Google | Leaflet | Terms of Use

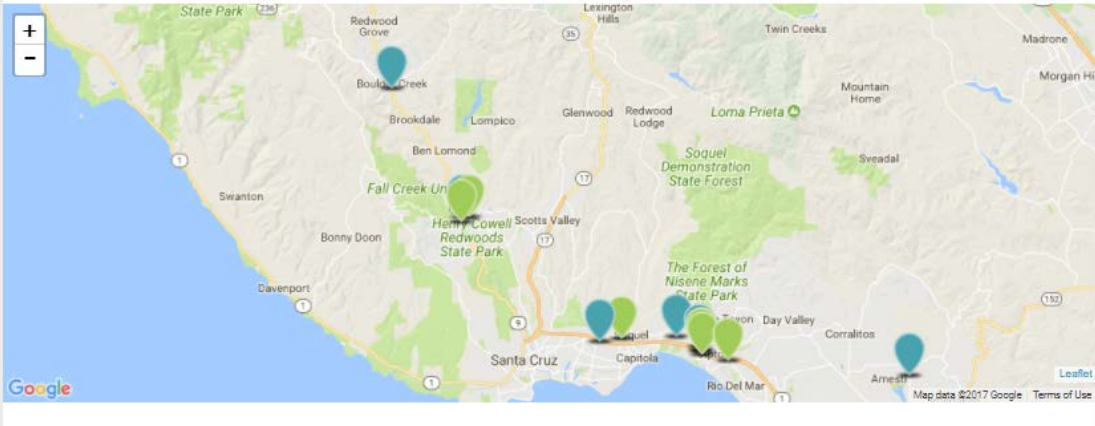
# Santa Cruz County

**Starting Point**  
Zipcode

**Radius**  
5 miles

**SEARCH**

Unwanted Medicine Kiosks     Mail-Back Package Distribution Sites    **CLEAR FILTERS**



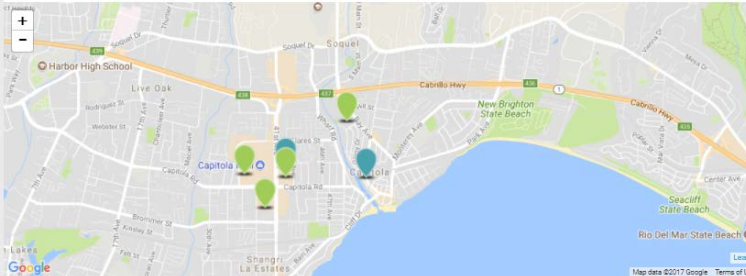
## Additional sites in City of Capitola in Santa Cruz County

**Starting Point**  
Zipcode

**Radius**  
5 miles

**SEARCH**

Unwanted Medicine Kiosks     Mail-Back Package Distribution Sites    **CLEAR FILTERS**



# King County, WA


## Starting Point


Zipcode

## Radius

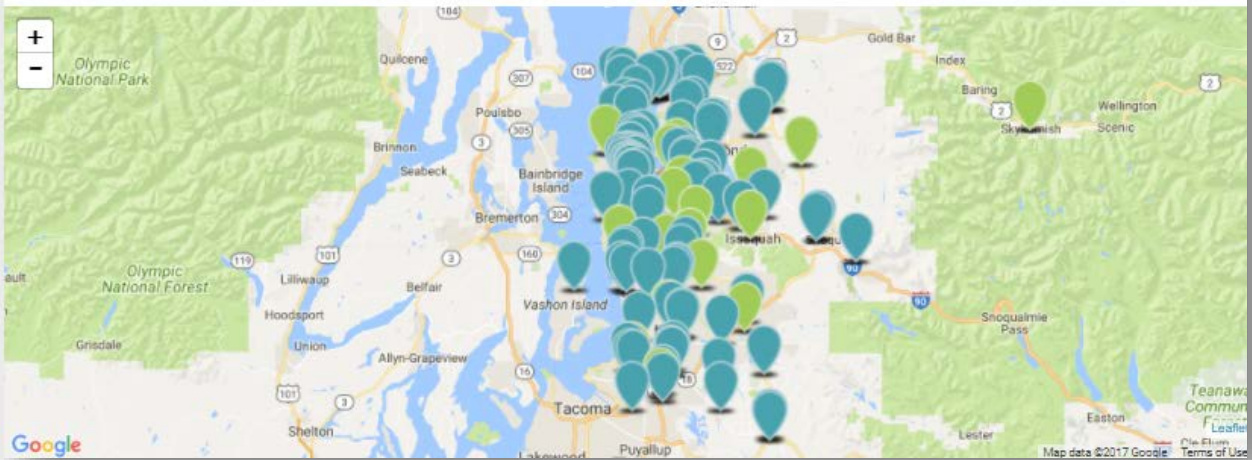
5 miles

SEARCH

 Unwanted Medicine Kiosks

 Mail-Back Package Distribution Sites

CLEAR FILTERS





## Appendix II: Federal Agency Disposal Guidance for Pharmaceuticals Provide a Disposal Hierarchy

The state auditor's report summarized disposal guidance of federal agencies, and concluded that the guidance is in conflict. But the auditor's review failed to note that this guidance does provide a hierarchy of disposal recommendations. The FDA, DEA, and EPA all recommend medicine take-back programs as the preferred disposal method. Trash disposal of medicines is only recommended in situations where no take-back program is available. Flushing of specific drugs is also only recommended by the FDA if no take-back program is available. The table and examples in this Appendix provide further explanation.

### Food & Drug Administration (FDA)

[www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm)

"Many community-based drug "take-back" programs offer the best option."

The detailed disposal guidance is:

- Follow any specific disposal instructions on the prescription drug labeling or patient information that accompanies the medicine. Do not flush medicines down the sink or toilet unless this information specifically instructs you to do so.
- Take advantage of programs that allow the public to take unused drugs to a central location for proper disposal. Call your local law enforcement agencies to see if they sponsor medicine take-back programs in your community. Contact your city's or county government's household trash and recycling service to learn about medication disposal options and guidelines for your area.
- Transfer unused medicines to collectors registered with the Drug Enforcement Administration (DEA). Authorized sites may be retail, hospital or clinic pharmacies, and law enforcement locations. Some offer mail-back programs or collection receptacles ("drop-boxes"). Visit the DEA's website or call 1-800-882-9539 for more information and to find an authorized collector in your community.

If no disposal instructions are given on the prescription drug labeling and no take-back program is available in your area, throw the drugs in the household trash following these steps:

1. Remove them from their original containers and mix them with an undesirable substance, such as used coffee grounds, dirt or kitty litter (this makes the drug less appealing to children and pets, and unrecognizable to people who may intentionally go through the trash seeking drugs).
2. Place the mixture in a sealable bag, empty can or other container to prevent the drug from leaking or breaking out of a garbage bag.

## **Drug Enforcement Administration (DEA)**

[www.deadiversion.usdoj.gov/drug\\_disposal/](http://www.deadiversion.usdoj.gov/drug_disposal/)

The DEA encourages residents to use authorized collectors and drug take-back programs for secure drug disposal. Since Fall of 2010, the DEA has been coordinating the National Take-back Initiative and holding twice-a-year National Prescription Drug Take-Back Days in conjunction with local law enforcement.

DEA materials for these take-back events state:

- Unused prescription drugs thrown in the trash can be retrieved and abused or illegally sold. Unused drugs that are flushed contaminate the water supply. Proper disposal of unused drugs saves lives and protects the environment.
- Take-back programs are the best way to dispose of old drugs. But if a program is not available:
  - ▶ Take the meds out of their bottles;
  - ▶ Mix them with something unappealing like used kitty litter or coffee grounds;
  - ▶ Seal them in a bag or disposal container, and throw that away.

The DEA's Drug Disposal Information website links to the medicine disposal guidance of the FDA and the DEA.

## **Environmental Protection Agency (EPA)**

[www.epa.gov/hwgenerators/collecting-and-disposing-unwanted-medicines](http://www.epa.gov/hwgenerators/collecting-and-disposing-unwanted-medicines)

EPA encourages the public to take advantage of pharmaceutical take-back collection programs that accept prescription or over-the-counter drugs, as these programs offer a safe and environmentally-conscious way to dispose of unwanted medicines. This may be at a location such as a local enforcement agency, retail pharmacy, hospital or clinic. To find any available collection programs in your community, contact your city or county government's household trash agency.

As a second choice, the public can utilize EPA's [guidelines for household disposal of medicines \(PDF\)](#).

### **Guidance to flush unwanted medicines:**

The FDA's guidance suggests checking the drug product label for disposal instructions because the FDA recommends flushing rather than trash disposal for a specific list of especially dangerous medications. The FDA's materials on drug disposal could be more self-consistent and clear in prioritizing take-back programs over flushing of medicines on the "flush list", but that hierarchy is clear in FDA's online explanation of the "List of Medicines Recommended for Disposal by Flushing"<sup>12</sup>, which states:

---

<sup>12</sup> FDA website "Disposal of Unused Medicines: What You Should Know"  
<https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm>

**“Flushing of Certain Medicines.** There are a small number of medicines that may be especially harmful and, in some cases, fatal with just one dose if they are used by someone other than the person for whom the medicine was prescribed. To prevent accidental ingestion of these potentially dangerous medicines by children, or pets, it is recommended that these medicines be disposed of quickly through a medicine take-back program or by transferring them to a DEA-authorized collector. If these disposal options are not readily available, it is recommended that these medicines be flushed down the sink or toilet as soon as they are no longer needed.”

Currently the FDA “flush list” consists of 45 drugs, including products containing oxycodone, buprenorphine, and fentanyl. The FDA specifically recommends flushing for immediate disposal of used fentanyl patches (brand name Duragesic) due to potential risk of exposure to children if used patches are disposed in the household trash.<sup>13</sup>

The FDA’s medicine “flush list” is not aligned with the disposal guidance of many local jurisdictions across the country that advise that residents should never flush any unwanted medicines. Local wastewater and water agencies, as well as environmental and public health organizations, have asked the FDA to end its “flush list” recommendation and work with other federal agencies to create a consistent medicine disposal guidance that focuses on use of secure medicine take-back programs. In a 2016 letter responding to a statement of concern submitted to the FDA by a large number of organizations, a Deputy Commissioner of the FDA stated<sup>14</sup>:

“FDA supports the proper disposal of unused or unwanted prescription drugs through drug take-back programs and continues to include this as the first recommendation in our information to the public.”

“Again, please note that this recommendation (*flushing*) is secondary to the preferred method of disposal of these drugs via a drug take-back program when available.”

---

<sup>13</sup> FDA Consumer Update. April 2012, Updated Sept. 2013. “Fentanyl Patch Can Be Deadly to Children” <https://www.fda.gov/forconsumers/consumerupdates/ucm300803.htm>

<sup>14</sup> National Stewardship Action Council. “End U.S. Food and Drug Administration (FDA) Medicine “Flush List”” webpage at <https://nsaction.us/campaigns/>

The manufacturers' MED-Project program is providing a consistent disposal message.

Example of the MED-Project educational brochure provided in San Francisco. Available in English, Chinese, Russian, Spanish, and Tagalog. Online at: <https://med-project.org/locations/san-francisco/medinfo>.

## WHAT SHOULD YOU DO WITH YOUR UNWANTED OR EXPIRED MEDICINES?

# SAFELY DISPOSE OF UNWANTED & EXPIRED MEDICINES

There are a number of ways to dispose of expired or unwanted medicines.

For more information about the MED-Project program, go to [www.med-project.org/SF](http://www.med-project.org/SF) or call 1-844-MED-PROJ

What should you do with your expired or unwanted medicines?

Medicines help treat diseases, manage chronic conditions, and improve health and well-being for millions of Americans. It's vitally important that patients take their medicine as prescribed by their health care provider and as indicated on the label or packaging. It's also important to be sure to store medications securely to prevent accidental ingestion or misuse by others in your household, especially children.

If you have expired or unwanted medication, proper disposal is easy. To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials before using any of the following disposal options.

(Source: U.S. Food and Drug Administration)

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of the MED-Project or the producers participating in the MED-Project Product Stewardship Plan.

CHECK THE PACKAGE

CONVENIENT KIOSKS

MAIL-BACK

TAKE-BACK EVENTS

[www.med-project.org/SF](http://www.med-project.org/SF)

## DISPOSAL OPTIONS

## What items can I dispose of?

## DISPOSAL OPTIONS

**1 CHECK THE PACKAGE**

If there are specific instructions for disposal on the label, package or package insert, please follow those instructions.

**ACCEPTED:**  
MEDICATIONS IN ANY DOSAGE FORM, EXCEPT FOR THOSE LISTED BELOW, IN THEIR ORIGINAL CONTAINER OR SEALED BAG.

If transferring medications to a sealed bag, please be sure to recycle all remaining packaging.

**3 MAIL-BACK**

Mail-Back Services for unwanted medicine are available to differentially-abled or home-bound residents upon request. Visit [www.med-project.org/SF](http://www.med-project.org/SF) to order a mail-back package.

**2 CONVENIENT KIOSKS**

To find convenient kiosks in your area, visit [www.med-project.org/SF](http://www.med-project.org/SF) for more information. Mail-back package distribution locations may also be available in your area.

**NOT ACCEPTED:**  
HERBAL REMEDIES, VITAMINS, SUPPLEMENTS, COSMETICS, OTHER PERSONAL CARE PRODUCTS, COMPRESSED CYLINDERS, AEROSOLS, INHALERS, MEDICAL DEVICES, SHARPS, ILLICIT DRUGS, IODINE-CONTAINING MEDICATIONS.

**4 TAKE-BACK EVENTS**

Local take-back events offer residents a free and convenient way to dispose of expired or unwanted medicines. Visit [www.med-project.org/SF](http://www.med-project.org/SF) for information on events in your area.

To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials before using any of the disposal options listed above.

**Technical Review:**

LA County's Proposed Pharmaceutical and Sharps Takeback Program

**Date:**

October 12, 2017

**Review Provided by:**

Angela L. Batt, Ph.D.

- Dr. Batt received her Ph.D. in Environmental Analytical Chemistry from the University at Buffalo in 2006.
- She has been conducting research as a federal scientist for 11 years studying environmental chemical contaminants, and has published 24 peer reviewed publications.
- The views expressed in this review are those of Dr. Batt, and do not necessarily represent the views of her agency or the United States.

**Summary:**

My area of technical expertise is studying the occurrence of active pharmaceutical ingredients in the environmental water cycle, and estimating exposures to humans and the aquatic ecosystem from environmental concentrations of pharmaceuticals. I have reviewed the documents provided pertaining to the proposed pharmaceutical and sharps takeback program, and my comments are focused on the area of the proposal where my area of expertise would be beneficial, namely the environmental data, information, and references supporting that information. Overall, I found the environmental information to be very clear, easy to follow, and a correct interpretation of our current understanding of the issue of pharmaceuticals and their pathways into the environment. The interpretation of the literature was correct, appropriate references were cited, and the stated conclusions were supported by these references, with one minor exception that is specifically noted below.

There are many studies that report the presence of pharmaceuticals in the aquatic environment, typically at concentrations from low ng/L up to high µg/L. The USGS and the U.S. EPA have conducted the most comprehensive national surveys of these compounds in U.S. wastewater, surface water, and drinking water, and those references are noted below in response to Question 1. Assessing the environmental impacts of pharmaceuticals has proven to be a complicated issue. Based on measured concentrations widely reported in drinking water, surface water, and wastewater, the risks to humans from consuming pharmaceuticals at these concentrations is very low. To put this into perspective, it would take a person anywhere from roughly a year to *tens of thousands of years* of drinking 2L of water a day to consume a single prescribed dose of a pharmaceutical at the concentrations typically measured in wastewater or drinking water.

However, assessing exposure and the resulting risks to aquatic organisms, such as fish, invertebrates, bacteria ext., and the wildlife that consume those aquatic organisms is a much more complicated issue. There are some studies that have been published highlighting the possible environmental impacts that pharmaceuticals may have. In the past decade, there have been several studies surrounding the investigation of diclofenac residues in treated cattle and goats as the cause of the decline, and almost extinction, of the vulture populations in Asia (see Reference 10 below). Although this exact scenario is unlikely to occur in the United States because of the different approved uses of diclofenac, it is an example of how one species can unexpectedly display a very different sensitivity to a chemical. Another example of reported effect would be found in the exposure of fish to 17α-ethynylestradiol, which is a synthetic

estrogen prescribed as an active ingredient in many birth control pills. Exposure of a studied fish population to low ng/L of 17 $\alpha$ -ethynylestradiol led to the feminization of male fish and altered reproduction (Reference 11 below).

More research is currently needed to provide reliable sub-lethal effect level data at all environmentally-relevant concentrations for aquatic life across the full range of species. This research is going to be very time consuming, expensive, and difficult to complete. And often, by the time a problem is observed, the impacts to an ecological community can be devastating. When this much uncertainty in effect levels exists, preventing environmental contamination by identifying point sources of contamination pathways, and implementing reasonable solutions to limit those sources of chemicals from entering the environment in the first place is almost always a much more cost effective approach than trying to address problems after they have occurred. Because one of the pathways of pharmaceuticals into the environment is the disposal of surplus drugs into the sewage system or landfills, drug-take back programs do provide a simple solution for reducing the amount of these chemicals that enter the environment at the source.

### Minor comments on document:

1. Page 6, paragraph 2, under “Environmental Documentation” states that “*There is a growing body of evidence that when drugs enter the waste stream through the sewer system, trash, and/or septic systems, they have a deleterious impact on the environment, including the water supply system.*”

I felt as though this statement was a little strong, and there may not be enough data at this time to support this conclusion just yet. There are many detections of pharmaceuticals in the water supply, however, risks to humans from concentrations typically reported in drinking water or other parts of the water supply would be very low (References 1-3 below). There is still some concern for exposure to aquatic life, wild life, and other ecosystem organisms, however, which I have addressed in-depth in the response to Questions 2 below. I would suggest revising this statement to something along the lines of “*There has been a growing concern that when drugs enter the waste stream through the sewer system, trash, and/or septic systems, they may have a deleterious impact on the environment, including the water supply system, as pharmaceuticals are inherently designed to cause a biological response in an organism.*”

1. Furlong, E. T., **Batt, A. L.**, Glassmeyer, S. T., Noriega, M. C., Kolpin, D. W., Mash, H., Schenck, K. M. Nationwide reconnaissance of contaminants of emerging concern in source and treated drinking waters of the United States: Pharmaceuticals. *Science of The Total Environment* **2017**, 579, 1629-1642.
2. Benson, R., Conerly, O. D., Sander, W., Batt, A. L., Boone, J. S., Furlong, E. T., Glassmeyer, S. T., Kolpin, D. W., Mash, H. E., Schenck, K. M., Simmons, J. E. Human health screening and public health significance of contaminants of emerging concern detected in public water supplies. *Science of The Total Environment* 2017, 579, 1643-1648.
3. Kostich, M. S., **Batt, A. L.**, Lazorchak, J. M. Concentrations of prioritized pharmaceuticals in effluents from 50 large wastewater treatment plants in the US and implications for risk estimation. *Environmental Pollution* **2014**, 184, (0), 354-359.

2. There needs to be a consistent format for references in the document. It doesn't matter which format is used, it just needs to be the same format so that readers can locate a reference if needed. Additionally, a few references do not have adequate information included. For example, page 255 (Bibliography, page 3), the two references at the bottom (Kolpin and Kostich) are journal articles, but the journal name and/or volume and page numbers were not included.
3. I think the document would benefit from adding a few bullets discussing some of the studies that have reported observed effects in the ecosystem, and I have included some suggestions below in the response to Question 4.

### Response to specific questions:

#### 1. Identify any relevant existing studies that quantify chemical components of pharmaceutical and sharps waste entering the water stream.

Response: I am not as familiar with the quantification of sharps in the environment, however, there have been many studies that have reported the presence of pharmaceuticals in the water system of the United States. Typical concentrations of the compounds in the water system range from low ng/L up to high µg/L, although occasionally they are found at higher concentrations near point sources, such as health care facilities or near pharmaceutical industries. Many of those studies have been cited in this document, but here is a list of the most comprehensive studies published that provide national scale data on the presence of pharmaceuticals in U.S. wastewater, surface water, and drinking water:

4. Paul M. Bradley, Celeste A. Journey, Kristin M. Romanok, Larry B. Barber, Herbert T. Buxton, William T. Foreman, Edward T. Furlong, Susan T. Glassmeyer, Michelle L. Hladik, Luke R. Iwanowicz, Daniel K. Jones, Dana W. Kolpin, Kathryn M. Kuivila, Keith A. Loftin, Marc A. Mills, Michael T. Meyer, James L. Orlando, Timothy J. Reilly, Kelly L. Smalling, and Daniel L. Villeneuve. Expanded Target-Chemical Analysis Reveals Extensive Mixed-Organic-Contaminant Exposure in U.S. Streams. *Environmental Science & Technology* **2017** 51 (9), 4792-4802.
5. Furlong, E. T., **Batt, A. L.**, Glassmeyer, S. T., Noriega, M. C., Kolpin, D. W., Mash, H., Schenck, K. M. Nationwide reconnaissance of contaminants of emerging concern in source and treated drinking waters of the United States: Pharmaceuticals. *Science of The Total Environment* **2017**, 579, 1629-1642.
6. **Batt, A. L.**, Kincaid, T. M., Kostich, M. S., Lazorchak, J. M., Olsen, A. R. Evaluating the extent of pharmaceuticals in surface waters of the United States using a National-scale Rivers and Streams Assessment survey. *Environmental Toxicology and Chemistry* **2016**, 35, (4), 874-881.
7. Kostich, M. S., **Batt, A. L.**, Lazorchak, J. M. Concentrations of prioritized pharmaceuticals in effluents from 50 large wastewater treatment plants in the US and implications for risk estimation. *Environmental Pollution* **2014**, 184, (0), 354-359.
8. Kostich, M. S., **Batt, A. L.**, Glassmeyer, S. T., Lazorchak, J. M. Predicting variability of aquatic concentrations of human pharmaceuticals. *Science of The Total Environment* **2010**, 408, (20), 4504-4510.
9. Kolpin, D.W., Furlong, E.T., Meyer, M.T., Thurman, E.M., Zaugg, S.D., Barber, L.B., Buxton, H.T. Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999–2000: A National Reconnaissance. *Environmental Science & Technology* **2002** 36 (6), 1202-1211.

**2. Explain whether pharmaceuticals and sharps are causing an impact to the environment, describe these impacts, and indicate if the impacts are short term or expected to be long-term.**

Response: Assessing the environmental impact(s) of pharmaceuticals is a complicated issue. Pharmaceuticals in the environment have been of public and scientific concern because unlike some other environmental contaminants, they are specifically designed to cause a biological response in an organism. Pharmaceuticals are studied in mammals, such as rats, mice, and humans before they are approved by the FDA for prescription use, and there is a considerable amount of information on their dose/response, mode of action, metabolism, and elimination from the body. That information can be used to estimate risks posed to humans and other parts of the ecosystem. Based on measured concentrations widely reported in drinking water (References 1 and 2) (and even wastewater Reference 3), the risks to humans from consuming pharmaceuticals at these concentrations is very low. To put this into perspective, it would take a person anywhere from roughly a year to *tens of thousands of years* of drinking 2L of water a day to consume a single typical prescribed dose of a pharmaceutical at the concentrations we have measured in environmental waters (See Reference 3 above).

However, exposure and assessing the risks to aquatic organisms, such as fish, invertebrates, bacteria ext., and the wildlife that consume those aquatic organisms is a much more complicated issue. Some effect endpoints, such as death, are straight forward to measure. But other endpoints, such as behavioral changes that affect an organism's ability to reproduce or catch prey and feed, can be more difficult to measure and determine the long term effects on a community. Furthermore, different organisms and species can display very different sensitivities to the same chemicals.

There are some studies that have been published highlighting the possible environmental impacts that pharmaceuticals may have. In the past decade, there have been several studies surrounding the investigation of diclofenac residues in treated cattle and goats as the cause of the decline, and almost extinction, of the vulture populations in Asia (see Reference 10 below as one of the earliest reports on the issue). Diclofenac is not approved for the same uses in the United States, and concentrations in waterways would be expected to be lower than in recently treated animals, but this is an example of how some species can display a very different sensitivity to a chemical with devastating consequences.

Another important example of observed effects would be found in the exposure of fish to a synthetic estrogen. Kidd et al (Reference 11) conducted a 7-year, whole-lake experiment at an experimental lake area in Ontario, Canada. This study showed that chronic exposure of fathead minnow (a species of fish) to low concentrations (5–6 ng/L) of 17 $\alpha$ -ethynylestradiol (the main ingredient in many birth control pills) led to the feminization of males of the exposed fish, altered reproduction, which ultimately led to a near extinction of this species from the lake.

Additionally, some questions have been raised as to how environmental concentrations of antibiotics may contribute to the development of antibiotic resistant bacteria. Although at this point it does not look like wastewater or surface water concentrations of antibiotics would directly select for antibiotic resistant bacteria, there have been recent studies that suggested environmentally relevant antibiotic concentrations (including sulfamethoxazole at a water concentration of 500 ng/L) can induce a variety of functional shifts in river bacterial community composition, which may in the long term lead to a disruption of important ecosystem processes, such as nutrient cycling.



More research is currently needed to provide reliable sub-lethal effect level data at all environmentally-relevant concentrations for aquatic life across the full range of species. This research is going to be very time consuming, expensive, and difficult to complete.

10. Oaks, J. Lindsay, Martin Gilbert, Munir Z. Virani, Richard T. Watson, Carol U. Meteyer, Bruce A. Rideout, H. L. Shivaprasad, Shakeel Ahmed, Muhammad Jamshed Iqbal Chaudhry, Muhammad Arshad, Shahid Mahmood, Ahmad Ali and Aleem Ahmed Khan. Diclofenac residues as the cause of vulture population decline in Pakistan. *Nature* 427, 630-633 (12 February 2004); doi:10.1038/nature02317
11. Kidd, KA, Blanchfield, PJ, Mills, KH, Palace, VP, Evans, RE, Lazorchak, JM, and Flick, RW. 2007. Collapse of a fish population after exposure to a synthetic estrogen. *Proc Natl Acad Sci USA* 104: 8897-8901.
12. Yergeau, E, Sanschagrín, S, Waiser, MJ, Lawrence, JR, and Greer, CW. 2012. Sub-inhibitory concentrations of different pharmaceutical products affect the meta-transcriptome of river biofilm communities cultivated in rotating annular reactors. *Environmental Microbiology Reports* 4: 350-359.

**3. Assess whether a reduction in the amount of pharmaceuticals and sharps waste entering the environment will have an impact on the environment.**

As mentioned above, assessing the environmental impacts of pharmaceuticals is a complicated issue, and much research needs to be done to determine effect levels for many drugs across the possible full range of aquatic organisms and wildlife. However, this incredibly time consuming and ultimately expensive research will take years, if not decades, to complete. And often, by the time a problem is observed, the impacts to an ecological community can be devastating. When this much uncertainty in effect levels exists, preventing environmental contamination by identifying point sources of contamination pathways, and implementing reasonable solutions to limit those sources of chemicals from entering the environment in the first place is almost always a much more cost effective approach than trying to address problems after they have occurred.

**4. Please review environmental studies referenced in the May 3, 2016 Board Letter and all attachments. Determine if findings from studies not referenced in the Board Letter should be considered. Summarize if the findings found in these additional studies support or do not support the LAC ordinance.**

Response: It would be beneficial to reference a few more studies on the effects of pharmaceuticals in the environment. The first three studies below have been noted above, but here is a list of references with some preliminary information of the effects of pharmaceuticals in the environment on wildlife and aquatic life that may be considered. It is important to note, however, that there is still uncertainty in the ecological effects cause by environmental concentrations of pharmaceuticals, and more work is needed to create a larger body of evidence. Some of the endpoints can be difficult to measure, and some of these reported effects occur at concentrations above what we typically see in the environment. However, when this much uncertainty in effect levels exists, preventing environmental contamination by identifying point sources of contamination pathways, and implementing reasonable solutions to limit those sources of chemicals from entering the environment in the first place is almost always a much more cost effective approach than trying to address problems after they have occurred. Because one of the obvious pathways of pharmaceuticals into the environment is the disposal of surplus drugs into the sewage system or landfills, drug-take back programs do provide a

simple solution for reducing the amount of these chemicals that enter the environment at the source.

- Oaks, J. Lindsay, Martin Gilbert, Munir Z. Virani, Richard T. Watson, Carol U. Meteyer, Bruce A. Rideout, H. L. Shivaprasad, Shakeel Ahmed, Muhammad Jamshed Iqbal Chaudhry, Muhammad Arshad, Shahid Mahmood, Ahmad Ali and Aleem Ahmed Khan. Diclofenac residues as the cause of vulture population decline in Pakistan. *Nature* 427, 630-633 (12 February 2004); doi:10.1038/nature02317
- Kidd, KA, Blanchfield, PJ, Mills, KH, Palace, VP, Evans, RE, Lazorchak, JM, and Flick, RW. 2007. Collapse of a fish population after exposure to a synthetic estrogen. *Proc Natl Acad Sci USA* 104: 8897-8901.
- Yergeau, E, Sanschagrin, S, Waiser, MJ, Lawrence, JR, and Greer, CW. 2012. Sub-inhibitory concentrations of different pharmaceutical products affect the meta-transcriptome of river biofilm communities cultivated in rotating annular reactors. *Environmental Microbiology Reports* 4: 350-359.
- Zenker, A, Cicero, MR, Prestinaci, F, Bottoni, P, and Carere, M. 2014. Bioaccumulation and biomagnification potential of pharmaceuticals with a focus to the aquatic environment. *Journal of Environmental Management* 133: 378-387.
- Lamichhane, K, Garcia, SN, Huggett, DB, DeAngelis, DL, and La Point, TW. 2014. Exposures to a selective serotonin reuptake inhibitor (SSRI), sertraline hydrochloride, over multiple generations: Changes in life history traits in *Ceriodaphnia dubia*. *Ecotoxicology and Environmental Safety* 101: 124-130.
- Bisesi Jr, JH, Bridges, W, and Klaine, SJ. 2014. Effects of the antidepressant venlafaxine on fish brain serotonin and predation behavior. *Aquatic Toxicology* 148: 130-138.
- Gonzalez-Rey, M, Mattos, JJ, Piazza, CE, Bainy, ACD, and Bebianno, MJ. 2014. Effects of active pharmaceutical ingredients mixtures in mussel *Mytilus galloprovincialis*. *Aquatic Toxicology* 153: 12-26.
- Schultz, MM, Painter, MM, Bartell, SE, Logue, A, Furlong, ET, Werner, SL, and Schoenfuss, HL. 2011. Selective uptake and biological consequences of environmentally relevant antidepressant pharmaceutical exposures on male fathead minnows. *Aquatic Toxicology* 104: 38-47.

**FINAL REPORT**

**Pharmaceuticals in the aquatic environment:  
Occurrence and toxicity**

**K.A. Maruya and A.C. Mehinto**

**Southern California Coastal Water Research Project Authority**

**submitted to**

**M. Pantoja and P. Holland**

**Los Angeles County Department of Public Works**

**10 March 2017**



## Executive Summary

1. Have pharmaceuticals been detected in the environment?

Yes, hundreds if not thousands of scientific studies have reported on the detection of pharmaceuticals in the environment. Traces of pharmaceuticals are frequently detected in surface water, groundwater and untreated and treated drinking water. In addition, many studies have shown that the same drugs are found at relatively higher concentrations in discharged effluent from wastewater treatment plants (WWTPs), in septic system and landfill leachates, and even in storm water runoff. These studies clearly identify the connection between water resources and regulated and non-regulated sources of pharmaceuticals.

2. Explain whether pharmaceuticals are causing an impact to the environment and what these impacts are? If there are impacts, are they short term or expected to be long-term?

Yes, there is scientific consensus that pharmaceuticals have caused impact to the environment. Diclofenac, an anti-inflammatory medicine, was implicated in causing widespread vulture mortality in Asia and Africa. There is also strong evidence that ethynyl estradiol (EE2), a birth control drug, can cause feminization of fish leading eventually to population decline in subsequent generations. The cases of diclofenac and EE2 suggest that long-term impacts are possible for terrestrial and aquatic biota subjected to prolonged exposure to pharmaceuticals.

3. Would reducing the amount of pharmaceuticals from entering the environment have an impact to the environment?

Yes, as evidenced in the case studies for diclofenac and EE2, restrictions and/or removal of pharmaceuticals resulted in recovery of some of the afflicted populations. Although no clear impacts due to drugs have been reported in the aquatic environment, it can be surmised from these lessons that reducing input of pharmaceuticals into receiving waters could prevent, or certainly reduce the likelihood of impacts. Whereas restrictions levied on individual drugs can be effective, the occurrence of multiple drugs that share common modes of therapeutic activity point to the potential shortcomings of managing drugs on a case-by-case basis.

4. Are there any studies that were not referenced in the above documents that should be considered by the Working Group?

Yes, there are additional studies on the occurrence and potential for impacts from pharmaceuticals in the aquatic environment that might be of interest. New pharmaceutical monitoring data at the regional and national scales are now publicly available. Studies that assess the impacts of chemical mixtures also deserve attention to better understand how they impact aquatic health. Long-term studies provide valuable information on the effects of low level pharmaceuticals, and the potential for recovery of impacted organisms once levels are reduced. New monitoring and assessment tools are being developed and/or adapted to assess the long-term effects of bioactive chemicals, including pharmaceuticals, on aquatic systems.

## Background

Pharmaceuticals, including prescription, non-prescription, brand name and generic “drugs”, are a class of so-called contaminants of emerging concern (CECs) that are being increasingly detected in the environment. Separate from health supplements such as vitamins, minerals, substances contained in natural products, and synthetic chemicals in personal care products (e.g. lotions, sunscreens, toothpaste, hair care formulations), drugs represent a wide variety of therapeutic classes (e.g. anti-inflammatory, lipid regulating and beta blocking drugs) and chemical structures are available to the public.

Whether applied to and/or consumed by human or non-human targets, or disposed of unused, drugs have found their way into our waterbodies. Increasingly sensitive sampling and analytical methods can detect their presence in water at exceedingly low concentrations, i.e. at less than parts per quadrillion (nanogram per liter). Several pathways from the prescription bottle to the coastal ocean (“cradle to grave”) are possible, with discharge in treated domestic wastewater as one of the primary sources to our receiving waters, including both surface and groundwater resources. Leachate from septic systems and landfills, and even storm water runoff in urban areas contain measurable amounts of pharmaceuticals.

To combat the unnecessary input of drugs into the environment, government agencies, including several counties in California, have implemented drug disposal programs designed to reduce the amount of drugs available for unintentional discharge into waterbodies. The County of Los Angeles recently considered an ordinance (<http://file.lacounty.gov/SDSInter/bos/supdocs/103374.pdf>) to effect the collection of unused pharmaceuticals. One of the stated benefits in the ordinance is the protection of beneficial uses of water resources potentially impacted by disposal of unused drugs. Loosely translated, the ordinance, citing several scientific studies, points to the possibility of detrimental impacts to water quality should drugs continue to be introduced into our waterways.

In response to the request from LACPW staff to vet statements contained in the ordinance pertaining to the effects of drugs on the aquatic environment, this report summarizes the state of the science of the occurrence and toxicity of pharmaceuticals in the aquatic environment.

## Objectives

The investigators addressed the following questions, posed by LACPW staff:

1. Have pharmaceuticals been detected in the environment?
2. Explain whether pharmaceuticals and sharps are causing an impact to the environment and what these impacts are? If there are impacts, are they short term or expected to be long-term?
3. Would reducing the amount of pharmaceuticals from entering the environment have an impact to the environment?
4. Are there any studies that were not referenced in the above documents that should be considered by the Working Group?

## Approach

In 2009, the State of California commissioned a panel of experts, to make recommendations on monitoring of constituents of emerging concern (CECs) in recycled water, and subsequently in ambient waters impacted by discharges regulated under the Porter-Cologne (Clean Water) Act by the State Water Board (SWB). This panel, known hereafter as the “CEC Panel”, endorsed and performed a risk-based assessment to identify CECs worthy of monitoring. To accomplish this task, the CEC Panel compiled a database of CECs, which included several common use pharmaceuticals, in wastewater treatment plant (WWTP) effluent. The Panel also commissioned studies to investigate the occurrence of CECs in other regulated contaminant sources, such as storm water runoff. Their final report identified two pharmaceuticals – diclofenac and ibuprofen – for monitoring in waterways in which flow is dominated by WWTP effluent (Anderson et al. 2012). The database compiled by the Panel served as the basis for occurrence and toxicity data presented in this report.

To further establish the current state-of knowledge on the topic, the authors performed a series of computerized literature searches using the SCOPUS and PubMed scientific databases, which search a wide range of publication types, including journal articles, reports, book chapters, books and meeting abstracts. Because the authors utilized the information compiled by the CEC Panel in their 2012 report, searches on drug occurrence were conducted post-2011. Searches on toxicity were not constrained by date to preclude missing information on new or novel drugs, i.e. those not previously identified by the CEC Panel.

To represent drugs, the keywords “DRUG#” OR “MEDICINE” OR “PHARMA#” were used.

For occurrence studies, the keywords “OCCUR#” OR “CONCENTRATION#” OR “LEVEL#” OR “ENVIRONMENT#” OR “WATER#” OR “SEDIMENT#” OR “TISSUE#” OR “GROUNDWATER#” OR “LEACHATE#” were searched.

For toxicity studies, the keywords “TOXIC” OR “EFFECT” OR “CHRONIC” OR “FISH” OR “INVERTEBRATE” OR “AQUATIC” OR “ENVIRONMENT” were searched.

To search for time series or trend studies, the keywords “TEMPORAL#” OR “TREND#” OR “TIME SERIES” were used.

To limit the search geographically, the keywords “CALIFOR#” OR “US” OR “USA” were used.

## Results

### 1. Have pharmaceuticals been detected in the environment?

Since the landmark survey of PPCPs in U.S. surface waters demonstrated their ubiquity (Kolpin et al. 2002), thousands of peer-reviewed articles published over the past 15 years have documented their presence in source and receiving waters worldwide. Waterbodies investigated in these studies include ponds, lakes, rivers, embayments, estuaries, coastal waters and the ocean. Groundwater, septic systems, landfill leachate and wastewater treatment plant (WWTP) effluent have been targeted as sources in these investigations. Brief summaries of key studies are included below:

#### Monitoring Strategies for Chemicals of Emerging Concern (CECs) in California's Aquatic Ecosystems. Recommendations of a Science Advisory Panel. Final Report (Anderson et al. 2012).

Summary: With assistance and input from the discharger and water community in California, the Panel compiled a database of CEC occurrence in final wastewater treatment plant (WWTP) effluent, and reported maximum and 90<sup>th</sup> percentile concentrations. The Panel screened the quality of data made available, by analyzing the performance of QA/QC measures instituted by the submitting agencies. A summary of these concentrations for commonly detected drugs is shown in **Table A-1**.

#### Screening studies for CECs in effluent dominated waterways in the Los Angeles region. (Maruya 2012, 2015; Sengupta et al. 2014; Maruya et al. 2016).

Summary: A series of investigations on the occurrence of CECs, including pharmaceuticals, in effluent dominated waterways and coastal embayments in the Los Angeles (CA) region were undertaken beginning in 2010. Water samples from the Los Angeles, San Gabriel and Santa Clara river systems, each of which receive discharge from multiple WWTPs year-round, were collected during two dry season sampling events and analyzed by research grade analytical methods. River stations were located upstream and immediately downstream from WWTPs. Maximum concentrations of 13 pharmaceuticals, including acetaminophen, carbamazepine, diazepam, diclofenac, dilantin, 17 $\alpha$ -ethinylestradiol (EE2), fluoxetine, gemfibrozil, ibuprofen, meprobamate, sulfamethoxazole and trimethoprim, were detected at stations immediately below discharge points from WWTPs (**Table A-1**). Most of the pharmaceuticals targeted were frequently detected in water samples from these systems, with the exception of EE2.

#### Nationwide reconnaissance of pharmaceuticals in source and drinking waters (Furlong et al. 2017).

Summary: Scientists at the U.S. Geological Survey and U.S. Environmental Protection Agency teamed up to analyze source (influent) and treated (effluent) water from 25 drinking water treatment plants (DWTPs) across the USA. This study, spanning the period 2007-2012, investigated more than 100 pharmaceuticals in two phases, the second of which greatly expanded the list of drugs targeted for analysis (118 in Phase II vs. 24 in Phase I). Maximum concentrations reported for some of the more common drugs analyzed in environmental studies are included in **Table A-1**. Roughly half of the drugs targeted were detected in at least 1

sample. In Phase I, the most commonly detected drugs in source waters were bupropion (89%), carbamazepine (78%), venlafaxine (78%), caffeine (67%), and sulfamethoxazole (56%). The summed concentrations of all quantified pharmaceuticals varied between 0 and 270 ng/L, with a median concentration of 11.8 ng/L. The median number of total pharmaceutical detections in all Phase II source-water samples was eight, reflecting that pharmaceuticals and other CECs typically occur as mixtures. Thirty-seven different pharmaceuticals were present in quantifiable concentrations; 13 pharmaceuticals were quantified 3 or more times in different DWTPs; and 24 pharmaceuticals were quantified in only 1 or 2 source water samples. Excluding lithium (which occurred in µg/L concentrations), individual pharmaceutical concentrations ranged between 0.02 to 163 ng/L. Sulfamethoxazole, metoprolol, carbamazepine, and hydrochlorothiazide were the most frequently detected pharmaceuticals in source water samples at maximum concentrations of 160, 38, 36, 0.29, and 67 ng/L, respectively. Pharmaceuticals detected in Phase II source-water samples typically fall below 36 ng/L; except for lithium (75th percentile concentration of 33 µg/L).

#### The fate of PPCPs, EDCs, metabolites and illicit drugs in a South African WWTP and environmental waters (Archer et al. 2017).

Summary: In 2015, a study was performed to investigate the fate, occurrence and risk potential of 90 CECs, including more than 30 pharmaceuticals and their transformation products, above and below a WWTP discharging into a river in South Africa. Average ( $\pm$  standard deviation) mass loadings of drugs into the WWTP ranged from  $2.6 \pm 2.0$  g/d for azithromycin to  $10500 \pm 3220$  g/d for acetaminophen, whereas mass loadings discharged into the river from the WWTP averaged between  $<0.2$  g/d (several drugs) and  $95.1 \pm 5.6$  g/d, illustrating the variable recalcitrance of pharmaceuticals when subject to conventional staged physicochemical and biological wastewater treatment processes. Average pharmaceutical concentrations downstream of the WWTP ranged from  $6.4 \pm 3.4$  ng/L for azithromycin to  $1460 \pm 509$  ng/L for diclofenac (**Table A-1**). Comparing the concentrations of drugs measured in river water to predicted no effect concentrations (PNECs), the authors concluded that carbamazepine, diclofenac and ibuprofen be considered as priority constituents for monitoring due to their regular occurrence and potential to impact aquatic health.

#### Pharmaceuticals in groundwater aquifers of the midwestern United States (Dodgen et al. 2017).

Summary: Fifty-eight samples of groundwater from the Salem Plateau in southwestern Illinois, a mixed used landscape where septic systems are prevalent, were collected between 2013 and 2015 and analyzed for 12 PPCPs. One or more PPCPs was quantified in 89% of samples, with a median detection of 3 compounds. The sum of all PPCPs ranged from below detection limits to 142 ng/L, with a median sum of 4.60 ng/L. The greatest number of detections (7) and maximum concentration (142 ng/L) were found in the same sample. Gemfibrozil was the most frequently detected pharmaceutical (119 ng/L max)(57% detection). Six or more PPCPs were detected in at least 10% of samples, namely trimethoprim (29%, max 4.73 ng/L), naproxen (22%, max 49.9 ng/L), carbamazepine (21%, max 2.11 ng/L), caffeine (16%, max 43.0 ng/L), sulfamethoxazole (12%, max 8.11 ng/L), and fluoxetine (10%, max 4.01 ng/L) (**Table A-1**). This study is indicative of the ubiquitousness of drugs in groundwater, an important source of drinking water around the world.



Pharmaceuticals in groundwater impacted by septic systems (Schaidler et al. 2016).

Summary: Drinking water samples from 20 shallow wells in Cape Cod, MA (USA) were collected in 2011 and tested for 12 pharmaceuticals. Two drugs (carbamazepine and sulfamethoxazole) were detected in at least one-quarter of wells tested, whereas several others, including gemfibrozil, meprobamate, primidone and trimethoprim, were more infrequently detected. Maximum concentrations of the detected drugs ranged from 1 ng/L (trimethoprim) to 60 and 62 ng/L for sulfamethoxazole and carbamazepine, respectively. Based on the correlation of measured septic indicators (nitrate, boron) with the occurrence of drugs, the authors concluded that septic systems were the likely source of pharmaceuticals in these samples, but could not rule out the influence of landfill leachate.

Endocrine disrupting chemicals in fish, seawater and WWTP effluent discharged to the coastal ocean. (Vidal-Dorsch et al. 2012; Maruya et al. 2012).

Summary: Due to concerns over chronic, long-term impacts to aquatic life found near ocean outfalls discharging large volume of treated wastewater into the southern California Bight, an integrated study was commissioned in 2008 to investigate the sources, occurrence and effects of endocrine disrupting chemicals (EDCs) present in the marine environment. SCCWRP and multiple agencies and universities teamed to document the occurrence of 56 CECs, including several pharmaceuticals in discharged WWTP effluent, seawater collected from the discharge zone near the bottom of the ocean and tissue of flatfish found in abundance on the seafloor in the outfall zones. Pharmaceuticals such as atenolol, gemfibrozil and naproxen, sulfamethoxazole and trimethoprim were detected at concentrations approaching 1000 ng/L in effluents from 5 different WWTPs, but concentrations in seawater, when detected, were several orders of magnitude lower (**Table A-1**), ostensibly due to the high degree of instantaneous dilution observed in these environments. Diazepam, a tranquilizer, was detected in 100% of hornyhead turbot livers, at mean and maximum concentrations of 56 and 110 ng/g, respectively.

Survey of CECs in mussels and seawater along the California coast. (Alvarez et al. 2014; Dodder et al. 2014; Maruya et al. 2014a, 2014b).

Summary: Mussels (*Mytilus* spp.) were collected at 68 stations along the California coast in 2009-10, and analyzed for 88 individual PPCPs using research grade methods. The 68 stations were selected to represent a cross-section of urbanized, open space and agricultural landscapes from the Oregon to International borders. Whereas most pharmaceuticals targeted were infrequently detected (i.e. in < 20% of samples), lomefloxacin (an antibiotic) and sertraline (an antidepressant) were detected in greater than 60% of mussel samples, at maximum concentrations of 170 and 5.5 ng/g, respectively. Analysis of passive sampling devices deployed at 11 of the 68 stations coast wide revealed the presence of cotinine (a metabolite of nicotine), carbamazepine, and trimethoprim, with the pharmaceuticals detected at 70% or more of the stations, at maximum concentrations up to 32 ng/L.

Pharmaceuticals in fish collected from effluent dominated rivers across the USA (Ramirez et al. 2009).

Summary: To determine if the occurrence of drugs in aquatic life was widespread, a national pilot study analyzed a suite of 24 pharmaceuticals in composited filet (muscle) and liver tissue from fish collected from 5 effluent dominated rivers across the USA in 2006. The analytical methods utilized were subject to strict quality assurance/quality control guidelines, as evidenced by surrogate recoveries ranging between 91 and 140%. Norfluoxetine, sertraline, diphenhydramine, diltiazem and carbamazepine were routinely detected, with concentrations of sertraline as high as 19 and 545 ng/g in filet and liver, respectively. Mean concentrations were mostly in the range of 0.1 to 10 ng/g for filet and 1 to 100 ng/g for liver, suggesting lipid content was an important factor. This study was among the first to demonstrate the widespread occurrence of commonly used consumer drugs in aquatic life.

Recent monitoring of CECs in Los Angeles area wastewater treatment plant effluent (2014 Constituents of Emerging Concern Monitoring Results, memo from A.T. Heil to C. Morris, dated 15 April 2015).

Summary: To comply with requirements set forth by the Los Angeles Regional Water Quality Control Board, the Los Angeles County Sanitation Districts (LACSD) embarked on a 1-year special study in 2014 to monitor a suite of pharmaceuticals in final effluent from 9 WWTPs that discharge treated effluent. Eight of the 9 WWTPs are tertiary plants that discharge to inland freshwater systems, whereas the remaining plant ("JWPCF") utilizes secondary treatment processes and discharges to the coastal ocean. Table 1 in the subject document lists maximum concentrations of individual CECs, including 13 pharmaceuticals, detected in final effluent from the 9 WWTPs, which are reproduced in **Table A-1**. Table 2 in the subject document categorized CECs by frequency of detection. Among the pharmaceuticals categorized as "always detected" were azithromycin, carbamazepine, diclofenac, Dilantin, gemfibrozil, meprobamate and sulfamethoxazole. Whereas many of the maximum concentrations across the 9 WWTPs are attributable to the JWPCF, some are not, illustrating the importance of source and other factors that influence treatment efficiency and removal of pharmaceuticals.

Pharmaceuticals in landfill leachate across the United States (Masoner et al. 2016).

Final leachates (i.e. leachate after storage or treatment processes) from 22 landfills in 12 states across the USA were collected in 2011-12 and analyzed for 90 prescription and 16 non-prescription pharmaceuticals. More than 50 drugs (43 prescription and 12 non-prescription) were detected in leachate samples, with the most frequently detected being lidocaine (91%, local anesthetic), cotinine (86%, nicotine degradate), carisoprodol (82%, muscle relaxant) and carbamazepine (77%, anticonvulsant). Concentrations of drugs spanned several orders of magnitude, ranging between ~100–10 000 ng/L for nonprescription pharmaceuticals and between ~10–10 000 ng/L for prescribed drugs. Carbamazepine was detected in 77% of samples with an estimated maximum concentration of 810 ng/L (**Table A-1**). Acetaminophen was found in 41% of samples, sometimes at exceedingly high concentrations (42,600 ng/L max). Moreover, pharmaceutical concentrations in leachate from active landfills were greater than those in leachate from closed, unlined landfills, and were also greater in untreated leachate compared with treated leachate.

A review of the occurrence of micropollutants in the aquatic environment and their fate and removal during wastewater treatment (Luo et al. 2014). This review provides summaries of drug concentrations reported in surface water and groundwater from around the world. Maximum concentrations extracted from Tables 4 and 5 from this article are entered in **Table A-1** for comparison to other media and sources of drugs in the environment. Some of the highest reported concentrations originate from studies abroad.

Emerging organic contaminants in groundwater: a review of sources, fate and occurrence. (Lapworth et al. 2012). This review provides box plots of CEC concentrations by source including landfill, septic tanks and WWTPs, as well as reported maximum concentrations of frequently occurring pharmaceuticals in groundwater from around the world (as Table 1). The latter data are entered in **Table A-1** for comparison to other media and sources of drugs in the environment.

2. Explain whether pharmaceuticals are causing an impact to the environment and what these impacts are? If there are impacts, are they short term or expected to be long-term?

Chemical-by-chemical risk assessment is a method frequently used to identify pharmaceuticals of concern. Employed by the CEC Panel (Anderson et al. 2012), this approach is based on a comparison between measured concentration of a pharmaceutical (MEC) in water or sediment and lowest effect concentration (LOEC) reported in an invertebrate or vertebrate species. These values are used to derive a monitoring trigger quotient (or hazard quotient calculated as MEC/LOEC). A quotient less than 1.0, (i.e.,  $MEC < LOEC$ ) indicates that the potential risk associated with a specific chemical based on currently available information is low. If the quotient is greater than 1.0 (i.e.,  $MEC > LOEC$ ), the chemical is assumed to pose a potential risk in the environment. The risk-based approach can also be applied to chemicals with limited occurrence and toxicity data. In this case, predicted environmental concentrations and predicted no-effect concentrations can be used to evaluate the potential toxicity (Schmitt et al. 2010). Both methods have shown comparable outputs leading to the conclusion that individual pharmaceuticals detected in the environment are not likely to cause toxicity. However, the assessment does not include the potential for mixture effects which is an important factor in the environment where pharmaceuticals and other occurring bioactive chemicals can act simultaneously on non-target species.

Despite the tremendous effort and resources invested in monitoring and assessment of aquatic systems, particularly those known to be impacted by human activity, there is little if any direct evidence to date that definitively show impacts due to the occurrence of pharmaceuticals. The single instance where a drug (diclofenac) was irrefutably shown to cause impacts to wildlife, described in more detail below, did not occur in the aquatic environment. Also described in more detail in the following, the landmark study that demonstrated the potential for aquatic impact due to very low concentrations of a synthetic hormone (EE2) was performed in Canadian lakes that were intentionally dosed with pure EE2, i.e. an artificial exposure scenario.

In the absence of direct evidence, there are dozens of studies that suggest impacts at exceedingly low levels are possible. The following summaries, taken from a cross-section of articles available through the peer-reviewed literature, describe such impacts.

The anti-inflammatory drug diclofenac responsible for the decline of vulture population in South Asia and Africa. (Oaks et al. 2004, Naidoo et al. 2009, Prakash et al. 2012)

Summary: Surveys on the mortality of several Asian and African Gyps vulture species showed that their populations had been rapidly declining since the 1990s. Consequently, these species were listed as critically endangered and studies were conducted to identify the source of the poisoning. Researchers found that vulture feeding on the carcasses of livestock treated with diclofenac died of renal failure. In 2004, Oaks et al. (2004) were able to replicate the levels of diclofenac residues and renal disease in Asian vulture fed with diclofenac-treated livestock. This study provided a direct correlation between diclofenac residues and mortality of the vulture. Other studies followed demonstrating the effects of the drug on other African vulture species. Six years after the drug was banned in South Asia, a new survey indicated that the mortality rates had slowed down and some populations were recovering.

Effects of long-term exposure to the synthetic estrogen ethinylestradiol resulted in the collapse of a fish population (Kidd et al. 2007, Blanchfield et al. 2015)

A 7-year whole-lake experiment conducted in Canada using low levels of ethynyl estradiol (5-6 ng/L) showed that prolonged exposure of fathead minnows impacted gonadal development resulting in the feminization of males (ovarian tissues in male testes also known as intersex) and altered egg production in females. Ultimately, the species became nearly extinct in the lake. After 7 years of ethynyl estradiol treatment, the researchers stopped adding the chemical and monitored the health of the remaining fish population for another 7 years. They reported that by the fourth-year post-treatment, testicular anomalies were no longer detected and the abundance of adult size fish had returned to pretreatment levels. Based on their observations, the authors stated that 'results suggest that wastewater treatment facilities that reduce discharges of estrogens and their mimics can improve the health of resident fish populations in their receiving environments'.

Laboratory studies suggest that chronic waterborne exposure to environmental pharmaceuticals can potentially impair fish health (Galus et al. 2013, Pelli and Connaughton 2015).

Summary: Carbamazepine and gemfibrozil are often detected in waterways. Researchers have shown that adult female zebrafish exposed to 1,000 ng/L of either of these pharmaceuticals for six weeks exhibited abnormal gonad histology. Within 10-15 days of exposure, both chemicals caused ovarian atresia resulting in a reduction of the number of eggs laid per female. Another study found that the antidepressant fluoxetine adversely impacted survival and normal avoidance behavior of juvenile guppies after 3 weeks of exposure to levels as low as 30 ng/L. The behavior of adult guppies was also altered and a delay in predator avoidance response was

reported. Based on the bioaccumulative properties of fluoxetine and the adverse effects observed at such low levels, the authors suggested that fluoxetine could impact the health of aquatic organisms in the environment.

3. Would reducing the amount of pharmaceuticals from entering the environment have an impact to the environment?

To address this question, the risk-based assessment carried out by the CEC Expert Panel was revisited using the updated occurrence and toxicity data in this report (**Tables A-1 and A-2**). Using reported maximum concentrations in different types of receiving waters, the risk or hazard quotient for two pharmaceuticals – diclofenac and fluoxetine – exceeded unity (**Table 1**). This indicates that diclofenac and fluoxetine would be among the highest priority for monitoring in receiving waters. In contrast, common drugs such as atenolol (a beta blocker), metformin (a pain killer) and the two antibiotics on the list exhibit very low hazard quotients (i.e.  $\ll 0.1$ ), suggesting that these would be lower priority drugs for aquatic monitoring. In between these extremes, drugs like carbamazepine, gemfibrozil and ibuprofen occur at high enough concentrations as to warrant a closer look, based on  $0.1 < HQ < 1.0$ . It is also no coincidence that carbamazepine, diclofenac, fluoxetine and gemfibrozil have the lowest toxicity thresholds among the examples in Table 1. Even an incremental increase in loading of these pharmaceuticals may result in greater exceedances of the hazard quotient, not in itself a direct indication of risk, but rather these screening values should be construed as an early warning system that additional input may result in observable impacts. Moreover, single chemical hazard quotients do not address the contribution of other, non-monitored drugs that act via common or similar modes of bioactivity, nor do they protect against synergism that may increase the potency of chemical mixtures (see also Question #2 above).

4. Are there any studies that were not referenced in the above documents that should be considered by the Working Group?

One of the most difficult challenges in justifying the effort to eliminate “drugs down the drain” is parsing out the amount of unused drugs that are disposed of and enter the aquatic waste stream, vs the amount of consumed drugs that are excreted by consumers and enter the same waste stream. A recent study by Petrie et al. (2016) takes advantage of stereochemistry and our ability to separate stereoisomers of certain drugs, in this case fluoxetine, using analytical instrumentation to identify pulses of drug input into waste streams, e.g. raw wastewater. By measuring the balance between stereoisomers of un-consumed and metabolized fluoxetine, it is now possible to employ enantiomeric fingerprinting to ascertain the degree of human excretion.

Exposure to multiple pharmaceuticals can exacerbate the toxicity and lower effect concentrations of the individual chemicals (Cleuvers 2004, Quinn et al. 2009, Painter et al. 2009, Schultz et al. 2012).

Summary: While chemical by chemical risk assessment and laboratory studies conducted with individual pharmaceutical indicate that environmental concentrations of individual pharmaceuticals may have little to no effect on fish health, studies conducted with pharmaceutical mixtures suggest that concentration addition and/or synergism may result in toxicity of the mixtures (Cleuvers et al. 2004, Painter et al. 2009). Examples of synergistic effects and mixture toxicity are described here. Schultz et al. (2012) reported that exposure of adult fathead minnows to the anti-biotic triclocarban (1.6 µg/L) altered their aggressive behavior. However, the effect concentration of triclocarban decreased to 179 ng/L when mixed with 560 ng/L of triclosan, another anti-biotic compound. Complex mixtures of pharmaceuticals with different modes of action can also act additively as evidenced by Quinn et al. (2009). In this study, the authors found that a complex pharmaceutical mixture containing anti-inflammatory drugs, lipid regulators, anti-convulsants and anti-biotics affected the morphology and behavior of a cnidarian species (related to sea anemone and jellyfish), and the individual drugs were present at concentrations 2-3 times lower than their individual toxicity threshold.

## Literature cited

### 1. Peer-Reviewed

\*Alvarez DA, Maruya KA, Dodder NG, Lao W, Furlong ET, Smalling KL. 2014. Occurrence of contaminants of emerging concern along the California coast (2009-10) using passive sampling devices. *Mar Pollut Bull* 81:347-354.

Anderson PD, Denslow ND, Drewes JE, Olivieri AW, Schlenk D, Scott GI, Snyder SA. 2012. Monitoring Strategies for Chemicals of Emerging Concern (CECs) in California's Aquatic Ecosystems. Recommendations of a Science Advisory Panel. Final Report. Southern California Coastal Water Research Project. Costa Mesa, CA. Technical Report 692.

Archer E, Petrie B, Kasprzyk-Hordern B, Wolfaardt GM. 2017. The fate of pharmaceuticals and personal care products (PPCPs), endocrine disrupting contaminants (EDCs), metabolites and illicit drugs in a WWTW and environmental waters. *Chemosphere* 174:437-446.

Blanchfield PJ, Kidd KA, Docker MF, Palace VP, Park BJ, Postma LD. 2015. Recovery of a wild fish population from whole-lake additions of a synthetic estrogen. *Environ Sci Technol* 49:3136-3144.

Cleuvers M. 2004. Mixture toxicity of the anti-inflammatory drugs diclofenac, ibuprofen, naproxen, and acetylsalicylic acid. *Ecotoxicol Environ Saf* 59:309-315.

\*Dodder NG, Maruya KA, Ferguson PL, Grace R, Klosterhaus S, La Guardia MJ, Lauenstein GG, Ramirez J. 2014. Occurrence of contaminants of emerging concern in mussels (*Mytilus* spp.) along the California coast and the influence of land use, storm water discharge, and treated wastewater effluent. *Mar Pollut Bull* 81:340-346.

Dodgen LK, Kelly WR, Panno SV, Taylor SJ, Armstrong DL, Wiles KN, Zhang Y, Zheng W. Characterizing pharmaceutical, personal care product, and hormone contamination in a karst aquifer of southwestern Illinois, USA, using water quality and stream flow parameters. *Sci Tot Environ*. 578:281-289.

Furlong ET, Batt AL, Glassmeyer ST, Noriega MC, Kolpin DW, Mash H, Schenck KM. 2017. Nationwide reconnaissance of contaminants of emerging concern in source and treated drinking waters of the United States: Pharmaceuticals. *Sci Tot Environ* 579:1629-1642.

Galus M, Kirischian N, Higgins S, Purdy J, Chow J, Ranganjan S, Li H, Metcalfe C, Wilson JY. 2013. Chronic, low concentration exposure to pharmaceuticals impacts multiple organ systems in zebrafish. *Aquat Toxicol* 32-133:200-211.

Kidd KA, Blanchfield PJ, Mills KH, Palace VP, Evans RE, Lazorchak JM, Flick RW. 2007. Collapse of a fish population after exposure to a synthetic estrogen. *Proc Natl Acad Sci USA* 104:8897-8901.

Kolpin DW, Furlong ET, Meyer MT, Thurman EM, Zaugg SD, Barber LB, Buxton HT. 2002. Pharmaceuticals, hormones and other organic wastewater contaminants in U.S. streams, 1999-2000: A national reconnaissance. *Environ Sci Technol* 36:1202-1211.

Lapworth DJ, Baran N, Stuart ME, Ward RS. 2012. Emerging organic contaminants in groundwater: a review of sources, fate and occurrence. *Environ Pollut* 163:287-303.

County Sanitation Districts of Los Angeles (LACSD). 2014 Constituents of Emerging Concern Monitoring Results, Memo from A.T. Heil to C. Morris, File No. 31-300.25, dated 15 April 2015.

Luo Y, Guo W, Ngo HH, Ngheim LD, Hai FI, Zhang J, Liang S, Wang XC. 2014. A review of the occurrence of micropollutants in the aquatic environment and their fate and removal during wastewater treatment. *Sci Tot Environ* 473-474: 619-641.

\*Maruya KA, Vidal-Dorsch D, Bay SM, Kwon JW, Xia K, Armbrust KL. 2012. Organic contaminants of emerging concern in sediments and flatfish collected near outfalls discharging treated wastewater effluent to the Southern California Bight. *Environ Toxicol Chem* 31:2683-2688.

Maruya KA, Dodder NG, Schaffner RA, Weisberg SB, Gregorio D, Klosterhaus S, Alvarez DA, Furlong ET, Kimbrough KL, Lauenstein GG, Christensen JD. 2014a. Refocusing Mussel Watch on contaminants of emerging concern (CECs): the California pilot study (2009-10). *Mar Pollut Bull* 81:334-339.

Maruya KA, Dodder NG, Weisberg SB, Gregorio D, Bishop JS, Klosterhaus S, Alvarez DA, Furlong ET, Bricker S, Kimbrough KL, Lauenstein GG. 2014b. The Mussel Watch California pilot study on contaminants of emerging concern (CECs): synthesis and next steps. *Mar Pollut Bull* 81:355-363.

Maruya KA, Dodder NG, Sengupta A, Smith DJ, Lyons JM, Heil AT, Drewes JE. 2016. Multi-media screening of contaminants of emerging concern (CECs) in coastal urban watersheds in southern California. *Environ Toxicol Chem* doi: 10.1002/etc3348.

Masoner JR, Kolpin DW, Furlong ET, Cozzarelli IM, Gray JL. 2016. Landfill leachate as a mirror of today's disposable society: Pharmaceuticals and other contaminants of emerging concern in final leachate from landfills in the conterminous united states. *Environ Toxicol Chem* 35:906-918. doi:10.1002/etc.3219.

Naidoo V, Wolter K, Cuthbert R, Duncan N. 2009. Veterinary diclofenac threatens Africa's endangered vulture species. *Regul Toxicol Pharmacol* 53:205-208.

Oaks JL, Gilbert M, Virani MZ, Watson RT, Meteyer CU, Rideout BA, Shivaprasad HL, Ahmed S, Chaudhry MJ, Arshad M, Mahmood S, Ali A, Khan AA. 2004. Diclofenac residues as the cause of vulture population decline in Pakistan. *Nature* 427:630-633.

Painter MM, Buerkley MA, Julius ML, Vajda AM, Norris DO, Barber LB, Furlong ET, Schultz MM, Schoenfuss HL. 2009. Antidepressants at environmentally relevant concentrations affect predator avoidance behavior of larval fathead minnows (*Pimephales promelas*). *Environ Toxicol Chem* 28:2677-2684.

Pelli M, Connaughton VP. 2015. Chronic exposure to environmentally-relevant concentrations of fluoxetine (Prozac) decreases survival, increases abnormal behaviors, and delays predator escape responses in guppies. *Chemosphere* 139:202-209.

Prakash V, Bishwakarma MC, Chaudhary A, Cuthbert R, Dave R, Kulkarni M, Kumar S, Paudel K, Ranade S, Shringarpure R, Green RE. 2012. The population decline of Gyps vultures in India and Nepal has slowed since veterinary use of diclofenac was banned. *PLoS One* 7:e49118.

Quinn B, Gagné F, Blaise C. 2009. Evaluation of the acute, chronic and teratogenic effects of a mixture of eleven pharmaceuticals on the cnidarian, *Hydra attenuata*. *Sci Total Environ* 407:1072-1079.



Petrie B, Youdan J, Barden R, Kasprzyk-Hordern B. 2016. New framework to diagnose the direct disposal of prescribed drugs in wastewater - A case study of the antidepressant fluoxetine. *Environ Sci Technol*. 50:3781-9. doi: 10.1021/acs.est.6b00291. Epub 2016 Mar 24.

Ramirez AJ, Brain RA, Usenko S, Mottaleb MA, O'Donnell JG, Stahl LL, Wathen Jb, Snyder BD, Pitt JL, Perez-Hurtado P, Dobbins LL, Brooks BW, Chambliss CK. 2009. The occurrence of pharmaceuticals and personal care products in fish: Results of a national pilot study in the United States. *Environ Toxicol Chem* 28:2587-2597.

Schaider LA, Ackerman JM, Rudel RA. 2016. Septic systems as sources of organic wastewater compounds in domestic drinking water wells in a shallow sand and gravel aquifer. *Sci Tot Environ* 547:470-481. doi:10.1016/j.scitotenv.2015.12.081.

Schmitt H, Boucard T, Garric J, Jensen J, Parrott J, Péry A, Römbke J, Straub JO, Hutchinson TH, Sánchez-Argüello P, Wennmalm A, Duis K. 2010. Recommendations on the environmental risk assessment of pharmaceuticals: Effect characterization. *Integr Environ Assess Manag* 6 Suppl:588-602.

Schultz MM, Bartell SE, Schoenfuss HL. 2012. Effects of triclosan and triclocarban, two ubiquitous environmental contaminants, on anatomy, physiology, and behavior of the fathead minnow (*Pimephales promelas*). *Arch Environ Contam Toxicol* 63:114-124.

\*Sengupta A, Lyons JM, Smith DJ, Heil A, Drewes JE, Snyder SA, Maruya KA. 2014. The occurrence and fate of chemicals of emerging concern (CECs) in coastal urban rivers receiving discharge of treated municipal wastewater effluent. *Environ Toxicol Chem* 33:350-358.

\*Vidal-Dorsch DE, Bay SM, Maruya KA, Snyder SA, Trenholm RA, Vanderford BJ. 2012. Contaminants of emerging concern in municipal wastewater effluents and marine receiving water. *Environ Toxicol Chem* 31:2674-2682.

## 2. Other

Maruya KA. 2012. Screening study for constituents of emerging concern (CECs) in selected freshwater rivers in the Los Angeles Region – Final Report. Southern California Coastal Water Research Project. Costa Mesa, CA. 66 pgs.

Maruya KA. 2015. Screening study for constituents of emerging concern (CECs) in selected freshwater rivers in the Los Angeles Region – Phase 2. Southern California Coastal Water Research Project. Costa Mesa, CA. 37 pgs.

\* cited in LACPW Ordinance (<http://file.lacounty.gov/SDSInter/bos/supdocs/103374.pdf>)

Table 1. Hazard quotients for drugs commonly detected in surface waters. The hazard quotient is defined as the ratio of maximum concentrations of drugs in surface water (or sources) to the lowest published aquatic toxicity threshold.

Drug	Class	CAS#	Occurrence		Toxicity LOEC (ng/L)	Hazard Quotient	
			Cw,max <sup>a</sup> (ng/L)	Cs,max <sup>b</sup> (ng/L)		Receiving	Source
acetaminophen	anti-inflammatory	103-90-2	63.7	42600	10000	0.0064	<b>4.3</b>
atenolol	beta blocker	29122-68-7	272	3140	3200000	0.0001	0.0010
carbamazepine	anti-convulsant	298-46-4	749	810	1000	0.7490	0.8100
diazepam	anti-depressant	439-14-5	6.1	42.1	13000	0.0005	0.0032
diclofenac	anti-inflammatory	15307-86-5	1460	322	1000	<b>1.5</b>	0.3220
fluoxetine	anti-depressant	54910-89-3	109	n/a	30	<b>3.6</b>	n/a
gemfibrozil	lipid regulator	25812-30-0	324	4300	1000	0.3240	<b>4.3</b>
ibuprofen	anti-inflammatory	15687-27-1	36800	12000	100000	0.3680	0.1200
metformin	anti-diabetic	657-24-9	175	838	40000	0.0044	0.0210
naproxen	anti-inflammatory	22204-53-1	1110	13100	330000 <sup>a</sup>	0.0034	0.0397
sulfamethoxazole	anti-biotic	723-46-6	1010	2870	210000000 <sup>b</sup>	0.0000	0.0000
trimethoprim	anti-biotic	738-70-5	899	980	123000000 <sup>b</sup>	0.0000	0.0000

<sup>a</sup> maximum concentration in surface water

<sup>b</sup> maximum concentration in source

## APPENDICES

Table A-1. Summary of occurrence data for final effluent from wastewater treatment plants (WWTP Effluent), in stormwater runoff and in surface waters in California and abroad. Maximum, mean or 90<sup>th</sup> percentile concentrations are given in units of ng/L.

<u>Compound</u>	<u>CAS#</u>	<u>CEC Panel</u> <u>max</u>	<u>WWTP Effluent</u>		<u>SoCal</u> <u>max</u>	<u>Stormwater</u> <u>CEC Panel</u> <u>max</u>	<u>Landfill</u> <u>Leachate</u> <u>max</u>
			<u>CEC Panel</u> <u>90th perc.</u>	<u>LACSD</u> <u>max</u>			
acetaminophen	103-90-2	550	550		11000		42600
atenolol	29122-68-7	1800	1780		3140	<1	1042
carbamazepine	298-46-4	480	400	329	360	<0.5	810*
diazepam	439-14-5	5	NA			<.25	42.1*
diclofenac	15307-86-5	230	230	322	180	<10	
17 $\alpha$ -ethinyl estradiol	57-63-6			<0.50			
fluoxetine	54910-89-3						
furosemide	54-31-9	63	63				
gemfibrozil	25812-30-0	4300	3550	905	3800		
ibuprofen	15687-27-1	1000	500	69	12000	26	
meprobamate	57-53-4	430	430	792	570	1.8	1530*
metformin	657-24-9		NA				838
naproxen	22204-53-1	860	851		13100	24	
propranolol	525-66-6						
sulfamethoxazole	723-46-6	2100	1400	2870	2040	2.5	861
trimethoprim	738-70-5	120	112	299	980	<0.25	

\*detected at concentration below reporting limit

Table A-1 (cont.)

<i><b>Compound</b></i>	<b>Surface Water-CA</b>				<b>Surface Water - outside CA</b>			<b>Groundwater</b>	
	<i><b>Ocean</b></i>	<i><b>Coast/Bay</b></i>	<i><b>Coast/Bay</b></i>	<i><b>Rivers</b></i>	<i><b>USA</b></i>	<i><b>South Africa</b></i>	<i><b>Abroad</b></i>	<i><b>USA (IL)</b></i>	<i><b>Abroad</b></i>
	<i><b>max</b></i>	<i><b>max</b></i>	<i><b>mean</b></i>	<i><b>max</b></i>	<i><b>max</b></i>	<i><b>mean</b></i>	<i><b>max</b></i>	<i><b>max</b></i>	<i><b>max</b></i>
acetaminophen	11	0	0	26		63.7			
atenolol	11				29.8	272			
carbamazepine	0.9	21	2.6	330	35.7	280	749	2.11	390
diazepam				6.1					
diclofenac	0.6			124		1460	266		477
17 $\alpha$ -ethinyl estradiol							1.9		230
fluoxetine		0	0		0.53	109		4.01	
furosemide					17.5				
gemfibrozil	13			324				119	
ibuprofen	30			40	17.7	312	36788		395
meprobamate	1.5				14.2				
metformin						175			
naproxen	26					1113	87	49.9	263
propranolol									
sulfamethoxazole	3.4	1.3	0.19	932	161	1013	284	8.11	117
trimethoprim	2.1	2	0.3	180	9.9	899	122	4.73	

Table A-2. Summary of toxicity data for pharmaceuticals. NOEC – no observed effect concentration. LOEC – low observed effect concentration.

PhACs	Class	Data from CA Expert Panel literature search			Mehinto literature search (Pubmed search engine)		
		NOEC (endpoint)	LOEC	References	NOEC (endpoint)	LOEC (endpoint)	References
Acetaminophen	anti-inflammatory	9.2 mg/L (acute Daphnia reproduction, growth, survival)		Kuhn et al. 1989	1 ug/L	10 ug/L (zebrafish cumulative egg production)	Galus et al. 2013
Amphetamine		NO RELEVANT DATA on amphetamine-induced toxicity to wildlife					
Ampicillin	antibiotic	NO RELEVANT TOXICITY DATA but impact related to <u>antibiotic resistance</u> must be considered					
Atenolol	beta blocker	1 mg/L (FHM condition index)	3.2 mg/L (FHM condition index)	Winter et al. 2008			
Atorvastatin	lipid regulator	NO RELEVANT DATA on atorvastatin-induced toxicity to wildlife					
Bezafibrate	lipid regulator					70 mg/g food (zebrafish diet study)	Velasco-Santamaria et al. 2011 NO DATA on waterborne exposure to bezafibrate only
Carbamazepine	anticonvulsant	30.6 mg/L (zebrafish embryo development)		van den Brandhof & Montforts 2010		1 ug/L (zebrafish cumulative egg production)	Galus et al. 2013
Diazepam	antidepressant				13 ug/L (FHM reproduction)		Lorenzi et al. 2014
Diclofenac	anti-inflammatory	1000 ng/L (kidney and intestine damage in fish)		Triebkorn et al. 2007			
Dilantin	anticonvulsant	NO RELEVANT DATA on dilantin-induced toxicity to wildlife					

Fluoxetine	antidepressant					0.03 ug/L (Guppy growth and avoidance behavior) 2.9 ug/L (stickleback reduced nest building activity)	Pelli and Connaughton, 2015 ____ Sebire et al. 2015
Furosemide	beta blocker				156 ug/L (Cerodaphnia reproduction)	312 ug/L (Cerodaphnia reproduction)	Isidori et al. 2006
Gemfibrozil	lipid regulator					1 ug/L (zebrafish cumulative egg production)	Galus et al. 2013
Hydrocodone	opiod	NO RELEVANT DATA on hydrocodone-induced toxicity to wildlife					
Ibuprofen	anti-inflammatory				10 ug/L (medaka egg production)	100 ug/L (medaka egg production)	Flippin et al. 2007
Indomethacin	anti-inflammatory	NO RELEVANT DATA on indomethacin-induced toxicity to wildlife					
Meprobamate	antidepressant	NO RELEVANT DATA on meprobamate-induced toxicity to wildlife					
Metformin	anti-diabetic					40 ug/L (fathead minnow intersex, 1yr exposure)	LIMITED tox DATA available (from 1 lab)
Metoprolol	beta blocker	12.6 mg/L (zebrafish embryo development)		van den Brandhof & Montforts 2010			
Miconazole	antifungal					22 ug/L (Daphnia reproduction)	LIMITED tox DATA available (Furuhagen et al. 2014)

Naproxen	anti-inflammatory					330 ug/L (EC50 Cerodaphnia)	Isidori et al. 2005
Paroxetine	antidepressant				440 ug/L (Cerodaphnia reproduction)	880 ug/L (Cerodaphnia reproduction)	Henry et al. 2004
Progesterone	steroid hormone	10 ug/L (Daphnia sex development)		Kashian & Dodson 2004			LIMITED DATA on progesterone exposure alone
Propranolol	beta blocker				2 ug/L (sea urchin larvae abnormalities) 10 ug/L (FHM egg hatchability)	5 ug/L (sea urchin larvae abnormalities) 100 ug/L (FHM egg hatchability)	Ribeiro et al. 2015 ____ Giltrow et al. 2009
Simvastatin	lipid regulator				0.8 ug/L (sea urchin larvae abnormalities)	2 ug/L (sea urchin larvae abnormalities)	Ribeiro et al. 2015
Sulfamethoxazole	antibiotic					210 mg/L (Cerodaphnia LC50 -acute)	Isidori et al. 2005
Trimethoprim	antibiotic				100 mg/L (zebrafish survival-acute)	123 mg/L (Daphnia LC50 -acute)	Halling-Sorensen et al. 2000

\*\*Priority pharma list based on CEC Expert Panel (SCCWRP Tech. Rep. 692, April 2012)

Kostich et al 2014. Environ Pollut 184: 354-359

Cizmas et al 2015. Environ Chem Lett 13: 381-384