

Date: December 16, 2013
To: Rachel Wagoner and Rebecca Newhouse
Senate Environmental Quality Committee
From: Brian Brown
Subject: Home-Generated Pharmaceutical Waste Programs

In a letter dated July 24, 2013, you asked our office to provide information related to the environmental and public health problems associated with improper disposal of pharmaceutical waste and stockpiling of pharmaceuticals by consumers. Specifically, you asked us to: (1) provide background information on generation and disposal, environmental and public health impacts, and current laws associated with home-generated pharmaceutical waste; (2) discuss local efforts to collect and dispose pharmaceutical waste, including whether any of these efforts are appropriate for statewide consideration; and (3) identify statutory and regulatory restrictions to including all types of pharmaceutical waste in a statewide waste reduction program. We address each of the above areas below.

BACKGROUND

Overview of Pharmaceutical Waste in California

Health Care Facilities Likely Generate Most Pharmaceutical Waste. Hospitals and licensed health care facilities prescribe and administer most pharmaceuticals and, therefore, likely generate the majority of pharmaceutical waste (meaning leftover or expired medications). Based on data reported by CalRecycle, across the United States, these facilities generate about 250 million pounds of pharmaceutical waste each year. Assuming this total was related to population, California hospitals would be responsible for about 30 million pounds of this waste each year.

In California, the Department of Public Health (DPH) has the authority to regulate medical waste, including pharmaceutical waste generated in hospitals. Typically, this waste is collected and incinerated. However, some pharmaceuticals (such as chemotherapy medicines) are categorized as hazardous waste and subject to hazardous waste regulations through the Department of Toxic Substance Control. These hazardous waste regulations require special segregated collection, transportation, and disposal.

Home-Generated Pharmaceutical Waste Subject to Different Laws and Regulations. Pharmaceutical waste produced by the general public is generally not subject to the same laws and regulations as hospital-generated waste. Current state law exempts home-generated pharmaceutical waste from laws regulating hospital and medical facility waste. There are no state laws specifically governing the handling and disposal of home-generated pharmaceutical waste—it is subject only to solid waste regulations. Like other non-hazardous household waste,

pharmaceutical waste generated by the public can be treated as garbage and placed in trash cans or flushed down the toilet. However, as explained in further detail below, these two disposal methods can be harmful to the environment and public health. Therefore, local governments and state agencies recommend that the public dispose pharmaceutical waste by either (1) grinding up pills and mixing them with cat litter or other granular trash or (2) using collection programs. The amount of home-generated pharmaceutical waste in California is not tracked or measured. Nationally, studies estimate that between 3 percent and 50 percent of prescriptions become waste.

Collection programs in California collect about 200,000 pounds of home-generated pharmaceutical waste each year. It is important to note that current state laws and regulations treat pharmaceutical waste differently when subject to collection programs. In particular, DPH's regulations consider collected pharmaceuticals to be medical waste and subject to the same regulations as medical waste generated in medical facilities. In addition, some household hazardous waste collection programs, which allow the public to dispose of hazardous materials (such as pesticides), also accept home-generated pharmaceutical waste. At the collection point, these medications are added to other hazardous wastes and are subject to the same transport and disposal regulations as other household hazardous materials. Finally, existing federal regulations require law enforcement to be present for any pharmaceutical collection program that collects controlled substances—including narcotics, steroids, stimulants, depressants, and hallucinogens—even if the pharmaceuticals are home generated. Although the federal Secure and Responsible Drug Act of 2010 included changes to permit individuals to dispose of controlled substances at collection programs that do not have law enforcement on site, the Drug Enforcement Agency (DEA) has not yet made the corresponding changes to its existing regulations.

Impacts of Home-Generated Pharmaceutical Waste

The impacts of home-generated pharmaceutical waste on public health and the environment are not well known, and data from existing studies are often problematic for several reasons. As discussed in more detail below, such studies (1) primarily test for the presence of one drug rather than many; (2) must rely on effects to present themselves in a population, which may take anywhere from several years to decades; and (3) must attempt to differentiate the effects of pharmaceutical waste exposure, other environmental conditions, and pharmaceuticals taken as directed but that, as a result of excretion, result in pharmaceutical waste in the water supply.

Public Health Impacts of Pharmaceutical Waste. There are two major types of public health impacts of pharmaceutical waste: (1) direct impacts from improper consumption associated with hoarding (such as overdose, poisoning, and diversion for illegal use) and (2) more indirect impacts from environmental exposure. The impacts of both of these effects are difficult to quantify. Hoarding often occurs because individuals do not know how to properly dispose of their medications, are holding on to medications for future use, or forget that they have old medications in their homes. Overdose can result from hoarding pharmaceuticals. However, since overdose may also occur with appropriately prescribed and current medications, it is impossible to quantify what proportion of overdoses is attributable to improper consumption of leftover

medication. Similarly, poisonings can result from consumption of appropriately prescribed and maintained medications, as well as with hoarded medications. For example, a child may find an appropriate, current prescription and consume quantities that cause poisoning in small children. Such incidents are not accounted for separately from those involving hoarded medications. In addition, while some national data show an increase in illegal use of prescription drugs, it is unclear how much of that drug supply is associated with diversion of hoarded medications versus other means of acquiring those drugs.

The environmental public health implications of pharmaceutical waste are even more complex and challenging to quantify. The largest environmental public health impact is through the water supply, but the impact of dumping specifically is hard to measure. Currently, the most common method of measuring medications in the water supply is to perform a point-in-time calculation of a specific medication in a particular body of water. While pharmaceuticals have been detected in the water supply, the amount that originates from improper consumer disposal cannot be separated from the amount that is excreted following the normal consumption of medication. There have been several national and international studies regarding the overall concentration of certain pharmaceuticals in the water supply. For example, a cross-national study found measurable amounts of estrogen in the water supply in several countries. These studies largely show that the concentration of specific medications in the water supply is lower than an impactful dosage. However, prescription rates have increased sharply in recent years, so there may be some concerns about increases in the concentration of medications in the water supply, though there has not been research on this trend.

In addition, a point-in-time measurement of individual pharmaceuticals in the water supply may not account for the full range of potential impacts on human health, including:

- ***Long-Term Cumulative Effects.*** Though the concentration of medication in the water may not be substantial at a specific point in time, low dosage lifetime exposure may have adverse impacts on human health. Long-term drug exposure may lead to small but substantial population health effects. The effects of such low, long-term dosages of pharmaceuticals are not well known.
- ***Additive Effects.*** The concentration of pharmaceuticals in the water supply is commonly measured by specific drug or biosimilar drugs. However, there may be compounding effects of drugs that have the same biological effect. For example, there are many formulations of pain medications. Though each medication may only exist in the water supply in non-significant doses, the totality of all the medications may have significant bearings on human health.
- ***Synergistic Effects.*** Research on the impact of pharmaceuticals in the water supply has largely focused on individual drugs. However, there is concern that the variety of drugs in the water supply may have negative impacts on human health. People may be exposed to multiple medications in the water supply, including mental health medications, anti-hypertensives, antibiotics, and others. These medications may interact and produce adverse health effects. Though the concentrations of each medication in the water supply is likely too low to have a biological impact, it is

possible that interactions between the drugs, especially over time, may have some negative effects.

- ***Limited Understanding of Pharmaceutical Mechanisms.*** Though many medications have proven to be effective in treating a wide variety of diseases, the mechanism by which they work is not always well understood, which is particularly true of behavioral health medications. As a result, it is uncertain what the effects of low dosages over time may be. Similarly, it is especially difficult to estimate the synergistic and additive effects of these medications, given that we are unsure of its mechanism even when it is a stand-alone treatment.
- ***Effects on Vulnerable Populations.*** Measures of pharmaceutical concentrations in water are largely focused on whether the concentration is high enough to produce biological effects in those populations who typically receive that prescription. However, there are many groups for whom lower concentrations may have serious effects, including infants, children, and individuals with compromised health.
- ***Pathogen Resistance.*** One of the most serious issues of pharmaceutical dumping is the possible constant, low-level concentration of antibiotics in the water supply. There have been several instances of drug-resistant pathogens in recent years, and concerns have been raised about overconsumption of antibiotics, which can lead to drug-resistant diseases. While there is no evidence of drug-resistant pathogens in humans as a result of antibiotics in the water supply, there have been studies showing effects in water fowl. Thus, it is possible that consistent low dosages of antibiotics in the water supply could exacerbate the problem of drug-resistant pathogens.

Environmental Impact of Pharmaceutical Waste. The biggest environmental concerns with pharmaceutical waste is the effect of waste on animal species. As discussed above, home-generated pharmaceutical waste that is flushed down the toilet or, to a lesser extent, put in the trash can finds its way into the water. As a result, aquatic species or predators that feed on aquatic species are most at risk. Data is limited, but some studies suggest that hormone supplements in water can cause fish to change breeding behavior or even their sex. In addition, vulture populations in Asia were decimated by the presence of a non-steroidal anti-inflammatory medication. Studies report that over 90 percent of the vulture population has died off over the last decade, primarily due to pharmaceutical exposure. While most species do not appear to be as affected by low dose pharmaceuticals as vultures, the effects may compound over time.

LOCAL ACTIONS TO REDUCE PHARMACEUTICAL WASTE

Overview of Local Efforts

Local communities take various actions to reduce pharmaceutical dumping and hoarding. The extent to which local agencies engage in such actions vary considerably. However, the most common approach taken is to offer programs that encourage and make it easier for the public to return excess medications. Chapter 542, Statutes of 2007 (SB 966, Simitian), required CalRecycle to create state guidelines for pharmaceutical collection programs and evaluate such

programs for accessibility, safety, cost, and return rates. As a result, CalRecycle conducted a survey of such collection programs in June 2010 regarding their operation between 2008 and 2010 and assessed the various types of programs based on accessibility to consumers, safety, cost, and amount of pharmaceutical waste collected. In total, CalRecycle identified 297 programs during the survey period, though the department's report did not identify the location of each program.

One-Time Drug Take-Back Events. The most common method of pharmaceutical waste control is "Drug Take-Back Days." These events are usually administered by county health offices, the Sheriff's Department, or resource management departments. These events usually permit the disposal of over-the-counter (OTC) and prescription medications, but not illicit or controlled substances. Once the pharmaceuticals are dropped off, the collecting entity transports them to a safe disposal site, such as a hazardous waste facility. CalRecycle reported that 53 known take-back events occurred in California between 2008 and 2010, costing about \$6 per pound of waste collected. These events collected a total of about 5,000 pounds of pharmaceutical waste.

Permanent Take-Back Programs. Several entities also provide take-back locations that operate year-round, typically providing permanent installations (usually bins) at points throughout a county. They are most commonly located at sheriff's offices, police departments, hospitals, pharmacies, and university campuses. The contents of these bins are transported to hazardous waste disposal facilities. Though the take-back installations are permanent, some locations may have restricted hours or access. For example, some pharmacies only accept drop-offs during business hours and/or their own prescriptions. In addition, take-back services are usually limited to OTC and noncontrolled substances medication unless the program is held at a law enforcement agency. We note that some counties provide services to pick up pharmaceutical waste from elderly or disabled residents. CalRecycle reported the existence of 241 permanent take-back programs between 2008 and 2010, costing about \$4 per pound of pharmaceutical waste. These programs collected about 30,000 pounds of waste within the survey period.

Mail-Back Programs. Some pharmacies sell specially designed envelopes with pre-paid postage and prefilled mailing labels for consumers to mail back medications. Specifically, consumers place prescription or OTC medications in the envelopes, deposit them in any U.S. Postal Service mailbox, and the envelopes are delivered to a hazardous waste facility. The CalRecycle survey identified only three such mail-back programs operating in California. These programs cost an average of \$6.50 per pound and collected 898 pounds during the survey period.

Information Campaigns. State and local agencies and some nonprofit organizations also encourage the proper disposal of home-generated pharmaceutical waste via informational campaigns. These campaigns often direct the public to not flush or toss their waste, to package pharmaceutical waste more safely for solid waste collection, and/or to participate in collection events or programs. The CalRecycle survey did not evaluate public information campaigns, so it is unclear how common, expensive, or effective they are. However, public information may help limit confusion and direct individuals to collection programs.

Accessibility, Safety, Cost, and Return Rates of Local Efforts Vary

In accordance with Chapter 542, CalRecycle developed state guidelines for pharmaceutical collection programs in 2008. (We note that most take-back programs were established prior to 2008.) The CalRecycle guidelines are voluntary, and as of 2010 only about one-third of programs had implemented changes to meet these state guidelines, with costs cited as the major barrier to meeting the guidelines. Despite not meeting these guidelines, CalRecycle found in its 2010 survey that California programs operated reasonably effectively across the four markers CalRecycle used for measurement—accessibility, safety, cost, and return rates.

Pharmacy Programs Rank Highest in Accessibility. Of the various programs discussed above, CalRecycle found that permanent take-back programs at pharmacies had the greatest accessibility to the public since there are so many locations and consumers seemed most comfortable returning drugs to the places where they originally received them. However, accessibility at pharmacies is somewhat limited presently because current federal regulations prohibit pharmacies from accepting controlled substance medication. In addition, pharmacy programs ranked relatively low in safety because many do not have dual key systems—one key in the possession of an on-site manager and the other by the designated hauler—to provide extra security against theft or drug reuse. Pharmacy programs cost about \$5.50 per pound of waste and are one of the more popular programs in the state. In 2010, 112 of 297 known collection programs in California were operated by pharmacies, collecting an average of two pounds of pharmaceutical waste per day.

Law Enforcement Programs Rank High in Security, Lower in Accessibility. Because law enforcement programs are staffed by law enforcement officials, they rank high on security. This also means they can accept controlled substances, providing some additional accessibility compared to pharmacy programs. Law enforcement take-back programs are also open more hours of the day. However, there are several other factors that limit public access to these programs. In particular, there are fewer law enforcement locations than pharmacies and they are often in less accessible areas. In addition, CalRecycle concluded that some individuals may feel nervous dropping off expired pharmaceuticals to law enforcement. Based on our conversations with CalRecycle, they thought this may be especially true when individuals have a large volume of medication, the medication was not prescribed to them, or if other complicating factors exist (such as if the person has a criminal record). Reliance on law enforcement to manage take-back programs could therefore result in decreased compliance with recommended disposal practices. CalRecycle found that the 63 law enforcement take-back programs in the state cost an average of \$4.50 per pound of waste collected and retrieved an average of about seven pounds per day of operation. While this amount of collection was high, the largest law enforcement program reported suspicions that the collection rate was driven up by a large amount of waste from businesses rather than from households.

Drug Take-Back Days Encourage Stockpiling. One-time collection events typically provide reasonable security because law enforcement usually participates, and such events are relatively inexpensive because they do not operate on an ongoing basis. However, the infrequent nature of these events means that the public is not always aware of them, especially if locations and event days are not consistent. In addition, CalRecycle concluded that event programs may encourage

people to stockpile pharmaceuticals to bring in to events, which has the potential to contribute to accidental poisonings, misuse, or abuse. Take-back events collected from 2 to 480 pounds of pharmaceutical waste per day of operation and cost about \$6 per pound.

Mail-Back Programs Have Highest Costs. Take-back program managers—usually pharmacies or local governments—must pay for the postage of mailing envelopes whether or not they are used, contributing to high upfront program costs. Mail-back programs typically charge pharmaceutical consumers \$4 or \$5 dollars to purchase a special envelope with which to mail back their unused prescriptions, whereas all other collection programs are free to the public. While more expensive for consumers, mail-back programs are convenient since envelopes are sold where consumers purchase their drugs and they can dispose of medications through the U.S. postal system. They are easy to implement because they do not require the creation of new collection infrastructure. They also rank high in safety because fewer people handle the medications before they reach their ultimate destination for disposal. Despite convenience, it is possible that the relatively high cost of an envelope may encourage individuals to stockpile pharmaceuticals to more fully fill an envelope before mailing in order to reduce the total number of mailings. CalRecycle reports that these programs collect an average of two pounds of pharmaceutical waste per day.

Considerations Associated With a Statewide Program

Currently, all of the above programs are implemented at the local level. Although several state entities provide information to the public about where and how to dispose of home-generated pharmaceutical waste, there is no unified state program for disposal. Per your request, we discuss below the benefits and challenges of creating a statewide program to collect and dispose of home-generated pharmaceutical waste.

Statewide Approach May Increase Program Consistency and Return Rates. Localities vary considerably in the types of collection programs available, frequency of collection events, and collection locations. Anecdotal evidence suggests that this variation in approaches may contribute to public confusion about disposal and collection programs. A more consistent approach across the state—perhaps with a statewide public information campaign—may make it easier for the public to know how and where to properly dispose of pharmaceutical waste. This then could increase use of collection programs and, hence, return rates. A statewide approach would not necessarily require significant state expenditures if, for example, it involved developing mandatory guidelines for local entities that choose to operate programs. It could be more expensive if, on the other hand, it included a major public information campaign and regulatory enforcement.

It is likely that any of the approaches described above—permanent, one-time, or mail-back programs—could be adapted into a statewide program. While it is expensive to run many different types of programs, it could make sense for consumers to have access to multiple disposal programs. This would increase the likelihood that there was a convenient disposal option for different pharmaceutical users. For example, people in urban areas may prefer taking unused medications back to pharmacies, but rural residents may prefer a mail-back program or

scheduled drop-off days due to the larger geographic distance between these residents and pharmacy locations.

Determining Financial Responsibility. An important consideration in establishing a statewide approach is the question of who should bear financial responsibility for any new costs to more properly dispose of waste. One way to think about this is to consider what entities bear most responsibility for creating the waste. There are a number of different parties involved in the generation of pharmaceutical waste, including pharmaceutical companies, doctors who prescribe medication, pharmacies that dispense medication, and patients who consume these medications and dispose of unused medication. Of these entities, pharmaceutical companies are most directly responsible for creating medication, and consumers are most responsible for their consumption and disposal. Therefore, one approach would be to have collection programs funded either by charging an assessment on producers of medications or a disposal fee paid by consumers. Both of these funding mechanisms would likely result in a rise in the price of medications. However, the assessment on pharmaceutical producers might be shared by a larger population, spread out through insurance companies and other entities.

Coordination Among Private, Local, and State Entities Is Vital. The most effective take-back programs—in terms of accessibility, safety, cost, and return rates—require a high level of collaboration between governmental and private organizations. As described above, this commonly includes pharmacies, local law enforcement, qualified waste collection contractors or agencies, and local public health or resource agencies. To run a state program, at least one state department (such as CalRecycle or DPH) would need to take an oversight role in organizing and managing all partners within the program, and potentially use its regulatory authority to require private entities to participate, much like local governments currently do on a smaller scale. To the degree that pharmaceutical collection programs were administered by private organizations (such as pharmaceutical companies) as happens in other industries (such as for carpet), it would still be important to have government agencies perform oversight and coordination functions given the specific safety and accessibility challenges associated with pharmaceutical waste.

RESTRICTIONS ON CERTAIN PHARMACEUTICAL WASTE COLLECTION

As discussed above, federal regulations restrict the ability of non-law enforcement take-back programs to collect controlled substances that are home-generated pharmaceutical waste. These restrictions could impact a statewide collection program. However, the DEA is currently revising these regulations to expand legal transfer of controlled substances for collection programs. In the future, individuals may be able to drop off controlled substances at any organized collection event, subject to whatever federal regulations are developed, even without the presence of law enforcement.

I hope this information meets your needs. Please contact me at (916) 319-8325 if you have any additional questions.