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Protecting California’s Marine Environment from Flushed Pollutants

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I. INTRODUCTION

Big cities produce a lot of sewage, which often contains pharmaceuticals, illicit drugs, and caffeine. These flushed pollutants can remain in wastewater even after processing by a wastewater treatment plant, and may have negative effects on marine organisms and ecosystems if introduced into the marine environment. California is home to Los Angeles, San Diego, and San Jose—three of the ten most populous cities in the United States. All three are located in coastal counties and utilize wastewater treatment plants (“publicly owned treatment works” or “POTWs”) that discharge treated wastewater effluent directly

3. 40 C.F.R. § 403.3 (2016) (“POTW means a treatment works . . . which is owned by a State or municipality. . . . The term also means the municipality . . . which has jurisdiction over the Indirect Discharges to and the discharges from such a treatment works.”); 33 U.S.C. § 1292 (2012) (“[T]reatment works' means any devices and systems used in the storage, treatment, recycling, and reclamation of municipal sewage or industrial wastes of a liquid.”).
into the Pacific Ocean. As our cities grow, municipal wastewater is expected to contain increasing concentrations of flushed pollutants, posing a heightened threat to the health of our coasts and the marine environment more broadly. However, monitoring and regulation of flushed pollutants is currently insufficient, allowing them to be introduced into the marine environment undetected. This raises serious concern that flushed pollutants may devastate the marine environment beyond repair.

The precautionary principle, a central tenet of environmental law and policy, “asserts that regulators and decision makers should act in anticipation of environmental harm, without regard to the certainty of the scientific information pertaining to the risk of harm.” In the face of great uncertainty as to the amounts of flushed pollutants being introduced into the marine environment and the effects they will have on marine organisms and ecosystems, a precautionary approach is necessary to ensure adequate protection. This Article advocates for policy reform to increase monitoring and regulation of pharmaceuticals, illicit drugs, and caffeine in wastewater, and to ultimately minimize the amounts of these flushed pollutants that are discharged into California’s coastal waters. Part I provides an overview of the wastewater life cycle as a pathway for flushed pollutants to enter the marine environment. This is followed by a discussion of the effects that pharmaceuticals, illicit drugs, and caffeine may have on marine organisms. Part II discusses the current legal and regulatory landscape for managing pollutants in municipal wastewater and its inadequacies in preventing flushed pollutants from harming marine organisms and ecosystems. Part III proposes various legislative tools that can be used to address this issue and suggests topics for future research.


II.
THE WASTEWATER LIFE CYCLE—A PATHWAY TO THE OCEAN

In addition to their contributions to tourism and the economy, coastal ecosystems offer unique recreational and educational opportunities, hold important cultural value, and provide a variety of ecosystem services. California’s ocean economy produced over $44 billion in 2013 and its coastal counties are home to almost three-quarters of the state’s population, despite comprising less than a quarter of the state’s land area.6 Coastal ecosystems can be incredibly complex and marine organisms vary in their sensitivity to pollutants. The discharge of treated wastewater effluent containing pharmaceuticals, illicit drugs, and caffeine into coastal waters raises concerns for the health of these ecosystems and humans alike. This Part introduces three categories of flushed pollutants that are of particular abundance and concern and provides an overview of the means by which flushed pollutants are discharged into the marine environment. It then discusses the potentially devastating effects that these pollutants may have on marine organisms and ecosystems.

A. Flushed Pollutants

When humans consume pharmaceuticals, illicit drugs, and caffeine they excrete a portion of these substances as waste. In turn, this waste is flushed down toilets. Flushing is also a common means of disposal of unwanted pharmaceuticals and illicit drugs. In the context of large cities, flushed wastewater is generally transported through a network of sewers to a POTW.7 These facilities employ a variety of technologies and processes designed to remove solid waste, bacteria, and other pollutants.


from municipal wastewater. The levels of pharmaceuticals, illicit drugs, and caffeine that remain in treated wastewater effluent largely depend on the technology used. POTWs located in coastal regions, such as the Hyperion Treatment Plant in Los Angeles, the Point Loma Wastewater Treatment Plant in San Diego, and the San José/Santa Clara Water Pollution Control Plant in San Jose, often discharge treated wastewater effluent directly into coastal waters. This makes POTWs the last safeguard to prevent flushed pollutants from reaching coastal waters.

Although POTWs reduce the concentrations of pharmaceuticals, illicit drugs, and caffeine in wastewater, some measure of these pollutants still remains in wastewater after treatment and is thus introduced into the marine environment. A recent study in Southern California tested effluent from four large POTWs that discharge into coastal waters through marine outfalls. The study found pharmaceutical hormones such as estradiol, testosterone, progesterone, and estrone in 63–100% of effluent samples. Another alarming study detected cocaine in 36% of mussel tissue samples collected along the California coast and caffeine in 19% of the samples. As more research is conducted to determine the levels of pharmaceuticals, illicit drugs, and caffeine in POTW influent and effluent, concern is growing over the effects these pollutants may have on marine organisms and ecosystems.

8. Id.
11. Id. at 2678 tbl.2.
B. The Effects of Flushed Pollutants on Marine Organisms

Pharmaceuticals, illicit drugs, and caffeine have been detected in California’s coastal waters, but little research has been done to determine the rate at which these pollutants are being introduced into the marine environment. The persistence of these pollutants and the effects they have on marine organisms and ecosystems are also largely unknown. If these pollutants prove to be harmful and persistent, exposure and bio-accumulation could threaten the collapse of ecosystems already imperiled by climate change, overfishing, and other anthropogenic impacts. This section introduces pharmaceuticals, illicit drugs, and caffeine, and summarizes what is known about the concerning effects these pollutants may have on marine organisms and ecosystems.

1. Pharmaceuticals

Pharmaceuticals include both prescription and over-the-counter medications. Antibiotics, antidepressants, and reproductive hormones are a few examples of particular concern. In a 2012 study, almost half of Americans reported using at least one prescription medication in the past 30 days, and pharmaceutical use in the United States continues to rise. The body absorbs only a portion of pharmaceutical compounds that are consumed and excretes the remainder as waste. With prescription drug abuse and overdose rates on the rise, unused pharmaceuticals are also commonly flushed as a method of disposal.


disposal. Pharmaceutical pollution has been detected in treated wastewater effluent and in surface waters throughout the nation,\textsuperscript{17} and has been documented in detail along the South Florida Coast.\textsuperscript{18} In fact, according to the National Centers for Coastal Ocean Science, pharmaceutical pollution may be as common in the marine environment as agricultural pollution.\textsuperscript{19} However, as compared to agrochemicals, far less research has been conducted on the effects of pharmaceuticals on marine organisms and ecosystems.

Pharmaceutical antibiotics, antidepressants, and reproductive hormones (birth control) are endocrine-disrupting chemicals ("EDCs") that have been detected in treated wastewater effluent.\textsuperscript{20} EDCs interfere with "the production, release, transport, metabolism, binding, action, or elimination of natural hormones in the body responsible for the maintenance of homeostasis and the regulation of developmental processes."\textsuperscript{21} EDCs have been linked to reproductive and developmental toxicity, carcinogenesis, immunotoxicity, and neurotoxicity in humans,\textsuperscript{22} and research indicates EDCs may have similar impacts on wildlife.\textsuperscript{23} Exposure to pharmaceutical EDCs has been shown to have devastating consequences for freshwater organisms\textsuperscript{24} and preliminary research indicates marine

\textsuperscript{17} Dana W. Kolpin et al., Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999–2000: A National Reconnaissance, 36 ENVTL. SCI. & TECH. 1202 (2002).
\textsuperscript{18} Simrat P. Singh et al., Occurrence and Distribution of Steroids, Hormones, and Selected Pharmaceuticals in South Florida Coastal Environments, 19 ECOTOXICOLOGY 338, 338–50 (2010).
\textsuperscript{20} See Kolpin et al., supra note 18.
\textsuperscript{21} Weida Tong et al., Development of Quantitative Structure-Activity Relationships (QSARs) and Their Use for Priority Setting in the Testing Strategy of Endocrine Disruptors, 1 REG. RES. PERSP. 1, 13 (2012).
\textsuperscript{22} Id. at 2.
\textsuperscript{24} See Stefan Örn et al., Gonad Development and Vitellogenin Production in Zebrafish (Danio rerio) Exposed to Ethinylestradiol and Methyltestosterone, 65
organisms may be similarly affected. Appropriately, there is growing concern in the environmental community over the introduction of pharmaceutical EDCs into coastal ecosystems through treated wastewater.

2. Illicit Drugs

For the purposes of this paper, illicit drugs are those for which nonmedical use or possession is prohibited by federal law. A 2013 report prepared by the Substance Abuse and Mental Health Services Administration estimated roughly 9.4% of Americans aged 12 or older had used at least one illicit drug in the past month. Similar to its treatment of pharmaceuticals, the human body does not absorb a large portion of illicit drugs that are consumed. Illicit drugs thus “enter the wastewater network . . . by human excretion after illegal consumption or by accidental or deliberate disposal.” A variety of illicit drugs have been detected in surface waters and treated wastewater effluent from POTWs across the United States, including cannabis, cocaine, MDMA, methadone, and methamphetamine.

AQUATIC TOXICOLOGY 397, 397 (2003) (finding that zebrafish experienced complete sex reversal when exposed to ethynyl estradiol, an EDC found in estrogen-progestin forms of oral contraception).

25. See James L. Pinckney et al., Sublethal Effects of the Antibiotic Tylosin on Estuarine Benthic Microalgal Communities, 68 Marine Pollution Bulletin 8 (2013) (showing that benthic microalgal communities experienced a reduction in biomass and primary productivity, and stunted diatom growth when exposed to tylosin, an antibiotic used in veterinary medicine).


the effects of illicit drugs on marine organisms and coastal ecosystems are not well studied. Research indicates that exposure to illicit drugs could produce devastating effects in freshwater organisms, including genetic damage and mutation. 31 Illicit drugs may have similarly disastrous consequences when introduced into the marine environment.

3. Caffeine

The consumption of caffeine, which is found most notably in coffee and tea, has been linked to reduced fatigue and heightened mental alertness. 32 Caffeine is widely enjoyed throughout the United States, with roughly 85% of Americans consuming at least one caffeinated beverage daily. 33 A portion of the caffeine that is consumed by humans is excreted as waste. 34 Caffeine originating in human waste has been detected in coastal waters across the United States, including Puget Sound, 35 Boston Harbor, 36 and the Oregon coast. 37 The ubiquitous nature of caffeine in our nation’s surface waters and treated wastewater effluent is well-documented and concern over the continuous discharge of caffeine into coastal waters is tempered as compared with concerns over pharmaceuticals and


31. See Tristan Darland & John E. Dowling, Behavioral Screening for Cocaine Sensitivity in Mutagenized Zebrafish, 98 PROCEEDINGS NAT’L. ACAD. SCI. U.S. 11691 (2001) (finding that exposure to cocaine resulted in defects from genetic mutations in freshwater zebrafish). See also A. Binelli et al., Illicit Drugs as New Environmental Pollutants: Cyto-genotoxic Effects of Cocaine on the Biological Model Dreissena polymorpha, 86 CHEMOSPHERE 906 (2012) (finding that exposure to cocaine resulted in significant primary DNA damage in freshwater Zebra mussels).


33. Id.

34. Zoe Rodriguez del Rey et al., Occurrence and Concentration of Caffeine in Oregon Coastal Waters, 64 MARINE POLLUTION BULLETIN 1417, 1418 (2012).


37. Rodriguez del Rey, supra note 35, at 1421.
illicit drugs. However, the effects of caffeine on marine organisms and coastal ecosystems have not been well-researched and are largely unknown. One laboratory study indicated that a seven-day exposure to environmental concentrations of caffeine induced a stress syndrome in Mediterranean mussels, causing the mussels to undergo detoxifying processes.\textsuperscript{38} Bioluminescence inhibition, fertilization impairment, algal bleaching, and mortality have also been observed in marine species as a result of exposure to high concentrations of caffeine.\textsuperscript{39} Although current environmental concentrations of caffeine are thought to be too low to significantly affect the survival, growth, and reproduction of marine organisms, there is concern that higher concentrations of caffeine released into the marine environment may have devastating effects.

### III. EXISTING LEGAL AND REGULATORY LANDSCAPE

This Part provides an overview of the primary state and federal laws that address pollutant flushing, wastewater treatment, and discharges of treated wastewater effluent into the marine environment. When it comes to flushed pollutants, the Clean Water Act and Porter-Cologne Water Quality Control Act provide the most effective protection for the marine environment through the regulation of discharges of pollutants by hospitals and other large-scale flushers into the sanitary sewer system, as well as discharges of effluent from POTWs into the ocean. The Controlled Substances Act (as amended) and California Uniform Controlled Substances Act help to reduce household flushing of unwanted pharmaceuticals by providing alternative mechanisms for safe and legal disposal. The Resource Conservation and Recovery Act and California Medical Waste

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38. Marco Capolupo et al., \textit{Use of an Integrated Biomarker-based Strategy to Evaluate Physiological Stress Responses Induced by Environmental Concentrations of Caffeine in the Mediterranean Mussel Mytilus Galloprovincialis}, 563–64 SCi. THE TOTAL ENV'T 538, 538–48 (2016). The study found “Environmental concentrations of [caffeine] are comprised in the range of 2–1600 ng/L, with higher values reported for estuarine and coastal waters,” \textit{id.} at 539.

39. \textit{Id.} at 540.
Management Act regulate the disposal of unused pharma-ceuticals by hospitals and other large-scale generators of pharmaceutical waste. And finally, the Endangered Species Act and California Endangered Species Act seek to protect marine species that are especially vulnerable to extinction from harmful pollutants contained in POTW effluent. These laws provide a patchwork of protection for marine ecosystems, but as the following Sections illustrate, they are vastly inadequate to prevent flushed pharmaceuticals, illicit drugs, and caffeine from harming marine organisms.

A. The Clean Water Act and Porter-Cologne Water Quality Control Act

The Clean Water Act (“CWA”) is the primary federal law regulating water quality and water pollution in the United States. Its goal is to “restore and maintain the chemical, physical, and biological integrity of the Nation’s waters.” Under the CWA, it is unlawful for any person to discharge pollutants from a point source into the ocean, contiguous zone, or any other navigable waters of the United States, except in compliance with a National Pollutant Discharge Elimination System (NPDES) permit. The Porter-Cologne Water Quality Control Act (“Porter-Cologne Act”) is a state law dedicated to protecting water quality and the beneficial uses of waters within California. It implements many CWA provisions, including the NPDES permit program and the national pretreatment program.

Pharmaceuticals, illicit drugs, and caffeine contained in wastewater effluent are considered pollutants under the CWA.
As point sources, POTWs that discharge effluent into the ocean are therefore required to obtain and comply with individual NPDES permits. A POTW may not obtain an NPDES permit that authorizes the discharge of pollutants if the State Director determines that the discharge “will cause unreasonable degradation of the marine environment after application of all possible permit conditions.” NPDES permits issued to POTWs establish effluent limitations that are determined using technology-based effluent limitations (“TBELs”) based on secondary treatment standards (or the equivalent to secondary treatment standards) and water-quality based effluent limitations (“WQBELs”) established by the United States Environmental Protection Agency (“EPA”). TBELs generally focus on the overall biochemical oxygen demand, total suspended solids, and pH of wastewater. These standards and limitations, however, generally do not specifically address the levels of flushed pollutants in wastewater effluent.

The national pretreatment program is designed to prolong the useful lifespan of POTWs and to help POTWs comply with NPDES permit requirements. Pretreatment standards are generally expressed as numeric effluent limitations, narrative prohibitions, and best management practices. All indirect chemicals discharged into the marine environment to treat farmed salmon for infection, disease, and sea lice are pollutants under the CWA), aff’d 339 F.3d 23 (1st Cir. 2003).

46. 40 C.F.R. §§ 122.1(b)(1)–(2), 125.120 (2016).
47. Id. at § 125.123(b). See also id. at §§ 122.2, 125.122.
48. Id. at § 122.44. See also U.S. EPA, NPDES PERMIT WRITERS’ MANUAL ch. 5 TECHNOLOGY-BASED EFFLUENT LIMITATIONS (2010), https://www.epa.gov/sites/production/files/2015-09/documents/pwm_chapt_05.pdf [https://perma.cc/9EZE-4MUB].
49. 40 C.F.R. § 125.3 (2016).
50. Id. at §§ 133.100–133.101.
53. National Pollutant Discharge Elimination System (NPDES) Pretreatment Standards and Requirements, EPA, https://www.epa.gov/npdes/pretreatment-
dischargers,\textsuperscript{54} including most hospitals, are subject to a set of general national pretreatment standards.\textsuperscript{55} Most POTWs are also required to develop local pretreatment programs that indirect dischargers must comply with.\textsuperscript{56}

Together, the CWA and Porter-Cologne Act provide advocates with the strongest tool for protecting the marine environment against flushed pollutants. This tool, however, is inadequate. The NPDES permit program and the national pretreatment program do not apply to household flushing. NPDES permit conditions for POTWs do not specifically monitor and regulate discharges of pharmaceuticals, illicit drugs, and caffeine.\textsuperscript{57}

Furthermore, the national pretreatment program fails to impose standards of heightened stringency specifically designed for hospitals and other large, indirect dischargers of pharmaceutical waste.

B. The Controlled Substances Act and California Uniform Controlled Substances Act

The Controlled Substances Act ("CSA") is the primary federal law regulating the importation, manufacture, distribution, possession, and use of controlled substances.\textsuperscript{58} Similarly, the California Uniform Controlled Substances Act ("Uniform Controlled Substances Act") prescribes state drug policy.\textsuperscript{59} Drugs that are considered controlled substances under the CSA are listed and classified into five schedules.\textsuperscript{60} Controlled substances covered by both Acts include pharmaceuticals and illicit drugs such as amphetamines, cannabis, cocaine, MDMA, methadone,
methamphetamine, morphine, and prescription opioids.\(^61\) Under the CSA, it is unlawful for “any person knowingly or intentionally to possess a controlled substance unless such substance was obtained . . . from a practitioner, while acting in the course of his professional practice . . . .”\(^62\) The Uniform Controlled Substances Act delineates fines and other punishments for possession offenses.\(^63\) Because the mere possession of a controlled substance is often a punishable offense, available methods for legal disposal of unwanted controlled substances are very limited.

In an attempt to reduce household flushing of unwanted controlled substances, the Secure and Responsible Drug Disposal Act of 2010 (“Disposal Act”)\(^64\) and the Disposal of Controlled Substances Rule\(^65\) amended the CSA to allow for the disposal of over-the-counter prescriptions and controlled substances that are lawfully possessed via take-back events,\(^66\) mail-back programs,\(^67\) and collection receptacles.\(^68\) However, only ultimate users and persons legally entitled to dispose of a deceased ultimate user’s property may employ these methods to dispose of controlled substances.\(^69\) An ultimate user is “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household.”\(^70\) Long-term care facilities with authorized collection receptacles may also dispose of certain controlled substances on behalf of an ultimate users who reside or have resided onsite.\(^71\)

\(^66\) Id. at § 1317.65.
\(^67\) Id. at § 1317.70.
\(^68\) Id. at § 1317.75.
\(^69\) Id. at §§ 1317.65, 1317.70, 1317.75.
\(^71\) 21 C.F.R. § 1317.80 (2016).
Because these disposal alternatives are only available to limited individuals and only allow for the disposal of certain controlled substances, they are a step in the right direction, but are far from sufficient. They may help to reduce the flushing of unwanted pharmaceuticals by ultimate users, but do nothing to reduce the flushing of illicit drugs. Limited public awareness of the availability of these disposal alternatives and the relative ease of flushing further diminishes the efficacy of these options.

C. The Resource Conservation and Recovery Act and California Medical Waste Management Act

The Resource Conservation and Recovery Act ("RCRA") is a federal law that governs the management of non-domestic hazardous solid waste.\(^{72}\) Under RCRA, healthcare providers and reverse distributors that generate large amounts of pharmaceutical hazardous waste must comply with extensive tracking and reporting requirements as the waste is transported to a permitted facility for proper treatment and disposal.\(^{73}\) Waste is defined as any substance that is discarded or intended to be discarded.\(^{74}\) Some pharmaceuticals, including unused nicotine products, are regulated as hazardous waste under RCRA. However, EDCs that are of particular concern in the context of the marine environment (such as antibiotics, antidepressants, and reproductive hormones) are not regulated under RCRA.\(^{75}\)

The California Medical Waste Management Act ("Medical Waste Management Act") is a state law governing the management of medical waste that is generated and treated in

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\(^{75}\) 40 C.F.R. § 261.33 (2016).
California.\(^\text{76}\) Under the Act, regulated medical waste includes all prescription and over-the-counter drugs that are discarded or intended to be discarded, and are not regulated by RCRA.\(^\text{77}\) Medical waste generators include hospitals, clinics, medical and dental offices, research laboratories, and unlicensed health facilities such as hospices and long-term care facilities.\(^\text{78}\) Medical waste treatment facilities are those permitted for offsite handling, storage, and treatment of medical waste.\(^\text{79}\) The Medical Waste Management Act requires medical waste generators and treatment facilities to ensure pharmaceutical waste is incinerated or disposed of through limited alternative methods.\(^\text{80}\) Flushing is not listed as an acceptable method of disposal under the Act.\(^\text{81}\)

Together, RCRA and the Medical Waste Management Act regulate the disposal of all non-domestic pharmaceutical waste generated in California. However, in practice, these acts may not be effective at preventing pharmaceutical flushing by healthcare facilities. Navigating two layers of regulation can be extremely complex and hospitals and other large generators of pharmaceutical waste find compliance to be exceedingly onerous and costly.\(^\text{82}\) As a result, flushing remains a common method of disposal for unused pharmaceuticals.\(^\text{83}\)

\(^{76}\) CAL. HEALTH & SAFETY CODE §§ 117600, 117605 (West 2017).
\(^{77}\) Id. at §§ 117690, 117747.
\(^{78}\) Id. at § 117705.
\(^{79}\) Id. at §§ 117715, 117725.
\(^{80}\) Id. at § 118215.
\(^{81}\) Id.
\(^{82}\) Memorandum from Tri-TAC to POTW Pretreatment Coordinators and Managers (Sept. 23, 2003), http://cwea.org/p3s/documents/TriTAC\%20Pharmaceutical\%20Memo\%20FINAL.pdf [https://perma.cc/8H4A-ZPSF] (stressing that there is “increasing pressure on medical facilities to minimize their disposal costs by [flushing] waste pharmaceuticals.”).
\(^{83}\) Id. See also Management Standards for Hazardous Waste Pharmaceuticals, 80 Fed. Reg. 58014, 58018 (proposed Sept. 25, 2015) (to be codified at 40 C.F.R. pt. 261, 262, 266, 268, 273) (stating that disposing pharmaceuticals down the drain is a “common disposal practice among healthcare facilities,” and “many healthcare facilities, particularly long-term care facilities, are using drain disposal as a routine disposal method for pharmaceutical wastes.”).
D. Endangered Species Act and California Endangered Species Act

The Endangered Species Act of 1973 ("ESA") is a federal law devoted to the protection of species that are in danger of extinction or are likely to become in danger of extinction within the foreseeable future. The California Endangered Species Act ("CESA") is a state law that is similarly purposed and designed. Both the ESA and CESA provide protection for listed endangered and threatened species, though the Acts differ in their listing processes and criteria. Over 140 marine species are federally listed as threatened or endangered and are afforded protection by the ESA. Under the ESA’s take prohibition, it is unlawful for any person subject to the jurisdiction of the United States to kill, harm, harass, pursue, capture, or collect an individual of a listed endangered species, or to attempt to do so, within the United States, the territorial sea of the United States, or upon the high seas. In addition to individuals, this prohibition applies to instrumentalities of the Federal Government and of any State, municipality, or political subdivision of a State. This includes POTWs.

Although the ESA’s prohibition on harmful activities affecting listed species is sufficiently broad and the prohibition applies to POTWs, the ESA provides inadequate protection for marine species against potentially harmful pollutants contained in treated wastewater effluent. The CESA is similarly

85. CAL. FISH & GAME CODE § 2052 (West 2013).
86. 16 U.S.C. § 1532(20) (2012) (defining threatened species as “any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range”).
87. 16 U.S.C. § 1532(6) (2012) (defining endangered species as “any species which is in danger of extinction throughout all or a significant portion of its range . . .”).
90. Id. at § 1538.
inadequate. The ESA and the CESA only protect listed species, which comprise just a small percentage of known marine organisms. Furthermore, little research has been conducted on the impact that exposure to flushed pollutants has on particular species in the marine environment.\textsuperscript{91} Marine ecosystems are also dynamic and complex, and the relationships and interdependencies between marine organisms are not well understood.\textsuperscript{92} Furthermore, marine organisms generally have larger ranges than their freshwater and terrestrial counterparts.\textsuperscript{93} Thus, the distance between an individual marine organism and a particular source of pollution may vary greatly over time, along with the impact that the pollution will have on the individual. These factors make it exceedingly difficult to show that the take of a listed endangered marine species has occurred as a result of the discharge of pollutants from a POTW into the marine environment.

IV. TOOLS FOR PROTECTING THE MARINE ENVIRONMENT

As American consumption of pharmaceuticals, illicit drugs, and caffeine persist, so too will concentrations of these pollutants in effluent discharged from POTWs into the marine environment. Although our existing laws and regulations are currently failing to protect the marine environment from flushed pollutants, there is a way forward. In light of the uncertainty surrounding the effects these pollutants have on marine organisms and ecosystems, precautionary solutions are necessary.

\textsuperscript{91} Sally Gaw, et al., Sources, Impacts, and Trends of Pharmaceuticals in the Marine and Coastal Environment, 369 Phil. Transactions Royal Soc’y B. 1, 1 (2014) [https://perma.cc/H2JY-WGVP] (“by contrast [to freshwater ecosystems], significantly less attention has been paid to understanding releases of pharmaceuticals from sewage and other routes into coastal environments and their potential marine impacts.”).

\textsuperscript{92} See, e.g., John H. Steele, The Structure of Marine Ecosystems (Harvard Univ. Press,1974).

\textsuperscript{93} Mark H. Carr et al., Comparing Marine and Terrestrial Ecosystems: Implications for the Design of Coastal Marine Reserves, 13 Ecological Applications (Special Issue) S90, S91 tbl.1 (stressing that the “openness” of marine ecosystems is a key factor with respect to environmental and ecological features, and the patterns and consequences of human impacts).
to protect the health of our oceans. The marine environment can be protected by reducing the overall amount of flushed pollutants entering POTWs and by compelling POTWs to remove flushed pollutants from wastewater effluent. These goals can be accomplished through policy reform, the introduction of new legislation, public education, and continued research.

A. Policy Reform and Legislative Amendments

When it comes to flushed pollutants, our current laws and policies provide a patchwork of minimal protection for the marine environment. Reforming existing policies to specifically address flushed pollutants and enacting new legislation to reduce flushing of pharmaceuticals and illicit drugs will provide more comprehensive protection for marine organisms and ecosystems. This section discusses reform that has been introduced but not yet adopted and proposes additional measures that can be taken to reduce the impact flushed pollutants have on the marine environment.


The EPA proposed the Management Standards for Hazardous Waste Pharmaceuticals Rule to help healthcare providers understand and comply with regulations pertaining to the disposal of pharmaceutical waste. The Rule also strives to reduce the amount of unused pharmaceuticals flushed by healthcare facilities including hospitals, pharmacies, long-term care facilities, and pharmaceutical reverse distributors. Healthcare facilities often flush hazardous waste pharmaceuticals that are also DEA-recognized controlled substances to avoid having to comply with both RCRA and CSA regulations. If finalized, the Rule will

95. Id. at 58014, 58018.
96. Id. at 58028.
prohibit healthcare facilities from flushing hazardous waste pharmaceuticals. The Rule also narrows the household hazardous waste exemption under RCRA to exclude pharmaceutical hazardous waste generated at long-term care facilities.\textsuperscript{98} Under the Rule, this waste would be regulated pursuant to RCRA management standards.\textsuperscript{99} Because long-term care facilities treat elderly and severely ill individuals, they accumulate large quantities of pharmaceutical hazardous waste.\textsuperscript{100} On the national level, keeping this waste out of POTWs would contribute greatly to the protection of the marine environment from flushed pollutants. However, in the context of California, this Rule would mostly reiterate provisions of the Medical Waste Management Act.

As of this writing, the Safe Drug Disposal Act of 2009 has also been introduced but has not yet been enacted. The Act is a proposed amendment to the Federal Food, Drug, and Cosmetic Act.\textsuperscript{101} It bans drug labeling that recommends disposal by flushing. This simple prohibition would help reduce household pharmaceutical flushing, which is not otherwise regulated.

2. Amending the CWA/Porter-Cologne Act

The NPDES permit program and national pretreatment program prescribed by the CWA and implemented by the Porter-Cologne Act provide a strong regulatory framework for minimizing the discharge of pollutants into the marine environment. These programs fail, however, to specifically recognize pharmaceuticals, illicit drugs, and caffeine as pollutants of particular concern. This oversight allows flushed pollutants to enter the

\begin{flushleft}
\textsuperscript{97} Id. at 58016.
\textsuperscript{98} Id. at 58026.
\textsuperscript{99} Id.
\textsuperscript{100} AARP Public Policy Institute, Insight on the Issues: Assisted Living and Residential Care in the States in 2010, http://www.aarp.org/content/dam/aarp/research/public_policy_institute/ltc/2012/residential-care-insight-on-the-issues-july-2012-AARP-ppi-ltc.pdf [https://perma.cc/V5YZ-GQXS] (last visited May 9, 2016) (reporting that residents of long-term care facilities take an average of seven or eight prescription pharmaceuticals and two over-the-counter medications daily).
\end{flushleft}
marine environment undetected, causing harms of unknown scale and severity.

To remedy shortcomings in the NPDES permit program, the CWA, and the Porter-Cologne Act should be amended to require the development of TBELs and WQBELS that address pharmaceuticals, illicit drugs, and caffeine. NPDES permit conditions for POTWs and large-scale direct dischargers (such as healthcare and drug treatment facilities) should also include monitoring requirements and effluent limitations targeted at flushed pollutants.

To remedy shortcomings in the national pretreatment program, categorical pretreatment standards that currently apply to healthcare facilities that are direct dischargers should be evaluated and amended, if necessary, to minimize the direct discharge of flushed pollutants into the environment. Similarly, equally protective categorical pretreatment standards that specifically address flushed pollutants should be developed for healthcare facilities that are indirect dischargers. This will reduce the concentrations of pharmaceuticals, illicit drugs, and caffeine contained in POTW influent, and therefore effluent.

3. Amending the CSA/Uniform Controlled Substances Act

The Disposal Act allows for individuals to dispose of legally possessed controlled substances via take-back events, mail-in programs, and collection facilities. Improving public awareness and availability of these methods of disposal will offer added protection for the marine environment against flushed pollutants. However, illicit drugs cannot be legally disposed of using these methods, and the U.S. Department of Justice offers no advice to individuals looking to dispose of unwanted illicit drugs.102 Because illicit drugs thrown out as household refuse pose a threat to humans and animals that may find them, and domestic incineration of illicit drugs is potentially hazardous,

flushing is the only remaining disposal option. To reduce the amount of illicit drugs that are flushed into POTWs, and ultimately into the marine environment, a safe and legal method for disposing of illicit drugs must be developed.

Drug possession prohibition laws severely complicate efforts to dispose of illicit drugs. Individuals looking to dispose of illicit drugs will be unwilling to transport or mail them out of fear of criminal prosecution. Additionally, illicit drugs that are found or intercepted pose a high risk of accidental overdose. For these reasons, developing a mechanism for individuals to dispose of small amounts of illicit drugs will prove to be challenging, perhaps prohibitively so. Individuals looking to dispose of large quantities of illicit drugs, however, may warrant more contemplation. Relaxed enforcement of possession laws may be considered in limited circumstances to allow individuals to forfeit illicit drugs through prescribed mechanisms. Drug rehabilitation facilities that collect illicit drugs from their residents also have no legal disposal mechanism, and likely resort to flushing. Regulations should be drafted to provide a process by which these facilities can destroy illicit drugs onsite or can transfer them into DEA custody for destruction. Keeping these drugs out of human hands and out of the marine environment through safe and legal confiscation and destruction is an important cause that is worthy of innovative regulatory reform.


Pharmaceutical Extended Producer Responsibility ("EPR") programs should also be implemented throughout California. Alameda County devised the first mandatory drug take-back program in the state by enacting the Safe Drug Disposal Ordinance.\textsuperscript{105} The ordinance requires pharmaceutical manufacturers who sell or distribute certain prescription and over-the-counter medications in Alameda County to develop, fund, and implement a Product Stewardship Program that facilitates the collection, transportation, and disposal of unwanted pharmaceuticals.\textsuperscript{106} Trade associations representing pharmaceutical manufacturers challenged the ordinance, alleging violation of the Dormant Commerce Clause.\textsuperscript{107} The Dormant Commerce Clause places an implied limitation on a state’s power to enact laws that burden interstate commerce.\textsuperscript{108} The Ninth Circuit Court of Appeals validated the ordinance, holding that the ordinance did not discriminate against or directly regulate interstate commerce, and that the burden on interstate commerce did not clearly exceed the local benefits of the ordinance.\textsuperscript{109} The United States Supreme Court declined to hear the case on appeal, allowing the ordinance to stand and opening the door for similar legislation in other California counties.\textsuperscript{110} Similar EPR laws have been passed in Marin County,\textsuperscript{111} the City and County of San Francisco,\textsuperscript{112} San Mateo County,\textsuperscript{113} and Santa

\textsuperscript{105} ALAMEDA, CAL., HEALTH & SAFETY CODE §§ 6.53.010 et seq. (2016) [https://perma.cc/5BKC-QY83].
\textsuperscript{106} Id. at §§ 6.53.040–6.53.050.
\textsuperscript{107} Pharm. Research & Mfrs. of Am. v. Cty. of Alameda, 768 F.3d 1037 (9th Cir. 2014) (holding that the ordinance did not violate the Commerce Clause), cert. denied 135 S. Ct. 2348 (2015).
\textsuperscript{108} Or. Waste Sys., Inc. v. Dep’t of Envtl. Quality of State of Or., 511 U.S. 93, 98 (1994) (“[T]he [Commerce] Clause has long been understood to have a ‘negative’ aspect that denies the States the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce.”).
\textsuperscript{109} Pharm. Research, 768 F.3d at 1041–46.
\textsuperscript{110} Pharm. Research, 135 S. Ct. 2348.
\textsuperscript{111} MARIN CNTY., CAL., CODE OF ORDINANCES, Safe Drug Disposal Ordinance, tit.7, ch.7. at 90 (2016).
\textsuperscript{113} SAN MATEO CNTY., CAL., ORDINANCE CODE, Safe Medicine Disposal Ordinance, tit. 4, ch. 4.116 (2015) [https://perma.cc/S4W5-KRC5].
Clara County. An EPR ordinance has also been proposed in Los Angeles County.

4. Adoption Of A Universal No-Pharmaceutical-Flushing Policy

Another way to reduce pharmaceutical flushing is to abandon the U.S. Food and Drug Administration (“FDA”) Flush List and to adopt a universal no-pharmaceutical-flushing policy. The FDA Flush List recommends disposal by flushing for pharmaceuticals that present particular concern for abuse and overdose. While this policy is meant to keep humans and pets from ingesting potentially dangerous unused drugs, it favors the introduction of these pharmaceuticals into the marine environment. Because we currently lack sufficient safeguards to prevent flushed pollutants from harming marine organisms and ecosystems, these pharmaceuticals should instead be disposed of through take-back events or transfer to a DEA-authorized collector. Adopting a universal no-pharmaceutical-flushing policy would encourage the use of these alternative disposal methods.

Because many of the pharmaceuticals on the FDA Flush List present an especially high risk of overdose to children and others to whom they were not prescribed, the adoption of a universal no-pharmaceutical-flushing policy could be met with potentially insurmountable political opposition. The development of safe disposal alternatives that are more accessible and convenient than current methods would make the adoption of such a policy more feasible. Innovation of wastewater treatment technology targeted at listed pharmaceuticals and development of marine-
safe versions of listed pharmaceuticals would also help to reduce the impact that these flushed pollutants have on the marine environment.

B. Public Education and Continued Research

In order to evaluate the scope and severity of this issue, research is desperately needed to determine the amounts of flushed pollutants entering the marine environment and the effects these pollutants have on marine organisms and ecosystems. Further research is required to determine acceptable levels of flushed pollutants in treated wastewater effluent discharged into the marine environment to eliminate or minimize these effects, and to determine whether existing technologies are sufficient and economically viable to attain discharge levels deemed acceptable.

Imposing comprehensive monitoring requirements and stringent effluent limitations specific to flushed pollutants in POTW effluent will encourage the development of more efficient technological processes for removing pharmaceuticals, illicit drugs, and caffeine from wastewater. Establishing similar requirements and limitations for discharges from healthcare facilities such as hospitals, pharmacies, rehabilitation centers, and long-term care facilities may also put pressure on pharmaceutical companies to engineer medications that are benign to the marine environment and may even prompt government agencies to develop safe and legal disposal alternatives to flushing illicit drugs.

Public education is one of the strongest tools for reducing the effects that flushed pollutants have on marine organisms and ecosystems. Household flushing contributes a significant percentage of pharmaceuticals, illicit drugs, and caffeine entering POTWs, yet the general public knows very little about wastewater treatment and oceanic discharge. Campaigns to dispense information about safe and legal disposal methods for unwanted pharmaceuticals and to raise awareness of the potential effects that flushed pollutants may have on marine organisms and ecosystems could help to reduce household flushing of unwanted pharmaceuticals.
V. Conclusion

Recent studies indicate that flushed pollutants such as pharmaceuticals, illicit drugs, and caffeine are entering the marine environment through discharges of wastewater effluent from POTWs. Due to a lack of monitoring and regulation, the rate at which these pollutants are released into the marine environment is unknown. The effects that these pollutants may have on marine organisms and ecosystems are also not well-understood, raising concern that undetected discharges of flushed pollutants could have devastating consequences. In the face of great scientific uncertainty, extreme precaution should be exercised to protect marine resources.

Our current laws and regulations are inadequate to protect the marine environment from flushed pollutants. By strengthening existing policy and introducing new legislation, we can develop a more comprehensive regime to regulate the discharge of flushed pollutants into the marine environment. We can reduce household flushing of unwanted pharmaceuticals and illicit drugs through prudent pharmaceutical labeling, policy innovation, and public awareness campaigns. Industrial flushing of unused pharmaceuticals and illicit drugs can also be lessened through the imposition of new categorical standards for health services facilities and the development of safe and legal disposal alternatives. The amount of flushed pollutants discharged into the marine environment can be further reduced through the inclusion of specific monitoring requirements and numeric effluent limitations for pharmaceuticals, illicit drugs, and caffeine in NPDES permits issued to POTWs. Future scientific research and development may also yield pharmaceuticals that are less harmful to the marine environment and more effective and economical technological methods for removing flushed pollutants from wastewater.

Protecting the marine environment from flushed pollutants will require legislative reform, extensive research, and public education. It will require a dynamic and multifaceted effort and will present scientific and political challenges requiring innovative solutions. However, taking action now to protect the
marine environment from flushed pollutants is extremely important for the future of marine organisms and ecosystems, which provide us with great economic, recreational, educational, and cultural value.