

What the Brita Won't Purify: Why Kentucky is in Need of Strict Pharmaceutical Disposal Regulations

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INTRODUCTION

Water is a vital part of our everyday lives; we use it from the time we wake up until we hit the pillow at night. The quality of the water we put into our bodies is not often something we think about when we turn on the faucet for a drink. We trust the water we are drinking is pure and not contaminated. Unfortunately, there are quite a few contaminants affecting our water supply. In 2002, the U.S. Geological Survey ("USGS") conducted a survey of several streams and found seven chemical compounds present in the water.¹

The Toxic Substances Hydrology Program of the USGS found a broad range of chemicals were typically found at low concentrations downstream from areas of intense urbanization and animal production.² The types of chemicals found during the survey include human and veterinary pharmaceuticals, natural and synthetic hormones, detergent metabolites, plasticizers, insecticides, and fire retardants.³ These chemicals are commonly found in the home, agricultural sites, and waste water.⁴ Waste water is water affected by human use.⁵ It can include water used within the home from sinks, showers, and washing machines, as well as water used by businesses and industries.⁶ Wastewater is

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¹ *Pharmaceuticals in the Water Supply*, AM. RIVERS, <https://www.americanrivers.org/threats-solutions/clean-water/pharmaceuticals-personal-care/> [<https://perma.cc/Z7MQ-X4F4>] (last viewed Jan. 20, 2020).

² U.S. Geological Survey, *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams*, USGS (June 2002), <https://toxics.usgs.gov/pubs/FS-027-02/>, [<https://perma.cc/BB59-L7BN>].

³ *Id.*

⁴ *Id.*

⁵ U.S. GEOLOGICAL SURVEY, *Wastewater Treatment Water Use*, USGS, https://www.usgs.gov/special-topic/water-science-school/science/wastewater-treatment-water-use?qt-science_center_objects=0#qt-science_center_objects [<https://perma.cc/RZA9-N7BL>] (last viewed Jan. 31, 2020).

⁶ *Id.*

then treated and used again.⁷ Wastewater not treated to rid the water of chemicals will have harmful effects on human health, wildlife, and agriculture.⁸

In 1948, The United States Environmental Protection Agency (“EPA”) enacted the Clean Water Act (“CWA”).⁹ The CWA, originally called the Federal Water Pollution Control Act, established the basic structure for regulating the discharge of pollutants into the waters of the United States.¹⁰ The EPA implements programs setting wastewater standards for industry and water quality recommendations for the pollutants in surface waters.¹¹

In 2008, the public became aware of the pharmaceuticals in our water, which was supplied to over 41 million Americans.¹² Even though the pharmaceuticals were found in small amounts, it led to questions about the long-term effects of having these pharmaceuticals enter people’s bodies from everyday sources in the home.¹³ It was revealed the water companies were not voluntarily disclosing these results to the public, leaving them in the dark.¹⁴ Of the thirty-five watersheds (natural source of nation’s water supply) tested, twenty-eight pharmaceuticals were detected after the water treatment process.¹⁵

In order for a pollutant to be regulated by the EPA, it must be considered high risk after going through two mechanisms monitoring pollutants.¹⁶ First, the pollutant must make it onto the list established by the EPA prioritizing concerning pollutants.¹⁷ Second, the unregulated contaminant monitoring rules require all water supply utilities serving more than 10 thousand consumers to monitor the previously discussed list of contaminants.¹⁸ The results of this list are further

⁷ *Id.*

⁸ *Id.*

⁹ Clean Water Act, 33 U.S.C § 1251 et seq. (1972).

¹⁰ U.S. GEOLOGICAL SURVEY, *supra* note 5.

¹¹ *Id.*

¹² *Probe: Pharmaceuticals In Drinking Water*, CBS NEWS (Mar.10, 2008) <https://www.cbsnews.com/news/probe-pharmaceuticals-in-drinking-water/> [<https://perma.cc/BV5X-ZJBW>].

¹³ U.S. GEOLOGICAL SURVEY, *supra* note 5.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

investigated to determine if the containment is a risk and whether it should be fully regulated.¹⁹

States such as California have taken the extra step to start developing regulations to monitor pharmaceuticals in reused water.²⁰ Although the EPA sets regulations for water pollutants, as of 2019, there have been no federal regulations establishing limits for pharmaceuticals in water.²¹ States have the ability to implement higher standards for regulating pollutants in water. As of now, there are no specific regulations in Kentucky relating to the proper disposal and treatment of pharmaceuticals found in the water.²² Increasing state regulations on pharmaceuticals in the drinking water could help push for federal regulations by showing this is an increasing public concern and should not be put off.

This Note will explore how pharmaceuticals enter the waterways in Part I. Part II will go on to describe the effects pharmaceutical contamination has on the environment, including mutation of fish and crops. Part III will describe pharmaceutical disposal methods and the implementation and enforcement of policy-based approaches will follow in Part IV. Finally, Part V will highlight the long-term effects contamination will have on the environment if creation of environmentally friendly pharmaceuticals and the implementation of proper disposal regulations is not prioritized.

I. HOW DO PHARMACEUTICALS ENTER WATERWAYS?

A. Population

Consumer use of pharmaceutical drugs has increased exponentially over the past few years.²³ Kentucky falls within the top ten states with the highest rates of prescribing medication.²⁴

¹⁹ U.S. GEOLOGICAL SURVEY, *supra* note 5.

²⁰ *Id.*

²¹ *Id.* at 2.

²² See *Water Quality Standards Regulations: Kentucky*, U.S. ENV'T PROT. AGENCY, <https://www.epa.gov/wqs-tech/water-quality-standards-regulations-kentucky#state> [https://perma.cc/5962-6LNY] (last viewed Mar. 28, 2021).

²³ Pharmaceuticals in the Water Supply, *supra* note 1.

²⁴ Nat'l Inst. on Drug Abuse, *Opioid Summaries by State*, DRUGABUSE.GOV (Apr. 16, 2020), <https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state> [https://perma.cc/76Q7-6M39].

For every 100 persons, providers in Kentucky wrote 79.5 opioid prescriptions.²⁵ With the declaration of the opioid crisis and the population's use and abuse of these prescriptions at an all-time high, our water is at risk for high levels of contamination, which ultimately puts the public's health in danger. One of the most common ways the general population contributes to the contamination of the water supply is the excretion and improper disposal of prescription medications.²⁶ Drugs thrown away and flushed down the toilet contribute to the water contamination.²⁷ Prescription drug waste enters landfills, then the runoff from the landfills gets treated through wastewater systems and, when eventually discharged, finds its way into local waterways.²⁸ In order to reduce the amount of prescription drugs being disposed of, which in turn contaminate waterways, it is important to start at the source.

Aside from creating pharmaceuticals known as "green drugs," discussed later in this Note, the opioid crisis in Kentucky requires examination as well. Provider regulations and utilization of the Prescription Drug Monitoring Programs ("PDMP") can help reduce the amount of prescription drugs entering the waterways.²⁹ The PDMP monitors controlled substance prescriptions through an electronic database to provide prescribers with information about a patient's medical history and ensures they are not being overprescribed medications, specifically opioids.³⁰ As a result, reducing the amount of prescriptions given will reduce improper disposal and excretion, leading to less contamination of the water sources.³¹

A. *Pharmaceutical Manufactures*

²⁵ Nat'l Inst. on Drug Abuse, *Kentucky: Opioid-Involved Deaths and Related Harms*, OPIOID SUMMARIES (Apr. 16, 2020), <https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/kentucky-opioid-involved-deaths-related-harms> [<https://perma.cc/8TM9-K2PT>].

²⁶ Clean Water Action, *Keeping Drugs Out of Our Waterways: Safe Drug Disposal Program*, CLEAN WATER ACTION, <https://www.cleanwateraction.org/features/keeping-drugs-out-our-waterways-safe-drug-disposal-program> [<https://perma.cc/L3RP-FLQG>] (last viewed Mar. 28, 2021).

²⁷ *Id.*

²⁸ *Id.*

²⁹ See CTR. FOR DISEASE CONTROL & PREVENTION, *What States Need to Know About PDMPs*, CDC, (June 10, 2020), <https://www.cdc.gov/drugoverdose/pdmp/states.html> [<https://perma.cc/DP3H-TSGW>] (last viewed Mar. 28, 2021).

³⁰ *Id.*

³¹ See Clean Water Action, *supra* note 26.

Pharmaceutical manufacturing plants, hospitals, and clinics are significant contributors to contamination of waterways through the production of an expansive range of pharmaceutical products.³² These facilities are not always required to deem their products non-infectious prior to disposal.³³ In Kentucky, medical waste is characterized as municipal solid waste, meaning it can be disposed of in landfills.³⁴ Due to the lack of regulation and environmental consideration, chemicals are being released into the environment and eventually into our waterways.³⁵

The Kentucky Cabinet for Health and Family Services requires certain public health facilities to treat medical waste run-off on or off-site.³⁶ Although medical waste must be declared nonhazardous, the disposal process still includes waste being dumped in landfills.³⁷ A study conducted by the U.S. Geological Survey revealed wastewater treatment plants receiving discharge from pharmaceutical facilities had levels of active pharmaceutical ingredients were ten thousand times higher than a treatment plant not receiving discharge.³⁸ The most common amount of active pharmaceutical ingredients range from 2–400 µg/L.³⁹ This measurement means 2–400 micrograms of active pharmaceuticals are found per liter of water. This study highlights a direct link from pharmaceutical manufacturing plants to higher levels of active pharmaceutical ingredients in wastewater.⁴⁰

Producer-financed waste collection, commonly referred to as “extended producer responsibility,” is supported by the Clean

³² Rebecca Kessler, *Industry Issues: Pharmaceutical Factories as a Source of Drugs in Water*, NAT'L INSTITUTE OF ENVTL. HEALTH SERVICES, (Sept. 2010), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2944108/> [<https://perma.cc/W577-98LT>].

³³ *Id.*

³⁴ Kentucky Energy and Environment Cabinet, *Background: Overview of Medical Waste in Kentucky*, KY.GOV, <https://eec.ky.gov/Environmental-Protection/Waste/recycling-and-local-assistance/Pages/medical-waste.aspx#:~:text=Background%3A%20Overview%20of%20Medical%20Waste,fluids%2C%20or%20potentially%20infectious%20materials.&text=In%20Kentucky%2C%20there%20are%20no,with%20jurisdiction%20over%20medical%20waste> [<https://perma.cc/Q3SM-TW2W>] (last viewed Mar. 7, 2021).

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ Kessler, *supra* note 32.

³⁹ Kentucky Energy and Environment Cabinet, *supra* note 34.

⁴⁰ Kessler, *supra* note 32.

Water Action.⁴¹ Extended producer responsibility requires pharmaceutical manufacturers to take responsibility for the drugs throughout their entire lifecycle, including disposal.⁴² Unfortunately, the United States has not implemented this practice.⁴³ If adopted, it would decrease contamination in the waterways. Cost should not be a reason for pharmaceutical manufacturers to shy away from this practice. Countries such as Canada, Mexico, and several European nations have implemented this system, and the cost has proven to be minimal.⁴⁴

II. EFFECTS OF PHARMACEUTICAL CONTAMINATION OF WATERWAYS

A. *Animals*

The unregulated pharmaceuticals in our water have more than just an effect on the water quality. Animals have started to display side effects caused by long-term exposure to water contaminated by pharmaceuticals.⁴⁵ Fish have been found to be one of the animals directly affected.⁴⁶ Fish, such as salmon, are being exposed to medications, like Xanax, commonly over prescribed in the medical field.⁴⁷ Studies show salmon exposed to these pharmaceuticals migrate twice as early as unexposed salmon.⁴⁸ Migrating early can result in the death of the salmon because they are arriving at sea underdeveloped and in

⁴¹ Clean Water Action, *supra* note 26.

⁴² *Id.*

⁴³ *See id.*

⁴⁴ *Pharmaceuticals and Water Pollution*, CLEAN WATER ACTION, <https://www.cleanwateraction.org/files/publications/CA%20Pharma%20Fact%20Sheet.pdf> [<https://perma.cc/W4QVL7Y4>] (last viewed Feb. 7, 2021).

⁴⁵ Pharm. in the Water Supply, *supra* note 1.

⁴⁶ Rebecca Giggs, *Human Drugs Are Polluting the Water—And Animals Are Swimming in It*, THE ATLANTIC (May 2019), <https://www.theatlantic.com/magazine/archive/2019/05/pharmaceutical-pollution/586006/>, [<https://perma.cc/DZ4R-HL8A>].

⁴⁷ Rebecca Giggs, *Human Drugs Are Polluting the Water—And Animals Are Swimming in It*, THE ATLANTIC (May 2019), <https://www.theatlantic.com/magazine/archive/2019/05/pharmaceutical-pollution/586006/>, [<https://perma.cc/DZ4R-HL8A>]; *see also* Brendan L. Smith, *Inappropriate Prescribing*, AM. PSYCHOL. ASS'N (June 2012), <https://www.apa.org/monitor/2012/06/prescribing> [<https://perma.cc/JE4W-Sf4F>].

⁴⁸ Giggs, *supra* note 46.

unfavorable seasonal conditions.⁴⁹ The salmon are not receiving the same biological signals after being exposed to these medications.⁵⁰ This is directly related to the drugs being consumed and effecting their natural instincts.⁵¹

Fish are also being physically altered by water contaminated by pharmaceuticals.⁵² Male bass in the Potomac river have started displaying female features.⁵³ Endocrine disruptors are presumed to be responsible for these changes.⁵⁴ Some noted effects include male fish producing eggs, and intersex fish have been discovered as well.⁵⁵ Additionally, minnows in Ontario were utterly wiped out due to exposure to hormonal dugs found in water.⁵⁶ This kind of extreme consequence has the potential to disrupt the entire ecosystem when a whole species is eliminated.⁵⁷

While the majority of current policy regarding quality of water is reactive, implementing proactive policy to combat pharmaceutical pollution in waterways is imperative to seeing improvement in the health of these animals. Upgrading water systems can be costly and most are unwilling to spare the expense; the most efficient way to limit the pharmaceutical residue is to limit its use in the first place.⁵⁸ Lawmakers can make this push by promoting restrictions on the use of pharmaceuticals in agriculture as well as implementation of green pharmacy and promoting public environmental health.⁵⁹

B. Agriculture

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² Pharm. in the Water Supply, *supra* note 1.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ Damian Carrington, *Drugs flushed into the environment could be cause of wildlife decline*, THE GUARDIAN (Oct. 12, 2014), <https://www.theguardian.com/environment/2014/oct/13/drugs-flushed-into-the-environment-could-be-cause-of-wildlife-decline> [https://perma.cc/9CSZ-2BZC].

⁵⁷ *Id.*

⁵⁸ THE ORG. FOR ECON. COOP. & DEV., *Emerging policy instruments for the control of pharmaceuticals in water*, OECD ILIBRARY (2019), <https://www.oecd-ilibrary.org/sites/4781cb74-en/index.html?itemId=/content/component/4781cb74-en&mimeType=text/html> [https://perma.cc/88C2-U9D4].

⁵⁹ *Id.*

Crops are often treated with wastewater, especially during times of drought.⁶⁰ A study conducted by a research group at Sultan Qaboos University in Oman analyzed the effects using treated water has on crops compared to those treated with water without any pharmaceutical contamination.⁶¹ The research group tainted water with common pharmaceutical products such as amoxicillin, sulfamethoxazole, trimethoprim, and ibuprofen.⁶² Two sets of radish plants were grown, one with water not contaminated by pharmaceuticals and one with contamination.⁶³ Although pharmaceuticals were undetectable in the soil due to degradation, a physical inspection showed vast physical differences in the two groups.⁶⁴ Plants receiving the water contaminated by pharmaceutical products lost several leaves and some did not survive to maturity.⁶⁵

B. Population

The population is exposed to water contaminated by pharmaceuticals on a daily basis.⁶⁶ Pharmaceutical products produced by manufacturers and used by the general population have increased rapidly in recent years so, as of now there are not many long-term studies done to show major effects on human health.⁶⁷ With what we do know, there are negative effects that should be taken seriously to ensure the health of the population in the years to come. Water contaminated with pharmaceutical products is known to lead to hormonal imbalances in humans.⁶⁸ Endocrine disruptors found in these pharmaceutical products can lead to imbalances after prolonged exposure, which is likely to

⁶⁰ Alexander Beadle, *The Agricultural Perspective on Water Contamination by Pharmaceuticals*, TECH. NETWORKS (Aug. 21, 2018), <https://www.technologynetworks.com/applied-sciences/articles/the-agricultural-perspective-on-water-contamination-by-pharmaceuticals-307839> [https://perma.cc/D2WP-E4NF].

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Information Sheet: Pharmaceuticals in Drinking Water*, WHO, https://www.who.int/water_sanitation_health/diseases-risks/risks/info_sheet_pharmaceuticals/en/ [https://perma.cc/4ZKE-XYH4] (last viewed Jan. 30, 2021).

⁶⁷ *Id.*

⁶⁸ Beadle, *supra* note 60.

happen since almost all people drink water every day.⁶⁹ Effects such as infertility, ovarian or prostate cancer, and an increased risk of autoimmune diseases can also occur after prolonged exposure.⁷⁰

Low-income neighborhoods are at an even higher risk for pharmaceutical contamination in the drinking water.⁷¹ These low-income communities are often exposed to a disproportionate amount of pollution and water contamination compared to others.⁷² Higher levels of arsenic and nitrates have been found in the water in these communities.⁷³ The higher level of these contaminants was correlated with pharmaceuticals in drinking water.⁷⁴ In response to the disproportionately negative impact COVID-19 has on low-income communities, on April 30, 2020, the EPA released a statement that grant funding will be provided to low-income and minority communities in an effort to support environmental justice in communities in Kentucky.⁷⁵ This grant will fund projects addressing healthy housing issues including the impact of the polluted water in these communities and possible solutions.⁷⁶

C. Wastewater

Wastewater is a prevalent way pharmaceutical contaminants can enter the drinking water.⁷⁷ Wastewater includes raw sewage such as septic system leakage, water overflow, and sewage

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ Laurel A. Schaider et al., *Environmental justice and drinking water quality: are there socioeconomic disparities in nitrate levels in U.S. drinking water?*, ENV'T HEALTH (Jan. 17, 2019), <https://doi.org/10.1186/s12940-018-0442-6> [<https://perma.cc/9ZWW-V5TB>].

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ Jason McDonald, *EPA Provides Grand Funding to Support Environmental Justice Communities in Kentucky Impacted by COVID-19*, U.S. ENV'T PROTECTION AGENCY, (Apr. 30, 2020), <https://www.epa.gov/newsreleases/epa-provides-grant-funding-support-environmental-justice-communities-kentucky-impacted> [<https://perma.cc/HNR5-G48L>].

⁷⁶ *Id.*

⁷⁷ *Pharmaceuticals and Other Chemicals Common in Landfill Waste*, USGS https://toxics.usgs.gov/highlights/2014-08-12-leachate_pharm.html, [<https://perma.cc/4QH4-RGSB>] (last viewed Jan. 30, 2021).

illegally dumped into unauthorized areas.⁷⁸ Wastewater does not pass through the same treatment surface water does in order to reach quality standards.⁷⁹ Wastewater contains many contaminants including pharmaceutical contamination able to pollute surface water.⁸⁰ Because it is difficult to control and regulate accidental leakage, it is important to set high regulation standards for surface water to make up for the untreated water added.

III. DISPOSAL METHODS

A. In the home

Disposing of pharmaceutical products properly will help decrease the number of pharmaceuticals in our drinking water and will protect the health of our plants, animals, and human population. A few methods of disposal should be avoided, including flushing and open burning.⁸¹ These methods will lead to pharmaceuticals in the water and in the case of burning, pollution in the air.⁸² Most pharmaceuticals are prescribed and used as directed in the home; however, pharmaceuticals can also be over-prescribed and become addictive, resulting in the abuse of these medications and an abundance of pharmaceuticals in the home not being disposed of properly.⁸³ The opioid crisis continues to have a devastating impact on the state of Kentucky and throughout the United States.⁸⁴ Preventing the over-prescription of medications is a necessary part of the prevention of

⁷⁸ *Wastewater Treatment Use*, USGS, https://www.usgs.gov/special-topic/water-science-school/science/wastewater-treatment-water-use?qt-science_center_objects=0#qt-science_center_objects [<https://perma.cc/U5AR-CEMG>] (last viewed Jan. 30, 2021).

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ Kentucky Energy and Environment Cabinet, *Guidelines for Household Pharmaceutical Waste Collection Programs* (2012), <https://eec.ky.gov/Environmental-Protection/Waste/recycling-and-local-assistance/Fact%20Sheets/Guidelines%20for%20Household%20Pharmaceutical%20Waste%20Collection%20Programs.pdf> [<https://perma.cc/XDS5-4A4S>].

⁸² *Id.*

⁸³ Mutaseim Makki et al., *The Prevalence of Unused Medications in Homes* (June 13, 2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6631141/> [<https://perma.cc/76GA-L9RB>].

⁸⁴ *Kentucky: Opioid-Involved Deaths and Related Harms*, DRUGABUSE.GOV (Apr. 3, 2020), <https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/kentucky-opioid-involved-deaths-related-harms> [<https://perma.cc/74AD-XNX4>].

pharmaceutical waste ending up in our waterways. Until over-prescription is stopped, people need a way to rid their homes of unused and unwanted prescriptions.

The Kentucky Department of Environmental Protection recommends disposing of pharmaceuticals via collection centers as the best way to avoid environmental contamination.⁸⁵ Any type of medication is accepted at these locations working closely with law enforcement agencies to ensure the drugs are safely disposed of.⁸⁶ Once the drugs are secured and ready to be disposed of, they are transported in compliance with Department of Transportation requirements for transporting household pharmaceuticals to facilities for proper disposal.⁸⁷ The pharmaceuticals are solidified into sawdust or dissolved in water, and taken in a sealed container to a landfill.⁸⁸

A. Incineration

Incineration is a low-cost and fairly environmentally friendly way to dispose of pharmaceuticals.⁸⁹ The incineration should be done at a high temperature. Low temperature burning in an open container can pose a serious risk to the quality of the air.⁹⁰ Toxic pollutants can be released if not incinerated properly.⁹¹ Higher temperature incinerators are also used to destroy unwanted and unused pharmaceuticals.⁹² These incinerators must meet strict emission standards.⁹³ Although this is a low-cost method, proper research and emission control standards must be used in order to regulate the amount of chemicals released into the air.⁹⁴ Just like regulations for pharmaceutical disposal, regulations must be imposed before

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ WORLD HEALTH ORGANIZATION, *Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and After Emergencies* (1999), https://www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf [<https://perma.cc/P8FU-93QY>].

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

incineration of the pharmaceuticals to ensure contaminants are not released into the air.⁹⁵

B. End of Pipe Policy Implementations

Unlike the preventative measures mentioned before, the policy to develop further end of pipe measures happens after the pharmaceuticals have already entered the waterways in an attempt to eliminate pharmaceuticals from the water.⁹⁶ The first policy option to accomplish better end of pipe measures is introducing more advanced technology to the process.⁹⁷ This method requires a combination of technologies to identify and eliminate pharmaceutical substances.⁹⁸ This approach has the potential to be costly because it involves the need for investment into the water systems as well as energy consumption harming the environment.⁹⁹ Possible consequences include increased carbon emissions and the formation of toxic transformation products.¹⁰⁰ There are many entities involved with this approach, including pharmaceutical industries, wastewater utilities, and health environment officials.¹⁰¹

Although implementing these regulations can be costly and complicated, it has been done before and produced positive results. Switzerland has implemented advanced activated carbon technologies in order to reduce the amount of pharmaceutical pollution.¹⁰² Making an effort like this is necessary to see improvements in the water quality.¹⁰³ These advanced treatments can also be applied directly to a major source of the pharmaceutical contamination of our water, wastewater discharged from hospitals.¹⁰⁴ This approach allows for early separation of the pharmaceuticals from hospital wastewater plants before continuing any further in the process.¹⁰⁵ The population is at a much lower risk of being exposed to the

⁹⁵ WORLD HEALTH ORG., *supra* note 89.

⁹⁶ ORG. FOR ECON. COOP. & DEV., *supra* note 58.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² ORG. FOR ECON. COOP. & DEV., *supra* note 58.

¹⁰³ *Id.*

¹⁰⁴ *See id.*

¹⁰⁵ *Id.*

pollutants at this point, and addressing the problem as soon as possible can reduce the amount of work needed during the end of pipe treatments.

IV. POLICY BASED APPROACHES

A. *Source-Directed*

The source-directed approach focuses primarily on imposing policy upon pharmaceutical companies and companies purchasing pharmaceutical products in bulk.¹⁰⁶ This policy approach seeks to provide incentives and regulate how large companies dispose of drugs in a way avoiding contamination in our water supply.¹⁰⁷ Not only would this policy create a healthier water supply, it would also reduce the cost of alternative approaches including upgrading wastewater treatment facilities.

In 2009, United States Representative, Candice Miller, introduced the Drug Free Water Act of 2009.¹⁰⁸ The Act requires the EPA Administrator to assemble a task force to make recommendations on proper methods to dispose of pharmaceuticals used by the consumer and health care providers.¹⁰⁹ The purpose of this Act is to reduce the effects contamination has, not only on our environment, but on human health as well.¹¹⁰ This Act also touches on the need for the public to be educated on recommended ways to dispose of unused –and unwanted prescription medication.¹¹¹ Although this Act can be viewed as the government taking action against this growing problem, it only scratches the surface and leaves room for improvement. This is not a stopping point for government intervention, but simply the start of the conversation.

As more research surfaces regarding the pollution of our water by pharmaceuticals, states have pushed for regulation. In 2014, The Department of Justice Drug Enforcement Administration clarified the meaning of “disposal” in Title 21 Code of Federal Regulations Part 1317 Disposal of Controlled

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ Drug Free Water Act of 2009, H.R. Res. 276, 11th Cong. (2009).

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

Substances.¹¹² The goal of this clarification was to establish guidelines for collecting and securely destroying pharmaceuticals to be consistent with the Disposal Act's goal to limit pharmaceuticals introduced into the environment.¹¹³

This Act specifies the limits on the authorization of the collection of prescription drugs from pharmacies and drop off programs.¹¹⁴ These restrictions will help limit improper disposal derived from home use. States have taken it upon themselves to take the restrictions further. The state of Illinois passed the Safe Pharmaceutical Disposal Act, restricting hospitals from simply flushing excess pharmaceuticals down the drain.¹¹⁵ Although there will still be pharmaceutical residue in our water from human waste, regulating the improper disposal of large amounts of drugs is a good place to start.

In 2018, the EPA, under the administration of Andrew Wheeler, imposed a new hazardous waste pharmaceutical rule requiring health care providers to take on a role in the disposal of pharmaceutical drugs.¹¹⁶ This new rule also specifies that grocery store chains, chiropractors, and nursing care facilities are required to comply instead of being excluded under the household waste exclusion.¹¹⁷ The rule continues to expand the scope of those who are responsible for their own environmental pollution. Big companies, along with these smaller facilities under the EPA rule, are required to register with the EPA, give training to staff, and separate the hazardous pharmaceuticals from non-hazardous materials.¹¹⁸ An issue arises with an exemption under the EPA—pharmaceuticals collected during a take-back program (including programs set up by law enforcement for the public to drop off medication with no questions asked) are considered exempt from regulation.¹¹⁹ This leaves a gap in how these pharmaceuticals should be safely disposed of. Starting with EPA policy,

¹¹² 21 C.F.R. § 1317 (2014).

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ Safe Pharmaceutical Disposal Act, Pub. Act 096-0221, 210 ILL. COMP. STAT. ANN. 150 (2010).

¹¹⁶ Marlys Palumbo & Gwendolyn Keyes Fleming, *New Hazardous Waste Pharmaceutical Rule Imposes New Obligations on Health Care Providers*, THE NAT'L LAW REVIEW (Apr. 5, 2019), <https://www.natlawreview.com/article/new-hazardous-waste-pharmaceutical-rule-imposes-new-obligations-health-care> [https://perma.cc/K4AX-C663].

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

regulations must be implemented across the board to see any sort of positive result within the environment.

B. Public Policy

Green public procurement is another policy-based approach to pharmaceutical regulation. This approach would implement biodegradable pharmaceuticals having lower toxicity and are “eco-effective,” often known as “sustainable chemistry.”¹²⁰ Changing how pharmaceuticals are manufactured is a long-term goal the environment would greatly benefit from in the future by reducing the environmental risks and stopping the problem at the source.

In order for regulations to be implemented to make this approach possible, there needs to be incentives for the manufacturers.¹²¹ Although health should be the main concern, policy makers need to highlight financial benefits to make this approach marketable. Concerns have been expressed which include needing the upfront cost to be outweighed by long-term savings by changing the way pharmaceuticals are manufactured.¹²² The policy can create tax incentives, ERA-dependent authorization of new drugs, and guidelines for procurement of pharmaceuticals.¹²³

C. Manufacturing Procedures

Creating laws restricting manufacturing plants and provide guidelines for the process of the design and operation of manufacturing plants help to stop water pollution at the source. Besides requiring the pharmaceuticals to be engineered in an eco-friendly way, this is the next logical step to prevent pollution.¹²⁴ Using the Best Available Techniques policy can help reduce emissions from manufacturing plants.¹²⁵ Creating regulations using this policy would mean setting limits for the amount of discharge acceptable if avoiding discharge is completely

¹²⁰ ORG. FOR ECON. COOP. & DEV., *supra* note 58.

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

impossible.¹²⁶ This policy approach would give manufacturing plants freedom when it comes to how they choose to operate in a friendlier way to the environment. Good manufacturing practices can be used as another approach during the production of pharmaceuticals.¹²⁷ Environmental preservation and protection has not been integrated into this policy technique, but it leaves room to be incorporated. This approach is similar to the Green Pharmacy policy approach in that it seeks to create restrictions to ensure the entire lifecycle of the pharmaceutical, from creation to excretion, is considered.¹²⁸ Due to the enormous impact pharmaceuticals have on the environment, including water and agriculture, which people consume daily, it is in the best interest of the policymakers to start regulating from the creation stage.

D. Use-centered

Changing how manufacturing companies operate and imposing regulations is essential to improving pharmaceuticals's disposal and the overall quality of drinking water and the environment. The population with a hand in the process, including physicians, pharmacists, and farmers, must start to see improvement.¹²⁹ This policy approach centers on changing the way users and manufacturers think. As previously mentioned, the United States has declared an opioid crisis; by changing the approach to prescribing medication, not only will there be a reduction in the amount of medication prescribed and therefore entering the environment, but there will be a decrease in consumption and cases of fatal overdose.¹³⁰ For the prescribers to see a benefit in altering their methods, policymakers must push incentives to change. For example, the government might offer subsidies in return for a commitment to the reduction of pharmaceutical waste and environmental responsibility.¹³¹ Changing the way pharmaceuticals have been prescribed and

¹²⁶ ORG. FOR ECON. COOP. & DEV., *supra* note 58.

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ NAT'L INST. ON DRUG ABUSE, *supra* note 24.

¹³¹ ORG. FOR ECON. COOP. & DEV., *supra* note 58.

used in the environment is no small task. It will take robust policy implementation, especially in states heavily impacted by opioid overuse and pharmaceuticals, like Kentucky, to commit to drastically reduce use and subsequent environmental pollution, specifically pharmaceutical runoff into our water supply.

E. Health-Care Centered Policy

Improvements to our environment for preventing pharmaceutical runoff into waterways contaminating the water we drink and affect our crops and animals will take some time to implement. While these changes are developing, a useful policy approach centers around healthcare providers. A shift in the reduction of unnecessary opioid prescriptions will ease the human cost of the crisis and decrease the amount of pharmaceutical runoff.

Healthcare professionals often have many patients and not enough time to properly diagnose. This leads to healthcare professionals prescribing the wrong medication and re-prescribing another medication when such medication fails to work. Mandating enough time for patients to visit with healthcare professionals would allow for more accurate medical prescriptions and decrease pharmaceutical pollution from incorrect prescriptions.

F. Veterinary Approach

Using pharmaceuticals is a common practice to boost animals' growth, but these pharmaceuticals pose a risk to environmental health. Pharmaceuticals can be released into the water through excretion and leakage from storage tanks holding animal waste.¹³² Pharmaceuticals are also frequently prescribed to racehorses.¹³³ It is common for racehorses to get Lasix to increase performance during high stakes athletic events, like the Kentucky Derby.¹³⁴ This drug prevents horses from bleeding

¹³² *Id.*

¹³³ See Don Wolken, *Opinion: As Kentucky Derby week starts, here's what the drug Lasix does, why it's controversial*, USA TODAY (Apr. 29, 2019), <https://www.usatoday.com/story/sports/horses/triple/derby/2019/04/29/kentucky-derby-lasix-horses/3610686002/> [https://perma.cc/JBF7-5RQF].

¹³⁴ *See id.*

through their nose, something commonly occurring as a result of exercise-induced pulmonary hemorrhage due to the rupture of capillaries in their lungs after a high-stress physical competition.¹³⁵

Recently, twenty-three horses were euthanized in a short period due to being overworked.¹³⁶ As a result, horse tracks, including Churchill Downs have begun phasing out performance-enhancing drugs and with plans to eliminate use by 2021 completely.¹³⁷ Not only is the use of the drug unnecessary and completely avoidable, but the runoff and waste consequently pollute Kentucky's water supply. The House Bill Horseracing Integrity Act of 2017 was the first step towards federal regulation.¹³⁸ This bill would introduce new uniform-racing medication rules and promoted medication authority and anti-doping.¹³⁹ Simple changes like the termination of unnecessary veterinary pharmaceuticals for sport and performance improvement will change the public view on pharmaceutical regulation and its effect on our environment.

G. Regulations

The question turns to, how likely it is the public will regularly participate in public disposal methods. To ensure disposal methods are adhered to, it is necessary to impose legislation. Sweden has implemented mandatory participation in take-back programs, with an estimated 75 percent of unused or unwanted prescriptions being returned through these programs.¹⁴⁰ The United States has not yet implemented such a program; based on the success in other countries, it is likely to impact disposal and eventually in our waterways if implemented positively.

A simple way to increase public participation in prescription medications' safe disposal is to inform each customer of disposal options when they pick up prescriptions from their local provider. Providers can encourage the customers to bring in used and unwanted prescription bottles at their next pick-up and inform

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *See id.*

¹³⁸ Horse Racing Integrity Act of 2017, H.R. Res. 2651, 115th Cong. (2017).

¹³⁹ *Id.*

¹⁴⁰ THE ORG. FOR ECON. COOP & DEV., *supra* note 58.

them of the closest disposal location, so they have all the information to make the easy choice to dispose of the medication to keep our environment safe properly.

Until pharmacies and other providers make it a standard practice to inform customers of disposal options, national projects such as the Urgent Love Initiative have filled the gap by establishing and promoting safe pharmaceutical disposal.¹⁴¹ This initiative encourages disposal through mail-in prescription bags.¹⁴² Anyone can go online and have a pre-paid package sent to them to put in any unused and wanted medications into and send them off for proper disposal.¹⁴³ Even though this will greatly benefit the environment, it will also help to rid homes of prescriptions having the potential to be abused by others. If Kentucky implemented policy requiring pharmacies to provide a mail in bag for each customer, it would provide the consumer with a simple solution only requiring them to put the sealed bag in the mail and increase participation in proper disposal.

H. Enforcement

The National Environmental Policy Act expanded upon the Food and Drug Administration's ("FDA") duties to ensure animal and public safety as well as environmental impacts.¹⁴⁴ This expansion would put environmental protection at the forefront of the drug approval process and not as an afterthought. This change would not only save money during water treatment, but would additionally prevent health problems in our animals and population. If this new Act is not adhered to, there would be the possibility of judicial review brought by an interested party, including those in the agricultural industry who have had animals and crops directly affected and can establish a causal relationship between the conduct and injury that followed caused by the pharmaceutical pollution in the water.¹⁴⁵

¹⁴¹ *National Pilot Project: Questions and Answers*, URGENT LOVE INITIATIVE (2019), <https://www.disposeofmeds.org/q-a> [perma.cc/2D34-VFSS8].

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ National Environmental Policy Act, 42 U.S.C. § 4321 (1969).

¹⁴⁵ *Id.*

This Act requires manufacturers to submit an environmental assessment when submitting an application for the creation of a new drug to the FDA.¹⁴⁶ The report must contain information for the FDA to determine if the drug will have significant impacts on the environment; impacts of pharmaceutical pollution of the water should be one of the many considerations.¹⁴⁷ If the FDA has concerns, an environmental impact study will be the next step to dig deeper into the possible effects the drug will have on the environment and make the ultimate determination of whether or not the drug will be approved.¹⁴⁸ Unfortunately, if the FDA does not determine there is a possibility for significant impact on the environment, the process is over.¹⁴⁹ There is not a requirement for further assessment on potential long-term effects on the environment.¹⁵⁰ Environmental impact assessments should not just be required at the beginning of the creation of the drug but required every few years to monitor impact and any negative effects that may occur. This will allow for quick intervention in the case of water contamination by the pharmaceuticals.

V. LONG-TERM EFFECTS

In 2010, Great Lakes Environmental Law Center and the Natural Resources Defense Council filed a petition with the FDA to revoke the exemption of new drugs from environmental impact review if the concentration of the drug in the water supply is below 1 part per billion.¹⁵¹ This petition came after samples of the Lake Michigan revealed pharmaceutical contamination despite dilution and wastewater plants not being close to the source where the sample was taken.¹⁵² The remedy sought is accountability.¹⁵³ New drugs would not be prohibited from being

¹⁴⁶ Environmental Impact Considerations, FOOD AND DRUG ADMIN. (Feb. 5, 2021), <https://www.fda.gov/animal-veterinary/development-approval-process/environmental-impact-considerations> [https://perma.cc/MLR2-2UEH].

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Great Lakes Environmental Law Center and NRDC file petition to close loophole on pharmaceutical drugs in drinking water*, GREAT LAKES LAW (July 2010), <https://www.greatlakeslaw.org/blog/2010/07/great-lakes-environmental-law-center-and-nrdc-file-petition-to-close-loophole-on-pharmaceutical-drug.html> [https://perma.cc/F3LA-AR7N].

¹⁵² *Id.*

¹⁵³ *Id.*

put on the market, but the FDA would be required to announce the environmental risks and potential for harm.¹⁵⁴ It would also be required that the FDA continue studies to assess the risks.¹⁵⁵ Unfortunately, this petition was denied.¹⁵⁶

The Economic Development Administration explained extraordinary circumstances doing serious harm to the environment would need to be shown for a petition like this to be approved.¹⁵⁷ The response also stated dilution of the pharmaceuticals in large bodies of water was not taken into account.¹⁵⁸ Even though dilution does occur once pharmaceuticals are released into bodies of water and our water supply, we know through recent studies that enough pharmaceuticals are still present to have an effect on animals, agriculture, and even on the drinking water found in our homes.¹⁵⁹ Until a significant effect is seen in humans, it is unlikely these administrations will make a serious effort to regulate and evaluate the pharmaceuticals present in our water.

In 2015, pharmaceuticals were found in Lake Michigan, which is among some of the largest lakes in the United States.¹⁶⁰ Being one of the largest lakes, pharmaceuticals may not be expected to be found due to dilution, especially if the source of entry is not close to where the sample was taken.¹⁶¹ According to scientist Rebecca Klaper, this was not the case.¹⁶² In the sample of Lake Michigan, a diabetes drug was found three miles from the sewage treatment plant, this was not one of the original drugs on the list to be tested that Klaper expected to find.¹⁶³ Mutation of

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ Dawn Fallik, *This New Study Found More Drugs in Our Drinking Water Than Anybody Knew*, THE NEW REPUBLIC (Dec. 11, 2013), <https://newrepublic.com/article/115883/drugs-drinking-water-new-epa-study-finds-more-we-knew> [<https://perma.cc/4VFM-2S2Z>].

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ Annette Küster & Nicole Adler, *Pharmaceuticals in the environment: Scientific Evidence of Risks and its Regulations*, U.S. NAT'L LIBR. OF MED. NAT'L INST. OF HEALTH, (Nov. 19, 2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4213597/> [<https://perma.cc/PS6X-43LX>].

¹⁶⁰ Brian Owens, *Pharmaceuticals in the environment: a growing problem*, THE PHARM. J. (Feb. 19, 2015), <https://www.pharmaceutical-journal.com/news-and-analysis/features/pharmaceuticals-in-the-environment-a-growing-problem/20067898.article?firstPass=false> [<https://perma.cc/2RVT-EM9B>].

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ *Id.*

male fish reproductive systems like those previous discussed was found in the fish in lake Michigan.¹⁶⁴

The United States is not the only country beginning to see the repercussions of pharmaceutical pollution. Germany and other countries around the World have experienced the impact.¹⁶⁵ German studies found 156 pharmaceuticals have been found in the ground water, surface water, and drinking water.¹⁶⁶ These pharmaceuticals, including anti-depressant medications, have been reported at “environmentally relevant” concentrations, meaning they have the ability to have an effect on the animals in the water.¹⁶⁷

The mass production and consumption of pharmaceuticals will continue to aid this problem to grow across the World. Pharmaceuticals can be a necessary part of our health, but a global effort needs to be made to educate the population and treat the problem where it has already occurred. Even though areas such as Bloomington, Indiana follow EPA guidelines very closely on how to treat the water to try to produce the highest quality for everyday use, the EPA fails to account for the pharmaceuticals in the water.¹⁶⁸ Out of the ninety contaminants for which the EPA requires testing, pharmaceuticals that have been discovered as present in the water supply are absent from the list.¹⁶⁹ Sporadic exposure to pharmaceutical drugs may not be a big concern, but the exposure to these drugs several times a day should be enough to implement pharmaceutical regulation in the water treatment process. The effect of the inadvertent consumption of a combination of drugs by people of all ages in a society has not been studied to show how it can negatively affect people after decades of cumulative use.

¹⁶⁴ *Id.*

¹⁶⁵ Küster & Adler, *supra* note 159.

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ Leigh Boerner, *The Complicated Question of Drugs in the Water*, NOVA (May 14, 2014), <https://www.pbs.org/wgbh/nova/article/pharmaceuticals-in-the-water/> [<https://perma.cc/56Y5-J6DP>].

¹⁶⁹ *Id.*

VI. CONCLUSION

Research has only scratched the surface regarding how pharmaceutical contaminated water will affect our population, animals, agriculture, and the overall health of the environment in the future. We have discovered fish and crops have begun to mutate due to the constant exposure to pharmaceuticals and we are left to wonder what harmful effect it will have on the human population decades from now. Consideration of the environmental effects during drug creation needs to be taken seriously and when potential negative effects are discovered, a proper response is necessary—which includes outright denial of creation of the drug until a more environmentally friendly result can be produced. Until proper policies and regulations are implemented and adhered to, all producers and pharmaceutical users must take part in proper disposal methods. Kentucky can do its part by making a concerted effort to educate the public on the effects of pharmaceutical contamination and the simple methods to properly dispose and reduce pharmaceutical waste.