

The Edge of Chaos
Household Hazardous Waste Disposal II:
Prescription Medication in Jefferson County Wastewater
Proceedings from the Wicked Problem Discussion
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1. INTRODUCTION

1.1 About The Edge of Chaos

The notion of The Edge of Chaos comes from author Steven Johnson, who postulates that collaborative solutions to wicked problems occur in an environment that runs a fine line between order and chaos. To put it another way: innovation happens at the edge of chaos. Colliding minds is a central notion. When the same kinds of folks always work on the same kinds of problems, you get the same kinds of answers. Mix it up and you find innovative solutions. It happens when you put the poet, engineer, professor, and manufacturer together. Real solutions are the goal of The Edge of Chaos. Bringing together academia, business, and the community, we are more likely to find real and workable solutions to our most difficult problems. Collaborative solutions to a wicked problem occur on the fine line between order and chaos. This is not simply about the theoretical pursuit of what's possible. Mix up the kind of individuals that are working on a solution.

Academia + Business + Community = REAL solutions.

1.2 About Wicked Problems

Definitions abound for "wicked problems." At The Edge of Chaos, we think wicked problems are the big ones. They're the problems that continually plague communities. Wicked problems have no simple solutions, or worse, they have solutions that just cause more problems. We at The Edge of Chaos believe that, much like the Chinese fable of the elephant and the blind men, we can only understand and solve wicked problems through collaboration and the sharing of perspectives.

1.3 Specific Aims of the Discussion

The Wicked Problem discussed in this report reads as follows:

Prescription medications, if disposed of improperly, persist in wastewater even after treatment, are difficult and expensive to measure effectively, and pose a possible risk to public health, the existence and severity of which has yet to be determined.

Specifically, our discussion sought to explore several facets of this issue, as well as to recommend future directions and innovative solutions to each area.

1. Hazard Characterization - What known threats do prescription medications in wastewater pose to public health?
2. Prevalence - To what extent does this hazard affect community members of Jefferson County?
3. Treatment - To what extent does current water treatment infrastructure address this potential problem?
4. Prevention - What systems are currently in place to prevent the introduction of prescription medications into water? How efficacious are these systems?
5. Summary of Recommendations - What are the recommendations for the county going forward regarding best systems, practices, and/or technologies?

2. HAZARD CHARACTERIZATION

The first question that must be asked of this issue, as of any Wicked Problem, is deceptively simple - why might this be considered a problem? Several threats are possible, though few if any are backed up by data.

2.1 Antimicrobial Resistance

One concern is that elevated levels of prescription antibiotics in water may lead to an increase in the number and diversity of antibiotic resistant bacteria. This phenomenon has already been shown to occur in runoff and groundwater contaminated with the manure of animals fed with antimicrobial-laced food and water (Chee-Sanford *et al.* 2002; Winokur *et al.* 2002). However, solid dose-response studies at the ecosystem level are scarce, and the existing studies have failed to show a detectable dose-response relationship (Costanzo, Murby, & Bates 2005). Thus, though correlation is definite, and causation probable, the extent of this threat in the context of human wastewater cannot currently be determined.

2.2 Piscine Endocrinology

Another concern of pharmaceuticals in wastewater is the potential threat to fish life. There is a sufficient body of evidence to suggest that oral hormonal therapeutics - specifically birth control medications - can alter endocrine physiology at the individual level and can decrease the male-to-female ratio at the population level. This has been demonstrated in artificial (Kidd *et al.* 2007) and natural (Vajda *et al.* 2008) environments. The implications of this for human health are significant. Various fish species are present at multiple levels of the food chain. Among other things, a decreased male-to-female ratio in a lower food chain species (such as *P. promelas* (fathead minnows) in Kidd *et al.* 2007 or *C. commersoni* (white sucker fish) in Vajda *et al.* 2008) can lead to a decline in higher food chain species, such as bass, trout, and catfish, on which some humans depend for sustenance. Furthermore, a decline in lower food chain species leads to a rise in zooplankton and other small aquatic animals, which will now prey to a greater extent on small plant species such as algae, on which the entire ecosystem (including humans) depends for dissolved oxygen (DO). The amount of DO is a standard indicator as well as a direct determinant of overall water quality in rivers (Masters & Ela 2008), from which much of the drinking water for Alabama is taken. Low pre-treatment water quality means increased costs of treatment to meet federally mandated safe drinking water quality standards.

2.3 Biochemical Oxygen Demand (BOD)

BOD, closely related to DO, is another common measure of pollutant stress on a water supply or an aquatic environment. If an organic compound can serve as a reactant or substrate in a microbial (bacteria, algae, protozoa, *etc.*) reaction or process that also requires oxygen, it is considered an oxygen-demanding compound. The addition of excessive amounts of oxygen-demanding waste to water is another mechanism by which total DO can drop. There is little evidence to prove or disprove that

pharmaceuticals significantly increase BOD in water. The forum concludes that the contribution of pharmaceuticals to overall BOD is plausible, though likely insignificant.

2.4 Depletion of Tertiary Treatment Resources

As will be discussed later on, conventional tertiary treatment methods such as ozone (O₃), chlorine (Cl₂), and UV-light (UV) are somewhat effective in removing pharmaceuticals from wastewater (WHO 2011). This is by and large a good thing. Many pharmaceutical compounds enter the sewer system by excretion through urine. However, the practice of flushing away unneeded pharmaceuticals necessitates treatment by these non-specific, finite resources - resources that could be used to treat other pollutants more effectively, or otherwise not be used in the first place. However, the question "How much extra money does this preventable phenomenon cost treatment plants" given common treatments like those in Jefferson County, has not been evaluated scientifically. In Orange County, CA, reverse osmosis has been shown to be an extremely effective though expensive treatment method (AP 2008). This technology, however, is not found in Central Alabama, and thus is not valid to our discussion. Therefore, it can only be said that this hazard more likely than not occurs, but the severity of it has yet to be determined.

2.5 Conclusion and Recommendations

The members of the discussion conclude several probable hazards resulting from the disposal of prescription medications in wastewater. However, the severity of nearly all of these hazards has not yet been determined. The discussion group recommends further research on the severity of the aforementioned hazards, either locally (*e.g.* UAB School of Public Health; UAB School of Medicine; Samford University School of Pharmacy, *etc.*) or nationally. They also opine, whatever the extent of the hazard, general water quality would be higher (to what extent cannot be known) were pharmaceuticals not disposed of in the sewer system.

3. Prevalence

3.1 Quantitative Chemical Data

Currently, neither prescription medications nor their byproducts are monitored in drinking water. Reasons for this abound. First, as stated above, the hazard data is lacking to warrant monitoring. Second, monitoring pharmaceuticals and/or their byproducts is excessively costly. Most drinking water treatment facilities, including those in Jefferson County, monitor only for required contaminants. The members of the discussion hypothesized that if any monitoring were done, it would need to be only a select few common byproducts - those with the most precursors, the best predictive value of total pharmaceutical prevalence, and/or those with the most severe consequences. Estrogen, or 17- β -estradiol, was submitted as an example. However, even the most stripped down monitoring program for pharmaceuticals may not occur unless pharmaceuticals become regulated pollutants.

A study of Jefferson County's Valley and Village creeks conducted between 2000 and 2001 tested for Triclosan (an antimicrobial/antifungal agent found in soaps, detergents, and even toys), 17- β -estradiol, and Cotinine (a metabolic breakdown product of nicotine), but only Triclosan was found consistently above detectable levels; however, these levels were never found to be above 0.5 $\mu\text{g/L}$ (USGS 2002). The Reference Dose (RfD) - the daily oral dose below which little-to-no harm can reasonably be expected to occur over a lifetime - for chronic consumption in humans is 1.4 $\text{mg kg}^{-1}\text{d}^{-1}$, signifying improbable cause for alarm (MDH 2014). Triclosan may be harmful to aquatic ecosystems (which, again, concerns humans because of the effect on water quality); however, hot debate exists on the subject (Haden 2014; DeLeo & Sedlak 2014).

3.2 Quantitative Behavioral Data

The last comprehensive questionnaire of drug disposal behaviors in the US was conducted in 1996, was relatively large (n=500), and revealed that 35.4% of persons polled disposed of unwanted medication using their drain (Kuspis and Krenzlok 1996). The discussion members anticipated that Alabama's rate would be at or above this percentage; however they had no data to support this hypothesis. A new national or state survey would be welcomed in order to reflect how the state has changed over the past 20 years.

3.3 Conclusions and Recommendations

The members of the discussion recommend more exposure assessment research to better assess the prevalence of pharmaceuticals in Jefferson County wastewater. Without knowledge of both hazard *and* prevalence, true risk cannot be assessed, and costly interventions cannot be justified. The ideal exposure assessment would include both chemical and behavioral data, seeing as both factor into a solid understanding of the problem as well as potential solutions.

4. TREATMENT

4.1 Most Effective Practices

A literature review conducted by WHO revealed that the most effective treatment practices for the removal of medication from wastewater are Reverse Osmosis (RO), Nanofiltration (NF) Powdered Activated Carbon (PAC), and Granulated Activated Carbon (GAC), though a precise percentage removed for any of the aforementioned treatments has not been established (WHO 2011).

4.2 Most Cost-Effective Practices

Though RO is the most effective treatment procedure, doubts persist as to whether it is a *cost-effective* intervention. RO, implemented on a large scale, was estimated in Los Angeles to cost a household of four an additional \$15/month (AP 2008). GAC is significantly more cost-effective than reverse osmosis, shown in one instance to cost \$0.94/month for a family in Cincinnati (AP 2008), but is a fixed filtration method that increases maintenance costs and may require more monitoring to ensure filter integrity. NF is similarly cost-effective in comparison to RO, but requires periodic replacement and

proper disposal. PAC is added to secondary treatment tanks, and may be cost-effective if used *only* when needed; it is not, however, cost-effective if used constantly, and the lack of cost-effective monitoring programs makes knowing when the appropriate time is difficult (UNM 2009). Cl₂, O₃, and UV have been shown to remove sizeable but comparatively smaller fractions in relation to RO, PAC, and GAC. These chemical treatments, however, are commonly already used for nonspecific treatment (as discussed in Section 2.4), and their use to treat pharmaceuticals does not require the added costs of installation or maintenance.

All things considered, depending on a specific facility's budget and to what extent it considers pharmaceuticals and other unmonitored wastes a threat to public health, NF, GAC, and/or PAC may be effective *and* cost-effective solutions. However, for facilities that have neither the budget nor the perceived threat level sufficient to take treatment action, standard tertiary treatments are most likely sufficient (It should be noted that by the word "sufficient", we do not mean to say it is not a problem, but that the existing data either does not support or is not sufficient to support the claim that these new treatments will be the best thing for a facility).

4.3 Septic Systems

In Jefferson County, a sizeable portion - 59% (100,000/245,000) - of the county's population lives in housing serviced by a septic tank (JCC 2015). Septic tanks do not commonly include tertiary (chemical) treatment, and therefore it can be estimated that they do not remove pharmaceuticals as effectively. There is little evidence to suggest that septic systems exposed to pharmaceuticals in wastewater contribute to antimicrobial resistance (Pierce *et al.* 2011; Sayah, Kaneene, Johnson, & Miller 2005).

4.5 Conclusions and Recommendations

It is the view of the members of the discussion that new treatment systems other than what is currently in place would not do the county any good as far as cost-effectiveness. The data, as stated above, either negates or is insufficient to support that notion. Furthermore, the prevalence of septic systems minimizes the removal potential of technological innovations for wastewater treatment plants. The discussion members feel that, as will be discussed in the next section, prevention innovation would be far more cost effective.

5. PREVENTION

Public Health is founded on the proverb "Prevention is better than Treatment". It is no different in this case. The behavior of refraining from wastewater disposal of drugs and taking part in a drug take-back program will cost less than any one of the aforementioned monitoring or treatment programs, and will reduce the burden of pharmaceuticals on water quality and health more than all of them combined. For this reason, the members of the discussion chose to focus on innovation in this mostly-behavioral area rather than on technological innovation in the other.

5.1 Take-back Programs

At any point in time, unused medication can be surrendered to an office of law-enforcement via receptacle (much like a mailbox - anyone can put something in, but only an authorized person can take something out), by which it will be delivered to the local branch of the US Drug Enforcement Administration (DEA). This program exists with the purpose of removing medications that could result in the acute poisoning of minors, abuse and dependence in a person for whom the prescription may or may not have been written, and/or the synthesis of illicit drug. However, it is also seen as a safe option for the disposal of all unused pharmaceuticals (DEA 2015). Medications collected in this manner are incinerated either in a no-hazard low-temperature incinerator or in a hazardous waste high-temperature incinerator. The ash is then disposed of in a landfill of the appropriate hazard designation (hazardous or non-hazardous (Smith 2002).

5.2 The Era of Take-back Days

Until the end of 2014, medication take-back days in the US were funded by the DEA. On a Drug Take-back day, pharmacies and other specialized sites throughout the country could collect unused medication in addition to law enforcement offices.

5.3 Barriers to Proper Disposal during the Take-back Days era.

Several main barriers to disposal were identified by the members of the discussion: access and knowledge.

5.3.1 Knowledge

Even for those who did have easy access, knowledge of these days' existence was by no means prevalent. Though all members of the discussion knew of the official hazards, few knew about take-back days or the locations thereof. Many thought they still existed until informed that 2014 November 27 was the final one. The discussion members intuited that if experts on the subject were not aware of these, it was likely that publicity was not executed sufficiently for every-day citizens.

Another aspect of the knowledge gap that was explored was the regional and generational variation in best practices in the US. One member remarked that in Alabama years ago, he was always taught the *importance* of disposal in wastewater (flushing) so that poison and abuse could be prevented, and that it wasn't until a couple years ago with the new research that he learned not to. Another stated that in Minnesota, this was never the common teaching, and that medications are more commonly returned to pharmacies there than in Alabama.

It must also be noted here that, in addition to a lack of knowledge regarding take back days, there exists a lack of knowledge regarding law enforcement offices' ability to collect unused medications.

5.3.2 Access

During the era of the DEA-sponsored take-back days, take-back sites were few and far between. For example, if a hypothetical individual living in ZIP code 35233 (the ZIP code in which The Edge of Chaos is located) wanted to return unused prescription medications, and was not informed as to law-enforcement offices' ability to collect them, he/she would have to go to Oneonta (42 miles away) or Sylacauga (43 miles away). Therefore, even if some knowledge existed, access proved difficult.

It should also be noted that not every law enforcement office acts as a take back site. For Jefferson County, the subject of our discussion, this is not *as pressing* a problem as for others. There are 14 collection sites in Jefferson County - the most in any North Alabama County. In fact, of Alabama's 30 northern counties, only 8 have collection sites (DOJ 2015). Even in Jefferson County, it is plausible that not everyone to whom medication is prescribed has private means of transportation, and even if true access exists, perceived access may be low due to current issues with civilian mistrust of law enforcement. It should be noted that the previous statements are only plausible possibilities and have no data to support or negate them.

5.4 The new era: The Secure and Responsible Drug Disposal Act of 2010

In 2010, the Secure and Responsible Drug Disposal Act (SRDDA) was signed into law, giving the DEA authority to license "authorized collectors", namely health care facilities and pharmacies, to implement receptacle collection programs and mail-back programs. The law took effect upon its final ruling in September 2014; the final national take-back day was later that year (US Congress 2010; DEA 2014).

Though a part of it may be a lack of funding on the DEA's part, the official and positive aim of the SRDDA is to expand access to proper disposal pathways by enabling more establishments to take part in collection. The hope of the act is to further decrease the amount of unused medication in circulation, but environmental health scientists and Water, Sanitation, and Hygiene (WASH) engineers hope that it will also further decrease the incidence of improper disposal.

5.5 The need for partnership and innovation in the new era

Numerous issues were brought to the DEA's attention regarding cost-of-implementation in the wake of the new regulations, many of which were brought up in the discussion. One such issue was that becoming an authorized collector is voluntary, and no financial incentive is offered by the government to become one. Thus, critics argue, "it is unlikely that registrants will voluntarily accept the financial burdens associated with the provision of collection opportunities" (DEA 2014). Various commenters on the rule suggested either the DEA offer incentives, or mandate that all pharmacies install receptacles. To this the DEA responded that, in order to ensure that no entity was

coerced into providing these programs, they did not make any rule mandating that any entity fund this programs. In the opinion of the author, they did not directly address the question of incentives, but the full text of the dialogue between the DEA and commenters has been referenced so that the reader can decide for his/herself.

On another question regarding incentives, the DEA response was that partnership among different entities was "neither permitted nor prohibited". Though it is the opinion of the author that the question "Why didn't the DEA provide financial incentives?" was still not answered (Some suggest that the DEA does not have sufficient funds to do so (WPR 2014)), barring future change in the regulation, this is the era in which we currently live: one with the potential to provide the service of collection and proper disposal to a great deal more people than ever before, but also one in which private or public entities must create partnerships or individually foot the bill.

As the members of the discussion pondered this paradigm, two important questions were asked: "Who *holds the responsibility* of paying for these programs?" and "Who *would benefit* from funding these programs?" Both, the members felt, needed to be answered before a solution for the county could be discovered.

5.5.1 Who holds the responsibility of funding take-back programs?

Throughout the discussion, this question was answered in several different ways that spanned a number of ethical worldviews. One was that pharmacies and health care centers, who are the primary candidates for acting as authorized collectors, should pay for receptacles and mail-programs, as well as contract reverse distributors as one of the many health services they provide. The reasoning behind this argument is quite utilitarian. All people who have prescription medication either stole it (improbable) or received it from a pharmacy, clinic, or hospital. Therefore, it can be deduced that the vast majority of persons with unused medication have access or are close to someone who has access to these establishments. By this line of reasoning, pharmacies and hospitals providing this service would reduce the problem to the greatest extent possible and therefore benefit the most people possible, *ergo* pharmacies and hospitals should provide this service whether or not they receive outside funding, and fund it themselves if no partnerships can be created.

Another was that pharmaceutical manufacturers, though not positioned be effective authorized collectors, should help fund take-back programs. They introduced a drug into society; therefore, they hold some responsibility to make sure it leaves in the correct manner. This "cradle-to-grave" mindset mirrors the ethics behind the Resource Conservation and Recovery Act of 1976. It would indeed be interesting to see if an unregulated entity volunteered funding under this ethic, when most applications of said ethic in the present day are legal obligations.

A third possible answer is that of libertarian ethicists - that no one *should* fund proper disposal programs. This view submits that the only entities with an imperative to prevent improper disposal are the entities that stand to lose the most as a consequence of *nobody* doing it. Thus, either water treatment plants can fund it and charge more for their overall services to the people, the DEA can decide to fund it again because they are concerned with the consequences of circulating drugs, or the people (who also benefit) can lobby to have the service funded by the government and pay taxes on it. Critics might argue that this view presents a fallacy - that because the potential consequence of reduced water quality, it is actually everyone who is affected by poor or sufficient water quality - *ie everyone* - that stands to gain or lose. Thus, one could also argue by libertarian ethics that all parties have an imperative (though not a moral imperative) to fund these programs.

5.5.2 Who would benefit from funding take-back programs?

The previous paragraph's discussion of libertarian ethics provides a perfect segue between the question of moral imperative and the question of self-serving benefit. As stated before, one could simply argue that all parties would benefit because of the potential for increased water quality. Specifically though, several parties were submitted as having personal agendas in line with this endeavor. Two examples are wastewater treatment plants and drinking water treatment plants. If, as stated in previous sections, it is difficult to supply high quality wastewater to the environment and high quality drinking water to citizens when pharmaceuticals are present, they would benefit not only financially but also in fulfilling their mission by helping fund take-back programs. By this same principle, a state government wanting to decrease the number of unused drugs in circulation may also contribute personnel or money, as is happening in Wisconsin (WPR 2015).

Less obvious was the submission that pharmacies, pharmaceutical manufacturers, and health care providers would actually benefit from taking financial responsibility for take-back programs. As a precedent, we look to CVS Caremark in 2014, when they stopped selling tobacco-containing products. The official reason was that the sale of cigarettes and the like was inconsistent with the mission of the company: to provide health care services and to improve public health across the nation (CVS 2014). Financially, the profit losses from tobacco sales were expected to be enormous. But the company did indeed "benefit" in that public perception of CVS changed from a profit-driven company to a mission-driven company, which actually served to increase its overall revenue (Stamper 2014). Maybe, one discussion member submitted, pharmacies would benefit from funding and providing these services by the same principle. "X Pharmacy cares about your health", she remarked, "and they also care about water quality. Don't flush your unused meds down the toilet; bring them to us!" It is quite the interesting proposition, and merits consideration at least.

Two final parties that may benefit from partial (though not complete) funding are the reverse distributor and the incinerator. By offering occasional discounts on services, they could promote their business and potentially increase their volume and therefore their overall revenue.

5.5.3 The need for pharmacists as health educators

Before the issue of funding is addressed further in the recommendation section, another area of concern must be addressed: that even with the existence of take-back programs across Jefferson County, the common citizen does not know about them or the benefit of taking part in them. For this, the members of the discussion found that it would be beneficial for all and would cost relatively little time and money if pharmacists took an extra second at the pharmacy or created a flyer to give out with medication detailing the location of the nearest law-enforcement take-back location. Thus, even if no new innovation for funding take-back systems came about, knowledge and access for the systems currently in place would increase.

5.6 Conclusions and Recommendations

What can be recommended for the county? Though water treatment entities would indeed benefit, there are more pressing concerns in WASH infrastructure currently, from which it would be unwise to draw funds. The discussion members recommend that local and regional pharmacy directors at least consider the potential benefits and risks to the county as well to themselves. Another collaborative initiative that could be recommended is a "partnership" between pharmacies and law-enforcement collection sites to cross-advertise in an attempt to disperse pharmacy return traffic equitably across the county, thereby diffusing costs. A third potential area for collaboration is in education. Samford University trains a sizeable portion of practicing pharmacists in Alabama, and has a good relationship with UAB. Were members of the UAB School of Public Health Department of Environmental Health to coordinate education efforts to instill the importance of prevention advocacy in future pharmacists, it could increase the number of practicing pharmacist who educate patients regarding law-enforcement take-back programs, and could possibly create a new culture of pharmacists more willing to encourage the companies for which they work to adopt these programs for themselves. A final collaborative initiative suggested by the discussion members involves primary schools. As part of science education, specifically rivers and water, it could be taught as a minor portion of the curriculum the proper and improper procedures for medication disposal. Primary education, one member remarked, is a highly-efficacious manner in which to indirectly educate adults.

6. FINAL CONCLUSIONS AND RECOMMENDATIONS

To recap, the discussion highlighted several research gaps that are essential to determining the true nature of the overall and relative risk prescription medications in wastewater pose to society and more specifically Jefferson

County. Despite these gaps, the discussion members felt that existing research warrants prevention efforts, though possibly not yet regulation. In the era of the current regulations on disposal, collaborative efforts are more important than ever. Will private and public entities take on these initiatives without government incentive or coercion? The discussion members certainly hope it will be considered, and that the conversation that began at The Edge of Chaos will continue on in the larger Jefferson County Community. The members feel they have built a strong case for the virtue and potential benefits of doing so, but recognize the challenges of for-profit benevolence efforts; thus they feel that, if nothing else, these potential policy changes and partnerships should at least be explored. In addition, the spread of knowledge through pharmacist-patient interactions, academic-pharmacy student interactions, and potentially primary educator-child interactions, with the end goal of increased knowledge of available take-back programs and subsequent increased usage.

The moderator would like to thank all discussion members for attending and contributing, and hopes that they find all proceedings accurate, and that they continue to remain available for future collaboration as Jefferson County moves forward in its HHW disposal culture.

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