November 8, 2010

Meghan Hessenauer
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US EPA, 1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Sent via email to: unusedpharms@epa.gov

RE: Comments on Draft "Guidance Document: Best Management Practices for Unused Pharmaceuticals at Health Care Facilities"

Dear Ms. Hessenauer,

Thank you for the opportunity to comment on the U.S. Environmental Protection Agency's (EPA) Draft "Guidance Document: Best Management Practices for Unused Pharmaceuticals at Health Care Facilities" (hereinafter "Guidance Document") produced by the EPA Office of Water, dated August 26, 2010. Public Employees for Environmental Responsibility (PEER) is a Washington D.C.-based non-profit, non-partisan public interest organization concerned with honest and open government. Specifically, PEER serves and protects public employees working on environmental issues. PEER represents thousands of local, state and federal government employees nationwide. PEER has been actively involved in the pharmaceutical and personal care product (PPCP) issue for several years now, and as such, has an interest in this draft guidance document.

Background. Although PEER does not believe that disposal of unused pharmaceuticals is the primary source of pharmaceuticals in the environment and water supplies, it is certainly a piece of the puzzle that needs to be addressed. However, we caution that even if unsafe disposal practices were completely eliminated, pharmaceutical pollution would still remain. Specifically, industry research estimates that patient use of medicines is the principal source of pharmaceuticals in the water supply; one such estimate is that unused pharmaceuticals account for only 12% of pharmaceutical pollution.[1] Therefore, regulating the disposal of unused pharmaceuticals is important, but it will not prevent water contamination.

Comments on Guidance Document. PEER has several concerns with the Guidance document as written. Our specific comments are set forth below.

EPA should issue mandatory regulations rather than a guidance document. Pharmaceutical contamination of waters is ubiquitous and of potentially dangerous to both wildlife and humans. Therefore, PEER believes that EPA should issue mandatory disposal regulations for unused pharmaceuticals that are both stringent and enforceable. Unfortunately, the Guidance Document states, "The discussion in this document is intended solely as guidance… This document is not a regulation itself, nor does it change or substitute for those provisions and regulations. Thus, this document does not

[1] Tischler, Lial, et al. "Landfill Disposal as an Approach to Reduce Discharges of Medicines from POTWs." Proceedings of the Water Environment Federation, WEFTEC 2008: Session 101 through Session 115.18 (2008): 7538-7555.

impose legally binding requirements on EPA, states or the regulated community. This document does not confer legal rights or impose legal obligations upon any member of the public" (Guidance Document, Disclaimer). PEER believes that the situation has reached the point where voluntary guidance is meaningless. In order to minimize risks to both human health and the environment, EPA should consider issuing these guidelines as enforceable regulations. Specifically, EPA could codify these requirements in one of two ways. First, the federal Clean Water Act (33 U.S.C. §1251 et seq.) provides EPA with authority to regulate both industry and domestic wastewater discharges. EPA could place numeric discharge limits on pharmaceuticals in these discharges. Second, the Safe Drinking Water Act (SDWA, 42 U.S.C. §300f et seq.) provides EPA with authority to require monitoring and treatment of contaminants in public water supplies that pose a risk to human health through consumption or other exposure. Given that pharmaceuticals have been found in numerous public water supplies throughout the country, EPA could limit pharmaceuticals through the SDWA.

Disclaimers in the Guidance Document render it inconsequential. The Disclaimer at the beginning of the Guidance throws doubt on the Best Management Practices (BMPs) outlined in the document itself. Specifically, the Disclaimer states:

> The general descriptions provided here reflect EPA's current views and may not apply to particular situations based upon the circumstances. Interested parties are free to raise questions and objections about the substance of this guidance and the appropriateness of the application of this guidance to a particular situation. EPA and other decision makers retain the discretion to adopt approaches on a case-by-case basis that differ from those described in this document where appropriate.

This disclaimer indicates that the facilities that should be implementing the BMPs are free to ignore all of the suggestions in the document, and indeed, the Guidance may not even apply to them. However, the unspecified situations in which the Guidance would not be appropriate are left entirely to the imagination, and thus throw the entire document into question.

The facilities for which the Guidance was developed are too narrowly defined. The Guidance Document states, "This guidance document describes Best Management Practices (BMPs) that EPA recommends to health care facilities, such as hospitals, long-term care facilities, medical clinics, and doctors' offices, when managing and disposing of unused pharmaceuticals" (p. 1). Although the terms "health care facilities" and "long-term care facilities" are not defined, the Guidance should also specifically apply to assisted living facilities, veterinary hospitals and offices, morgues, and dental offices.

Even if this document remains as voluntary guidance, EPA should issue regulations to prevent the disposal of unused pharmaceuticals to sewers. Page 2 of the Guidance Document states that, "EPA decided to study medical facilities because the Agency believes that these facilities dispose large quantities of unused pharmaceuticals to sewers." PEER believes that EPA should make the documents upon which it relied to make this assumption available to the public. If indeed health care facilities are disposing "large quantities" of unused pharmaceuticals to sewers, then it supports PEER's contention that mere guidance is not enough to deal with the situation.

The Guidance Document is potentially contradictory and confusing. The Guidance document contains what may be interpreted as contradictory statements. For example, page 2 of the Guidance Document states:

> Another source of unused pharmaceuticals is residue in used and partially-used dispensers, containers, and devices. Health care facilities may dispose of unused pharmaceuticals, especially

> residues, down the drain (e.g., intravenous (IV) bags emptied into the sink). For many years, a standard disposal practice at many health care facilities was to flush unused pharmaceuticals down the toilet or drain. EPA believes that facilities should not dispose of their pharmaceuticals down the drain.

It is unclear whether the phrase "Health care facilities ***may*** dispose of unused pharmaceuticals…down the drain" (emphasis added) is giving permission to do so, or simply stating that the possibility exists that health care facilities are disposing of pharmaceuticals down the drain. If it is the latter, EPA should re-word the guidance to emphasize that disposal down the drain is not a recommended practice.

The Guidance Document offers statistically unsound advice. Page 4 of the Guidance Document states:

> EPA recommends that the facility keep track of the unused pharmaceuticals for two weeks to one month. This time period may differ depending on the variety and frequency of services that the facility provides. Seasonality may also play a role in the types and quantities of pharmaceuticals being used. For example, the length of time depends upon how often doctors' offices dispose of expired pharmaceutical stock and samples, how often hospitals check their crash carts for expired medications, or how often long-term care facilities check their emergency kits for expired medications. Once the facility has the list of discarded pharmaceuticals, it can identify commonly wasted pharmaceuticals and identify reasons for the waste generation. Then, the facility can use the BMPs provided in Section 3 to reduce the amount wasted.

Keeping track of unused pharmaceuticals for two weeks to one month is nonsensical. EPA itself admits that the time period "may differ" depending on variables such as "seasonality." Health care facilities would need to keep track of unused pharmaceuticals for at least one year in order to obtain a more accurate picture of unused pharmaceutical disposal. Rather than institute policies based on an unrealistic snapshot of time, tracking of unused pharmaceuticals should be a continuous, ongoing process, and responses to the type and amount of unused pharmaceuticals should be dynamic.

Controlled substances should never be disposed of down the drain. The Controlled Substances Act (CSA) is administered by the DEA, and prohibits the return of controlled substances from end-users to dispensers. Although the Guidance Document states that, "Disposal of controlled substances by DEA registrants is carefully regulated to ensure that the substance is destroyed…[v]oluntary survey submittals, outreach meetings, and site visits indicate that disposing of controlled substances down the drain is a common practice to ensure destruction of controlled substances due to its affordability and ease." The Guidance Document goes on to state that, "EPA is recommending BMPs in this guidance to reduce and avoid drain disposal" (Guidance Document pp. 9-10). PEER is concerned that despite the fact that disposal of these controlled substances is supposed to be "carefully regulated," they are routinely disposed of down the drain. EPA's response to this practice, however, is even more disturbing. Instead of working with the DEA and the health care facilities to ensure that controlled substances are never disposed of down the drain, EPA issued voluntary guidance to "reduce and avoid" drain disposal. EPA should take steps to ensure that these controlled substances are not, under any circumstances, disposed of down the drain.

The Guidance Document should encourage use of medication until it reaches its expiration date.
It is unclear as to whether the requirement that a drug's expiration date must be more than six months out is legally required or simply a rule of thumb. Specifically, page 11 of the Guidance Document states that if the medication is still packaged properly, has been stored properly, has an intact label, and has an "expiration date a future date at least six months out," the medication can be re-used. If this expiration requirement is codified in a law or regulation, then EPA should work to eliminate it. If this is an arbitrary policy, the Guidance Document should allow medicines to be re-used until they expire. PEER

believes that this policy would result in the disposal of many drugs that are still viable. In fact, some researchers believe that drugs remain potent and usable for many years after their expiration dates.

EPA should consider revoking the effort to add hazardous pharmaceutical wastes to the Proposed Universal Waste Rule. In December 2008, EPA proposed adding hazardous pharmaceutical wastes to the Universal Waste Rule. This proposal would redefine health care facilities currently considered hazardous waste generators to be only pharmaceutical universal waste "handlers." This would then allow health care facilities to have a higher threshold of waste accumulation, keep the waste on site for a longer period of time, eliminate manifest requirements for the waste, and simplify training requirements for handling the waste. The rule is expected to be finalized in 2011. Given that approximately 5% of pharmaceuticals are considered hazardous, and the haphazard way these pharmaceuticals are currently handled and disposed of at many health care facilities, PEER believes that weakening the regulations for the handling of these wastes is contrary to public interest. Rather, EPA should be applying more stringent requirements on training, tracking, storage and disposal of these wastes to ensure they do not get disposed of down the drain.

Disposing of pharmaceuticals in landfills is not environmentally sound. Page 20 of the Guidance Document states that nonhazardous pharmaceutical waste "should be disposed in a solid waste landfill or incinerated in a solid waste incinerator." Specifically, the Guidance Document recommends mixing the medication with an undesirable substance, placing the waste mixture in a sealable bag, empty can, or other container, and disposing of it in the trash. PEER is concerned that EPA is suggesting this method of disposal, as the pharmaceuticals can leach out of the landfills and get into the environment. The Maine Department of Environmental Protection (MEDEP) recently discovered that landfill leachate from three landfills in Maine contained antidepressants, antibiotics, steroids, hormones, heart and asthma medications, and pain medications.[2] This leachate can then contaminate ground water and surface water supplies.[3] PEER therefore urges EPA to require incineration of pharmaceuticals rather than landfill disposal.

EPA should mandate that chemotherapy drugs be managed as hazardous waste. The Guidance Document states that because "not all chemotherapy pharmaceutical waste may be regulated as hazardous under the federal RCRA regulations, EPA recommends that facilities manage all unused chemotherapy pharmaceuticals as hazardous waste as a best management practice" (Guidance Document, p. 21). PEER does not believe that this voluntary recommendation goes far enough, and urges EPA to require that chemotherapy drugs be handled as hazardous.

Controlled substances should not be flushed down the drain. The Guidance Document states that health care facilities "may use disposal down the drain sewer (or flushing) as an acceptable destruction option for controlled substances" (Guidance Document, p. 23). PEER does not believe that this is an acceptable method of disposal, as most wastewater treatment plants cannot remove pharmaceuticals from the wastewater. Therefore, flushing or disposing of these controlled substances is comparable to dumping them into our water supplies.

Conclusion. PEER is concerned that the draft Guidance Document for the safe disposal of unused pharmaceuticals does not go far enough to protect the environment or human health. Therefore, PEER

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[2] http://www.mpbn.net/News/MaineNews/tabid/181/ctl/ViewItem/mid/3475/ItemId/10603/Default.aspx

[3] http://lib.wmrc.uiuc.edu/enb/2010/02/05/me-pharmaceutical-drugs-found-in-landfill-water/

urges EPA to develop stringent and enforceable regulations that prohibit the disposal of unused pharmaceuticals, particularly controlled substances and hazardous waste, in landfills or down the drain.

Thank you for the opportunity to comment.

Sincerely,

Paula Dinerstein, Senior Counsel, PEER

Kyla Bennett, Director, New England PEER