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Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Comments on the Insanitary Conditions at Compounding Facilities,
Draft Guidance for Industry – Revision 1, September 2018
Docket No. FDA-2016-D-2268**

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, submits these comments with regard to the draft guidance for industry "Insanitary Conditions at Compounding Facilities (Revision 1)," the availability of which was announced by the Food and Drug Administration (FDA) in the *Federal Register* on September 26, 2018 (Docket No. FDA-2016-D-2268).[1]

In general, Public Citizen supports the draft guidance. The numerous detailed examples of insanitary conditions provided in the draft guidance should assist compounding facilities in identifying and remediating insanitary conditions.

However, we strongly object to the FDA's addition of footnote 3 on page 1 of the guidance, which states the following:

> FDA generally does not intend to take action under section 501(a)(2)(A) [of the Food, Drug, and Cosmetic Act (FDCA)] against a physician who is compounding or repackaging a drug product, or who is mixing, diluting, or repackaging a biological product, provided that such activities occur in the physician's office where the products are administered or dispensed to his own patients.

This explicit policy statement indicates that for physician compounding or repackaging of drug products, the agency does not intend to enforce the requirements of the FDCA that prohibit the preparation, packing, and holding of drugs under insanitary conditions (21 U.S.C. 351(a)(2)(A)). However, there is no sound public health rationale for effectively granting a blanket exemption to physicians from the requirements to maintain sanitary conditions when compounding or repackaging drugs in the office setting, and declaring such a reckless exemption would endanger patients.

[1] 83 FR 48631.

Importantly, serious adverse events have been linked to compounding drugs in physicians' offices.[2] Moreover, physician compounding is not intrinsically safer than pharmacy compounding — to the contrary, there is evidence that that sterile drugs prepared outside of controlled pharmacy environments, such as in a hospital ward, are at higher risk for contamination.[3]

When compounding in physicians' offices occurs under insanitary conditions, that activity may not be detected until patients get hurt — and even then it may go undetected. Although state pharmacy regulators manage the oversight of compounding within pharmacies, they typically do not have jurisdiction over medical practices, which are regulated by state medical boards. This lack of oversight means that states have minimal insight into physicians' compounding practices and are unable to determine whether patients are at risk unless they sustain injuries that can be traced back to compounded drugs.

In closing, we urge the FDA to remove the footnote describing its non-enforcement policy for physician compounding under insanitary conditions.

Thank you for the opportunity to comment on this important public health matter.

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[2] Vasquez AM, Lake J, Ngai S, et al. *Notes from the field:* Fungal bloodstream infections associated with a compounded intravenous medication at an outpatient oncology clinic — New York City, 2016. *MMWR Morb Mortal Wkly Rep*. 2016;65(45):1274-1275.
[3] Stucki C, Sautter AM, Favet J, Bonnabry P. Microbial contamination of syringes during preparation: The direct influence of environmental cleanliness and risk manipulations on end-product quality. *Am J Health-Syst Pharm*. 2009; 66(22):2032-2036.