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Food and Drug Administration Pharmacy Compounding Listening Session

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Statement of Sarah Sorscher, Researcher, Public Citizen's Health Research Group

Good morning and thank you for organizing this listening session. Public Citizen's Health Research Group has found previous listening sessions to be helpful in informing our work as consumer advocates in the area of pharmacy compounding, and we are grateful for the opportunity to be here again.

In my comments today I will focus on the 503A and 503B bulk drug substances lists, office stock compounding, and several additional policies proposed in recently issued draft guidance documents.

503A and 503B Bulk Drug Substances Lists

Our group's director, Dr. Michael Carome, has served as the consumer representative member at the past several Pharmacy Compounding Advisory Committee (PCAC) meetings discussing substances nominated for inclusion on the 503A bulk drug substances list and other topics. We are generally pleased with efforts by Food and Drug Administration (FDA) reviewers to provide well-researched presentations and thoughtful analysis in an area where high-quality safety and effectiveness data is unfortunately often lacking.

Yet we have concerns about the FDA's approach to implementing requirements related to the 503A bulk drug substances list, as well as the similar bulk drug substances list authorized under section 503B. As we have previously stated in written comments,[1,2] we were disturbed by the FDA's decision to allow the production of drugs made with substances that have not yet been formally added to these lists, but are merely under consideration by the FDA. This strikes us as a dangerous practice,

[1] Regulations.gov. Comment from Public Citizen on the Food and Drug Administration (FDA) Other: Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry. FDA-2015-D-3539-0006, www.regulations.gov/#!documentDetail;D=FDA-2015-D-3539-0006. Accessed June 5, 2016.

[2] Regulations.gov. Comment from Public Citizen on the Food and Drug Administration (FDA) Other: Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry. www.regulations.gov/#!documentDetail;D=FDA-2015-D-3517-0006. Accessed June 5, 2016.

and our comments in particular asked the FDA to prevent the ongoing production of compounded drug products from bulk drug substances for which the FDA review team recommended against including such substances on the bulk drug substances list based on concerns about safety, effectiveness, or both. This could potentially be done under the FDA's proposed interim framework by expanding list 2 to include such substances.

We would also like to urge the FDA to promptly initiate a rulemaking on the bulk drug substances for which the PCAC has now completed review for inclusion in the 503A list. We hope that the FDA will proceed with such a rulemaking without waiting to review the 40 additional substances we understand to be currently under evaluation, as this review could potentially take years, if not decades, during which time such substances may remain in widespread use even though they have been determined by FDA reviewers, and in many cases also a majority of advisory committee members, to be unsafe or ineffective.

Office Stock Compounding

We wanted to express our strong support for the FDA's decision to prevent compounding pharmacies regulated under 503A from engaging in compounding for office stock. This restriction helps to create a clear line between traditional compounding and drug manufacturing and also helps ensure that drugs held in stock in physicians' offices for potentially extended periods are manufactured under appropriately high standards. Also, the restriction provides a key incentive for entities that wish to engage in drug manufacturing to register as outsourcing facilities (or seek new drug approval), rather than attempting to scale up production while continuing to benefit from the 503A exemption. It is difficult to see how the voluntary outsourcing registration system could successfully operate as intended without such a clear line restricting the scope of 503A compounding. This means the proposed restriction is central in enforcing the outsourcing scheme created by Congress when it drafted the Drug Quality and Security Act of 2013.

We also believe that this policy can be implemented without significantly impacting patient care, as physicians will continue to have options for obtaining standardized office stock, including substituting FDA-approved products in the place of compounded products and relying on outsourcing facilities when FDA-approved products are unavailable. In addition, healthcare providers will still be able to administer individually tailored products in the hospital or outpatient setting, either

by compounding these products in-house and dispensing them after making a notation in the patient's chart, or by sending a prescription to an outside compounding pharmacy in advance of a patient's scheduled appointment.[3]

Other Policies in Recent Draft Guidances

We hope to submit written comments on several other policy decisions recently proposed by the FDA in draft guidance documents:

In general, we support the FDA's proposal to allow 503A pharmacies to compound a 30-day supply of drugs in advance and hold these in stock while awaiting a patient-specific prescription.[4] We see this as a relatively clear and workable restriction on anticipatory compounding, as well as a reasonable interpretation of the "limited quantities" language employed by the statute.[5]

We also support the FDA's decision to require that all drugs produced within a 503B registered outsourcing facility comply with current good manufacturing practices (cGMP) (thus preventing compounding and outsourcing from taking place in the same geographic location).[6] Without this rule, it would be nearly impossible for consumers and healthcare providers to verify whether a particular product distributed by an outsourcer was actually manufactured in compliance with cGMP.

We look forward to more discussion of these and other issues during today's session.

[3] Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act. Guidance for Industry. April 2016. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf. Accessed June 5, 2016.

[4] Food and Drug Administration. Prescription requirement under section 503A of the Federal Food, Drug, and Cosmetic Act. Guidance for industry (Draft guidance). April 2016. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf. Accessed June 5, 2016.

[5] Food and Drug Administration. Prescription requirement under section 503A of the Federal Food, Drug, and Cosmetic Act. Guidance for industry (Draft guidance). April 2016. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf. Accessed June 5, 2016.

[6] Food and Drug Administration. Facility definition under section 503B of the Federal Food, Drug and Cosmetic Act. Guidance for Industry (Draft guidance). April 2016. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496288.pdf. Accessed June 5, 2016.