National Business Group on Health®

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Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

July 14, 2016

The Honorable Dr. Robert M. Califf, MD
Commissioner, Food and Drug Administration
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2016-D-0238 for "Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Availability."

Dear Commissioner Califf:

Thank you for the opportunity to comment on Docket No. FDA-2016-D-0238 for "Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Availability."

We concurrently applaud the agency for its effort to clarify the interpretation of what it means to be an outsourcing facility, and commend the agency's intent in doing so. Section 503B was specifically designed to subject entities that undertake mass production of compounded medications to current good manufacturing practice (CGMP) requirements, because these entities have the potential to impact large quantities of patients, and could affect entire geographic regions, and even the nation. These facilities are the only facilities that maintain a broad exemption for anticipatory compounding, and thus should be held to substantially higher standards than facilities performing drug compounding under section 503A(a)(2).

Thus, we support the clarification that, in order to be eligible for exemptions under section 503B, a drug product must be compounded in an outsourcing facility in which drugs are compounded only in accordance with section 503B.

Additionally, we strongly support the agency's intent to make clear that segregating the compounding of drug products at one geographic location violates the intent of the law, as we feel it is critically important that compounding at 503B facilities meet current good manufacturing practice (CGMP) regulations.

This important clarification ensures that all drugs compounded at 503B facilities will meet the higher standards that the law intended and solidifies that the intent behind compounding of medications under section 503A(a)(2) and section 503B were conceived of with very different objectives, specific to both immediate and long-term patient needs.

By eliminating the comingling of different standards at one geographic location, the agency can help payers and consumers feel confident that all drugs being compounded at 503B facilities meet CGMP requirements and increase transparency of quality and safety. Thus, we appreciate the agency's effort to close the loophole on segregation, which

presented an opportunity for confusion and could have resulted in compromised patient safety.

The National Business Group on Health represents approximately 425 primarily large employers, including 72 of the Fortune 100, who voluntarily provide group health plan coverage and other health programs to over 55 million American employees, retirees and their families.

We look forward to continuing to work with you on important health policy issues affecting large employers. Again, thank you for the opportunity to comment. Please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy, at (202) 558-3012, if you want to discuss our comments in further detail.

Sincerely,

Brian Marcotte
President and CEO