**ONE-PAGE SUMMARY**

**TESTIMONY OF GIL Y. ROTH**

PHARMA & BIOPHARMA OUTSOURCING ASSOCIATION

**MODERNIZING FDA'S REGULATION OF OVER-THE-COUNTER DRUGS**

BEFORE THE HOUSE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH

SEPTEMBER 13, 2017

- CMO/CDMOs play a key role in the American healthcare system. What do they do, and who is PBOA?

- FDA's current OTC Monograph program is outdated and under-resourced.

- The proposed OMUFA bill should help solve those issues, with greater funding, more transparency and commitments, and a path to innovations for established ingredients.

- PBOA's members are pleased that the legislation under discussion includes a fee model that reflects the differential value of OTC monograph products to CMO/CDMOs.

- We hope that PBOA and CMO/CDMOs will be included in future FDA user fee negotiations.

**TESTIMONY OF GIL Y. ROTH**

PRESIDENT

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UNITED STATES HOUSE OF REPRESENTATIVES

SEPTEMBER 13, 2017

Mr. Chairman, Mr. Ranking Member, Members of the Subcommittee: thank you for the opportunity to submit testimony today about the proposed "Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2017".

I am Gil Roth, President of the Pharma & Biopharma Outsourcing Association. PBOA is the leading trade association for Contract Manufacturing Organizations and Contract Development and Manufacturing Organizations (known as CMOs and CDMOs) in the pharma/biopharma space. PBOA's core mission is to advance the regulatory, legislative and general business interests of the CMO/CDMO sector. I am here today to express PBOA's support for the recently-released OMUFA draft, to urge this Committee and the Congress to advance this draft, and to express my thanks for ensuring that this draft takes into account the unique needs of the CMO/CDMO community. Your willingness to ensure our seat at the table was greatly appreciated, and, PBOA strongly believes, resulted in the release of a better OMUFA draft deserving of bipartisan support.

First, you might be wondering what a CMO/CDMO actually is and how these companies contribute to the development of drugs, or in this case, over-the-counter drugs. CMO/CDMOs are the true experts in manufacturing. Our members provide manufacturing and other services that enable drug companies to develop and commercialize medicines. They account for more than one-third of all doses dispensed to patients in America, producing innovator drugs and generics, small molecules and biologics, pills and injectables, OTC and biosimilars. CMO/CDMOs empower their customers to develop and commercialize life-saving, quality, cost-effective medicines for patients. I have been involved in the CMO sector since 1999 and have

witnessed the industry's rapid growth and the key role it plays in the American healthcare system.

I would like to commend the Committee for your continued focus on the important issues we will examine today. The FDA has long outstanding commitments to produce and finalize Over-The-Counter (OTC) monographs, work that began in the 1970s. In the current fiscal year, the FDA allocated $8 million to such efforts, a sum that can yield only minimal dedicated staffing and little progress. Industry, the FDA, and Congress agree that the monograph process is outdated. Further, there is recognition that monograph review cannot expand without additional resources.

The legislation under consideration should help solve those issues. It will provide resources to FDA to finalize long-unfinished monographs, giving manufacturers a degree of certainty. As with other user fee programs, the transparency and goals dictated by the commitment letter should provide industry with increased predictability.

OMUFA's path for innovations to established ingredients is overdue and could benefit marketers and manufacturers alike, particularly CMOs that specialize in unique dosage forms.

Although PBOA was not included in the negotiations between industry and FDA, we are pleased that the legislative text under discussion includes a fee model that reflects the differential value of OTC monograph products to CMO/CDMOs, and that it provides some relief from the facility

fees proposed to fund OMUFA. And, again, we are very appreciative of this Committee's role in ensuring all stakeholder voices were heard as you developed the OMUFA draft.

We hope that PBOA and the CMO/CDMO businesses it represents will be included in future FDA user fee negotiations, particularly ones that are considering contributions from the manufacturing sector, in the form of facility fees. And we look forward to continuing to participate in the legislative process relating to OMUFA, and to the day where this good legislation is signed into law.