April 20, 2018

The Honorable Johnny Isakson
United States Senate
131 Russell Senate Office Building
Washington, DC 20510

The Honorable Bob Casey
United States Senate
393 Russell Senate Office Building
Washington, DC 20510

Dear Senators Isakson and Casey:

The Pharma & Biopharma Outsourcing Association (PBOA) strongly supports S. 2315, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018. S. 2315 will allow for increased consumer protections, including more rapid action in the event of safety issues; increased consumer confidence, due to stronger support of the system by FDA; and increased consumer choice, facilitated by a system that enables innovation.

S. 2315 represents a balanced framework for regulating OTC medicines containing ingredients with a proven history of safe use. We believe these policy reforms will make the system even more flexible, responsive, and accommodating to innovation. The OTC Monograph system was created more than 45 years ago, but the process is still not complete. Movement on unfinished items has ground to a halt. Further, there is no system in place to innovate in a timely manner, benefiting consumers and the marketplace. Your legislation will allow advances in science, new safety information, and completing unfinished monographs.

The FDA, the regulated community, and the public all have an interest in the agency having the ability to make scientific decisions about established ingredients efficiently, and without having to resort to product-by-product determinations for medicines that are already on the market. An administrative order process with appropriate protections is a smarter means to this end.

As I stated in my testimony on September 13, 2017 before the House Energy and Commerce Health Subcommittee, in support of Monograph reform, CMO/CDMOs play a key role in the American healthcare system. 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.

We are pleased that the legislative draft under consideration includes a fee model that reflects the differential value of OTC monograph products to CMO/CDMOs, and that it provides that sector with some relief from the facility fees proposed to fund OMUFA. We are very appreciative of this Committee's role in ensuring all stakeholder voices were heard as you developed the OMUFA draft.

We look forward to continuing to work with you throughout the legislative process and we thank you for your leadership on this issue and look forward to the bill's passage.

Sincerely,

Gil Roth
President
Pharma & Biopharma Outsourcing Association

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PBOA Membership
(not all members manufacture OTC products)

3M Drug Delivery Systems
Afton Scientific
Alcami
Althea CMO
Avid Bioservices
Avista Pharma Solutions
Baxter BioPharma Solutions
Catalent Pharma Solutions
CMIC CMO USA, Inc.
Coating Place, Inc.
CPC - Contract Pharmacal Corp.
DPT, a Mylan Co.
Emergent Biosolutions
Grand River Aseptic Manufacturing
Groupe PARIMA
Halo Pharma
IDT Biologika
Jubilant HollisterStier
Lyophilization Services of New England (LSNE)
Metrics Contract Services
Mission Pharmacal/ProSolus Pharma
Particle Sciences, a Lubrizol Co.
Patheon Inc., part of Thermo Fisher Scientific
PCI Pharma Services
Pfizer CentreOne
Pharma Packaging Solutions
Piramal Pharma Solutions
Renaissance Lakewood
Sovereign Pharmaceuticals
Tapemark Inc.
Therapure Biomanufacturing
WellSpring Pharma Services