



*Advancing the regulatory, legislative, and general business interests
of the pharmaceutical and biotech services community*

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
2125 Rayburn HOB
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
2322 A Rayburn HOB
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Walden & Ranking Member Pallone:

As the President of the Pharma & Biopharma Outsourcing Association (PBOA), I am writing on behalf of our members to express our strong support for H.R. 2430, the FDA Reauthorization Act of 2017. PBOA represents the regulatory, legislative and general business interests of pharmaceutical and biopharmaceutical contract manufacturing organizations and contract development and manufacturing organizations operating in, or selling into, the United States. PBOA members provide the technologies and services that help the biopharmaceutical industry develop and manufacture drugs, biologics, vaccines, and other treatments safely and cost-effectively. Our members represent more than 20,000 domestic manufacturing jobs, and manufacture more than 220 billion doses annually.

In particular, PBOA is strongly supportive of the provisions of H.R. 2430 which reauthorize the Generic Drug User Fee Act (GDUFA II). This language makes important changes to this successful program, which will enhance FDA's resources for more timely approvals of generic drugs. We also strongly support the language in H.R. 2430 which will provide reduced facility fees for contract manufacturing sites, which are not referenced in approved Abbreviated New Drug Applications (ANDAs) owned by their parent companies or affiliates. Additionally, under this legislation facility fees will not be charged to a site until the first ANDA referencing that facility is approved, a policy strongly supported by PBOA.

Again, PBOA strongly supports swift enactment of H.R. 2430, and we commend you for your hard work in creating this important legislative package.

Sincerely,

Gil Roth
President
Pharma & Biopharma Outsourcing Association

PBOA

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Althea CMO
AMRI - Albany Molecular Research, Inc.
Avista Pharma
Baxter BioPharma Solutions
Catalent Pharma Solutions
Cook Pharmica
CMIC CMO USA
Coating Place, Inc.
CPC - Contract Pharmacal Corp.
DPT/Confab
Ei, a Pharmaceutical Solutionworks
Emergent Biosolutions
Groupe PARIMA
Halo Pharma
IDT Biologika
Jubilant HollisterStier
Lyophilization Services of New England (LSNE)
Metrics Contract Services
Mission Pharmacal/ProSolus Pharma
Patheon Inc.
PCI Pharma Services
Pfizer CentreOne
Pharma Packaging Solutions
Piramal Pharma Solutions
Tapemark Inc.
Therapure Biomanufacturing
WellSpring Pharma Services

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SCORR Marketing
TraceLink
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