

Navigating Challenges and Capturing Opportunities in a Dynamic CDMO Landscape

Gil Roth • President • PBOA

American Pharma Manufacturing & Outsourcing Summit

November 17, 2025

CONFIDENTIAL ©2025 PBOA



PHARMA & BIOPHARMA
OUTSOURCING ASSOCIATION

What is the Pharma and Biopharma Outsourcing Association?

Founded in 2014, the **Pharma & Biopharma Outsourcing Association (PBOA)** is a nonprofit trade association dedicated to advancing the regulatory, legislative and general business interests of CMOs, CDMOs, and other contract service providers.

PBOA's 36 Member companies and 24 Affiliate members provide the technologies and services that help the pharma and biopharma industry develop, manufacture and package drugs, biologics, vaccines, OTC products and other treatments safely and cost effectively.

PBOA CMO/CDMO Members

Adare Pharma Solutions

Afton Scientific

Alcami

Aragen Life Sciences

AustinPx

Avara Pharma Solutions

Bora Corp.

Catalent

CMIC CMO USA

Coating Place

Element

Enzene

Experic

GBI Bio

Grand River Aseptic Manufacturing

Groupe PARIMA

INCOG BioPharma Services

Kindeva Drug Delivery

Lifecore Biomedical

CONFIDENTIAL ©2025 PBOA



PHARMA & BIOPHARMA
OUTSOURCING ASSOCIATION

PBOA Affiliate Members

Brandwidth Solutions

CAI

Chrysalys Bio

DataLinks

Freund-Vector

Global Pharma Consulting

Informa

Iwata Label

MasterControl

Namicos Co.

Nicomac Taikisha

PharmaBioSource

ProPharma

rK3 Solutions

CONFIDENTIAL ©2025 PBOA

ramarketing

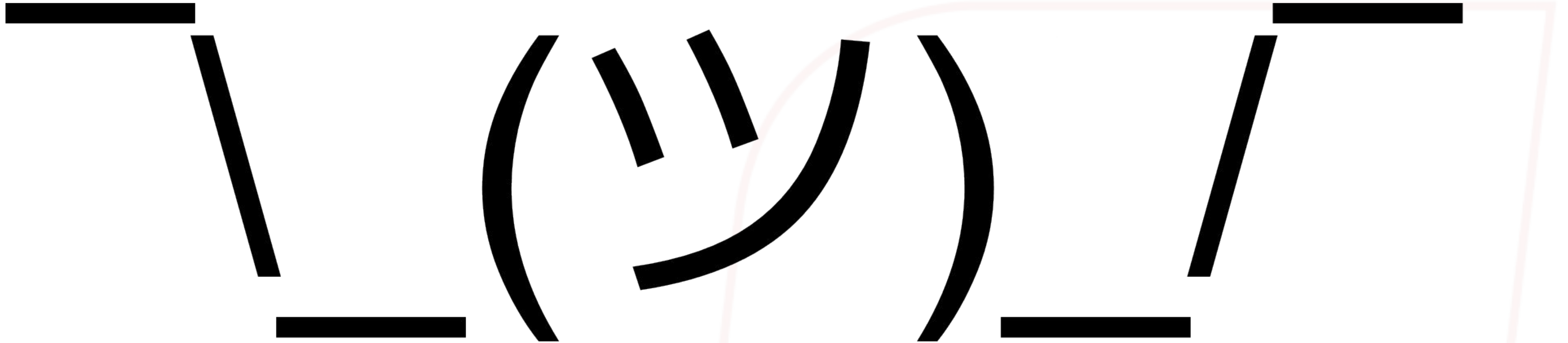


PHARMA & BIOPHARMA
OUTSOURCING ASSOCIATION

Policy Topics

- **Tariffs/Geopolitics**
- **Supply Chain Resilience/Reshoring**
- **HHS/FDA/NIH Cuts**
- **FDA's Future**
- **Market Trends**

Tariffs



Tariffs: State of Play

- **IEEPA vs. Section 232**
- **Canada / Mexico / China – ‘Fentanyl’**
- **ROW – ‘Deficits’ = Emergency**
- **Supreme Court Pending**
- **Hurting Domestic Investment NOW**

Tariffs: Pharma

- **Pharmaceuticals – Section 232 Probe**
 - **National Security Focus**
 - **Supply Chain for Ingredients, Finished Products**
 - **~1,000 Responses**
 - ***May* Lead To Sectoral Tariffs**

Tariffs: Pharma

- **Exemptions**
 - **EU, Japan – cap on pharma tariffs, while generics/APIs near zero**
 - **Switzerland – 39%→15%**
 - **China, India as key negotiations**
 - **Foreign Direct Investment?**
 - **(Ask Hyundai)**

Tariffs: Pharma

- **Or Is It 100%?**
- **Sept. 25 tweet:
“Under Construction”?**

Onshoring – Domestic Investment

- AbbVie - \$10 billion
- Amgen - \$1.5 billion
- AZ - \$50 billion
- Biogen - \$2 billion
- BMS - \$40 billion
- Celltrion - \$500 million
- Gilead - \$11 billion
- GSK - \$30 billion
- Hikma - \$1 billion
- J&J - \$55 billion
- Lilly - \$27 billion

Onshoring – Domestic Investment

- **Domestic Investment –**
 - **CapEx vs. Operations, R&D?**
 - **Equipment, Construction Bottlenecks**
 - **Workforce – CDMO risk?**
 - **Counting CDMO Spend as Investment**
 - **CDMO Opportunity**
- **H-1B Visa Change**

Onshoring – Domestic Investment

- **Afton Scientific - \$200 million**
- **Alcami - \$?**
- **Cambrex - \$120 million**
- **CordenPharma - \$?**
- **Curia - \$4 million**
- **Hovione - \$100 million**
- **LGM - \$6 million**
- **LTS/Renaissance - \$?**
- **Piramal - \$90 million**
- **Rovi - \$?**
- **Serán - \$?**

Onshoring – CDMO US Investment

- **Domestic Investment –**
 - **Will CDMOs “Count”?**
 - **Ex-US CDMOs Entering US**
 - **Not Just GLP-1s**
 - **Make Vs. Buy**
- **H-1B Visa Change**

Supply Chains & US Manufacturing

- **On-/Re-/Near-/Friend-shoring**
- **Executive Orders**
 - **Domestic Mfg.**
 - **PreCheck**
 - **SAPIR (small molecule) for Essential/Critical Meds**
- **China – BIOSECURE AGAIN!?**

Domestic Manufacturing EO – 5/6/25

- “Increase Fees for and Inspections of Foreign Manufacturing Plants”
- *Consider* Public List of Non-Reporting Foreign API Plants
- FDA Streamlining Recommendations
 - CDMO Catch-22
- EPA Streamlining
- Federal Point-of-Contact

FDA “Precheck” – 8/13/25

- **Communication Throughout Build**
- **Regulatory Streamlining**
- **CDMO Catch-22?**
- **Different from 2009 Pre-Operational Reviews (FMD-135)?**
- **Public Meeting + Docket**

BIOSECURE?

- House, Senate Revision
- Senate NDAA – Oct. 9
- Without Legislation?
- No Names?
- China Innovation
- State Dept. – RoK, et al.

U.S. Drugmakers Warn White House of Chaos as Trump Weighs Curbs on China

Behind the scenes, major pharmaceutical companies and Trump-tied billionaires are furiously lobbying in opposite directions over proposed anti-China measures.

FDA/HHS

- **Workforce Cuts**
 - **Feb. Probationary/Early Ret.**
 - **April RIFs, then Rehires**
- **CRLs, Missed UFA Goal Dates**
- **Vaccines? mRNA?**

FDA/HHS

Industry Should ‘Lead From The Outside’ With US FDA Policy Staff Decimated, Woodcock Says

Pink Sheet, Sept. 24, 2025:

Janet Woodcock said the US Food and Drug Administration ceded leadership in pharmaceutical policy development after its personnel cuts, and industry and other groups must step into the void.

“Because the agency has been so flattened, and their policy staff demolished and so forth, what I’ve been telling people is come together and lead from the outside,” the former acting commissioner and CDER director said.

FDA: User Fees

- **User Fees**
 - 45+% of FDA Budget
 - 4 Majors Due For 5-Year Reauthorization: PDUFA, GDUFA, BsUFA, MDUFA
 - Review Timelines, Inspections, Guidance, etc.
 - RFK, Jr. – Against / Makary – For (but smaller)
 - Facility Fees
 - Onshoring
- **FDA Commitments (mostly) = FTEs = \$\$\$**
- **NDA, BLA, ANDA Timelines?**

M&A Activity

- **Where There's PE . . .**
 - **CDMOs' Funds Coming Due**
- **Friendlier FTC?**
- **Tariff-Driven**
 - **Regionalization - Local Content/U.S. Ops**
 - **Waiting On Stability/Clarity**

Contact

Gil Roth • PBOA

Tel: US 1-201-788-7994

E-mail: gil.roth@pharma-bio.org

Web: www.pharma-bio.org

LinkedIn: [pboa-pharma-biopharma-
outsourcing-association](https://www.linkedin.com/company/pboa-pharma-biopharma-outsourcing-association)
(just start with @pboa)

Any questions?

