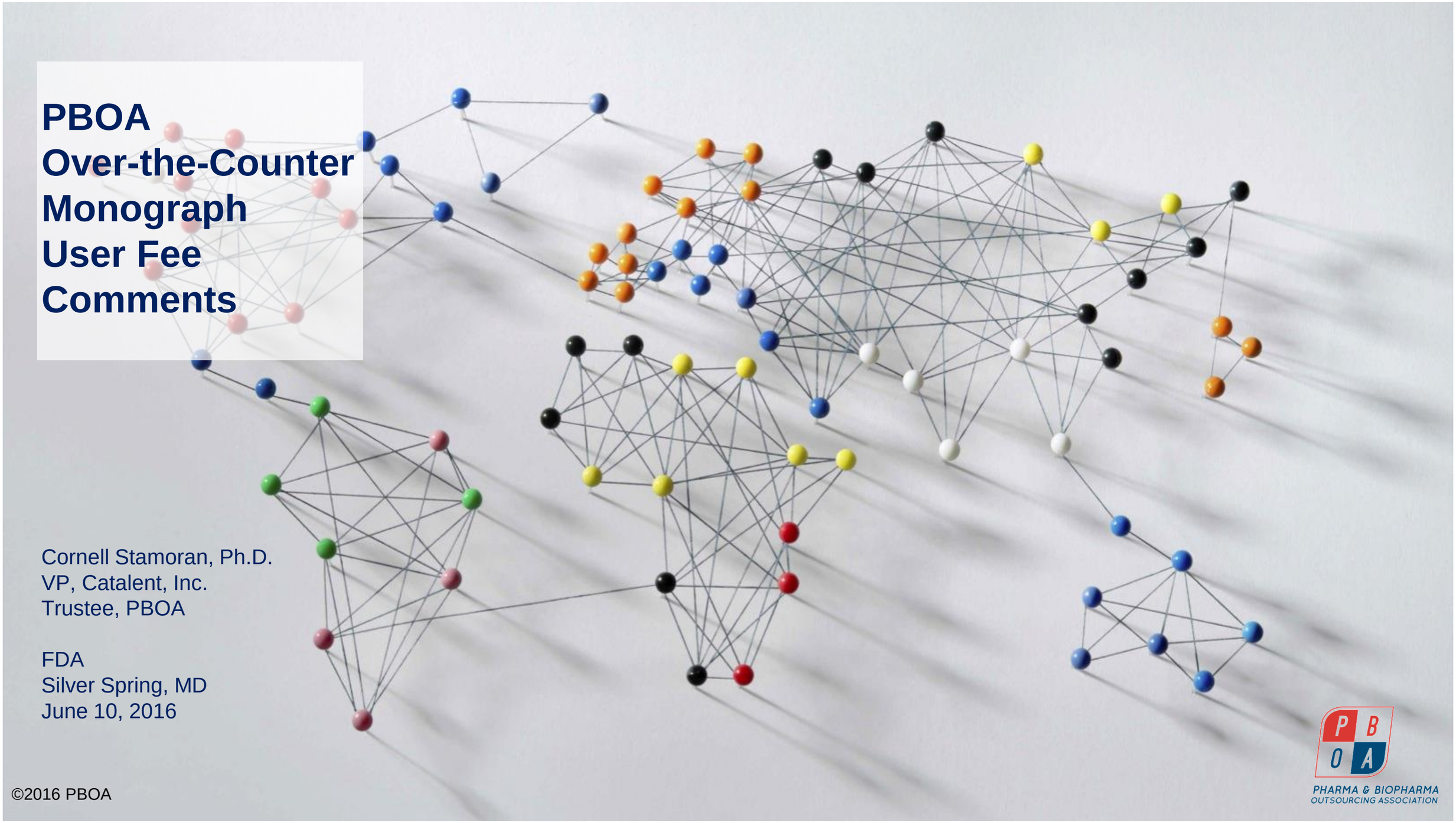
PBOA Over-the-Counter Monograph User Fee Comments



Cornell Stamoran, Ph.D.
VP, Catalent, Inc.
Trustee, PBOA

FDA
Silver Spring, MD
June 10, 2016

PHARMA & BIOPHARMA OUTSOURCING ASSOCIATION

Who is Pharma and Biopharma Outsourcing Association?

The **Pharma & Biopharma Outsourcing Association** (PBOA) is a nonprofit trade association dedicated to advancing the regulatory, legislative and general business interests of Contract Manufacturing Organizations (CMOs) and Contract Development and Manufacturing Organizations (CDMOs).

PBOA members provide the technologies and services that help the pharma and biopharma industry develop and manufacture drugs, biologics, vaccines, OTCs and other treatments safely and cost effectively.

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PBOA Member Companies

Patheon
A HEALTHIER WORLD. DELIVERED.

Mission PHARMACAL

ProSolus

Jubilant HollisterStier

3M

Catalent

DPT
Confab
A DPT COMPANY

COATINGS
Coating Place Inc.
THE ORIGINAL WURSTER TECHNOLOGY SOURCE

Baxter

Ei
A PHARMACEUTICAL SOLUTIONWORKS™

metrics contract services

Afton Scientific
cGMP Processing of Sterile Products

COOK PHARMICA

COLDSTREAM LABORATORIES INC.™

Piramal | Pharma Solutions
knowledge action care

Pfizer CentreOne
Contract Manufacturing

IDT

alcami.™

HALO PHARMA

therapure BIOMANUFACTURING
Passion for your Process, Product and Patients

WellSpring PHARMA SERVICES

PBOA
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CDMOs are Integral Players in Global Healthcare

PBOA Member Data – Rx and Consumer Health

Produce

200+ billion

doses per annum

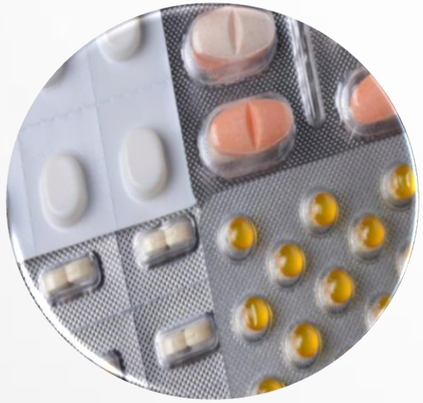
Employ

30,000+

people worldwide

200 regulatory &

1,500 customer audits annually



Manufacture >10,000 products/year, nearly every route of administration

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PBOA Supports OTC Monograph Model, Recognizes Current Limitations

- OTC products serve critical role in US healthcare market, enhancing consumer wellness and expanding access while reducing medical costs
- An effective Monograph-based system enables increased consumer-centric innovation and enhances competition
- Agree that “FDA is critically under-resourced” to sustain or modernize an effective OTC Monograph-driven process
- Substantial opportunity exists to enhance current OTC Monograph process, including greater scope, streamlined review, public-private partnership approaches, etc. discussed in 2014 meeting

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PBOA Currently Impacted by Most FDA User Fee Programs

- PBOA members are currently involved in most of FDA's User Fee programs– PDUFA, GDUFA, BSUFA, ADUFA, MDUFA
- Key design principles:
  - The party who receives the economic benefit from the program should pay the fees
  - The fee should fully recover cost of services provided, unless there's a public policy reason to do otherwise
  - Ability to implement: available data; auditability
- Real downside impact for PBOA members of mis-aligned fees and value: layoffs, reduced capacity available, reduced ability to invest in innovation/capacity

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PBOA Supports Consideration of OTC Monograph User Fees along with Other Enhancement Options

- PBOA recommends first incorporating process improvement ideas from Industry's 2014 input, which are likely to improve efficiency of Monograph development, finalization, and updating processes
- PBOA recommends consideration of :
  - One-time user license fees associated with future substantive updates to final monographs, creation of new monographs, and addition of new ingredients or technologies
  - Annual product fees for active products (based on existing NDC or SPL data)
- PBOA does not recommend facility-based fees based on FDA administrative complexity, inadequate alignment of fees with benefits

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Other User Fee Program Considerations

- FDA should continue to progress Tentative Final Monographs to Final while any program is being developed (FDA's current responsibility)
- Performance goals could be based on adherence to planned Monograph finalization/update multi-year timeline; timeliness of label revisions due to safety signals; number/timeliness of new actives, technologies added to Monograph
- Other issues for future consideration: Monograph integration/harmonization with USP, smoothing product transitions (non OTC to OTC, TFM to final)

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Questions