Follow-On Biologics Workshop

Panel: Naming & Pharmacovigilance

- Emily Alexander, AbbVie
- Gustavo Grampp, Amgen
- Helen Hartman, Pfizer
- Aaron Kesselheim, BWH / HMS
- Bruce Leicher, Momenta
- Angela Long, USP
- Mark McCamish, Sandoz
- Leigh Purvis, AARP
- Sumant Ramachandra, Hospira
- Marissa Schlaifer, CVS Caremark
- Emily Shacter, ThinkFDA LLC
- Harry Travis, Aetna

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Question:

How would unique or distinguishable USANs or non-proprietary names for biosimilars and interchangeable biologic medicines either reduce or increase confusion?

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Question:

- How would unique or distinguishable USANs or non-proprietary names likely affect:
  - Competition between biosimilars and reference biologics?
  - Competition between interchangeables and reference biologics?
  - Investment in biosimilars and interchangeables?

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Question:

If certain naming conventions could increase confusion or have anticompetitive effects, what justifications support the need to use unique or distinguishable USANs or non-proprietary names for biosimilars and interchangeables?

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Question:

- What is the best way to assure accurate and complete adverse event reporting?
- How could the current adverse event reporting system be improved?
- Should an adverse event reporting system be integrated with the new track and trace reporting system?