Follow-On Biologics Workshop
Panel: State Substitution Laws

- Geoffrey Eich, Amgen
- Ronny Gal, Bernstein
- Aaron Kesselheim, BWH / HMS
- Bruce Leicher, Momenta
- Bruce Lott, Mylan
- Jessica S. Mazer, PCMA
- Mark McCamish, Sandoz
- Steven B. Miller, Express Scripts
- Leigh Purvis, AARP
- Sumant Ramachandra, Hospira
- Marissa Schlaifer, CVS Caremark
- Emily Shacter, ThinkFDA
- Krystalyn Weaver, NASPA

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Question:

- How would particular provisions in new state substitution laws (or similar legislative proposals) 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 particular provisions may have anticompetitive effects, what justifications support the need for those provisions?

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Question:

Would it be useful for the FDA to create a new publication, comparable to the Orange Book, that provided an authoritative listing of FDA-approved biosimilars and interchangeables and their reference biologics?