Listening Session with AMA on Biosimilars
Wednesday July 9, 2014, 11:00 am - 12:00 pm EDT
White Oak Building 31, Room 3502

PARTICIPANTS

American Medical Association (AMA)

- Sandy Marks, Assistant Director, Federal Affairs
- Sylvia Trujillo, Legislative Counsel
- Cybil Roehrenbeck, Assistant Director, Division of Federal Affairs
- Barry D. Dickinson, PhD Director, Science and Biotechnology & Secretary, Council on Science and Public Health (*via Phone*)
- Daniel Blaney-Koen, Senior Legislative Attorney (*via Phone*)

Food and Drug Administration (FDA)

Office of the Commissioner (OC)

- Anna Fine, Director, Health Professional Liaison Program, OHCA
- Danielle Grote, Acting Director of Intergovernmental Affairs, Office of Policy, Planning and Legislation (OPPL)
- Zahava Hurwitz, Policy Analyst, Office of Policy
- Steven Immergut, Associate Commissioner for External Affairs
- Jeanne Ireland, Senior Advisor to the Commissioner
- Catherine Lorraine, Director, Policy Development and Coordination Staff, Office of Policy
- Heidi Marchand, Assistant Commissioner, Office of Health and Constituent Affairs (OHCA)
- Elisabeth Newcomb, Staff Fellow, Office of Planning, Economics Staff
- Christopher Pruitt, Associate Chief Counsel for Drugs, Office of Chief Counsel
- Karen Riley, Deputy Director for Strategy, Office of External Affairs (OEA)
- Cara Tenenbaum, Senior Advisor, Office of Health and Constituent Affairs (OHCA)
- Maryll Toufanian, Associate Chief Counsel for Drugs, Office of Chief Council

Center for Drug Evaluation and Research (CDER)

- Sandra Benton, Senior Policy Analyst, Office of Medical Policy (OMP)
- Steven Kozlowski, Director, Office of Biotechnology Products
- Janice Weiner. Senior Regulatory Counsel, Office of Regulatory Policy

Center for Biologics Evaluation and Research (CBER)

- Diane Maloney, Associate Director for Policy

Europeans Medicine Agency (EMA)

- Sabine Haubenreisser, European Medicines Agency liaison official at the US Food and Drug Administration

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AGENDA

I. Introductions (Anna)

II. Update on FDA Biosimliar Guidances (Steven and Sandra)

III. Biosimilars Policy (AMA)

- CSAPH Report 4: Background on the report, what AMA is hearing/learning from members on the biosimilar pathway and implementation
- Public/Provider Education Development: Existing and future education plans, average prescriber baseline knowledge and collaboration opportunities
- Interchangeability standards for Biosimilar products: AMA considerations

IV. Next Steps (AMA & FDA)