

FDA/FTC Workshop on a Competitive Marketplace for Biosimilars

March 9, 2020

FDA Headquarters, Silver Spring, MD

9:00 a.m. Welcome

Eva Temkin, Acting Director for Policy, Office of Therapeutic Biologics and Biosimilars, CDER, FDA

9:05 a.m. Opening Remarks

- Stephen M. Hahn, Commissioner, FDA
- Joseph J. Simons, Chairman, FTC

9:30 a.m. FDA Licensure Process and U.S. Biosimilar Markets

Objective

All FDA-licensed biological products, including reference, biosimilar, and interchangeable products, undergo a rigorous evaluation to ensure that patients can rely on their efficacy, safety, and quality. This panel will provide an overview of the process for development of biosimilar and interchangeable products. What factors influence and relate to decisions about uptake of licensed biosimilars? How do those factors affect competition more broadly, and what impact do they have on the cost of and access to biosimilars?

- Eva Temkin, Acting Director for Policy, Office of Therapeutic Biologics and Biosimilars, CDER, FDA
- Christine Simmon, Executive Director, Biosimilars Council, AAM
- Molly Burich, Director of Public Policy, Boehringer Ingelheim
- Surya Singh, President, Singh Healthcare Advisors, LLC

Moderated Panel Discussion

Meredyth Andrus, Attorney, Health Care Division, Bureau of Competition, FTC

10:15 a.m. Break

10:30 a.m. FDA and FTC Approaches to Help Ensure Truthful and Non-misleading Advertising and Promotional Communications

Objective

False or misleading promotional communications about medical products can negatively impact public health and competition. In the context of biosimilars, such communications have the potential to undermine public confidence about the safety and effectiveness of these products, which in turn could deter competition and affect the uptake of biosimilars.

In general, how do FDA and FTC address false or misleading advertising or promotional communications? What tools does each agency have to encourage truthful and non-misleading communications about biosimilars that will support competition and uptake?

- Dominic Cirincione, Regulatory Counsel, Office of Prescription Drug Promotion, CDER, FDA
- Richard Cleland, Assistant Director, Advertising Practices, Bureau of Consumer Protection, FTC

Moderated Panel Discussion

Lowell Schiller, Principal Associate Commissioner for Policy, FDA

10:55 a.m. FDA Draft Guidance for Industry: *Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products Questions and Answers*

Objective

Under the FD&C Act and FDA's implementing regulations, promotional labeling and advertising for prescription reference and biosimilar products must be truthful and non-misleading, convey information about the product's efficacy and risks in a balanced manner, and reveal material facts about the product. What does FDA's draft guidance recommend firms consider when presenting data and information about these reference or biosimilar products in FDA-regulated promotional materials?

- Dominic Cirincione, Regulatory Counsel, Office of Prescription Drug Promotion, CDER, FDA
- Elizabeth Pepinsky, Health Science Policy Analyst, Office of Prescription Drug Promotion, CDER, FDA

Moderated Panel Discussion

Catherine Gray, Staff Director, Office of Prescription Drug Promotion, CDER, FDA

11:20 p.m. Lunch

12:15 p.m. What's at Stake? The Benefits of Competition

Objective

Among other consumer benefits, more robust competition can reduce the prices of biological products and facilitate increased patient access to important therapies. How can biosimilar competition help achieve these benefits? What is necessary to ensure these benefits are realized? What are the challenges to realizing these benefits?

- Andreas Schick, Director, Economics, Office of Program and Strategic Analysis, CDER, FDA
- David R. Schmidt, Assistant Director, Applied Research and Outreach, FTC
- Murray Aitken, Executive Director, IQVIA Institute
- Alex Brill, Resident Fellow, American Enterprise Institute
- Inma Hernandez, Assistant Professor of Pharmacy and Therapeutics, University of Pittsburgh School of Pharmacy

Moderated Panel Discussion

Alison Falb, Regulatory Counsel, Office of Therapeutic Biologics and Biosimilars, CDER, FDA

1:15 p.m. Improving Stakeholder Engagement: Education and Understanding

Objective

Current research indicates health care providers' and patients' knowledge, awareness, and perceptions regarding biosimilars and interchangeable biosimilars can impact prescribing behavior, uptake and acceptance. What concerns regarding biosimilars have health care providers and patients shared? What is needed to increase patient and health care provider confidence in biosimilars?

- Cheryl Koehn, Founder & President, Arthritis Consumer Experts
- Sameer Awsare, Associate Executive Director, The Permanente Medical Group
- Michele Andwele, Editorial Director for Health Content, Arthritis Foundation
- Hillel P. Cohen, Executive Director, Scientific Affairs, Sandoz

Moderated Panel Discussion

- Sarah Ikenberry, Senior Communication Advisor, Office of Therapeutic Biologics and Biosimilars, CDER, FDA
- Elizabeth Jex, Attorney Advisor, Office of Policy Planning, FTC

2:00 p.m. Break

2:15 p.m. Biosimilar Disparagement as an Antitrust or Consumer Protection Cause of Action

Objective

Whether disparagement of biosimilars by biologic innovators could give rise to FTC enforcement or private causes of action, and if so, how, is a topic of ongoing debate. Can disparagement constitute false or misleading advertising? Can it constitute anticompetitive conduct? If so, under what circumstances?

- Michael A. Carrier, Distinguished Professor, Rutgers Law School
- Rebecca Tushnet, Frank Stanton Professor of First Amendment Law, Harvard Law School

Moderated Panel Discussion

- Richard Cleland, Assistant Director, Advertising Practices, Bureau of Consumer Protection, FTC
- Randall Weinsten, Attorney, Health Care Division, Bureau of Competition, FTC

3:00 p.m. Open Public Comment

- Sarah Ikenberry, Senior Communication Advisor, Office of Therapeutic Biologics and Biosimilars, CDER, FDA
- Eva Temkin, Acting Director for Policy, Office of Therapeutic Biologics and Biosimilars, CDER, FDA
- Catherine Gray, Staff Director, Office of Prescription Drug Promotion, CDER, FDA
- Antara Dutta, Economist, Bureau of Economics, FTC
- Armine Black, Attorney, Health Care Division, Bureau of Competition, FTC

4:45 p.m. Closing Remarks

Catherine Gray, Staff Director, Office of Prescription Drug Promotion, CDER, FDA