



FDA Outlook for 2022

Medmarc Webinar
January 26, 2022

Today's Speakers



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Joanne Hawana is a Member of the law firm Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, practicing in the Health/FDA Group and based in the firm's Washington D.C. office. She counsels global clients on the business impact of new U.S. federal and state actions related to drugs, biologics, cellular therapies, foods, and medical devices. Her counseling and compliance support work reaches into all aspects of FDA-regulated companies' operations, including determining regulatory status of novel products; pre-market and post-market compliance requirements; and enforcement-related matters.

Joanne has a masters degree in molecular genetics from UMDNJ and a bachelors degree in biology from the College of William & Mary. She received her JD from the University of Maryland Francis King Cary School of Law in 2007.

Benjamin Zegarelli is Of Counsel at the law firm Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, practicing in the Health/FDA Group and based in the firm's New York office. He provides counsel to a breadth of health care industry clients, including pharmaceutical, medical device, and bio tech companies, on the federal and state laws surrounding medical product development and marketing. In particular, Benjamin has extensive experience guiding medical device companies through the FDA regulatory process to identify the correct regulatory pathway, assisting with communications and meetings with FDA, ensuring that regulatory submissions meet regulatory requirements, and helping to establish robust post-market quality system and compliance controls.

Ben has a masters degree in organic chemistry from the California Institute of Technology and a bachelors degree in chemistry from Middlebury College. He received his JD from the Benjamin N. Cardozo School of Law in 2013.

OVERVIEW OF TOPICS

- Transitioning away from temporary COVID enforcement policies
- Laboratory developed tests
- Regulatory considerations permitting greater accessibility to devices
- Drug and biologic program reforms
- Observations on enforcement and inspections
- Dr. Robert Califf as FDA Commissioner
- Lightning Round!

Transitioning away from temporary COVID enforcement policies and back to normal premarket and marketing processes for medical devices

Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised)

Guidance for Industry and Food and Drug Administration Staff

June 2020
Updated October 2020

This document supersedes "Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" issued in March 2020 and updated June 2020.

Enforcement Policy for Remote Digital Pathology Devices During Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry, Clinical Laboratories, Healthcare Facilities, Pathologists, and Food and Drug Administration Staff

April 2020

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)

Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

April 2020

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)

Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

April 2020

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)

Enforcement Policy for Modifications to FDA-Cleared Molecular Influenza and RSV Tests During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

October 2020

Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)

Guidance for Industry and Food and Drug Administration Staff

September 2021

This document supersedes "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)" issued May 2020.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)

Enforcement Policy for Infusion Accessories During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

April 2020

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)

Enforcement Policy for Digital Health Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

March 2020

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

April 2020

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)

Laboratory Developed Tests (LDTs)

- What happened during the pandemic?
- How will laws and regulations change in 2022?



FDA considering more shifts to allow greater accessibility to devices

- COVID temporary policies
- Various issues and confusion about at-home use of devices

Drug and biologic program reforms:

- OTC drug monographs
- CBER reorganization
- Accelerated approval

An aerial photograph of a large university campus with multiple brick and concrete buildings, parking lots, green spaces, and roads. A semi-transparent white box with a dark border is centered over the image, containing the title text.

Observations on Enforcement and Inspections



What's old is new again: Dr. Robert Califf as FDA Commissioner



A white rectangular box with a thin teal border containing the text 'Lightning Round!' in a bold, teal, sans-serif font. The box is centered horizontally and partially overlaps the lightning bolt and the dark clouds.





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THANK YOU!

Feel free to reach out with any questions:

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