MINTZ

FDA Outlook for 2022

Medmarc Webinar

January 26, 2022

Today's Speakers

Joanne Hawana

Member

Washington, D.C.

jshawana@mintz.com // 202.434.7349

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

Of Counsel

New York

bmzegarelli@mintz.com // 212.692.6261

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.

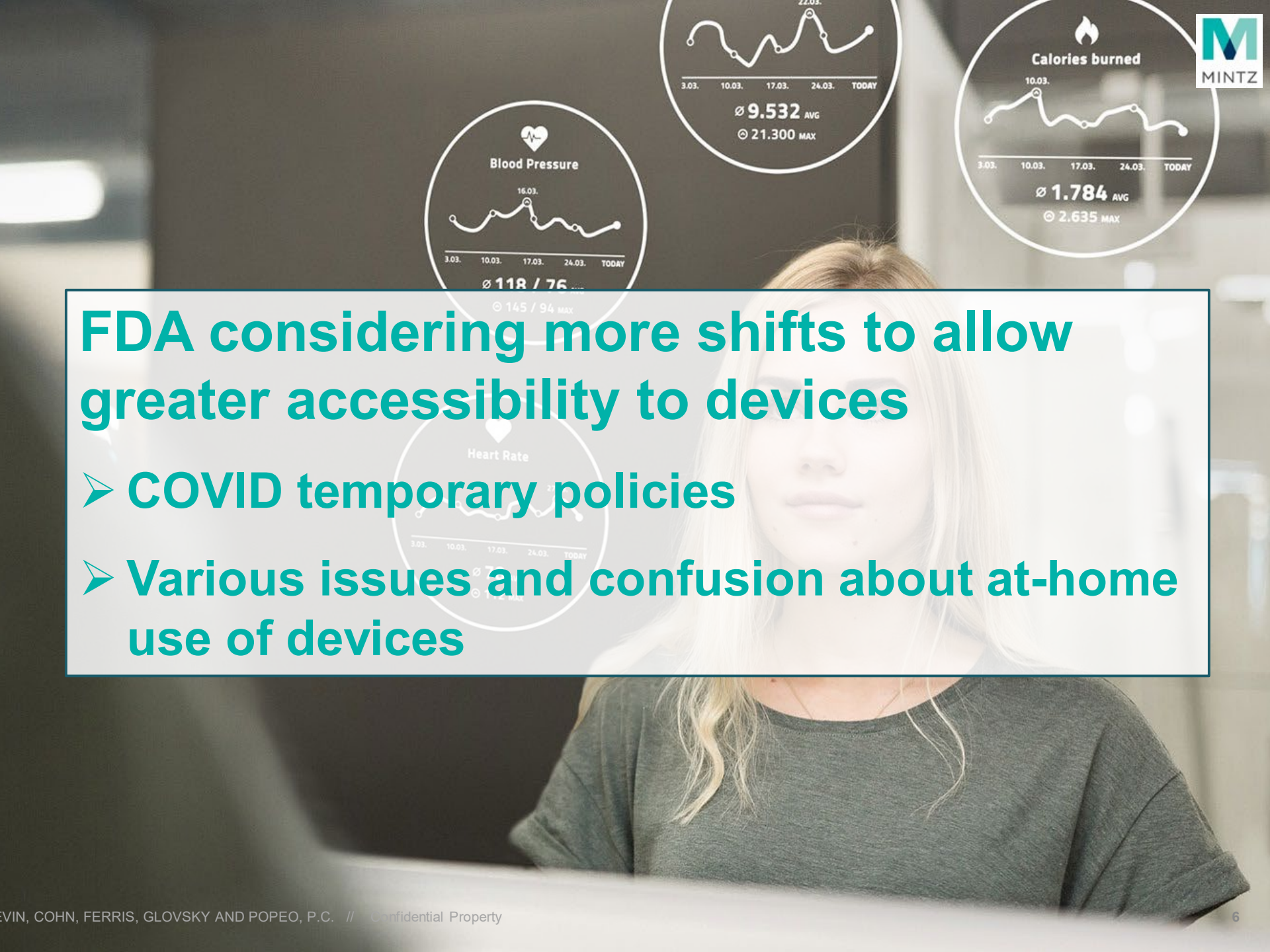
OVERVIEW OF TOPICS

- 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

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

Observations on Enforcement and Inspections

What's old is new again:

Dr. Robert Califf as FDA Commissioner


Lightning Round!

MINTZ

THANK YOU!

Feel free to reach out with any questions:

jshawana@mintz.com

bmzegarelli@mintz.com

Sign up for our Mintz Viewpoints blog posts at:
https://www.mintz.com/insights-center/fda-regulatory