

# Challenges and Opportunities for (non-COVID) Diagnostics in the Time of COVID-19

Allyson B. Mullen, Hyman, Phelps, & McNamara PC  
AMDMD 2021 Annual Meeting

# COVID-19 Focus

- COVID-19 has been everyone's focus for the last year
- Especially FDA's – a multitude of guidances across devices types, the vast majority of which touch on the COVID-19 pandemic
- OHT-7's unprecedented workload with COVID diagnostics
  - Weekly town hall meetings
  - FAQs

But, what has this meant for the rest of the diagnostic industry?

- Cancelled pre-submissions
- Delayed 510(k)s and PMAs

# The Most Unusual of Times . . .



Call for unusual measures  
and outside the box thinking



# Pre-Submissions

- Need to rethink standard process
  - Is it a need to know or a nice to know?
  - Could you make an argument on appeal if you had to?
- Breakthrough could be worth its weight in gold
- Investigational Device Exemption
- Consider calling

# Premarket Submissions

- What was once consistent and predictable is no longer
- Don't be afraid to communicate – sometimes the squeaky wheel gets the grease
- Consider alternative submission pathways
  - Third-party review
  - Triage 510(k)
- Do you need a submission at all? Is there another way?
- Highlights the need for the utmost clarity in communication
- Submitting to get in the queue?

# Risk Management

- This phrase has been put in a whole new light
- Getting comfortable in the uncomfortable grey area
  - Could changes be made without a submission?
  - Data gathering in a post-market setting?
  - Are claims consistent with cleared labeling?

# Managing Internal Expectations

- Misery loves company may not be much consolation to management
- Consider putting in touch with others
- Don't assume that regulatory flexibility will continue

# Questions & Discussion



# Contact Information

Allyson B. Mullen  
Hyman, Phelps & McNamara, P.C.  
700 Thirteenth Street, NW  
Suite 1200  
Washington, DC 20005  
(202) 737-9639  
[amullen@hpm.com](mailto:amullen@hpm.com)  
[www.hpm.com](http://www.hpm.com)  
[www.fdalawblog.net](http://www.fdalawblog.net)