

Tony Subketkaew, Suzie Trigg, Joanna Pearce and Neil Issar in Update Magazine: 'FDA Guidance in Response to COVID-19 and a Plan for Transition Back to Normal'

March 28, 2022 Suzie Trigg, Neil Issar

PRACTICES FDA Regulatory and Compliance, Food, Beverage and Restaurant, Healthcare and Life Sciences, Life Sciences, Precision Medicine and Digital Health, False Claims Act and Qui Tam Defense

From the outset of the COVID-19 public health emergency, the U.S. Food and Drug Administration (FDA) engaged in policymaking at a blistering speed compared to its historically measured pace. Robert Califf, who previously led the agency under Obama, was recently confirmed as FDA commissioner, and Califf's approach to agency guidance will be closely monitored by many stakeholders. With two COVID-19 vaccines now approved, some of the impacts of the pandemic can be mitigated, but as we return to a more measured cadence, it is worthwhile to consider the lessons learned from this exercise in policymaking at an accelerated speed.

In the early days of the COVID-19 public health emergency, FDA issued a flurry of guidance documents. Many of the COVID-19-specific guidance documents were issued without prior public participation in the development process. We now have the benefit of hindsight to evaluate whether bypassing such participation was warranted and the impacts of foregoing the customary process and pace.

FDA's guidance entitled "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency" (the Enforcement Policy) provides a helpful case study to:

- Review the statutory and regulatory foundations that enable FDA to issue guidance as a means of policymaking;
- Examine the need for policy due to the public health emergency;
- Analyze whether public participation would have improved the guidance under the circumstances; and
- Project some of the longer-term impacts and issues arising from the evolution of guidance policy.

Excerpted from the Food and Drug Law Institute's *Update Magazine*. Read more [here](#).