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This Teachable Moment: How COVID-19 Provides Lessons from FDA's Past and Present That Will Benefit Its Future Preparedness
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9. Federal Law's Protective Quilt: Understanding the Statutory Regimes for Personal Protective Equipment (PPE) and Recommending an Additional Piece

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We are so surrounded by personal protective equipment (PPE) in our daily lives that we pay little attention to it: the exam gloves at the doctor's office, eye protection while cutting wood at home, or the hardhat at the archaeological excavation. However, as the 2019 novel coronavirus spread causing COVID-19, the demand for PPE grew astronomically, resulting in widespread shortages reported by the nightly news. Healthcare providers and first responders could not obtain enough medical PPE, especially respiratory protection. Thus industrial, non-medical, PPE was diverted from its traditional commercial channels into medical ones, for which the Food and Drug Administration (FDA) issued various administrative actions allowing for this. Furthermore, to meet increased demand for items like respirators and masks, products were being imported from around the world.

COVID-19's disruption to the status quo provided an opportunity to better understand the federal statutory regime for PPE. There is no one statute or agency that governs the manufacturing and marketing of PPE. Instead, there are numerous laws and agencies that all play a role in regulating PPE. Some of the agencies are the Occupational Safety and Health Administration, the National Institute for Occupational Safety and Health, the Food and Drug Administration, and Consumer Product Safety Commission. The laws administered by these agencies come together to weave a quilt of sorts that seek to ensure that PPE is safe.

The COVID-19 pandemic has shed a light onto this interwoven quilt, identifying a small hole. Namely, the lack of a statute that expressly prohibits adulterated (or unsafe) PPE and provides a mechanism to seize that product, whether at the border or in domestic commerce. We have seen this issue arise during COVID-19 as Customs and Border Protection has actively worked to keep-out substandard PPE, usually on the theory that they are violative medical devices or they have violative trademarks. However, there can be substandard PPE that is not a medical device and has no trademark violations. What is Customs to do then?

This paper has two objectives: first, explore the current federal statutory framework governing PPE and how COVID-19 has demonstrated the potential need for a statute that explicitly prohibits unsafe PPE; and second, propose a modest statute that prohibits unsafe PPE. Using the Food, Drug, and Cosmetic Act as a model, the statute would define PPE, prohibit adulterated PPE, and create an enforcement mechanism to remove adulterated PPE from the market or prohibit its importation.

This proposal seeks to merely address this concern, rather than create a new statutory regime for the PPE industry. That would be disruptive to the marketplace and counterproductive as it ignores the legacy that has been built-up over the last one-hundred years – the federal government approved the first respirator PPE in 1920. A statute based on the Food, Drug, and Cosmetic Act offers a predictable solution, which can rely on well-established statutory interpretation, to address the challenge of removing problematic PPE when a bad actor is present.