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Why Would FDA's Emergency Actions Stick Around After the Emergency is Over?

While some of the Food and Drug Administration's actions in response to COVID-19 have been traditional, many others have been simplifications of regulatory requirements, and those simplifications could be made permanent.

Here's one type of activity that was traditional: The agency has been slapping down phony drug products. The moment the COVID-19 pandemic hit the scene, dietary supplement products claiming to cure or prevent the virus started to be offered for sale, and immediately FDA and the Federal Trade Commission started making a regular habit of issuing stern warnings to the makers of the products. FDA already has issued such warning letters to almost 70 different companies. The companies, for example, make unproven claims on product labels or on websites selling the products. They claim the products can prevent or cure COVID-19 or other diseases. The agencies alleged that that the companies' false labeling and advertising claims render the products drugs, and unapproved drugs to boot. Currently, there is no drug that's been proven to prevent or cure COVID-19. FDA has also taken action against "testing kits and personal protective equipment (PPE) sold online with unproven claims."

Without knowing the specifics of each product, one suspects the COVID-19 cure purveyors, um, know that they don't have proof of their claims. There have always been two kinds of targets for FDA enforcement actions. There are those FDA target companies that don't have bad intent and are trying very hard to comply with all of the voluminous and sometimes-vague FDA requirements, but fall short. The vast majority of companies fall into this category, despite the big number of recipients of those warnings about labeling and advertising violations. And then there are those FDA target companies who *aren't* trying to comply but are only trying to profit, and don't seem to care whether they mislead the public in the process. Hold those thoughts, we'll come back to them in a moment.

Separately from its warnings to makers of dubious COVID-19 products, FDA has been using its legal power to adjust its requirements in various ways when confronted with an emergency. For example, it's been working with companies to help them quickly develop valid new drugs to treat, prevent, or cure COVID-19, and it's been helping speed-to-market new diagnostic tests, masks, hand sanitizer, and other protective equipment and supplies, often by carving away some of the usual regulatory requirements that would otherwise have been required of the products or their makers.

FDA has been communicating regularly with the industries it regulates with advice about how food and other manufacturers can adjust to the new safety challenges the virus presents, and has also been explaining how the agency will adjust its own operations during the pandemic.

This pandemic-inspired theme of shaving away regulatory requirements fits nicely with the administration's overall ideological approach. You may remember that the administration had already imposed a requirement that called on agencies to withdraw two regulations for each new one it makes, and it's common to hear the president tout his administration's reduction of 'regulations,' which he talks about as if they are viruses that are always worthy of being eliminated.

What's more, FDA commissioner Stephen Hahn said in early June, "To the extent that the innovations and adaptations we implemented during the pandemic crisis worked and would be appropriate to implement outside of a pandemic situation, we will incorporate them into standard FDA procedures."

He specifically mentioned the use of "decentralized" clinical trials, and Real World Evidence (RWE), "such as data from electronic health records, insurance claims, patient registries and lab results," to evaluate drug safety and effectiveness.

However, Hahn reaffirmed the agency's commitment to safety, even as it may simplify some processes and requirements. After all, each of the various requirements imposed on makers of drugs and devices—from registering the factories with FDA to putting specific statements on the products' labeling to getting agency approval before hitting the market—is designed to help assure the products are safe and effective. Ideally, Congress and FDA should always be looking for ways to make life easier for those who are trying to comply, and harder for those who aren't.

Will drugs and devices be less safe and effective if FDA carves away some of those requirements? Well, we'll see. But, as noted, it's always been true and will continue to be true that the vast majority of regulated businesses try very hard to make products that are made correctly and are safe and effective, so maybe some of those regulatory requirements aren't needed after all. Remember, FDA has all those powers now, but still the COVID-19 hucksters are trying to sell their questionable products.

There have long been advocates of getting FDA out of the business of imposing many requirements on business, on the theory that they are burdensome and don't add to safety. After all, if you look at the history of drug regulation, there was a time when new drugs weren't approved by FDA before marketing, then there was a time when they were approved by FDA only for their safety, and now the law requires that FDA approve new drugs for their safety and their effectiveness for their intended use.

That's the law now, but that doesn't mean it will be the law forever. Sometimes change is gradual, and sometimes a crisis introduces changes that stay. **PW**

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