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Will FDA and DOJ Reassert Their Enforcement Muscle With Life Sciences in 2022?

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Takeaways

- Despite predictions that the Biden administration would devote increased enforcement resources to the life sciences industry broadly, so far, the FDA and DOJ have focused their efforts on COVID-related conduct.
- Although both the FDA and DOJ experienced lengthy delays in appointment and confirmation of top officials, the DOJ has recently announced new policies regarding corporate prosecutions, which could have significant consequences for life sciences companies.
- The question remains: Will 2022 see an uptick in enforcement and policy changes or will the focus continue to be on COVID-related misconduct?

FDA Inspections Are Sharply Down and Enforcement Has Shifted to COVID Products

Fiscal year 2021 saw a dramatic drop in U.S. Food and Drug Administration (FDA) inspection activity. The agency conducted 60% fewer domestic inspections and 94% fewer international inspections during 2021 than it did on average in the four years prior to the pandemic.

Perhaps unsurprisingly given the reduction in inspections, the overall level of enforcement activity also dropped in FY2021, even compared to FY2020, which itself was significantly down due to COVID-19. The FDA issued 56% fewer warning letters and brought 60% fewer injunctions in FY2021 than the year before, and product recalls dropped by approximately 27%.

Although at first blush the number of warning letters issued to drug, biologic and medical device companies during FY2021 appeared similar to pre-pandemic levels, the nature of the letters has shifted. In FY2021, many were issued in connection with fraudulent medical products marketed with unsubstantiated claims regarding the treatment, prevention or cure of COVID. The number of warning letters that would normally be issued to such companies as the result of significant inspectional findings is down significantly, as a direct consequence of fewer facility inspections.

Long before COVID, warning letters issued by the FDA's Center for Devices and Radiological Health (CDRH) had fallen off sharply, and were down 90% between 2015 and 2019. CDRH leaders had signaled this trend would change in 2020, but the exigencies of COVID and the concomitant reduction in inspections clearly challenged those plans. 2021 did not see a return to historic levels of CDRH warning letter activity, but did see the FDA issue six current good manufacturing practices (cGMP) warning letters based solely on remote record reviews conducted in lieu of inspections. However, all six were issued to foreign over-the-counter (OTC) drug manufacturers.

While the FDA may issue similar letters outside the OTC drug sector based on remote reviews if its inspection capabilities — and particularly its international capabilities — continue to be hampered by COVID, notably it has not yet done so more than 18 months into the pandemic.

Although the FDA began to resume domestic inspections in the second half of 2021, it announced in early January 2022 that it had again paused non-mission-critical inspections through at least mid-January due to the Omicron variant. As such, it remains to be seen whether inspections return to pre-pandemic levels in 2022, and whether that leads to more enforcement against prescription drug, biologic and medical device manufacturers.

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DOJ Enforcement Activity Is Also Down, but Newly Declared Priorities Could Change That

DOJ enforcement focus in 2021 was likewise trained on COVID, with the department taking action against companies allegedly touting fraudulent and ineffective vaccines, COVID treatments and faulty personal protective equipment. It also targeted fraud associated with use of funds available under the Coronavirus Aid, Relief and Economic Security (CARES) Act.

In traditional areas of DOJ life sciences enforcement — violations of the Anti-Kickback Statute (AKS); Food, Drug and Cosmetic Act; and False Claims Act — in 2021, the DOJ announced only 11 settlements of greater than $1 million involving drug, biologic or medical device manufacturers, and an additional two settlements of that magnitude involving alleged AKS violations by electronic health record system manufacturers. In contrast, by the end of September 2019, the DOJ had announced 18 such settlements with life sciences manufacturers.

There was one sign that enforcement may intensify in the future. In late October 2021, Deputy Attorney General Lisa Monaco announced several significant changes to DOJ corporate enforcement priorities that could have a substantial impact on the life sciences industry. These include:

- A focus on individual accountability and reversion to the Obama-era expectation that, to earn cooperation credit, companies will have to produce all nonprivileged information about the involvement of all individuals implicated in wrongdoing. To meet this expectation, companies may be required to reconsider how they conduct internal investigations.
- An intent to consider a company's total history of criminal, civil and regulatory misconduct in assessing corporate prosecution factors, rather than focusing only on previous misconduct of a similar nature. This could have implications not only for companies that have faced prior DOJ matters in unrelated areas (such as antitrust or environmental matters), but also those with a history of regulatory noncompliance, such as FDA warning letters or repeat FDA Form 483 inspection observations.
- An intent to closely scrutinize companies that commit wrongdoing while bound by nonprosecution agreements or deferred prosecution agreements, which have been used to resolve a number of life sciences cases because of the potential for exclusion from federal health care programs that can result from a conviction.

See "DOJ Steps Up Corporate Criminal Enforcement, Looks More Broadly at Past Misconduct."

Expect Policy Changes and Possibly Increased Enforcement as Key Officials Are Confirmed

Nearly a year after being elected, President Biden nominated Robert Califf to serve as FDA commissioner, the role he held during the last year of the Obama administration. Under Janet Woodcock, a long-serving FDA official who was acting commissioner since President Biden took office, the agency has largely focused on COVID and has not announced major policy or enforcement initiatives. If confirmed, FDA-regulated companies can expect Dr. Califf to direct the agency's resources to align with his policy priorities, such as further emphasis on real-world evidence, a focus during his prior tenure.

While top leadership was in place at DOJ headquarters in Washington, D.C., as of early January 2022, only approximately one-third of the 94 federal districts had confirmed U.S. attorneys in place. We expect DOJ enforcement activity to increase as additional new U.S. attorneys are confirmed, assume their roles and launch enforcement initiatives reflecting their priorities.