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Biden Administration's Expected Impact on Health Care and Life Sciences Enforcement

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This article is from Skadden's ***2021 Insights***.

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In 2021, the health care industry generally, and the life sciences sector in particular, is evaluating the potential impact of a change in administration on regulatory and law enforcement. Will investigations and enforcement actions increase? Will new regulations that impact sales and marketing efforts be adopted? Will any newly adopted regulations — for example, the recent "most favored nation" rule tying payment for Medicare Part B medications to the lowest price paid by certain other nations — be enforced, repealed, ignored, supplemented or expanded by the Biden administration?

Simple answers do not exist to any of these questions; however, detailed below are our thoughts on what clients should expect under the Biden administration.

Absent a rise in white collar prosecutions, will pursuit of federal health care offenses go up? While all white collar prosecutions dropped between 2013 and 2017, federal prosecution of health care defendants remained roughly at a steady rate that continued during the Trump administration. Most health care offenses are prosecuted by federal prosecutors funded by the Affordable Care Act, which restricts the Department of Justice's (DOJ) ability to shift the focus of those prosecutors to other areas of investigation. Thus, while the Trump administration diverted other resources from white collar investigations and enforcement to immigration and violent crime enforcement, health care prosecutors were not diverted from their congressionally assigned arena. Even without an increase in overall white collar prosecutions under the Biden administration, clients should expect the current level of health care enforcement to continue.

What level of enforcement do you expect from the regulatory agencies overseeing the sector? The DOJ cannot act alone in pursuing a regulatory investigation. If the relevant agencies do not want to pursue enforcement actions, including criminal prosecutions, those actions will wane even with strong DOJ interest. That said, it is likely that the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and the Office of Inspector General for the Department of Health and Human Services will be more active in the Biden administration because of Democratic priorities that will push the Biden administration to regulate more heavily than the Trump administration. Even if such regulatory interest does not rise to the level of federal criminal or civil enforcement actions, clients should expect greater regulatory scrutiny during the next four years.

Will federal False Claims Act enforcement increase? With some exceptions, False Claims Act (FCA) enforcement has dropped substantially since 2012, but clients should not expect this slide to continue. Over the past 20 years, FCA enforcement has largely been driven by relators pursuing *qui tam* actions, with the DOJ choosing from among those relators-filed actions which cases to pursue. Clients should expect an uptick in *qui tam* filings, as the relator bar will likely consider the Biden administration's DOJ to be more welcoming to those actions. Another issue to watch for is a potential uptick in the number of FCA actions alleging violations of the FDA's current Good Manufacturing Practice (cGMP) requirements in light of the 2017 case *United States ex rel. Campie v. Gilead Sciences, Inc.*, in which the U.S. Court of Appeals for the Ninth Circuit

found that certain alleged violations of the cGMP requirements met the materiality test in the U.S. Supreme Court's *Universal Health Services v. U.S. ex rel. Escobar* decision.

What do we expect with regard to FDA regulatory actions? FDA enforcement actions, especially such regulatory actions as the issuing of warning letters, will likely rise in the next two years once the FDA resumes domestic and international establishment inspections at pre-pandemic rates. Clients should expect the FDA's previous focus on the global supply chain, data integrity and cGMP compliance to continue. There is likely to be increased focus on compliance with combination product requirements as well now that regulations related to post-market adverse event reporting are in effect. The FDA will most likely remain focused on fraud related to COVID-19, and we expect coordination with the Federal Trade Commission and DOJ on efforts to police unapproved therapies making improper health claims. The FDA may also revisit some Trump-era policies related to discrete regulatory issues, such as the regulation of in vitro diagnostics and marketed unapproved drugs.

How will COVID-19 impact the change in administration? Federal, state and local authorities have implemented emergency legislation, regulations and other programs in response to the COVID-19 pandemic. For example, the Coronavirus Aid, Relief and Economic Security Act (the CARES Act) allocated $130 billion in economic programs, tax credits, deferrals and deductions available to companies in the health care industry. Given the significant increase in government spending around COVID-19, we anticipate a corresponding increase in enforcement — a trend that began in 2020 and should continue through the duration of the pandemic, as state and federal enforcement agencies continue to detect, investigate and prosecute COVID-19-related fraud.

Similarly, the FDA continues to actively monitor fraudulent or unproven medical products related to COVID-19, and we expect that enforcement priority to continue under the new administration. Given the FDA's expedited approval of so many products under its Emergency Use Authorization mechanism, more issues in manufacturing and quality are likely, which should also result in more enforcement.

Will new regulations stand? With an evenly divided Senate and a closely divided House of Representatives, congressional action to overrule new regulations seems unlikely. As an example, CMS recently finalized its "most favored nation" pricing model for Medicare Part B drugs, which will primarily impact the branded pharmaceutical industry. There are already several challenges against its enforcement already pending before the courts, which may result in deferred implementation of the rule. Moreover, because the new regulation has not been finalized for 60 days, it is subject to a memorandum President Biden issued on his first day in office that requires CMS "where appropriate and consistent with applicable law, [to] consider opening a 30-day comment period to allow interested parties to provide comments about issues of fact, law, and policy raised by those rules, and consider pending petitions for reconsideration involving such rules."

Thus, the rule is subject to further review, both by the agency (CMS) and, if that agency considers it appropriate, for further comment as well as potentially a revision or rejection. It is, at this point, impossible to predict whether this particular regulation will be implemented as published in November 2020 or whether it will be further edited or scrapped as a part of any future regulatory processes. It is also possible that, if CMS chooses to scrap the regulation, that decision may be challenged as not "appropriate or consistent with applicable law."

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Companies in the sector should remain vigilant in maintaining ethical corporate cultures and strong corporate compliance programs. Should an increase in regulatory and enforcement commence, both of these attributes should help clients weather the storm.