The Potential Impact of the Biden Administration on Life Sciences, Healthcare, and Consumer Product Companies and Investors

November 2, 2020

With Election Day tomorrow and the possibility of new President sworn in on January 20, 2021, in this article we highlight the potential implications of a Biden Administration on life sciences, healthcare, and consumer product companies and investors. Specifically, we explore potential Biden Administration policy changes that may impact these important sectors of the economy, taking into consideration a variety of factors including Congressional control,[1] composition of the President's cabinet, the administration's policy priorities, and outside factors such as the coronavirus pandemic and economy.

New policies may be implemented by a Biden Administration through a variety of mechanisms, ranging from executive orders and regulatory agency policy pronouncements to rulemaking and legislation. As described below in greater detail, based upon the decision by the Trump Administration to rely on executive orders and informal mechanisms to implement certain health policies, these policies may be readily reversed without the need for rulemaking or legislation should Biden win the election.

This article does not address the implications of a Trump victory, as we have previously published articles on these topics[2] and believe many of the trends we identified would continue in the event President Trump is reelected.

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[1] Although we cannot predict the composition of the Senate after the 2020 election, it is not anticipated that either party will have the necessary 60 votes to override a filibuster. If the legislative filibuster is maintained, bipartisan legislation may be needed to change certain substantive healthcare policies that are not amenable to the budget reconciliation process (which is not subject to a filibuster and permits the enactment of certain tax and spending bills by majority vote). Even for matters that require a simple-vote majority, several centrist Democratic senators may put a brake on broad legislative changes.

[2] Debevoise In Depth: Private Equity Guide to Consumer Product Investing Under the Trump Administration: Food and Drug Administration (FDA) Developments (Apr. 18, 2019); Debevoise In Depth: Private Equity Guide to Life Sciences Investing Under the Trump Administration: Food and Drug Administration (FDA) Developments (Mar. 15, 2018).

Issues to Watch: Life Sciences

New Food and Drug Administration (FDA) Commissioner

If Biden is elected President, he would be expected to nominate a new FDA commissioner subject to Senate confirmation. It is uncertain whether Dr. Stephen Hahn, the current FDA commissioner, would remain in the role pending confirmation of Biden's nominee. Dr. Joshua Sharfstein, the vice dean for public health practice and community engagement at Johns Hopkins University and former head of the Maryland Department of Health and Mental Hygiene, is being floated as a potential nominee. Dr. Sharfstein served as deputy FDA commissioner during the Obama Administration. A new FDA commissioner may work in closer alignment with the White House in certain areas to confront the pandemic than has been the case more recently.

Response to the Coronavirus Pandemic

Biden has indicated that if elected he will immediately take steps to address the coronavirus pandemic. Biden has promised to create a "Pandemic Testing Board" and substantially increase free testing capacity, including by establishing drive-through sites nationwide. A nationwide surge will of course depend on lab capacity and availability of test kits, which could prove to be limiting factors.

Biden has also promised to conduct a 100-day personal protective equipment (PPE) supply chain review immediately after inauguration to assess healthcare provider needs and to leverage federal buying power, including through the Defense Protection Act, Biomedical Advanced Research and Development Authority (BARDA), and federal procurement, to increase American-made supply capacity. This would likely result in greater federal funding for U.S. manufacturers of these products.

The Trump Administration's efforts to develop and manufacture vaccines and therapeutics are expected to continue, but a Biden Administration may place greater emphasis on the independent decision-making power of the career scientists at FDA. At least one member of FDA's Vaccines and Related Biological Products Advisory Committee has suggested that the committee may refuse to support an EUA for a vaccine based on interim analysis of trial results, which could delay a vaccine EUA by several months.

In addition, FDA may make an effort to better coordinate the clinical development of vaccines and therapeutics in order to increase efficiency and achieve more useful data, similar to the practical approach implemented by British authorities.

Medical Product Supply Chain and Onshoring

Congress and FDA have been studying the country's reliance on foreign-made pharmaceuticals for several years, particularly from China and India,[3] but the pandemic has magnified the need for a reliable supply of American-made medical products. It is likely that momentum for a policy that encourages U.S.-based manufacturing will continue for several years.

As part of his "Made in All of America" plan, Biden has proposed changing the tax code to eliminate the incentives for pharmaceutical manufacturers to move production overseas and establishing new incentives for companies to make critical products in the United States.

On October 30, 2020, FDA published a list of 223 essential drugs and biologics (including active pharmaceutical ingredients (APIs)) and 96 medical device countermeasures deemed critical for public health. The list includes prescription drugs and biologics, OTC drugs, and medical devices such as ventilators and personal protective equipment. The list was prepared to ensure sufficient and reliable supplies of these products by encouraging domestic production and reducing reliance on foreign supply chains. The list is open for public comment, and we expect private equity funds and strategic acquirers to scrutinize the list to identify potential investment opportunities, particularly for companies capable of expanding domestic production.

FDA Enforcement

A new FDA Commissioner may establish different enforcement priorities for the agency, which may lead to increased enforcement in certain areas. For example, FDA's Office of Prescription Drug Promotion (OPDP) has issued fewer Warning Letters in recent years and a new administration could bring renewed scrutiny of pharmaceutical advertising (despite certain First Amendment arguments that remain under review at the agency). FDA may also increase facility inspections, but this will likely depend on the course of the pandemic and whether inspections can be conducted safely, in particular for foreign inspections that have been significantly curtailed since early 2020.

Clinical Trial Reform

FDA will likely continue to reevaluate requirements for clinical trials and encourage the incorporation of technology such as telemedicine, which has accelerated in part due to the obstacles the pandemic has created for clinical trials. Earlier this year, FDA issued a guidance document addressing the conduct of clinical trials during the COVID-19 public health emergency, including how trials may be modified to protect the safety of

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[3] *See* Debevoise In Depth: Indian Pharma: Congress and FDA Continue Scrutiny of Foreign Drug Companies with Heightened Focus on Companies Located in India (Feb. 12, 2020).

participants.[4] In light of the rapid advancement in technology and telemedicine, it is now possible to effectively deploy a decentralized trial design where subjects can be assessed remotely and do not need to be in close geographic proximity to clinical trial sites. An FDA guidance document on decentralized trials is expected later this year or early next.

Laboratory Developed Tests (LDTs)

On August 19, 2020, the Department of Health and Human Services (HHS) announced that FDA will not require premarket review of LDTs absent notice-and-comment rulemaking. This is the latest development in the debate surrounding the regulation of LDTs, in vitro diagnostic tests that are designed, manufactured, and used within a single laboratory. FDA has traditionally exercised enforcement discretion for these tests and has not enforced premarket review or other applicable requirements in most situations, but prior to HHS's announcement FDA had required review of in vitro diagnostic tests to detect COVID-19. We expect the debate surrounding LDTs to continue into the new administration and it is likely that FDA looks to Congress to establish a framework for regulating LDTs. Both the House and Senate introduced bills to regulate LDTs in early 2020 and these bills may be taken up in the new Congress. More immediately, a Biden Administration may choose to reverse the recent HHS announcement and again require premarket review of some categories of LDTs—this policy change could be implemented immediately in the absence of rulemaking or legislation.

Rare Pediatric Disease Priority Voucher Program

This program was created in 2012 and is intended to encourage development of therapies for rare pediatric diseases. Companies that develop such therapies receive vouchers from FDA that allow the company to obtain a priority review for a subsequent drug application. These priority review vouchers, like those received through other programs, can be sold to third parties and thus are valuable assets in their own right. The program expires on December 11, 2020, and requires Congressional reauthorization. The House has passed a bill to extend the program through September 30, 2024, and it is currently stalled in the Senate. The next Congress will need to decide whether to reauthorize the program.

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[4] FDA, Guidance for Industry, Investigators, and Institutional Review Boards: FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency (updated Sept. 21, 2020).

Issues to Watch: Healthcare

Affordable Care Act

Biden has emphasized his commitment to the Affordable Care Act (ACA) and expanding health insurance coverage. The simplest change he can make is by regulation, reversing the Trump Administration regulations that facilitated the provision of lower-cost health insurance that does not satisfy the ACA's requirements, including short-term, limited-duration insurance plans for terms of longer than three months and association health plans. These lower-cost plans have been criticized because, among other things, they may not cover required benefits and may have coverage exclusions. As a result, these plans attract healthier patients, thereby making the pool of individuals in ACA-compliant plans relatively sicker and more expensive to insure. Biden appears likely to seek Congressional authorization to expand enrollment in ACA plans by increasing subsidies for the purchase of ACA-complaint plans, *e.g.*, by making the Advance Premium Tax Credit available to individuals who make more than 400% of the federal poverty level.

Initiatives that expand ACA coverage are likely to benefit health insurers that offer ACA-qualified plans. To the extent subsidies lead to expanded enrollment, providers and beneficiaries would benefit because there will be more individuals who have insurers funding their care. That said, expanding subsidies is very costly and Congress may seek to fund at least some of the expanded subsidies through cuts in reimbursement levels for government-funded healthcare programs.

Importantly, on November 10, 2020, the Supreme Court is scheduled to hear oral argument in *California v. Texas*, a constitutional challenge to the ACA's individual mandate.[5] The suit also seeks to invalidate remaining provisions of the ACA that cover a range of issues such as the regulation of private health insurance, changes to public healthcare programs, funding for preventive healthcare programs, and drug regulation. We believe it is unlikely that the Supreme Court will invalidate the ACA. Should the Supreme Court invalidate the ACA, however, private insurance markets, public health programs, and the entire healthcare ecosystem would be thrown into a state of flux requiring a legislative solution by Congress that may be politically fraught, making any form of compromise particularly challenging.

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[5] In its original form, the ACA included an individual mandate that imposed financial penalties on certain individuals who failed to comply with the requirement to maintain minimal levels of health insurance. In 2012, the Supreme Court upheld the mandate as a valid exercise of the federal government's taxing power. After Congress enacted tax reform in 2017 that lowered the financial penalty to zero, certain state attorneys general filed suit and argued that the individual mandate was no longer a tax and therefore was unconstitutional and that the rest of the ACA should be invalidated as a result. These arguments are now before the Supreme Court.

Public Option

Biden has also campaigned on a "public health insurance option"—a health insurance plan run by the federal government that would be offered along with other private health insurance plans on the insurance marketplace. It is uncertain whether Biden will pursue a public option, given that it would be highly controversial among many industry sectors. They key details of such a program are unknown, including how it would be funded, who would be eligible, and the level of reimbursement.

The impact of a public option would depend on its terms. If the public option offers insurance at significantly below-market rates, it could crowd out commercial health insurance plans and reduce business for providers of those plans. Further, the affordability of a public option would also depend on the level of provider payments, as private insurers typically pay higher prices than the Medicare or Medicaid rate for covered services—and a public health insurer may reimburse at Medicaid rates or less. Lower reimbursement rates under a public option would likely be a negative development for providers and drug companies, particularly assuming the public option plans attract individuals currently insured by commercial plans that provide reimbursement at higher rates.

Prescription Drug Costs

Biden has made prescription drug pricing a major campaign issue. In particular, Biden has proposed allowing the Medicare program to negotiate drug prices for Part D drugs and limiting prescription drug launch prices in certain instances.

The Biden Administration is likely to pursue regulatory initiatives in an effort to achieve certain policy objectives without the need for legislation. These include two areas where the Trump Administration has proposed rules but has been unable to finalize them, apparently largely due to the complexities of implementation: changes to the Medicare Part D PBM rebate structure to pass more of the rebates to consumers and restructuring Medicare Part B drug coverage to increase formulary management and limit payments.[6]

Surprise Billing

Biden has called for an end to "surprise billing."[7] "Surprise billing" is used to describe circumstances in which consumers are billed at out-of-network rates for certain providers at in-network hospitals or out-of-network emergency rooms. Last year, the House Energy and Commerce Committee announced that it was opening a bipartisan

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[6] See Debevoise Update: Trump's New Drug Pricing Executive Orders: Much More Bark Than Bite (July 29, 2020); Law360: Trump's Drug Pricing Order Is More Bark Than Bite (September 22, 2020).

[7] See Debevoise Update: Congressional Investigation Highlights Potential Risks for Private Equity Healthcare Investments (Sept. 19, 2020).

investigation into the role that private equity funds play in such billing practices, part of a broader trend of Congressional scrutiny of private equity firms and the role they play in the healthcare industry. There appears to be bipartisan support for legislation to ban such bills—at least in theory—but there have been differences of opinion (which cut across party lines) regarding the legal regime that should govern the rates that can be charged in such circumstances. Congress appeared to be nearing consensus on a "surprise billing" statute, but legislation was halted in part by the pandemic.

Telehealth

The COVID-19 pandemic has had a significant impact on the use of—and reimbursement for—telehealth.[8] Biden has endorsed continued expansion of telehealth services and is unlikely to reverse the regulatory flexibilities for telehealth issued during the current public health emergency. Many of the barriers to the provision of telehealth prior to the pandemic are statutory, however, and can be waived only for the duration of the public health emergency. Absent statutory changes, after the pandemic, Medicare will be authorized to reimburse for telehealth services only in the limited circumstance of rural patients who must travel to designated facilities. However, there appears to be bipartisan support for legislation that would remove these barriers. That said, Congress' ability to facilitate telehealth services is somewhat limited by the fact that many state laws limit the circumstances where out-of-state providers can provide telehealth services. While these laws have largely been relaxed during the pandemic, these limitations will resume after the emergency is over.

Stark Law

The federal Physician Self-Referral Law (Stark Law) is intended to protect patients from unscrupulous providers referring them to healthcare facilities in which the provider has a financial interest. Unfortunately, the outdated implementing regulations have posed a barrier to value-based care and care-coordination contracts, where patients benefit from close coordination between providers and healthcare facilities. To help accelerate the U.S. healthcare system's transition from a fee-for-service system to a value-based system, HHS has launched the "Regulatory Sprint to Coordinated Care" initiative, which aims to change the manner in which the healthcare regulatory framework has traditionally been applied to stakeholder arrangements, including implementation of proposed changes to modernize and clarify the Stark Law regulations. Biden appears to support the shift to value-based reimbursement models and is therefore expected to continue the process of revising the Stark Law implementing regulations begun by the Trump Administration. Healthcare and insurance companies are generally expected to benefit from increased value-based care arrangements generally and from streamlined Stark Law rules in particular.

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[8] Debevoise In Depth: Providers, Investors Need Clear Post-COVID Telehealth Picture (Sept. 22, 2020).

HHS' proposed changes to Stark Law would have critical operational and structural implications for arrangements between entities and referring physicians. The proposed exception, if finalized, would offer protection to a broad swathe of financial arrangements inherent to the healthcare industry, regardless of whether the compensation paid under such arrangement is consistent with fair market value or takes into account the volume or value of a physician's referrals.

Issues to Watch: Consumer Products

Federal Trade Commission's (FTC's) Ability to Seek Monetary Remedies in Federal Court

The Supreme Court will hear two consolidated cases this term addressing the question of whether the FTC may obtain equitable disgorgement or restitution in federal court.[9] If the Supreme Court rules against the FTC, the agency will likely continue efforts to have Congress expressly grant it the ability to proceed directly to federal court to obtain monetary relief. In fact, on October 22, 2020, all five FTC commissioners sent a letter to the House Energy and Commerce Committee asking Congress to enact legislation expressly authorizing the FTC to obtain monetary remedies pursuant to Section 13(b) of the Federal Trade Commission Act. Whether this is a realistic goal may depend on the upcoming election, the composition of Congress, and other competing legislative priorities. The FTC has sought this authority for many years, thus far without success. Until the Supreme Court issues its opinion, any company subject to an FTC investigation should keep the circuit split and upcoming decision in mind when negotiating with the agency.

Cosmetic Reform Legislation

The cosmetic provisions of the Federal Food, Drug and Cosmetic Act (FFDCA) have remained virtually unchanged since 1938, leading Congress to question whether the regulatory regime should be updated to enhance agency oversight. Many stakeholders have expressed support for cosmetic legislative reform, including the Personal Care Products Council (the industry association) and a number of large cosmetic companies. Reform legislation could address registration and listing of products and their ingredients, GMP regulations, mandatory reporting of adverse events, access to company records (including consumer complaints) during FDA's routine or for-cause

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[9] *See* Debevoise Update: Third Circuit Strikes Another Blow Against the FTC's Preferred Enforcement Power, Setting the Stage for a Supreme Court Showdown (Oct. 5, 2020). *See also* Debevoise In Depth: Seventh Circuit Strikes a Blow Against the FTC's Preferred Enforcement Power (Aug. 28, 2019); Debevoise Update: The Third Circuit Sharply Curtails the FTC's Preferred Enforcement Power (Mar. 1, 2019).

inspections, mandatory recalls, disclosure of known cosmetic allergens on a product's label, and ingredient review.

FDA Implementation of Over-the-Counter (OTC) Drug Reform

The March 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act included major reforms to the FDA regulatory regime governing OTC drugs. These reforms include a shorter pathway to market for OTC drugs (via administrative order instead of notice-and-comment rulemaking) and provisions to encourage innovation by granting 18 months of marketing exclusivity in certain circumstances. FDA has started the process to implement the reforms but has indicated that it will likely take several years for the first administrative orders to be issued. The Act also authorizes FDA to collect OTC drug user fees beginning in fiscal year 2021.

CBD Dietary Supplements and Foods

FDA continues to take the position that the sale and marketing of CBD dietary supplements and foods violates the FFDCA. FDA has the authority to alter this policy via notice-and-comment rulemaking and has been studying whether to proceed for some time. Rulemaking could take years, however, and industry's best opportunity at bringing these products to market may be through the next Congress. A CBD authorization bill addressing foods and dietary supplements was introduced in the House in early 2020 and may gain some momentum in the new Congress.

Nutrition Labeling and Other Food Regulatory Issues

A Biden Administration may prioritize the regulation of food labeling and advertising, in contrast with the more hands-off approach of the current administration. This may result in a renewed push for front-of-pack nutrition labeling and new guidelines to reduce sodium levels in foods.

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Please do not hesitate to contact us with any questions.

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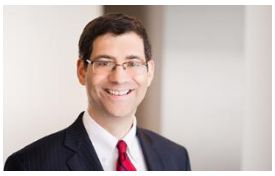
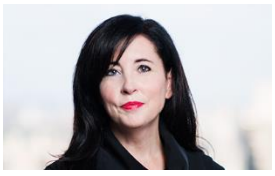
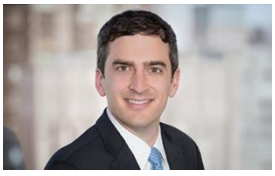

Andrew L. Bab
albab@debevoise.com


Jennifer L. Chu
jlchu@debevoise.com


Mark P. Goodman
mpgoodman@debevoise.com

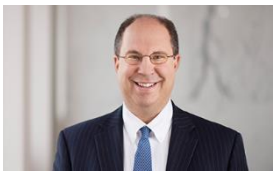

Maura Kathleen Monaghan
mkmonaghan@debevoise.com


Kevin Rinker
karinker@debevoise.com


Jacob W. Stahl
jwstahl@debevoise.com

WASHINGTON, D.C.


Kim Le
kle@debevoise.com


Paul D. Rubin
pdrubin@debevoise.com


Melissa Runsten
mrunsten@debevoise.com