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A SEA CHANGE

Biden Administration and What It Means for the Life Sciences Industry

SUMMARY

The Life Sciences industry was front and center in many significant legal and regulatory developments at the end of the Trump Administration—from the race to develop and authorize COVID-19 therapeutics and devices and related supply chain woes, to significant opioid settlements and battles over drug prices. King & Spalding's Government Matters practice group expects the Biden Administration's focus on the Life Sciences industry to remain high. In these pages, our colleagues weigh in with their predictions about how the Biden Administration may turn its focus on Life Sciences companies.

01 Accelerated Drug Pricing Reforms

After years of mounting budgetary and political pressure, the Biden Administration and the new Congress may take dramatic action to address the perceived "crisis" in drug pricing. The positive glow of the success of the vaccine development effort may not last long around the pharmaceutical industry. We do not foresee the wholesale government intervention in the market for pharmaceuticals that might have been attendant to "Medicare for All," but the federal and state governments will pass statutory and regulatory measures to punish drugmakers that increase their prices to levels deemed unreasonable.

We have already seen the beginnings of this trend. The line extensions rule in Medicaid, the current proposal to remove the AMP "cap" on Medicaid URA, state price transparency laws and the vigorous fight over the future of 340B all portend a muscular attempt to rein in drug prices.

In addition to these initiatives, we expect to see creative and potentially damaging policy proposals put forward by the Democratically-controlled Congress and Executive Branch. These measures could include permitting the use of closed formularies in Medicaid; inflation-indexed federal rebates in Medicare Parts D and B; the creation of drug price advisory boards to recommend federal reimbursement; government investigation of rebate walls; and perhaps even the authorization of march-in rights. The government could also take on patient affordability issues by pursuing the PBM rebate rule or requiring that copays be based not on list but on the net price insurers pay. These initiatives could be pursued through legislation, regulatory reform or demonstration projects via the innovation center.

The year 2020 unsettled the legal landscape for pharmaceutical companies, medical device manufacturers and other life sciences industry stakeholders. In response to the COVID-19 pandemic, the Food and Drug Administration ("FDA") relaxed regulatory requirements in an effort to spur innovative new tests, treatments and vaccines. Companies across the country took advantage of the increased flexibility, conducting accelerated clinical trials and obtaining emergency use authorizations. At the same time, stakeholders had to figure out how to modify their daily operations, including clinical trials, speaker programs, and manufacturing processes, to account for the global pandemic.

Looking to the future, we expect the U.S. Department of Justice ("DOJ") to focus both on the old and the new. As it has for many years, DOJ will continue to police perceived corruption throughout the life sciences industry, particularly what DOJ sees as unlawful kickback schemes. At the same time, DOJ will need to decide how to account for the unprecedented, chaotic circumstances that life sciences industry stakeholders faced throughout 2020. In our view, the Biden DOJ is likely to focus on a number of areas in 2021 and beyond, using the False Claims Act, the Food, Drug, and Cosmetic Act, and the Anti-Kickback Statute as its principal enforcement tools.

The Anti-Kickback Statute. The more things change, the more they stay the same. The AKS prohibits companies from supplying anything of value to induce referrals or services that are payable by federal healthcare programs. Consistent with its longstanding focus on the AKS, we expect DOJ to continue to investigate life sciences companies for using charitable foundations as conduits to pay the copayments of Medicare patients taking those companies' drugs. As the country exits the pandemic, we also expect the government to take a newly aggressive approach to physician speaker programs. On November 16, 2020, HHS OIG released an unusual Special Fraud Alert advising pharmaceutical and medical device companies to exercise caution in resuming in-person speaker programs. In a break with the past, the Biden DOJ is likely to view virtually all in-person speaker programs with suspicion.

The Opioid Crisis. Until COVID-19, the government viewed the opioid epidemic as the defining public health crisis of our time. When the pandemic recedes, the opioid crisis is likely to return to center stage. Indeed, in a February 2021 speech to the Federal Bar Association, the newly installed acting head of DOJ's Civil Division, Brian Boynton, listed the opioid crisis as the second out of six key False Claims Act enforcement goals. We expect DOJ to focus on false or misleading promotion of opioids, violations of FDA-imposed Risk Evaluation and Mitigation Strategies ("REMS") and other marketing strategies. DOJ is also likely to pursue pharmacies that allegedly dispensed opioids without reporting obvious red flags.

Clinical Trial Fraud. Pharmaceutical and medical device companies should also be aware that DOJ has intensified its enforcement activities related to FDA-regulated clinical trials. In a November 2020 speech, a senior DOJ leader specifically singled out clinical trial fraud as a "key area of drug and device related enforcement." We expect this trend to continue over the next few years. In several recent actions, DOJ has pursued criminal charges against individual investigators for fabricating data and participation of subjects in various clinical trials. As DOJ becomes more involved in policing this kind of fraud, we expect to see efforts to move up the chain to implicate Contract Research Organizations ("CROs") and perhaps the sponsors themselves.

Electronic Health Records. In recent years, DOJ has reached several major resolutions with suppliers of electronic health records ("ERH") software. We see no sign that DOJ's interest in this area has abated, and Acting Assistant Attorney General Boynton mentioned EHR software as one of the six key False Claims Act enforcement priorities that will continue under the Biden Administration. Consistent with past practice, we expect DOJ to focus not only on the software companies themselves, but also on entities with purchasing relationships with those companies. In particular, we expect DOJ to continue to scrutinize relationships between pharmaceutical companies, medical device manufacturers and EHR software companies to identify any efforts to utilize EHR software to influence physicians' prescribing decisions.

Support to advance digital health technologies is relatively bipartisan, and we expect that the Biden Administration will continue to focus on digital health products and to ensure that innovation in this space is not stymied by overregulation.

Last September, FDA launched the Digital Health Center of Excellence (DHCoE) within the Center for Devices and Radiological Health to help digital health products realize their full potential and to ensure comprehensive and consistent oversight. FDA also issued or revised four guidance documents announcing that it would not actively regulate certain low-risk digital health devices.

These policies, however, were not new and many were developed during the Obama Administration. Significantly, Bakul Patel, who was appointed the Director of the DHCoE in September 2020, has been a thought leader at FDA in the digital health space since 2010. Therefore, we do not expect dramatic changes in the Biden Administration's approach to digital health regulation. We expect that FDA's new DHCoE will continue to focus on the following topics:

Enabling Digital Health Tools that Improve Access to Care. Even before COVID-19, disruptive digital health technologies and platforms were beginning to enter the market and better enable access to care. Patients' need for remote medical care during the COVID-19 pandemic has accelerated the use of digital technologies that enable access. For example, clinical trial sponsors have adopted telehealth and remote patient monitoring technologies; and mobile medical apps have been used to support public health surveillance, to disseminate educational materials, and to keep patients and healthcare professionals connected.

Since the pandemic began, FDA has issued several guidances with temporary policies aimed at increasing the use of helpful technologies, such as contact-free digital thermometers. Although these polices are intended to last only for the duration of the pandemic, FDA is likely to build upon inroads that have been made in this space. For example, FDA intends to work toward continued and greater utilization of digital technologies in clinical trials and toward utilizing real-world data regarding the benefits and risks of digital health products used during the pandemic to expedite regulatory decisions on those products when the pandemic is over.

Artificial Intelligence/Machine Learning. On January 12, 2021, FDA issued an "Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan," which describes a multi-pronged approach to advancing FDA's oversight of AI/ML-based software. The plan responds to a discussion paper on AI/ML that FDA circulated in 2019, and it indicates that FDA will: (1) issue draft guidance on predetermined change control plans (for software's learning over time), (2) support the development of good machine learning practices to evaluate and improve machine learning algorithms, (3) foster a patient-centered approach, including device transparency to users, (4) develop methods to evaluate and improve ML algorithms and (5) advance real-world performance monitoring goals.

Pre-Certification Program. For the last several years, FDA has been operating a pre-certification pilot program to help inform the development of a regulatory framework for more streamlined and efficient regulatory authorizations for software as a medical device (SaMD). FDA envisions moving from episodic oversight of marketing submissions for software changes to more continuous oversight under the pre-cert program, which would ideally allow for less stringent oversight of products that are developed by companies that demonstrate certain principles of excellence. The pilot program has been criticized as being susceptible to bias, and there have been questions as to whether the program will actually be faster and less burdensome. FDA has also been criticized as lacking appropriate statutory authority for the program. As part of the user fee reauthorization legislation in September 2022, we expect FDA to push for legislation expressly giving the Agency authority for the program, and the industry will want to monitor the development of the legislation closely.

Cybersecurity. Currently, no statutory requirement expressly compels medical device manufacturers to address cybersecurity. FDA's FY 2021 Budget document contained a legislative proposal that would require that: (1) device software have the capability to be updated and patched in a timely manner; (2) premarket submissions to FDA include evidence demonstrating the capability, from a design and architecture perspective, for device updating and patching; and (3) device firms publicly disclose when they learn of a cybersecurity vulnerability. Although the FY 2022 Budget document has not yet been released (as of February 25, 2021), we expect FDA to continue to pursue this new authority, perhaps with the user fee reauthorization legislation in September 2022.

04 Limitations on Strength, Scope and Enforcement of Drug Patents

Under the Biden Administration and the 117th Congress, we may see a renewed effort to limit the strength and scope of U.S. patents covering innovative small-molecule and biologic drug products, in the name of reducing drug prices. The Biden-Sanders Unity Task Force identifies so-called "patent thickets" and patent "evergreening" as "abusive practices" by the pharma industry; legislative proposals under the 116th Congress evidenced bipartisan interest in weakening pharma patents on innovative treatment methods and drug formulations. HHS Nominee Xavier Becerra, in his role as Attorney General of California, has also proposed using Bayh-Dole "March-In" provisions to lower costs by compulsory licensing of patented drugs.

Likewise, we may see efforts under the Biden Administration and in federal and state legislatures to limit drug patent enforcement and shape generic and biosimilar competition through antitrust measures. The Biden-Sanders Unity Task Force, as well as the 116th Congress and the California legislature, have taken aim at so-called "pay-for-delay" settlements of Hatch-Waxman and BPCIA patent disputes. We may also see renewed legislative proposals and increased antitrust enforcement targeting "product-hopping" and "patent thickets" in the context of innovator vs. generic/biosimilar drug competition. The potential for competing state-level "pay-for-delay" provisions and other state proposals governing pharma competition also threatens to impede patent dispute resolutions and reduce business certainty.

05 Reasserting FDA's Authority over Laboratory Developed Tests

With the Biden Administration's focus on advancing testing strategies to help stop the spread of COVID-19, FDA's regulatory framework for in vitro diagnostic tests (IVDs) and laboratory developed tests (LDTs) will undoubtedly remain in the spotlight. But, the Biden Administration is expected to take a very different approach to regulating LDTs than its predecessor. In August 2020, the Trump Administration issued an announcement, titled "Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests," that stated that, absent notice-and-comment rulemaking, FDA cannot require premarket review for LDTs. This announcement upended FDA's decades-old approach to LDTs and effectively rescinded FDA's guidances in this space.

Despite long asserting that it has authority to regulate all LDTs, FDA has elected to actively regulate just a subset of LDTs, namely, tests related to pandemics, direct-to-consumer tests and pharmacogenomic tests. At the beginning of the pandemic, in keeping with its long-standing policy, FDA issued guidance making clear that laboratories developing COVID-19 LDTs were required to obtain Emergency Use Authorizations (EUAs) from the Agency. The Trump Administration's August announcement was intended to put an end to that policy and to give labs a choice of skipping the EUA process or voluntarily submitting their COVID-19 tests for review. But, because the announcement applied to all LDTs, not just COVID-19 LDTs, the announcement created significant uncertainty.

We expect the Biden Administration to attempt to revoke that policy and to restore FDA's ability to regulate LDTs as the Agency deems necessary to protect the public health. The Biden Administration may face political headwinds if any such action exacerbates the current backlog of EUA requests for COVID-19 tests. The Biden Administration may also face legal questions regarding FDA's jurisdiction over LDTs more generally. As a result, the Biden Administration is also likely to support legislative initiatives, like the VALID Act, that would allow for more comprehensive and equitable oversight of IVDs and LDTs. Congress is likely to be actively engaged on these types of legislative initiatives as it prepares for the September 2022 user fee reauthorization.

The Biden Administration has signaled its intent to build a more stable, secure and resilient supply chain for life sciences products and decrease the reliance on items and materials made or sourced in foreign countries. The Administration plans to onshore the manufacture of such products by, for example, prioritizing procurement contracts with domestic manufacturers and making investments to expand the manufacturing capacity of American companies. These so-called “Buy American” initiatives will present a wide range of both challenges and opportunities for life sciences companies.

On February 24, 2021, President Biden signed the “Executive Order on America’s Supply Chains,” which includes a specific requirement that federal agencies complete a review within 100 days of the U.S. supply chain for pharmaceuticals and active pharmaceutical ingredients (“APIs”). In addition, within one year, the Secretary of the U.S. Department of Health and Human Services must submit a more comprehensive report on supply chains for public health and biological preparedness.

This new initiative will have significant implications for life sciences manufacturers, and the timelines are short.

Previously, on January 25, 2021, President Biden signed the “Executive Order on Ensuring the Future is Made in All of America by All of America’s Workers.” The executive order directs a broad review and strengthening of policies and practices related to federal financial assistance awards and federal procurements that require or provide a preference for the acquisition of goods, products or materials produced in the U.S. This executive order will most significantly impact life sciences manufacturers that contract with the federal government.

Life sciences companies are well-positioned to engage with the Biden Administration to help shape mutually beneficial policies, and King & Spalding’s experienced, multi-disciplinary teams are ready and able to assist with such efforts.