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USA
Trends and Developments

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Trends and Developments

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The changes that have occurred in the healthcare and life sciences industries during the COVID-19 pandemic reflect the challenges and opportunities that companies and regulators have faced as a result of the crisis. Notably, the pandemic has given rise to a surge in collaborations among industry players, across industry sectors, with government, and beyond, as it has become clear that fighting the COVID-19 pandemic is beyond the ability of any single entity, organisation, or industry sector. Pre-pandemic healthcare paradigms and business models are continuing to change to reflect new and evolving expectations regarding patient care and employee and patient safety. Companies are contemplating shifting towards supplier diversification and domestic manufacturing, due to the supply and importation issues that many experienced during the pandemic. Similarly, companies conducting clinical trials may, as a result of both the regulatory easing that has occurred during the crisis and the needs that prompted it, adopt remote monitoring modalities and decentralised clinical trial designs. Below we explore these and other emerging trends and developments resulting from the continuing response to the pandemic in the biotechnology, medical device, pharmaceutical and health information technology sectors.

Biotechnology

The COVID-19 pandemic has led to a surge in collaborations among government entities, academic institutions, and companies in the biotech industry. The biotech industry has been at the forefront of efforts to contain the global COVID-19 pandemic, and these efforts have included harnessing the benefits of co-operation through private-private and private-public partnerships. Biotech companies should anticipate potential complexities in unwinding these relationships post-pandemic, paying particular consideration to the treatment of intellectual property after the conclusion of the partnership and competition safeguards where such partnerships involve direct competitors. Post-pandemic, we may see such partnerships serve as ongoing models for collaboration in the development of new medicines.

Biotech companies have relied heavily on government funding to develop vaccines and therapies for COVID-19. Biotech companies involved in research and development activities related to COVID-19 have depended heavily on government funding. Biotech companies seeking government funding will need to be careful to understand the unique contours of contracting with the government, particularly with regard to intellectual property. For example, the Bayh-Dole Act regulates the use and ownership of intellectual property and royalties arising from federal government-funded research. US companies developing COVID-19 therapeutics and vaccines have already received hundreds of millions of dollars in government funding. Due to the high cost of drug development, however, biotech companies developing COVID-19 products will likely continue to require additional, consistent government funding in the months and years ahead.

Biotech companies have been impacted by significant clinical trial disruptions and delays that have increased study costs and delayed projected study and drug development timelines. In the beginning of the COVID-19 pandemic, many biotech companies delayed initiating new clinical trials and paused enrolment for ongoing studies. Additionally, a number of academic institutions and local institutional review boards and research ethics committees implemented their own clinical study restrictions, such as limiting studies with healthy volunteers and delaying or deferring studies of agents for conditions other than COVID-19. Even when enrolment was not formally paused or suspended, biotech companies experienced difficulty enrolling new patients. As the pandemic continues, biotech companies are increasingly adjusting the conduct of clinical trials in response to COVID-19 and are beginning to resume more clinical trial activities. Although patient enrolment continues to be an issue, many biotech companies are turning to digital solutions, such as telemedicine and social media, to expand recruitment and engagement efforts. The number of clinical trial disruptions remains high, however, and many study timelines have been delayed by at least a quarter. Those trials that can be conducted remotely stand the best chance of weathering the storm. For its part, the US Food and Drug Administration (FDA) recognises that the COVID-19 pandemic may require protocol deviations. In general, the FDA's current approach gives trial sponsors some degree of flexibility to change course when doing so is necessary to ensure patient safety and/or data integrity. A sponsor may, for example, transition to remote monitoring of trial patients, or change patient-assessment locations if necessary or advisable. In the short term, at least, certain pandemic-related changes and deviations are likely to be permitted.

Medical Devices

The COVID-19 crisis has reversed growth trends for elective procedures, but may lead to pent-up demand. The postponement of procedures during the COVID-19 crisis has reversed growth trends in recent years for elective procedures, and by extension, demand for related medical devices. Elective procedures had been on the rise in recent years. With the onset of the COVID-19 pandemic, the US Centers for Medicare & Medicaid Services (CMS) recommended a moratorium on elective and non-essential procedures, starting in March 2020. CMS has since come out with recommendations on re-opening facilities to provide non-emergent, non-COVID-19 healthcare. The moratorium and slow phased reopening, in combination with patient fears of exposure to COVID-19 and hospital instructions to reduce elective procedures during the pandemic, has led to a steep reduction in demand for medical devices used in elective and non-essential procedures, such as those used for orthopaedics and aesthetics. However, as state and local government officials reopen their economies and hospitals restart essential non-COVID-19 procedures and non-essential procedures, pent-up demand for elective surgeries is expected. The immense demand for elective surgeries will present itself regionally, as different parts of the country reopen facilities for elective care at different times, and may not be constant if there are subsequent regional viral outbreaks. There may also be a continued shift in location where elective surgeries are performed. In a post-COVID-19 environment, if there remains a continued threat of recurrence, outpatient settings may continue to handle a greater proportion of urgent and non-urgent elective procedures so that hospitals retain some open capacity (ie, hospital beds and medical supplies) in preparation for subsequent outbreaks.

Supply chain disruptions and importation issues are likely to lead to a shift towards more supplier diversification and an increase in domestic manufacturing. Device companies, which in recent years have relied increasingly on foreign manufacturers, largely in Asia, for finished products or components, have experienced supply challenges as these suppliers suspended device production to combat the spread of COVID-19. Moreover, many foreign governments have restricted the exportation of critical medical devices, including ventilators and masks. Post-COVID-19, device manufacturers may restructure their supply chains and strive for increased diversification of suppliers to provide greater flexibility during times of crisis. The supply chain failures experienced during the pandemic highlight the risks associated with the United States' increased reliance on foreign manufacturing and may lead to the onshoring of more manufacturing over the long term, although the pace of such a shift is uncertain.

Shortages of critical medical supplies during the COVID-19 pandemic have driven a rapid response in the form of 3D printing of medical devices, which may lead to broader adoption of 3D-printing technology post-pandemic. Early in the COVID-19 outbreak, the FDA forecast that shortages of critical supplies would lead some entities to turn to 3D printing to meet demand. As anticipated, a number of non-traditional device manufacturers, such as healthcare providers, have been using 3D printing to manufacture devices needed in the fight against COVID-19, such as nasal swabs for coronavirus testing, surgical masks, face shields, and ventilator splitters. Accelerating this trend are a number of information exchanges set up by both private industry and individual entrepreneurs to connect those who have the capability to print in 3D with projects in need of 3D printing. These and other efforts may have long-term effects, spurring the use of 3D printing for a growing number of device types, due to the experience that both the FDA and 3D printers have gained during the COVID-19 pandemic.

Pharmaceuticals

Pharmaceutical supply chains will remain under pressure. The COVID-19 crisis has put pressure on supply chains, including manufacturer workforce and production challenges, that may be increased by over-concentration of supply chains in a single country or region hit hard by the crisis (eg, China, India). Generic drug companies may have greater sensitivity to supply-chain risk due to lower profit margins, greater dependence on China and India, and maintenance of lower inventories than branded companies. Going forward in 2021, manufacturers will need to consider diversifying supply chains to make them more robust against future disruptions. Efforts to bring manufacturing capacity for critical drugs and active pharmaceutical ingredients back to the United States may require significant innovation and government financial support to be affordable.

Marketing efforts must continue to adapt to social distancing. With in-person sales, marketing, and detailing efforts hindered by social distancing requirements, pharmaceutical companies have been forced to shift their marketing to remote engagements with healthcare providers, as well as social media and direct-to-consumer approaches. Reduced in-person marketing will continue to pose particular challenges to new drug launches in 2021 that typically require significant educational efforts to win over prescribers.

Expanded economic hardship due to the pandemic may increase patient demand for pharmaceutical company patient-assistance programmes in 2021.

During the pandemic, some major pharmaceutical companies have decided to expand their patient-assistance programmes. Going forward in 2021, the anticipated continued economic challenges of the pandemic are likely to increase the number of patients without insurance who meet financial-need eligibility criteria for programmes offering free drugs. In addition, job losses may cause people to move from employer-based insurance to Medicaid, and the resulting increase in Medicaid rebates may have a negative effect on pharmaceutical company revenues going forward.

Pharmaceutical research collaborations are expected to continue to increase. As a result of the challenges brought by the pandemic, the pharmaceutical industry has learned not only to adapt but also to excel and to accelerate its research. Flexibility and freedom to work from any location is expected to promote innovation and motivation. While clinical trials typically take nine to twelve months to get up and running, many pharmaceutical companies are shortening that timeline considerably, in some cases to only about four to six weeks, by increasing efficiencies, learning to use digital methodologies for recruitment purposes and conducting remote monitoring visits. These efficiencies are likely to be carried forward by pharmaceutical companies in 2021 and beyond.

FDA streamlining may result in faster approval process. The FDA has also streamlined its own processes to allow for speedier approvals and access for COVID-19 vaccines and other COVID-19-related drugs. While it is not entirely clear at present how this could impact drug approvals in the future, it shows that it is possible to develop products in a more streamlined manner and the benefits of that streamlined process are likely to continue in 2021.

Health Information Technology

Telehealth opportunities will continue to grow. Telehealth has emerged as a vital healthcare modality during the pandemic and represents a significant growth opportunity, as historical reimbursement and licensure barriers have — at least temporarily — fallen away. Virtual care data indicates that telehealth continues to account for a significantly higher number of total visits than before the pandemic and is expected to remain that way in 2021. The pandemic has also spurred the development of mobile telehealth technologies that are better analogues for in-person services. As we look ahead to 2021 and beyond, it is likely that telehealth is going to be a driving force in modern medicine. Aside from the added convenience–it takes the commuting factor out of healthcare–telehealth will become increasingly accessible to the public as it becomes more integrated within mobile health applications. Its success through 2021, however, will be largely contingent on whether and to what extent the reimbursement changes driven by the pandemic are made permanent. As the level of regulatory flexibility decreases following the cessation of the pandemic, it will be critical for companies in the telehealth and health IT space to monitor evolving state licensure requirements, FDA medical device regulations, as well as data privacy and security risks.

The pandemic is driving increased utilisation of remote digital health technologies. Prior to the pandemic, there were some indications that usage of certain remote digital health technologies was decreasing. In an effort to promote continued access to treatment while minimising patients' in-person contact with healthcare providers, the FDA, the US Centers for Medicare & Medicaid Services, and other regulators have issued statements allowing for the distribution and use of certain categories of remote healthcare devices during the pandemic without requiring compliance with typical regulatory requirements. Among the most notable of these policies are those allowing (i) the marketing of certain digital therapeutics for treatment of psychiatric disorders without clearance or compliance with other reporting requirements, (ii) the distribution and use of remote digital pathology devices without clearance, and (iii) modifications to the indications and software or hardware of non-invasive remote-monitoring devices to allow for remote monitoring and/or home use without FDA clearance. Although these policies are expressly limited to the time of the pandemic, the increased use of such technologies during the pandemic will increase their likelihood of continued use in 2021 and beyond, by offering providers, patients, and regulators the opportunity to become more comfortable with the value and effectiveness of such technologies, and for regulators to fine-tune their safety recommendations and standards.

Reliance on real-world data analyses powered by health-technology platforms to understand COVID-19 and potential COVID-19 therapies may lead to increased use of such real-world evidence in drug and medical device development moving forward. Over the past several years, there has been a rise in health IT company partnerships with both industry and the FDA to conduct real-world evidence analyses utilising vast databases of real-world data from sources such as medical claims and electronic health records. The FDA has recognised the important role that real-world data may play in medical product development and post-market surveillance, but its use in drug development in particular has been hindered due to limited agency comfort with real-world evidence to demonstrate efficacy, as well as lack of clear guidance for its use. As a result of the pandemic, however, the FDA and other regulatory authorities, as well as industry players, have relied heavily on real-world evidence to under-

stand COVID-19 and to assess potential treatment options. Innovations and adaptations that have been implemented by the FDA in response to the pandemic — such as the use of real-world data and real-world evidence — is likely to be considered by the FDA for incorporation in standard agency procedures in 2021 and beyond. Given the increased comfort the FDA has gained with real-world evidence in the COVID-19 context and ongoing efforts at the agency to clarify its approach to real-world evidence in drug and device development, the demand for the services of health IT companies offering industry and regulators access to large real-world databases and analytical tools will continue to grow in 2021.

Increased use of mobile data collection in clinical trials during the COVID-19 pandemic will drive further adoption and development of digital health technologies for research. The practical difficulties of collecting information at clinical trial sites during the pandemic have led the FDA to recommend "alternative methods" for data collection. In emergency guidance, FDA has made it clear that digitally supported alternatives to traditional site-based assessments such as remote patient-monitoring, telemedicine, and "virtual visits" may be necessary to ensure that important clinical trials can continue throughout the pandemic without compromising the integrity of the studies themselves. In the absence of regulatory guidance on remote decentralised trial designs, companies have been experimenting with different approaches to conducting such trials, but past and present FDA officials predict that the push toward remote monitoring during the pandemic will ultimately drive widespread adoption of decentralised trial designs using these technologies in the future. Companies developing products to support remote decentralised trials, however, should be prepared to address the complex legal and compliance issues that these technologies may pose, including considerations related to privacy, security, and good clinical practices requirements.

The COVID-19 pandemic has transformed the business landscape across the healthcare and life sciences industries, and is continuing to do so. The profound shifts that have resulted from the almost overnight change in the needs, priorities, and capabilities of patients, consumers, and industry players worldwide will be felt long after the waning of the pandemic. In the healthcare and life sciences industries, the transformative effects of COVID-19 have in some cases accelerated change already under way, and in other cases have reoriented it. The crisis has generated significant economic stress for many, which has yielded new forms of collaboration, as new relationships have been forged, and will be forged, to promote drug discovery, address patient needs and secure financial support. New, or strengthened, alliances and collaborations in numerous areas seem a feature of the pandemic response that will persist in 2021 as the world continues to battle the virus.

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Ropes & Gray LLP is a leading global law firm with offices in Boston, New York, Chicago, San Francisco, Washington, DC, Silicon Valley, London, Hong Kong, Shanghai, Tokyo and Seoul. The firm represents a broad range of emerging, mid-sized and Fortune 500 pharmaceutical, biotechnology, medical device, food, dietary supplement and consumer healthcare companies on cutting-edge, high-stakes matters, as well as the financial institutions that invest in the life sciences industry. With deep knowledge of FDA regulatory, government enforcement, intellectual property, private equity, securities and corporate law, the team of more than 150 life sciences lawyers and specialists work together in a co-ordinated fashion to cover a full range of legal areas, including M&A, licensing, financings, IPOs, FDA regulation, food and cosmetic regulation, patent due diligence, litigation, research compliance, healthcare compliance and research, government enforcement defence, and life sciences-related public policy.

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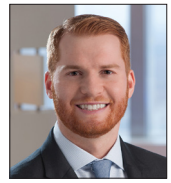

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