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Life Sciences and
Health Care Horizons
2021



Contents

Welcome	5
COVID-19	7
Clinical Trials	18
Precision and Regenerative Medicine	24
Digital Health	29
Privacy and Cybersecurity	34
Transactions	38
Patents, Litigation, and Beyond	45
Asia-Pacific	52
Europe	60
The United States	66
Latin America	75
Our Capabilities	81
Get in Touch	82

Welcome

Companies in the life sciences and health care industry, like most companies, navigated unparalleled challenges in 2020. But unlike other industries, they had to do so while simultaneously facing the biggest challenge of all – being at the epicenter of the global effort to manage, treat, and prevent further spread of COVID-19. For that, we first and foremost thank you for your tireless efforts, determination, and continued innovation to protect and improve human health. It is your efforts to make the world healthier, and our work alongside you that allows us to better navigate the uncertain, but hopeful future.

The pandemic forced the development and adoption of new technologies and innovations resulting in massive investments into virtual health solutions, telehealth products, and related cybersecurity measures. It also spurred new debate over drug and medical device regulatory standards, as many regulators permitted emergency use authorizations and granted temporary waivers for compliance obligations. One silver lining to 2020 may be the opportunity for regulators to take the experience gained from the need for rapid response, and apply the learnings to find ways to expedite development and review processes even after the health crisis subsides.

In the transactional space, companies found new ways to collaborate virtually, as the need for cooperation grew. After a brief hiatus in deal making, indications point to a robust M&A and partnering market in 2021. Similarly, stronger alliances were formed between government, industry, and academia, with all sectors recognizing the importance of defeating COVID-19. We advised clients on how new government initiatives presented new opportunities, while also educating companies on the compliance and litigation risks likely

coming to fruition in 2021 as companies that have taken advantage of the regulatory adaptability offered in 2020 may find themselves needing to come into quick compliance with the requirements that were enforced pre-pandemic.

In addition to the seismic shifts stemming from the novel coronavirus, life sciences and health care companies are being affected by unique issues in each geographic region. In the United States, a renewed awareness of racial justice issues helped focus attention on the need to address health equity and promote diversity in clinical study populations. Mexico has prioritized procurement reform, and medicinal use of cannabis has become a reality. Post-Brexit, the UK started differentiating from the EU in areas such as medical device regulation, and companies started adapting to the new arrangements under the EU-UK Trade and Cooperation Agreement. In Japan, a new system of annual drug price cuts and evolution of their patent linkage system affected investments. Similarly, we have been advising clients doing business in China on important amendments to the patent law and new expedited drug review programs.

These are just some of the current and evolving trends that are shaping the future of the industry, which we discuss in the following pages. Our global Life Sciences and Health Care team — comprised of more than 500 lawyers around the world who support more than 1,000 clients in the industry — stands at the ready to provide you with creative strategies for your most promising opportunities and integrated solutions that protect and support your business when issues arise. We hope that you find our view of the horizon thought-provoking and look forward to working together, and hopefully seeing each other, again soon.

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COVID-19

Emergency use authorizations

At the beginning of 2020, no one would have predicted the COVID-19 pandemic and the global health crisis it would create. Nor would they have predicted the way industry stepped up to confront the pandemic head-on through development and innovation, or how regulators would find creative ways to speed products to market while balancing the risks and benefits to public health.

In the U.S., the Food and Drug Administration (FDA) quickly started issuing emergency use authorizations (EUA) for ventilators, COVID-19 tests, and personal protective equipment (PPE) and issued the EUAs for the vaccines faster than has ever been seen before. We believe that FDA will continue to issue EUAs well into 2021, but these new products will need to address FDA's evolving understanding of what product characteristics should be prioritized during the public health crisis. Clearly FDA will continue to authorize vaccines and diagnostic/screening tests, but as FDA has limited resources and must prioritize its EUA review based on the agency's perception of need, this will mean that many EUA applications will not be accepted by FDA, and some will never even be reviewed.

In addition, as the COVID-19 response initiatives bring the pandemic under control, companies will need to plan for the end of the public health emergency and the lapsing of their EUAs –in terms of capital equipment that has been distributed (e.g., ventilators, temperature sensors, remote patient monitoring software and equipment), transitioning to normal market authorizations (or not), and preparing for regulatory enforcement for products that were released without following the appropriate regulatory channels (e.g., securing the necessary EUAs or authorizations in the EU).

In the EU and the UK, the pandemic also forced competent authorities to adapt their regulatory frameworks governing essential products, including COVID-19 tests, surgical face masks, and PPEs. Due to the emergency, some of these products have been temporarily authorized while not being CE marked. These special authorizations are becoming more difficult to obtain as the epidemic situation normalizes.

Most recently, the competent authorities also granted marketing authorizations to the first COVID-19 vaccines with the aim to definitively putting an end to the pandemic. We have been at the forefront with our clients as they respond to the public health need for tests, equipment, PPEs, and therapeutics, and we will continue to lead as we offer guidance while we emerge from this pandemic together.



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In vitro diagnostics

Within weeks of the COVID-19 outbreak, in vitro diagnostics (IVDs) – which include, in particular, diagnostic tests for SARS-CoV-2 – have taken the central role in the battle to contain the pandemic. IVD manufacturers responded by adjusting their R&D resources to develop COVID-19 tests and bring them to market. FDA also responded quickly by providing guidance on its EUA policy and authorizing SARS-CoV-2 tests since mid-March 2020, including molecular diagnostic tests, antigen diagnostic tests, serology/antibody tests, and tests for patient management.

FDA has been unprecedentedly flexible and innovative in the regulation of EUA tests, while keeping the rigorous standards for test performance and reliability. This has required IVD manufacturers to quickly adapt to the fast-changing regulatory landscape, and to become nimbler to shift focus as needed due to the ever-changing information that FDA and other health authorities are learning about the disease, and the evolving nature of the SARS-CoV-2 virus and its variants. As the disease remains uncontained, more IVD manufacturers are expected to enter this market, while FDA is identifying priorities in the review of hundreds of EUA applications to ensure that certain tests can rapidly enter the market. These FDA-prioritized tests include point-of-care tests, tests that can process high volumes of samples, and home use tests, which the agency views as providing the greatest public health benefit to contain or identify the spread of the virus. Companies need to be strategic in developing their tests and engaging with FDA so that their products align with FDA's priorities for granting EUA authorizations.

Hopefully sometime in 2021, when the COVID-19 crisis finally ends and the emergency declaration is lifted, EUA test manufacturers will face the challenge of obtaining traditional FDA premarket authorizations, and they should plan on strategies for developing clinical study plans to support the more rigorous requirements for FDA clearance or approval of the various assays.

Moreover, the volume of non-COVID-19 related tests are also expected to explode as the result of the backlog in development and delay in FDA review due to the pandemic. Companies need to have plans in place to be better positioned in the evolving regulatory environment.



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FDA inspections and pandemic-related backlog

On March 10, 2020, FDA halted most on-site inspections due to the COVID-19 pandemic. As a result, FDA conducted less than half the number of inspections in FY-20 as it did in FY-19 (approximately 624 for FY20 versus approximately 1,523 for FY-19).

FDA's postponement or cancellation of inspections due to the pandemic has resulted in a considerable inspection and drug approval backlog, and strained the pharmaceutical supply chain. Many of the inspections postponed or delayed in FY-20 were pre-approval inspections (PAIs) (FDA conducted approximately 250 PAIs in FY-19) for pending applications; many more were follow-up inspections at facilities referenced in applications on compliance hold due to such facilities' compliance status.

This significant backlog has caught the eye of the U.S. Government Accountability Office (GAO), which recently published a report pushing FDA to address the inspection backlog by, among other things, using the agency's alternatives to on-site inspections. FDA will be under pressure in 2021 and beyond to increase inspections and start relying more on alternative methods to traditional on-site inspections.

Thus, it is unlikely FDA will return to business-as-usual at the end of the pandemic. Rather, we expect FDA inspection activity to be in overdrive as the agency uses its records request authority and newly piloted virtual inspection tools on top of the agency's traditional on-site activities to address the backlog.

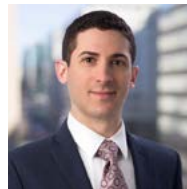
FDA's focus on the pharmaceutical supply chain will also likely mean enhanced scrutiny for manufacturers of critical medicines and manufacturers that are the sole source of product. This will likely mean more inspections

(on-site and virtual) and more records requests for manufacturing sites making important medicines and those that are critical to supply chain continuity — particularly those manufacturing sites located outside the U.S. This is consistent with the CARES Act, which requires manufacturers to develop and implement "redundancy risk management plans" to identify and evaluate supply chain risks for critical drugs.

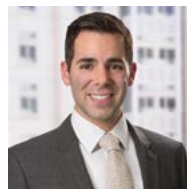
In the wake of COVID-19, FDA will also continue to encourage the adoption of advanced manufacturing technologies, including continuous manufacturing and Artificial Intelligence (AI), as a way to strengthen and ensure continuity of the pharmaceutical supply chain.



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Off-label use during the pandemic

Prescribing a medicinal product for therapeutic indications or at a dosage not indicated in its marketing authorization (MA) is a recurring issue for all actors: public authorities, prescribers, MA holders, and distributors. These parties may face liability for off-label use, unless such use occurs as part of so-called “early access” programs that enable pharmaceutical companies to supply unauthorized products to patients in accordance with strict regulatory requirements.

Pharmaceutical companies must monitor their medicinal products’ prescriptions and, depending on their jurisdiction, may have a duty to report to the competent authorities any use outside the terms of the MA. In practice, the efficient control by pharmaceutical companies of their products’ prescription in the scope of the MA’s indications is only possible when pharmacovigilance reports are made, or through company sales representatives. All health actors (e.g., prescribers, pharmacists, etc.) must act with transparency and in perfect collaboration with pharmaceutical companies.

At the start of the pandemic, some countries authorized the emergency and off-label use of the prescription drug hydroxychloroquine for treatment of COVID-19. The debate over the drug was not merely scientific, but turned political. Scientific uncertainty and disagreement within the medical community as to the efficacy of the

drug led to misunderstanding — and even, at times, defiance — from people who felt their government was preventing the larger public from having access to what some believed to be an effective medicine.

Courts have therefore in 2020 had the occasion to remind that off-label use was only allowed on condition that prescribers considered it essential to use such drug to improve their patients’ clinical condition, and that such assessment was to be made in light of the scientific accepted data. Through new debate and jurisprudence, the contention over hydroxychloroquine and COVID-19 treatments has brought new attention to the risks associated with off-label use, and spotlighted the issue as a compliance concern for companies in the life sciences and health care space.



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Approaches to COVID-19 vaccination programs in the biotech industry

Should biotech employers mandate that their employees receive COVID-19 vaccinations? The Equal Employment Opportunity Commission (EEOC) has implied that a mandatory program is lawful, and mandating vaccinations may result in a higher percentage of the workforce being vaccinated. But employers cannot practically mandate vaccines until vaccines become more widely available. Employers mandating vaccines must also accommodate employees on the basis of disability and religion. If an employer implements a mandatory program, in order to administer vaccines on its own or contract with a party to do so (rather than allowing employees to obtain the vaccine independently), it must meet a heightened legal standard of showing that an employee who does not get vaccinated will pose a direct threat to the health or safety of her or himself or others. This standard may pose a significant inconvenience for biotech employers that desire to offer on-site vaccination clinics to employees.

Employers may alternatively consider implementing a voluntary program. Employers offering a voluntary program generally can avoid dealing with questions of disability and religious accommodations, and are likely able to implement an on-site vaccination clinic without meeting the heightened legal standard above. Employers implementing voluntary programs may offer modest incentives to employees for getting vaccinated.



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You can access all of the firm's latest publications, webinars, and useful tools on the Hogan Lovells COVID-19 Topic Center.

U.S. privacy challenges in employer COVID-19 vaccination programs

As COVID-19 vaccinations become available, employers are evaluating whether to provide, or request proof of, employee vaccinations. In addition to employment law considerations, these programs have significant health privacy implications.

Either by administering, or requesting evidence of, vaccinations, employers will collect employee health information (e.g., vaccine date/dose, medical conditions affecting vaccination eligibility). However, employers should avoid requesting information on family medical history, as such is considered genetic information restricted by the Genetic Information Nondiscrimination Act (GINA).

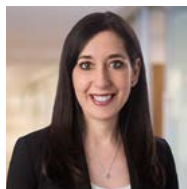
Employee vaccine information should be properly secured and separately maintained from personnel files, and access should be restricted to those with a need-to-know. Employers also should evaluate their intended collection, use, and disclosure (e.g., public health authorities) of such information in light of the Health Insurance Portability and Accountability Act (HIPAA), GINA, and applicable state health information privacy laws.

Employee health information held by an entity in its capacity as an employer is not protected health information under HIPAA. However, any information collected directly from a health

plan or provider (e.g., pharmacy or hospital) could be subject to HIPAA and require employee authorization to allow disclosure to the employer. In certain cases where the information is necessary for the employer's workplace safety monitoring requirements and created at the request of the employer, providing employees with notice that information will be shared with the employer may be sufficient. Requesting proof of vaccination from employees directly, rather than through a HIPAA-regulated entity, simplifies the privacy challenges, although state privacy laws may still apply. In addition, where employers intend to pay for vaccinations other than through an on-site medical clinic, this could create a health plan subject to HIPAA. This would create HIPAA compliance obligations with respect to the plan and the employer as plan sponsor if receiving PHI for plan administration.



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A new normal: Manufacturer considerations for post-pandemic HCP interactions

As pharmaceutical and medical device manufacturers look forward to a post-pandemic world, they face new compliance questions about what interactions with health care professionals (HCPs) and patients will look like.

The pandemic forced manufacturers to pivot to virtual HCP interactions, including speaker programs. But a rare Special Fraud Alert issued by the Department of Health and Human Services Office of Inspector General (OIG) in late 2020 has created uncertainty about whether the in-person speaker programs the industry has relied on to educate HCPs about emerging treatments and products will return in same form post-pandemic.

In the Special Fraud Alert, OIG flatly stated that it is “skeptical about the educational value of such programs” and that companies should “consider alternative less-risky means for conveying information” to HCPs. While noting “certain inherent risks” of speaker programs – since they involve remuneration for speakers (compensation) and attendees (meals) – OIG also identified factors that would render a speaker program suspect. Although generally reflective of industry best practices, these factors include new or more explicitly stated restrictions, including programs where alcohol is available (especially if free) and programs held at restaurants, without allowances for modest restaurants or with separate rooms appropriate for business meetings. Manufacturers looking to resume in-person speaker programs will need to reexamine the

structure and controls of their programs to protect against the suspect characteristics identified by OIG.

The pandemic also fundamentally transformed the landscape of manufacturer-patient interactions. Pandemic-related constraints have accelerated the acceptance of telemedicine by patients, HCPs, and payers. In response, manufacturers need to establish parameters for their interactions and engagements with telehealth vendors and providers while continuing to facilitate patient access to their products. Relationships between manufacturers and telehealth vendors, if not properly structured, may pose risks under federal fraud and abuse laws. The increased prominence of telemedicine is likely to be a permanent fixture in our post-pandemic reality, and manufacturers will need to carefully evaluate any proposed arrangements with telehealth vendors.



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Unique collaborations between academia, industry, and government

The events of 2020 illuminated the importance of cooperation across industries and disciplines to advance public health – especially for COVID-19 vaccines, therapeutics, and diagnostics. Academic-industry collaboration is nothing new, but the past year has brought unprecedented levels of mobilization to these relationships, both domestically and internationally.

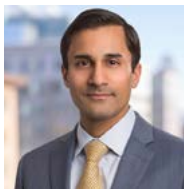
Moreover, policymakers are visibly focused on leveraging a combination of government and private resources to accelerate innovation and improve health outcomes. Several high profile public-private initiatives emerged in the wake of COVID-19, blurring the lines between stakeholders and completely reshaping the scientific landscape.

Cooperation across academia, industry, and government is the new normal. But the collaborative platforms across each sector are far from settled, and new models continue to emerge.

Regulatory complexities abound in government-funded projects. For example, protection of intellectual property and valuable data may be in tension with the principles of transparency and openness in federally-sponsored research.

Pressures on corporate budgets and perceptions of value have companies paying increased attention to opportunities to partake in government-funded initiatives. University-industry compacts also are on the rise, and the government has shown willingness to support them with public investment. However, organizations that receive federal funds as recipients, subrecipients, or contractors have important obligations; some of these obligations extend to participation in federal projects even without receipt of federal funds. The government's regulation of intellectual property, data sharing, and conflicts of interest may differ from how organizations traditionally approach these areas. Government interest in "foreign influence" in scientific research also is a factor as international research collaborations surge ahead.

Alliances between government, industry, and academia are imperative in the modern research environment. To the government's credit, myriad programs help to nourish and expand these interactions, but the government has limited regulatory flexibility in these projects, and organizations must be attentive to the downstream implications.



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Clinical Trials

The U.S. clinical trials landscape

The COVID-19 pandemic created unprecedented difficulties for the regulation and operation of clinical trials. These challenges include issues with travel restrictions, remote visits and monitoring, informed consent, supply chains, and more. Regulators responded with guidance acknowledging the impact of COVID-19 and provided greater regulatory flexibility in meeting protocol and Good Clinical Practice (GCP) requirements. As we look to a post-COVID world, the question is which of these changes will stick. Moreover, the recent focus on diversity has also impacted clinical trials, and this prioritization is likely to increase under the Biden Administration. Below, we focus on COVID-19 related changes that we believe could be permanent and analyze why.

Telehealth participation, remote informed consent, remote monitoring, and home delivery of investigational product

In a FDA guidance that has been updated repeatedly since March 2020, the agency has issued an evolving set of recommendations to address COVID-19-related challenges including:

- Managing protocol deviations that are related to the pandemic,
- Performing outcome assessments remotely,
- Proper administration of investigational drugs,
- Addressing supply chain disruptions,
- Home delivery and administration of study drugs,
- Using alternative facilities,
- Video conferencing for trial visits, and
- Conducting remote monitoring.

In the guidance, FDA indicated it will permit a substantial amount of flexibility to sponsors and investigators to protect the safety of subjects and the integrity of ongoing trials. For example, the guidance states: “Changes in protocol conduct necessary to immediately assure patient safety, such as conducting telephone or video contact visits for safety monitoring

rather than on-site visits, can be immediately implemented with subsequent review by the IRB and notification to FDA.”

We anticipate that this regulatory flexibility is likely to continue after the pandemic ends. Ex-FDA Commissioner Stephen Hahn has said that remote monitors and telehealth check-ins made necessary by COVID-19 may become permanent fixtures of clinical trials. We agree that after industry and regulators have seen benefits from the significant efforts made to streamline and maintain high quality remote care and patient satisfaction with on-line tools, these aspects of clinical trials could remain remote.

The guidance also promotes new methods for obtaining informed consent from hospitalized patients in isolation. FDA provides guidance on how to obtain informed consent from prospective trial participants in circumstances where the enrollment timeframe is limited and the patient can receive an informed consent form electronically. For example, the guidance cites the COVID-19 MyStudies App as an option for electronic informed consent when face-to-face contact is not possible. This trend is bolstered by the tremendous interest in digital tools to connect patients with their doctors and clinical trial sites. And, the cost savings might mean this can continue, particularly for trials that can be conducted in outpatient settings.

Despite the progress in FDA’s thinking about flexibility in clinical trials, significant questions remain about how sponsors and investigators will successfully implement these new approaches. For example:

- Will hospitals permit drug and device companies to access the hospitals’ electronic medical records to facilitate remote monitoring and source data verification?
- What will FDA’s long-term expectations be for new technologies that were first used during the pandemic (e.g. to facilitate remote patient

visits)? For example, will those systems need to comply with the agency's regulations for electronic records at 21 CFR Part 11?

- How will FDA ultimately view the integrity of data from clinical studies that were temporarily suspended due to supply chain disruptions or where there are numerous protocol deviations and missing data points?

We are closely monitoring these issues, as well as FDA's longer term adoption of more flexible standards for clinical trials.

Diversity in clinical trials

It is increasingly important that clinical trial populations reflect the racial and genetic diversity of the ultimate users of the product under study. In November 2020, FDA finalized a guidance on enhancing diversity in clinical trials. The guidance recommends several approaches to increase study population diversity with regard to demographic characteristics (such as age, sex, race, ethnicity, and location), as well as non-demographic characteristics.

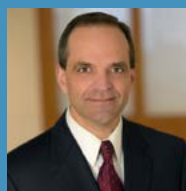
The new recommendations include broadening study subject eligibility criteria by using real-world data to find participants and using mobile medical professionals to visit participants at their locations instead of requiring clinic visits. The final guidance also has new information on the inclusion of racial and ethnic minorities, advancing community engagement, and making recruitment events more accessible. Last fall, we analyzed the guidance in a piece titled "A step in the right direction," and we see this trend – highlighted by vaccine wariness and the conditions surrounding the pandemic – as likely to continue especially as the Biden Administration promotes racial equality as a chief priority.

Since FDA issued the final guidance, we have seen many study sponsors implement new strategies to enhance diversity in their clinical trials. For example, as part of the routine evaluation process for new clinical sites, many companies now include a standard set of questions asking potential investigators about the diversity of patients under their care. In other cases, we have seen sponsors implement recruitment strategies to attract more diverse patients into their studies. Of course, in rolling out new programs such as these, it is

important for study sponsors to assure that they are complying with all ethical standards related to subject recruitment, as well as with privacy laws that may limit what type of race and ethnicity data may be collected about patients before they have signed a privacy authorization or informed consent form.

Despite the benefits of the tools we discuss above, the pandemic has delayed subject enrollment and left operational gaps in many ongoing clinical trials, which in turn has had a negative impact on trials programs and clinical data integrity – all in a time of regulatory uncertainty.

Our clinical trials team helps companies tackle some of the most challenging clinical research issues. We have advised many clients on the impact of COVID-19 on clinical trials, including issues related to patient travel, force majeure claims from clinical trial vendors, travel reimbursement, study conduct, supply chain issues, maintaining compliance with good clinical practice, and minimizing risks to data integrity. In these challenging times, our unmatched global resources and industry experience can assist you in developing practical strategies for clinical trial design and negotiate the necessary agreements to enable you to quickly and smoothly initiate or restart your clinical trials around the world.



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Clinical trials litigation risks

Clinical trials play a critical role in the understanding, detection and treatment of illnesses, and the number of clinical trials is increasing at a rapid pace. As of February 1, 2021, approximately 366,000 clinical studies were registered globally on ClinicalTrials.gov, as compared to approximately 2,119 registered in 2000. As the number of clinical trials conducted by pharmaceutical, biotechnology, and medical research companies increases each year, so does the possibility that these companies will become embroiled in litigation relating to these trials. While companies conducting clinical studies have to navigate complex medical, scientific, regulatory and ethical issues, it is important to be cognizant of the potential litigation risks and the steps that can be taken to mitigate those risks.

A clinical trial participant who experiences an adverse reaction during a trial may seek recovery from the sponsor based on theories of negligence, lack of informed consent, or strict liability. Such claims tend to be based on allegations that the participant was not adequately warned of the risks associated with the experimental product, was not an appropriate candidate for the study or that the study was not appropriately designed or conducted. A breach of contract claim may also be asserted based upon the compensation provision of the consent document. On the other end of the spectrum, a clinical trial participant may file a lawsuit seeking expanded or continued access to an experimental treatment after the study has ended.

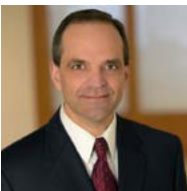
Clinical trial documentation is key to the defense of clinical trial claims. Sponsors should consider taking the following steps to mitigate potential litigation risks:

- Include clear statements in the informed consent regarding the known risks and the potential for unknown risks to assist with the defense to lack of informed consent cases and to support the assumption of risk defense. Also, consistent with FDA regulations, the consent document should be updated regularly and approved by the responsible ethics committee as new safety information is obtained about the investigational product.
- Ensure that the Investigator's Brochure documents the known and potential risks associated with the investigational product to support the learned intermediary defense to a litigation claim.
- State in the clinical trial agreement with the investigator and in the informed consent document that the investigator is not an agent of the sponsor to preserve the sponsor's defense to a claim for lack of informed consent, which is consistent with the regulatory framework requiring the investigator to obtain consent. Such a statement may also support the defense to a negligence claim that the sponsor owed no duty to the study participant.
- Include appropriate indemnification provisions in the clinical trial agreement pursuant to which the investigator and institution agree to indemnify the sponsor for any claims resulting from their negligence or misconduct.
- State in the informed consent that the investigational product will be provided only during the course of the study, that there is no commitment to provide the investigational product after the study has concluded, and that the sponsor may stop the trial at any time for any reason to protect against continued access claims.

- State in the informed consent that the investigational product is being provided during the study free of charge and is not otherwise available to the study participant in the stream of commerce to provide documentary evidence to support the defense to a strict liability that such a cause of action is not appropriate for a product that is not in the stream of commerce.
- State in the informed consent that the document is not a contract between the sponsor and the study participant to protect against breach of contract claims.
- In the clinical trial agreement and informed consent form, clearly define the scope of the medical expenses for which the sponsor will be responsible in the event of an injury, and make clear that the injury must be directly related to the proper administration of the investigational product to preserve the lack of causation defense.



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Learn more about our
Clinical Trials practice
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Clinical trials and the use of technology to monitor AB&C risks

The race to find therapeutics and a vaccine in the fight against COVID-19 has put the spotlight back on international clinical trials. Although international clinical trials are necessary, they often occur in unfamiliar business and regulatory environments, requiring pharmaceutical manufacturers to work with third-party clinical review organizations (CROs) that have local expertise. CROs, in turn, often interact with health care professionals (HCPs) who support the CROs as clinical trial consultants and/or investigators, and may be considered “foreign officials” under the FCPA or other anti-bribery and corruption (AB&C) laws. In the last two years alone, there have been hundreds of millions of dollars in resolutions arising from allegedly improper interactions with HCPs in connection with clinical trials.

Embracing technology

Companies are increasingly turning to innovative risk-management technologies, which can spot and assess patterns of problematic conduct quickly and efficiently. Machine learning and AI in particular can potentially help mitigate the risks inherent in high risk areas, such as international clinical trials.

Machine learning algorithms use statistics to find patterns in large amounts of data, such as:

- spotting patterns indicative of risky and/or non-compliant conduct in real time;
- help identify, prioritize, and mitigate risk areas; and
- streamline compliance monitoring efforts in regulation-heavy areas such as GDPR.

To date, companies have successfully used machine learning and AI to:

- assess whether their CRO has compliant relationships with HCPs, government officials, and local agencies by analyzing the nature and frequency of those contacts;
- monitor the timing of CRO-led regulatory submissions, recruitment of researchers, and other third-party interactions for potential AB&C issues;
- fill in gaps and identify potential issues concerning CRO contracts and payments to subcontractors or other third parties; and
- spot financial connections between CROs, subcontractors and government officials.

Embracing emerging technology does not remove the need for robust, well-staffed compliance programs, but can allow compliance groups to make data-driven decisions about what to investigate and where to focus their training, auditing, and remediation efforts.



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Cannabis and psychedelics: The transformative medicine frontier is here

Cannabis, cannabis derivatives, and a range of psychedelics like psilocybin, ibogaine, and lysergic acid diethylamide (LSD) are no longer relegated solely to the column of recreational drugs. There is a growing recognition of the therapeutic potential of these pharmacologically active substances and the need for disciplined science to harness their potential as treatments in indications ranging from neurological and mental health conditions to pain and addiction treatment.

The investigation, development, approval and marketing of these substances, which we call “Transformative Medicines,” present unusual regulatory challenges that require a thoughtful approach, engagement with regulators, and support from sound regulatory science.

Development and approval of Transformative Medicines raise a myriad of complex topics, including:

- **Challenges of development of a naturally sourced product:** While some regulators have sought to provide guidance on the development of botanical products, the reality is that few botanically derived products have been brought to market.
- **Patent protections and exclusivity:** Naturally derived compositions may require innovative IP strategies, and the issue of whether synthetic versions of natural-source constituents may be considered “interchangeable” raises uncharted regulatory questions.

- **Safety:** Psychedelics are likely to require additional efforts to ensure safe and appropriate use.
- **Scheduling:** In markets such as the U.S., products typically must be rescheduled under both the federal and certain state-controlled substances acts.
- **Decriminalization and legalization:** Like cannabis in the U.S., where the states have changed the regulatory scheme to provide access beyond that expected for a pharmaceutical, legislation at the local level can add to the complexity of developing and successfully marketing an approved pharmaceutical.

By applying sophisticated drug development tools, and working closely with regulators, sponsors of highly active psychedelic and cannabis substances have begun to chart a path for mainstreaming the regulation and approval of these substances into Transformative Medicines.



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They are fresh thinking and provide a balance between policy and business decisions.

Client, Healthcare, Chambers USA, 2020

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Precision and Regenerative Medicine

Cell, tissue, and gene therapies

We continue to see considerable interest in the field of cell, tissue, and gene therapy (CTGT) from our clients, spurred in recent years by FDA's approval of the first cell-based gene therapy products and FDA's framework for encouraging the development of regenerative medicines. The products range from highly complex gene editing therapies to minimally manipulated transplanted human tissues. While CTGT represents an emerging opportunity for our clients, CTGT products also pose significant regulatory issues, as the novel technologies of CTGT products challenge traditional FDA paradigms. The regulatory issues faced by our CTGT clients span a number of areas, including manufacturing, reimbursement, and clinical trial design.

FDA has committed to providing information to sponsors to assist with CTGT product development, releasing about 15 CTGT guidances in the last five years. These include guidances on CTGT product development for specific types of diseases, including hemophilia, rare diseases, and retinal disorders. They also have clarified the criteria for transplanted human cell and tissue products that qualify to be regulated solely under the authority of section 361 of the Public Health Service Act, and that consequently are eligible to be commercialized without premarket FDA review.

We expect FDA's commitment to CTGT product development to continue. Indeed, in the first month of 2021, we have already seen FDA issue guidances on CTGT manufacturing considerations during the COVID-19 public health emergency, and on CTGT product development for neurodegenerative disorders. FDA's agenda of planned guidances for 2021 also lists at least seven additional guidances on CTGT topics.

A consistent message from FDA is the importance of meeting early with FDA in CTGT product development. Hogan Lovells has been assisting clients with such early strategic interactions, including those through INTERACT meetings. We expect continued interest from clients in the field of CTGT over the coming year.



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Learn more about our Cell, Tissue, and Gene Therapies practice on our website.

CRISPR 2021: COVID-19 and Brexit divergence

While the world's attention has very much been on COVID-19, it may be easy to overlook the other scientific breakthroughs of 2020. Gene editing remained a hot topic, with Jennifer Doudna and Emmanuelle Charpentier being awarded the Nobel Prize for Chemistry for their discovery of the CRISPR/Cas9 genetic scissors, which has transformed the field. It was also reported in 2020 that the first ten patients treated with a gene editing therapy (CTX001 for sickle cell disease and beta thalassemia) remained symptom free without the need for blood transfusions.

The broad applicability of CRISPR has been evident in the current pandemic. CRISPR-based kits to detect SARS-CoV-2 have been rapidly developed and authorized under emergency use legislation, with the inventiveness demonstrated even in the naming of the kits ("SHERLOCK" and "DETECTR"). These enable rapid and cost-effective testing without the need for sophisticated equipment such as PCR machines. CRISPR is also being investigated as a potential anti-viral treatment, aptly named PAC-MAN, in which the Cas13d enzyme is directed against conserved regions of SARS-CoV-2 and degrades viral RNA.

Meanwhile, post-Brexit, there are signs that the UK may be diverging from the EU in this area. In 2018, the European Court of Justice ruled that gene edited organisms (including crops) fell within the GMO Directive, essentially putting a ban on genome editing in crops and livestock. The UK government has recently launched a consultation on the regulation of genetic technologies, primarily focusing on the regulation of gene edited organisms

containing genetic changes which could have been introduced by traditional breeding. The consultation document states that "DEFRA may change the legislation to amend the definition of a GMO as it applies in England." Views are also being gathered on the wider regulatory framework governing GMOs.

These changes might mean that in contrast to the EU, the UK would be able to use gene editing techniques to develop crops which have enhanced nutritional properties (such as wheat fortified with iron or gluten-free wheat), or which have resistance to disease meaning a reduced need for pesticides or fertilisers. It may also provide a mechanism to create fitter and healthier livestock. For example, CRISPR and other gene editing techniques have been used to create pigs lacking genes coding for antigens which are typically recognized by human antibodies, paving the way for rejection-free organ transplants, and as a source of medical products, such as heparin.

In addition, pigs have been raised with a resistance to viral diseases that may be able to be passed on to humans: a prospect with particular import to a world afflicted by virus. Scientific response to the consultation has been largely positive, but it will be crucial to attain wider public engagement if gene edited crops or animals are to become permitted under regulation.



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Bridging the gap: Partnering transactions between pharma and diagnostic companies

As precision medicine expands its reach across therapeutic areas, pharmaceutical and diagnostic companies have come to recognize the need to partner effectively with one another to deliver both therapies and companion diagnostics to patients. Both sides have to stretch beyond their respective comfort zones in order to strike deals with which both sides can live, given the historical differences between pharmaceutical and diagnostics companies in areas like product development, intellectual property protection, and deal-making, generally.

One of the challenges that exists in a companion diagnostic (CDx) development agreement is ensuring availability of the diagnostic. Where a pharma company is relying on a companion diagnostic to launch its product, it needs assurance that the diagnostic is validated and cleared for use, and available at the time of the drug's launch. However, where the sale of a CDx is simply not commercially viable, a CDx collaboration needs to strike a balance between both parties' interests. Further, the pharma company needs ongoing protections against any lapse in availability of the diagnostic, which may include the ability to partner with another diagnostic manufacturer to replace the original diagnostic.

Most diagnostic manufacturers appreciate the pharmaceutical partner's vulnerable position. In situations where the assay incorporates the diagnostic company's proprietary know-how, the diagnostic company would be reluctant to commit to a technology transfer or provide the partner (or worse yet, a competitor) with data or materials that would enable the test to be replicated. This is a particular concern for diagnostics companies that have limited patent

protection with respect to their assay, relying heavily (as many diagnostics manufacturers do) on trade secret protection. Such an obligation may be wholly unacceptable if it applies in contexts like regulatory delays, force majeure events, and delays due to the drug company, but is no easier where the assay is simply not commercially viable due to jurisdiction-specific reimbursement or supply chain challenges. The situation is different, of course, where the pharma company contributes significantly to the development of the assay, or where the assay is specific to its product.

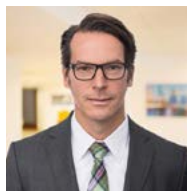
Bridging this gap demands a nuanced understanding of each party's key concerns and areas of exposures including commercial, regulatory, and IP risks; experience with industry customs and practice; and creatively drafted contractual provisions that align both parties' incentives toward ensuring the commercial success of both parties' products.



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Learn more about our Digital Health practice on our website.

Digital Health

In the last year, digital health technology has made great leaps forward as health care sought to address the needs of patients and providers during the COVID-19 public health emergency. Our societies have seen a growing number of new technologies and innovations being used during the pandemic, including:

- Remote patient monitoring solutions
- Telehealth platforms
- Wearable sensors used for facilitating collection of patient data in clinical trials

After some failed attempts to apply laws and regulations designed for more “traditional” technology to this sector, the legal and regulatory landscapes began to evolve iteratively to address it in a more tailored manner. As a result, the sector was well positioned as the COVID-19 pandemic has forced regulators to allow and even encourage the adoption of digital health technologies. Some of these policies will stay; while others will disappear once we emerge from the pandemic. Thus companies innovating or leveraging digital health technologies will need to demonstrate that they are agile and flexible to adapt to this evolving regulatory framework.

The coming year promises more developments – some through exciting partnership in AI, robotics, telehealth, and new types of technologies – to address chronic diseases, mental health, therapy adherence, and support for aging adults. At the same time, business models for digital health have not been firmly established, and digital health companies face tremendous pressure to demonstrate their commercial viability. On the other hand, some countries seek to foster the digital health environment via support through public

initiatives or first attempts of reimbursement for digital health applications.

In the months and years ahead, success in developing and leveraging new digital health products and services will require a deep understanding of numerous forces at work, and a nimbleness in shifting focus as needed to keep pace with the continued rapid evolution of both technology and regulation. Effective advocacy before the relevant regulators and the other players in the ecosystem, when appropriate, is also key. Our practice groups are well-versed in the increasingly complex patchwork of global privacy regulations, novel reimbursement models, and evolving paradigms for demonstrating the safety and effectiveness of digital health solutions to regulators and notified bodies, as well as the unique liability and intellectual property questions that arise with digital health products. We help clients daily to navigate strategically so that they can achieve the promise of these endeavors.



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Telehealth: The new normal, and here to stay

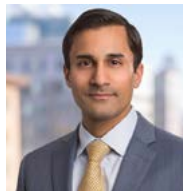
The events of 2020 brought unprecedented focus to virtual health solutions. Going forward, health care providers routinely will reach across borders using technology to provide medical services directly to patients and physicians or other health care providers. Telecommunication modalities such as e-mail, audio, video conferencing, and mobile apps are already facilitating diagnosis, consultation, treatment, and remote monitoring. Remote second opinions — whereby a health care provider is asked by either a clinician or a patient to verify a diagnosis or treatment from a distance — have also surged in the international and domestic medical sectors.

Although the practice of medicine is regulated across the globe, the practice of telemedicine does not always fit within the traditional areas of law and regulation applicable to the medical profession in a particular state or country. Where countries do regulate telemedicine, such laws do not necessarily address the circumstances in which a foreign physician sitting outside the country may render remote services into the country.

Telehealth solutions raise myriad complex topics:

- **Practice of medicine:** physicians and institutions that are considered “engaged” in the practice of medicine in a particular state or country may have licensure/ registration requirements or face limitations on the precise services that can be rendered lawfully from a remote location.
- **Privacy and data protection:** regulation of patient medical information and data varies significantly from country to country and sometimes from state to state, and use of genetic information is restricted in some jurisdictions. Processing health data must rely on a solid legal ground which will often be the patient’s consent.
- **Billing and reimbursement:** whether, and under what circumstances, telehealth services can be covered and reimbursed by government and other third party payers varies. Health care providers that receive reimbursement for services provided in a country may then be subject to various regulatory requirements imposed by that country.
- **Telehealth devices:** telehealth services are made possible thanks to software and connected devices. Such software may classify as a medical device. For example, as of 26 May 2021, the new European Regulations for medical devices (MDR) will apply, introducing new classification rules for medical devices software and creating new obligations for companies manufacturing, importing or distributing medical devices. The design of the solution must include from the outset the constraints resulting from medical device regulations.

Other challenging issues include liability and malpractice, e-commerce regulation, advertising constraints, intellectual property protection, and tax compliance.



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Check out our
Virtual Health
Horizons guide



AI: 2021 is the year for legal innovations

In previous issues of this publication, we have discussed the potential “future” opportunities and issues that AI could bring to the life sciences and health care industries. 2020 showed us that AI is very much here and happening; not only that, but it has played a pivotal role in the fight against COVID-19. Now is the time to get AI-ready, as the use of AI accelerates in 2021.

2020 was a good year for AI, as multiple companies across the life sciences and health care sectors formed collaborations to develop its use. Such collaborations saw mainstream players working with start-ups and tech companies dipping their toes into areas where they were not previously engaged. This led to some exciting developments. For example, AI has accelerated drug repurposing, which has been of profound importance in a year when swift drug development has been critical. We predict that the development and use of AI will firmly continue in 2021.

Against this backdrop, it has never been more important to ensure that companies are equipped with the best legal toolbox for managing the potential opportunities and risks associated with AI. In intellectual property, for example, the issue as to whether AI can be the inventor of a patent is being tested by courts and patent offices globally. The consequences of these decisions could impact ownership of IP where AI has been used as part of the innovative process. In data and privacy, companies wishing to enhance their AI applications with home-grown banks of data are urgently needing to consider the legal landscape around data use. As the world continues to face challenges ahead, never has it been more critical to have legal solutions in place for the novel issues raised by AI.



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Feeding AI with EU health data: The future of the future

The AI EU legal framework is still in its early development stages, and EU institutions and governments are working to strike a balance between innovation and safety. This requires those regulatory bodies to make sure that their AI legal policies comply with data protection principles, including:

- **Accountability.** The first step, before launching any AI project using EU data, is to ensure accountability including performing data protection impact assessments, understanding the relationship and distinction between controllers and processors in the AI context, as well as managing and documenting decisions taken with respect to AI-related risks.
- **Fair, lawful, and transparent processing.** AI projects must identify lawful bases, avoid potential discrimination, and document the source of input data.
- **Data minimization and security.** Data security issues are a major concern for AI and it is key to comply with the principle of data minimization, i.e., identifying the minimum amount of personal data needed, especially during the machine learning training and inference stages.
- **Compliance with individual data subject rights.** It is important to respect data subject rights in the context of data input and output of AI systems. If there is automated individual decision-making, including profiling, the system must be designed to facilitate effective human review.

Automatic decision rules and explainability are at the heart of AI usage of data. Algorithms and AI functioning must be fair, and the controller is responsible to guarantee that the chosen method does not lead to inappropriate results. For example, there should be no bias in its reasoning and output or opaque decision-making of discrimination. The future legal framework will work to ensure that AI systems are used ethically.



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AI – A brave
new world?



Privacy and Cybersecurity

Securing medical devices from increasing cyber threats

Medical device manufacturers have a critical role in health care organizations' sensitive infrastructures, as manufacturers increasingly handle larger amounts of health data, through connected devices and partnerships with other health sector stakeholders. Meanwhile, cyber threats have expanded from seeking health data to taking control or disrupting the function of the devices themselves, or using the devices as a springboard for further cyberattack activity; with these threats comes the potential for liability to be visited on the manufacturer.

Device cybersecurity is a high priority issue for regulators worldwide, and various government authorities are taking action so that entities involved in securing medical devices have detailed information to help prevent and manage cyber risks. These initiatives involve, among others, the U.S. FDA, the International Medical Device Regulators Forum (IMDRF) working group, and the European Commission Medical Device Coordination Group (MDCG). Regulators worldwide have recognized that device cybersecurity is a shared responsibility among manufacturers, health care providers, service providers, suppliers, patients, and regulators — with stakeholders each having a role in secure device deployment, operation, and management.

In all of these initiatives, stakeholders are encouraged to work holistically and coordinate to fortify cybersecurity practices. It is expected that cybersecurity be a component of the risk management evaluation across the entire product lifecycle that includes cybersecurity by design as a method to support developing

appropriate instructions and warnings through which developers are aware of potential vulnerabilities, allocation of responsibilities, and strategies for risk mitigation. A risk assessment that focuses on product safety, effectiveness, and performance can help manufacturers understand the risk through the design, manufacturing and commercialization phases, which in turn provides greater opportunity to mitigate product liability risks.

Our team is uniquely positioned to assist clients through the entirety of the product lifecycle as they identify and manage cyber risks to their patients, health care providers, and their business. When confronted with crises, clients must understand the issues, the risks presented and how best to mitigate them without disrupting the entire ecosystem, and they must have effective advocacy before relevant regulators and other stakeholders.



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The uncertain waters of transferring health data across the Atlantic

The lawful cross-border transfer of EU health data is now complex, and in some cases, impossible. In July 2020, in case referred to as Schrems II, the Court of Justice of the European Union (CJEU) invalidated the U.S.-EU Privacy Shield and questioned the validity of the Standard Contractual Clauses. Together, these were the two most common means that health and life sciences organizations had previously leveraged to transfer personal data from the EU to countries like the United States.

Since then, organizations have been scrambling to respond. Meanwhile, EU regulators are issuing guidance with no easy solutions. For example, the European Data Protection Board (EDPB) released a road map for compliance by July 2021, which requires significant effort by companies to assess, analyze, and map transfers and implement measures to address the requirements outlined by the CJEU in the Schrems II decision.

The effects of the decision are acutely felt by EU health care organizations working with U.S. life sciences and technology companies. For example, the Schrems II decision led to the challenge of whether the French government may lawfully engage Microsoft to host the French Health Data Hub (HDH). The HDH is a platform that would pull together public health databases to facilitate research and

other projects. Multiple legal challenges and contradictory decisions from authorities ultimately led the French government to decide to transfer the HDH to a French or European platform within two years, primarily due to fear of mass surveillance by the U.S. government.

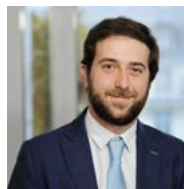
As a result, international health data transfers lack certainty at a time when data needs to flow to address the pandemic and to allow for future breakthroughs in medical science and patient care. Fortunately, with careful analysis of U.S. and EU laws, this uncertainty can often be overcome to enable the data sharing that the post-pandemic world will need.



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Transactions

Life sciences mergers and acquisitions

2020 was a year like no other, and certainly this was true in the M&A world as well. After a record year in 2019, life sciences deals came to a virtual halt in Q2 2020 due to COVID-19. Biopharma companies had to pivot in real time to focusing on conducting clinical trials and maintaining the integrity of their supply chains during a pandemic, among other hurdles posed by this very challenging environment. Further, there was uncertainty all around, which is never a good thing for deal making.

However, after a brief hiatus in Q2 2020, the M&A and broader transactional market had a nice comeback in the second half of the year. Deal makers adapted to the world of virtual due diligence and negotiations and deals progressed largely as before, even in the face of uncertainties around the U.S. presidential election and high valuations of many biopharma targets. We saw a trend towards greater volume of smaller “bolt-on” acquisitions and partnering deals versus big pharma “mega” mergers.

One area of deal making that proceeded with only a minimal pause was financing for biopharma companies. In 2020, this market was strong across the board, from venture financing to IPOs and follow-on offerings. From an M&A

perspective, access to capital helps seed new companies that later become targets and enables buyers to finance their transactions. However, it can create challenges for buyers of pre-revenue targets in that remaining independent, even for companies with high cash burn, is a real alternative.

Going forward, early indications point to a robust life sciences M&A and partnering market in 2021. While valuations remain high, healthy balance sheets and continued availability of financing should provide buyers with necessary capital for deals. Many of the drivers for transacting – including access to new products and technologies, rationalizing and filling revenue gaps across products lines, and venture-backed start-ups looking for an exit – are very much in play. Of course, the pandemic continues to remain a significant risk factor, as does uncertainty around what is likely to be a tighter regulatory environment under a new administration.



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Filling the digital pipeline – trends for cross-border licensing and collaboration deals on digital therapeutics

Traditional pharma companies increasingly realize that digital therapeutics (DTx) do not have to be an alternative and replace conventional pharmacological solutions. Rather, DTx can be designed to complement and improve patient compliance with drug therapies. However, creating user-friendly digital solutions requires specific digital skills and agility that are more often found in tech start-up businesses than in established pharma companies. Does that set-up sound familiar – a smaller start-up with a promising technology, but lacking money and resources, and a pharma company with the financial means and capability to do the heavy lifting of developing and bringing a product to market?

As with biotech companies, tech companies with a promising DTx solution will be looking to collaborate with pharma companies to benefit from their expertise and experience in clinical research, regulatory approval, reimbursement procedures, and promotion of products in a health care environment. Pharma companies, on the other hand, will be interested to collaborate with DTx companies to fill their pipeline with complementary digital health technologies.

However, the collaboration between DTx companies and pharma companies will often look different than the traditional biotech-pharma setting, where the pharma partner often purchases or in-licenses the early-stage technology and takes over the development program entirely. In digital therapeutics, the pharma partner will often

continue to rely on the specific digital expertise of the DTx partner much longer to pave the way for a successful commercialization, as branding and user experience are cultivated, delivered, and measured in very different manners in the digital world than in the analogue world.

Given the wide difference between the development and commercialization of DTx and conventional therapies, companies may even take a targeted approach to digital asset development where pharma and digital health companies work together from inception. Understanding each party's key concerns and areas of exposures will be key to create appropriate contractual arrangements and to ensure commercial success of the DTx solution.



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Post-acquisition integration: a compliance and disputes checklist

Acquisitions represent key opportunities for life sciences companies. But new distributors, suppliers, vendors, and other business partners bring risk as well. Shortcomings in post-acquisition compliance integration can result in successor liability under the U.S. Foreign Corrupt Practice Act (FCPA) and other anti-corruption laws. An essential aspect of ensuring a smooth and successful integration is creating a holistic and consistent risk management regime including compliance and disputes. It is critical to conduct post-acquisition compliance and dispute resolution review in tandem, so you are prepared if compliance requires an exit or dispute resolution. Here's our checklist on what to look for:

Compliance

- Set-up an integration plan with a layered and risk-based approach. Not all business partners can – or should – be reviewed immediately and with the same intensity. Assess the key risks and assess higher-risk partners first.
- Use objective criteria to categorize business partners. Previous adverse findings, higher revenues, riskier geographic regions, activities beyond mere distribution, etc. The more discretion the third party has, the higher the risk.
- Adjust your review to the category. The higher the risk profile, the more detailed the review. Key elements of a review can be: review of prior audits, public source data, reviewing contracts for commercial terms and compliance provisions, background checks, business partner's compliance system sufficiency, in-person or remote interviews, and exercise of audit rights and transaction-level reviews.

- Make efficient use of existing information. Previous diligence, internal audit/ investigation reports and contract reviews are a key source. Assess whether prior findings were addressed and remediated or they form a pattern.
- Understand legal boundaries. The review at all points needs to comply with applicable laws, in particular data privacy and competition laws. Violations can result in new risks for the company and the business relationship.
- Involve the business. Good relationships with business partners are a key goal. Involving business contacts and communicating the background and goals of the review helps to increase cooperation and make the process run smoothly.
- Document your efforts. Draft a report on the review, its outcome, and the steps taken. Such report might be needed to make your case of sufficient post-acquisition compliance with authorities. Keep in mind how to ensure privilege applies under U.S. and domestic laws.

Dispute resolution

- Review the termination provision. Understand the grounds for terminating for cause and not for cause. Be aware of notice and cure periods.
- Define potential liability. Identify limitations of liability clauses to assess the scope of potential claims.
- Analyze the dispute resolution clause. Find the governing law and check whether the contract provides for arbitration or domestic litigation. Be on the look-out for mandatory negotiation or mediation.

- Evaluate confidentiality. Business partners may look to publicize their dispute to gain leverage. Find out what confidentiality obligations the contract imposes and how to enforce them.
- Assess extra-contractual claims. Many jurisdictions have laws that provide distributors with additional rights, including the rights to lost profits even with a termination based on compliance findings. Look to whether there have been similar litigations or arbitrations.
- Consider proactive settlement. An amicable resolution is almost always preferable to litigation.



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Ranked Band 1 for Life Sciences

Chambers Global, 2021

Patents, Litigation, and Beyond

Global patent litigation into 2021 and beyond

2021 promises to be another exciting year in patent litigation. What themes will be keeping our patent litigators particularly busy during the next 12 months, and what important decisions or political developments will likely be at the forefront?

In the U.S., one of the most anticipated cases will be the Supreme Court's review of the *Arthrex Inc. v Smith & Nephew, Inc.* case that will likely affect the viability of the Patent Trial and Appeal Board (PTAB) as well as countless past, present, and future PTAB decisions. Even if the Court upholds the constitutionality of the PTAB, the issue will undoubtedly be hotly debated by courts on other grounds during 2021 and beyond.

In the UK, the Court of Appeal will consider issues that traverse questions about AI inventorship. In the Netherlands, we may see further guidance from the Dutch courts on fair, reasonable, and non-discriminatory (FRAND) issues, which most likely take into account recent developments in other parts of Europe and the rest of the world. In France, we expect an increased use of the new legal provisions creating an after-grant opposition procedure against French patents granted by the National Institute of Industrial Property (INPI), allowing third parties to request the revocation or modification of a patent through administrative proceedings.

In Germany, we continue to monitor the proposed reform of German patent law, to make the granting of injunctive relief in

patent infringement matters subject to a proportionality test, which is currently stuck in the Federal Council (Bundesrat). In Italy, the Supreme Court issued an important decision last year on infringement by equivalents, rejecting the so-called "prosecution history estoppel" doctrine. We will see in 2021 how the implementation of this ruling will strengthen the position of patent holders. In Russia, we've seen a positive trend for patentees, through the imposition by the Russian courts of permanent injunctions based on the mere threat of patent infringement and patent infringement claims. We expect this trend to continue and develop this year.

In Japan, recent revisions to the Patent Act provide a new discovery (disclosure) process allowing plaintiffs to request the inspection of defendants' facilities by a neutral expert to be designated by the court not dissimilar to the continental European systems for search and seizure. As the pandemic subsides, 2021 should provide an indication as to how much this procedure will be utilized. Similarly, China has amended its Patent Law, but in a more extensive way. Along with overhauling and "modernizing" almost all of its other IP laws, China has now implemented procedures for attaining patent term extensions and patent linking.



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Synergistic use of patent litigation, patent prosecution, and regulatory counsel to maximize commercial value

Unquestionably, the biggest asset an innovator pharmaceutical company has is its intellectual property protecting its commercially valuable drug products and its product pipeline.

Unfortunately, in patent enforcement proceedings, many life sciences innovators unexpectedly find themselves facing particularly difficult challenges in attempting to meet their infringement proofs. Troubling is that these difficulties could easily have been obviated by early planning by a multi-discipline team – patent litigation, patent prosecution, and regulatory counsel – working together in a holistic fashion. Many in the industry are yet to fully appreciate and embrace this holistic approach, but those innovators who have, considering and utilizing opportunities offered by regulatory and other means, have managed time and again to maximize their chance to meet the potentially burdensome proofs required for an infringement determination.

This approach is becoming more and more relevant as generic companies are attempting to find ways to avoid providing relevant information through discovery, and in doing so, hamper the ability of patentees to meet their burden of proving infringement. We have seen an increased use of third party research companies by generic Abbreviated New Drug Application (ANDA) filers, which conduct all the

generic product development, in part, to limit discovery during Hatch-Waxman litigations. These third party research companies are often based in countries that do not provide easy access to third party discovery. During subsequent patent litigation, that ANDA filer will then attempt to argue it has little more than the actual final ANDA document to produce, because all the research and development and other potentially relevant information is in the hands of a third party. The problem portrayed in this example can be mitigated by obtaining patent claims and drafting NDAs such that most, if not all, the claim elements can be established by reference to information that will likely need to be included in an approvable ANDA submission. Conversely, this example demonstrates the shortcomings of failing to fully appreciate the potential limitations of litigation discovery by patent prosecution counsel working in isolation and/or the failure of regulatory counsel to consider what aspects of the regulatory pathway can be utilized to ensure generic applicants fairly include information encompassed by the patent claims in their regulatory filings.



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New technologies come with new litigation risks

As life sciences companies increasingly embrace advanced technologies to aide research and development and other business critical efforts, they must also prepare for the inherent litigation risks. Yet, a recent Hogan Lovells survey of life sciences executives indicates that many companies have not taken steps to examine and mitigate these risks. Below is a summary of key litigation risks and risk mitigation strategies to consider.

Key technology risks

Cybersecurity: A data breach can lead to confidential medical data being exposed, and significant reputational damage. Such a breach may prompt regulatory investigations by multiple government enforcement agencies, collective and class action lawsuits, and even shareholder class actions. Moreover, while the adoption of Internet of Things (IoT) devices by pharmaceutical companies has allowed the industry to automate important business processes, the vast amounts of data stored and shared by these smart devices and systems compounds the cybersecurity-related litigation risk.

Privacy Risks: Consumers are increasingly focused on their privacy rights and many jurisdictions have tightened data privacy regulations. Failures to comply with fast-changing privacy regulations threaten significant reputational and financial consequences. Moreover, uses of consumers' data in ways that are not anticipated or beneficial to the consumer, even if legally compliant, could erode consumer trust.

Technology Failures: As technology advances, so too does the risk of a failure. Because product liability theories are applicable to many new and emerging technologies, a failure in a company's critical technology could lead to costly products

liability lawsuits.

Potential Inherent Biases: Most improvements in AI systems are made because of advances in machine learning. However, algorithms underlying machine learning often reflect unwanted biases found within the data on which they are trained. Algorithmic bias can also be embedded in business operations such as in technologies used to screen resumes and determine which applicants are qualified for open positions.

Partnership risks: The drive to get access to innovative technologies often leads life sciences companies to enter transactions with companies in new or emerging markets. Thus, life sciences companies are increasingly partnering with technology companies through joint ventures, mergers and acquisitions, and by outsourcing key business functions to technology companies. These ventures frequently must navigate regulatory regimes that may not have been designed with the current technology in mind, which may give rise to litigation risks.

Mitigation strategies

The following strategies should be considered to mitigate against the litigation risks described above:

- Enhance board oversight of technology risk by increasing the time the board spends discussing risk, adding new technology roles to the board, and creating a technology risk board committee where relevant.
- Review cyber incident response plans to ensure they have adequate input from the legal team, are up-to-date, and are regularly practiced through appropriate simulation exercises.
- Ensure suppliers have adequate cybersecurity practices in place.

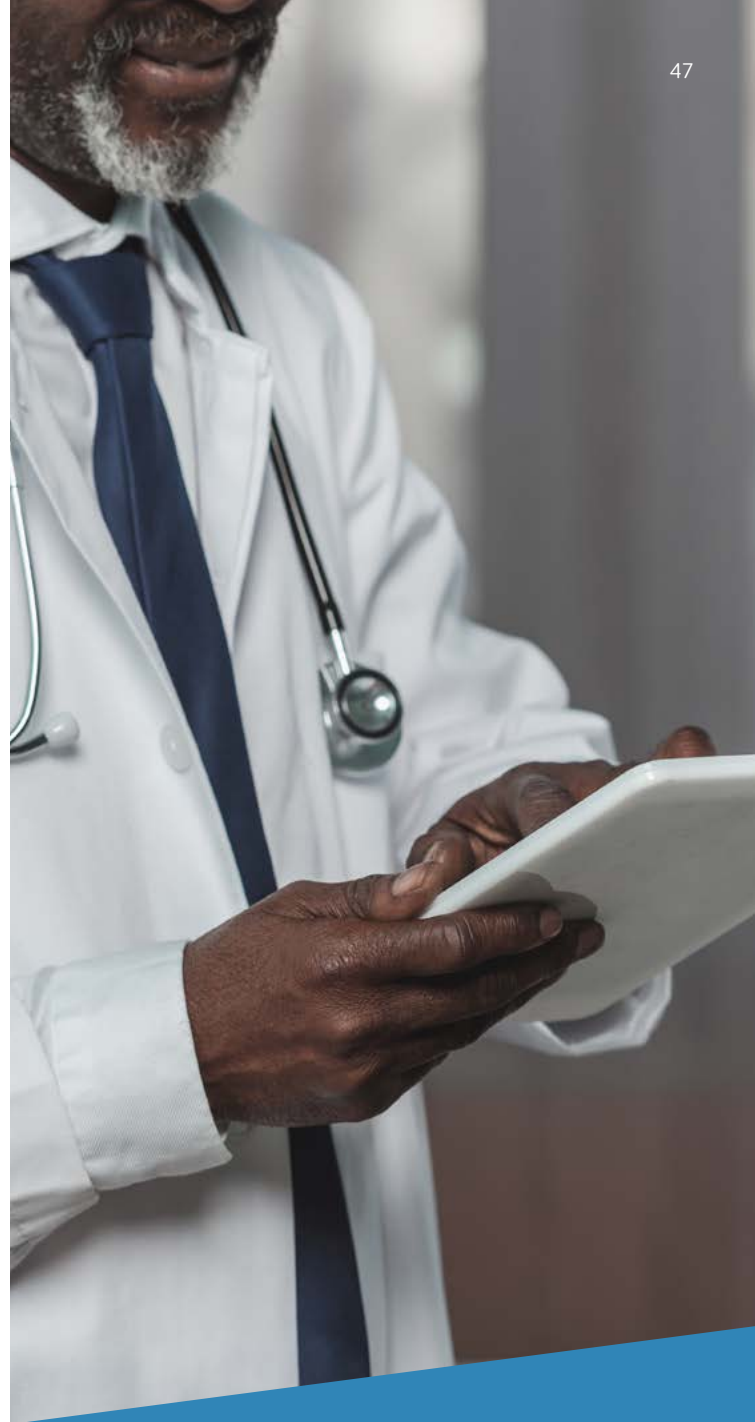
- Add privacy and cybersecurity specialists to your product development teams.
- Identify business-critical technologies and develop “crisis-management playbooks.”
- Involve the legal team in the entire lifecycle of transactions that relate to technology acquisitions.
- Eliminate bias in AI and machine learning technologies – both those technologies that are developed in-house and those procured from a third party.
- Establish and publish principles that will provide a clear framework for how technologies that raise ethical issues will be used and ensure that senior management and the legal team are involved in this effort.



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Litigation Landscape:
How to prevail when
technology fails

Arbitration looming large in life sciences

Life sciences is big business. The pharmaceuticals market expects global revenues to exceed US\$1300 billion in 2021. Market players cooperate on the basis of a range of contractual arrangements, such as licensing agreements, R&D agreements, co-promotion contracts, joint venture, and other M&A agreements, or supply and distribution agreements. Key players reported thousands of the above agreements, among those a large number of R&D and licensing agreements, per year.

It is no overstatement to say that all players in the life sciences sector operate on a global scale. Notably Asian market players feature prominently. China has become the leading supplier of active pharmaceutical ingredients, intermediates, and basic chemicals by volume. All 20 of the world's leading pharmaceutical companies have manufacturing facilities in China; many have established R&D centers. Foreign companies appear increasingly willing to license technologies to Chinese manufacturers and research institutes. India retains its position as a world leader in the production of generics and vaccines, with structural reforms kicking in.

It is thus no surprise that international arbitration looms large in life sciences. Arbitration is an attractive forum for any disputes arising out of cross-border agreements. It provides for a neutral forum, the parties can select their arbitrators and tailor the proceedings as required, they can agree on confidentiality; and, importantly, with the New York Convention providing for a regime for the recognition and enforcement of foreign arbitral awards, arbitral awards are enforceable even where court judgements are not, such as in Mainland China.

Currently, life sciences disputes account for between 5 percent and 10 percent of the overall caseload of major arbitral institutions such as the International Chamber of Commerce (ICC) and 15 percent of the caseload of the World Intellectual Property Organization (WIPO), attracting more technology driven disputes. The number of ICC disputes relating to the pharmaceuticals and health sector has more than doubled between 2015 and 2020, from 30 to 67 disputes. Disputes tend to be very large, with amounts in dispute exceeding US\$1 billion. The 2013 WIPO Survey on commercial disputes in technology driven sectors such as the life sciences sector indicated that license agreements as well as R&D agreements most commonly give rise to disputes.

If you are considering international arbitration as a dispute resolution mechanism for your agreement(s), or if you are facing an arbitral dispute, wherever you operate, please contact us. We are here to support you.



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Asia-Pacific

Life sciences in Japan

We expect continued investment in Japan by companies seeking to take advantage of the world's third-largest market, enhanced drug development, and potentially more flexible approaches to drug approval (such as multi-regional clinical trials) and the regulatory process.

A new system of annual drug price cuts (previously biennial) will start from 1 April 2021, applying to all medicines with more than a 5 percent difference between the government reimbursement price and the wholesaler price to health care providers such as hospitals and retail pharmacies (average deviation in 2020: 8 percent). This will likely affect 70 percent of all National Health Insurance listed drugs, with an estimated reduction of JPY430 billion (c. US\$4.1 billion) in FY-21.

The “patent linkage” system may continue to evolve. Historically, while a patent was valid and in force, the regulator would typically refrain from granting a marketing authorization in respect of a generic product falling within the scope of relevant patents, including while a decision of invalidity by the Japan Patent Office was being appealed to the IP High Court; now,

however, it is becoming much less clear to what extent the regulator will wait in respect of relevant patents (e.g., until all avenues of appeal are exhausted), especially given the Japanese government's promotion of generic drugs in the light of the increasing cost of medicine and the aging population.

COVID-19 has heightened public interest and awareness of the biopharma industry, including in respect of regulatory approvals, clinical trials, access to therapies, supply chains, storage and logistics. We may see efforts to educate citizens and to enhance access to new and innovative vaccines, including developments in respect of their evaluation and adoption, quality and regulatory standards, and management of adverse events, as well as their potential manufacture in Japan in the light of possible export restrictions elsewhere in the world.



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Chambers Asia-Pacific, 2021

China's further improved fast-track review regime for drugs

Prior to the promulgation of new Drug Administration Law (DAL) in 2019, the National Medical Products Administration (NMPA) has launched several expedited approval programs for marketing of innovative drugs in China in several scattered rules and notices, like the Opinions on Encouraging Drug Innovation and Implementing Priority Review and Approval issued earlier in 2017. The amended Measures on the Administration of Drug Registration released on 22 January 2020 to implement the new DAL formally adopts four procedural programs to accelerate the review and approval of certain categories of drug marketing applications based on, among other things, the clinical need for the drugs and the severity or rare nature of the illness that the drugs can treat, including:

- the breakthrough therapy program, which enables the applicant for the registration of innovative drugs for serious or life-threatening conditions to request communication with the Center for Drug Evaluation (CDE) at the clinical trial stage and to receive comments and guidance from the CDE reviewers on the applicant's clinical trial strategy and clinical data requirements;
- the conditional approval program, under which the drugs that treat severity or rare nature of the illness can be conditionally approved but the NMPA will place post-marketing conditions on drugs and a timeline for completion after conditional approval;
- the priority review and approval program, under which the drugs eligible for this program, including for example those have received a breakthrough therapy

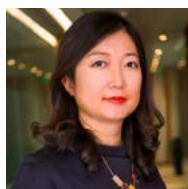
designation or conditional approval designation or these are urgently needed, will be granted with expedited review timeframe; and

- the special approval program, under which the drugs needed in responding to the public health emergency will be reviewed, inspected and examined by the NMPA in a unified and accelerated manner.

On 7 July 2020, the NMPA issued the working procedures on breakthrough therapy program, conditional approval program, and priority review and approval program. The working procedures provide pragmatic guidance for the application of the expedited approval programs by specifying the qualified drugs eligible to apply for the programs, how the applicants initiate the program as well as the review process conducted by the CDE.



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Compassionate use of medical devices allowed in China on a trial basis

After the draft version has been issued for more than half a year, on 14 March 2020, the NMPA and the National Health Commission (NHC) jointly released the Measures on the Administration of Extended Clinical Trials of Medical Devices (for Trial Implementation), which officially establish the system of “compassionate use” for investigational medical devices in China enabling patients in China who suffer from serious diseases can have early access to new therapy.

The compassionate use of investigational medical devices occurs where the patients who are not participants to the clinical trials uses the investigational medical devices in clinical trial institutions. The compassionate use can be initiated provided that certain conditions have been satisfied: (i) the patient is of a life-threatening disease for which there has been no effective therapy and is unable to participate in the clinical trial since the enrollment process for clinical trial has been completed; (ii) the researchers decide that risks resulting from the disease itself outweighs the risks resulting from using the medical device and the anticipated benefits outweigh the possible harms; (iii) the scope of application for such medical device will not exceed the scope in the clinical trial; (iv) it should be carried out in the same institutions where the clinical trials of such medical devices have been conducted; and (v)

the institution and the researcher meet the corresponding qualifications.

Several documents need to be executed in advance, including the informed consent form executed by the patients and the agreement signed by the patients, researchers, sponsor and clinical trial institution to clarify the rights and obligations among the parties. In terms of regulatory formalities, the sponsor is required to make record-filing with the local branch of the National Medical Products Administration, and the clinical trial institution is required to report to the local NHC office where the trial site(s) is located.



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The team provides prompt and succinct advice that considers legal requirements and business needs.

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Chambers Asia-Pacific, 2021*

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Important patent law changes in China

On 1 June, 2021, some important amendments to the Patent Law of China will take effect. The key changes for the life sciences industry are the adoption of a patent linkage system and a right to apply for a patent term extension for pharmaceutical patents. Life sciences companies doing business in China or that have Chinese patents should be preparing for these changes.

Patent linkage

New article 76 of the Patent Law provides a framework for China's long-awaited patent linkage system. Under this new system, the issuing of marketing authorizations for generic drugs is, to a certain extent, made dependent on the absence of infringement claims by patentees. The amendments provide that during the marketing authorization procedure for a generic drug, a patentee (or stakeholder) can bring an infringement proceeding before a court or the CNIPA, which, if successful, would lead to a suspension in issuing a marketing authorization. The patent owner will need to act quickly and start infringement proceedings within 45 days of the publication of the generic company's application for a marketing authorization.

Patent term extension for pharmaceutical patents

Similar to the legal regimes existing in the European Union, the U.S., and elsewhere, the amended Patent Law allows patentees of innovative pharmaceuticals to apply for a patent term extension of up to five years, with a cap so that the effective term of the patent after obtaining marketing approval would not be more than 14 years. The right to such extension is not granted automatically, and must be applied for by the patentee within three months of obtaining marketing approval. As is the case for the patent linkage regime, the details regarding patent term extension are left to implementing regulations. A draft version proposes that applications for patent term extensions can be made for certain patents covering chemical, biological, and Chinese herbal drugs.

Final versions of the regulations will be released closer to June 2021. Please visit Hogan Lovells Engage for our updates on patent linkage and patent term extensions in China and more information about what life sciences companies should consider.



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Dispute resolution for global life sciences companies

China's engagement with the global life sciences industry - pharmaceuticals, medical devices, diagnostics, and biotech, has rapidly increased. In 2013, China became the world's second-largest healthcare market. Due to its size and growth potential, China's life sciences market is one of the most attractive in the world for foreign investors. It is a high strategic priority market for global life sciences investors and companies.

Given the increase in investment and collaboration between Chinese life sciences companies and MNCs, parties are recommended to choose international arbitration as a method of resolving their disputes. This is in large due to the traditional benefits of arbitration – the ease of enforcement of an award under the New York Convention, neutrality, finality, confidentiality, and flexibility.

Although litigation has long been the default mechanism for resolving life sciences disputes, arbitration is on the rise. For example, a review of development collaboration and license agreements that are non-confidential exhibits to reports filed with the United States Securities and Exchange Commission during the first seven months of 2020 revealed that disputes shall be resolved by arbitration. These are agreements between biopharmaceutical firms for the development of preclinical or clinical stage assets, and the commercialization worldwide of one or more approved drugs developed from those assets.

One of the most important elements when drafting an arbitration agreement is the choice of the seat of arbitration. Hong Kong still is and will continue to be a popular destination for international arbitration, in light of its well-regarded and independent judiciary and arbitration institutions, and its arbitration-friendly laws.

Hong Kong also has a unique advantage for arbitrations involving interests in mainland China that global life sciences companies should consider. It is the first and only jurisdiction outside the mainland where the mainland courts can grant interim measures in aid of a foreign arbitration if administered by an institution based in Hong Kong. To date, the Hong Kong International Arbitration Centre (HKIAC) has processed 37 applications made to the Mainland Chinese courts for interim measures. Interim measures are a handy weapon for global life sciences companies to protect, for example, intellectual property rights and trade secrets.

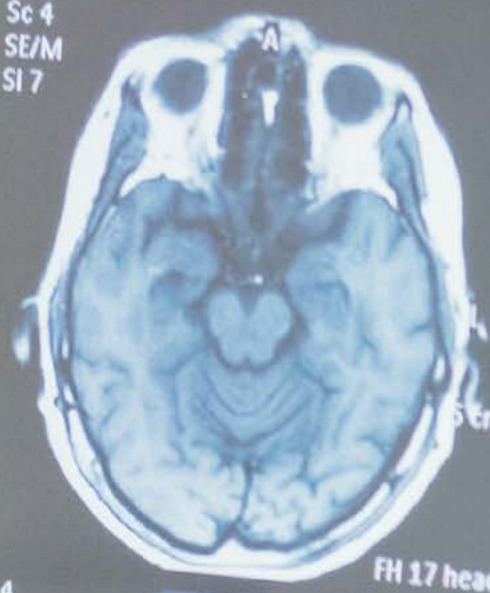
In addition, Chinese courts have historically enforced Hong Kong seated awards including those administered by the HKIAC. There have been very few Hong Kong awards that have been refused enforcement in mainland China (since 1999, only three HKIAC awards have been refused enforcement, according to that institution and confirmed by the Chinese Supreme People's Court).

Other recent developments in Hong Kong, such as allowing for third-party funding in arbitrations and the amendment to the Arbitration Ordinance to provide for clarification on the arbitrability of intellectual property rights, which are often a source of disputes in life sciences agreements, means that global life sciences companies should consider Hong Kong as the seat of arbitration for transactions with a mainland interest.



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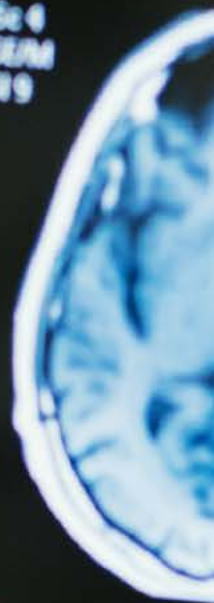
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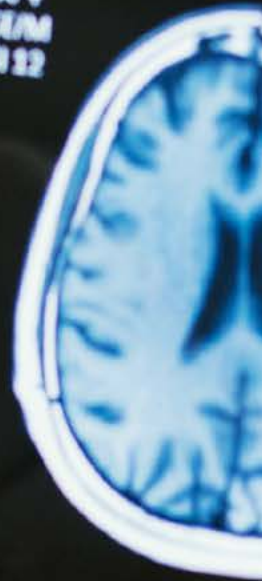


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Australia: Regulatory update on software based medical devices

Following public consultation in early 2019, the Australian government have implemented changes to the regulation of software-based medical devices (SaMDs).

SaMDs are primarily classified as Class I (low risk) devices as the current classification rules only consider the possible harm caused by a physical interaction of a medical device and a human. SaMDs do not have this direct physical interaction; rather, the risks posed by software often relate to incorrect calculation or incorrect diagnosis, which arguably cause greater harm to a person. For this reason, the Therapeutic Goods Administration (TGA) has proposed reforms to better address the classification of SaMDs in line with international best practices according to the factors identified by the International Medical Device Regulators Forum. These reforms are set out in the Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019.

Importantly, the new classification rules for SaMDs will result in higher risk products being reclassified at a higher level, particularly SaMDs intended for:

- diagnosing and screening for a disease or condition;
- monitoring the state or progression of a disease, condition, etc;

- specifying or recommending a treatment; and/or
- providing therapy (via provision of information).

Further, the TGA has sought to clarify the types of software products that will not be regulated as a therapeutic good in Australia. The Therapeutic Goods (Excluded Goods) Amendment (Software-based Products) Determination 2021 (2021 Determination) seeks to expand the list of excluded therapeutic goods under the Therapeutic Goods (Excluded Goods) Determination 2018. Generally speaking, whether the 2021 Determination applies will largely depend on the manufacturer's intended use and whether the software is intended to be used in clinical practice.

The above reforms come into effect on 25 February 2021 for new applications for inclusion in the Australian Register of Therapeutic Goods (Register). Transitional arrangements will apply for existing medical devices on the Register.



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Europe

EU embracing consumer class actions

The European Union is forcing all Member States to provide for collective actions in consumer matters by 25 June 2023 at the latest. The Life Sciences and Health Care sector is among the industries explicitly targeted by this approach.

Actions can bring infringements of EU consumer laws. The scope includes, among many other horizontal and sectoral laws, e.g., Regulation (EU) 2017/745 on medical devices, Directive 2001/83/EC on the Community code relating to medicinal products for human use (Articles 86-90, 98 and 100), Regulation (EU) 2016/679 (General Data Protection Regulation), and the Directive 85/374/EEC concerning liability for defective products.

EU Member States must adopt and publish the laws, regulations, and administrative provisions necessary to implement new Directive (EU) 2020/1828 by 25 December 2022. They must enable actions for redress measures, including compensation, and ensure that EU consumers can join the class of consumers concerned by the action. Only so-called qualified entities will have standing to bring the representative action but those qualifying for cross-border actions they will have standing in all Member States. They can move for injunctions, too.

It is important for the industry to understand how the Member States are going to implement the new directive, and which further changes may follow in the individual Member States. With regards to domestic litigation, the directive does not prevent them from adapting or retaining in force other types of class actions. Some may use this occasion to reshape or overhaul their mechanism for collective actions. We expect to see an increase in cross-border litigation in consumer matters. Having an international litigation strategy is more important than ever.



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Innovative therapies market access in France

With the expected wave of innovations, market access of innovative products is a priority for the industry. The French government has initiated regulatory changes in this respect.

The French Social Security Financing Act for 2021 amended early access and compassionate use of innovative products for patients. In parallel, the health authorities are initiating new methodologies for the scientific evaluation of innovative products (fast tracking, comparative approach, conditional assessment, organizational impact, etc.). These changes should result in the development of performance-based managed entry agreements, already negotiated in recent years with French pricing authorities, especially for gene therapies.

France is part of a European context of changes in the regulation of therapeutic innovations. Taking action concerning one of the most innovative field in pharmaceuticals, on 17 November 2020, the European Commission announced the revision of the “Tissues and Cells Directive” and the “Blood Directive” to fill the gaps in the current legislation, in particular for gene and cell therapies. A few days later, the Commission published a new Pharmaceutical Strategy, including as a main objective the accessibility and affordability of innovative products.

The steps taken by the Commission are important for the evolution of national legislations on market access - which remains a prerogative of member states.

These developments, though anticipated and called for by the industry, also happen in the context of the COVID-19 crisis. The availability of health products is now a major sovereignty issue. As announced by the French Government in September 2020, industrial presence will be included in the criteria for setting the price of pharmaceuticals and medical devices.

It might be too early to conclude whether this reflects the “dawn of a new era.” The nature of the pharmaceutical and medical devices market is shifting from “blockbusters” improving patients’ living conditions to “one-shot” therapies/products that cure long-term and rare diseases, such as the artificial heart of Carmat. The immediate prices of these innovations might be high for the payer, but the global impact on care management and reimbursement can be positive for all parties.

All of these elements should have an impact in the months and years to come on pricing and reimbursement negotiations for innovative products as well as their legal and regulatory framework, in France and across the EU.



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Launching first pharma product in Europe and early pitfalls

A pharmaceutical company planning to launch its first product in the EU needs to plan ahead to anticipate issues, such as applying for marketing authorization, setting up its first subsidiary, supply chain planning, and market access. In the EU, orphan drug manufacturers often engage even earlier in disease awareness activities and in finding patients. Depending on the launch sequence in the respective countries (e.g., often Germany is the first launch market), besides EU laws, local laws and industry rules must be respected – with many of them presenting early pitfalls. Based on recent issues we have observed with our clients, we recommend that pharma companies planning their first product launch in the EU:

- Ensure compliance with clinical trials and related data privacy obligations.
- Avoid entering the realm of pre-market promotion or direct-to-consumer advertising due to the very narrow definition of disease awareness in national laws.
- Develop a basic compliance structure and Standard Operating Procedures (SOPs) regarding engagement with public officials (like HCPs and market access representatives) as well as third parties, such as reimbursement advisors and patient advocacy groups (PAGs). Look out for contradictory local laws on fair market value (FMV) rates, contracting, mandatory transparency.
- Decide how best to comply with privacy obligations related to interactions with HCPs and PAG representatives.
- Prepare a legal review of your supply chain, especially when significant outsourcing is involved, including outsourcing to importers

and third party logistic (3PL) service providers. This is particularly important following Brexit. Check license requirements such as manufacturing/ import authorization (MIA), wholesale distribution license, and local requirements (e.g., exploitant in France).

- Be careful of involvement in named patient imports into the EU as these are regulated locally and may be prohibited or restricted.
- Set up inter-company agreements and demarcation of responsibilities, including medical, regulatory and legal review of communication, early pharmacovigilance, early product quality reviews (PQRs), etc.
- Ensure compliant governance of local subsidiaries, tax/finance agreements, and mandatory local requirements under local laws (e.g., minimum responsibilities of local managers)



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Beyond Brexit: TCA impact on medicines and medical devices

The Trade and Cooperation Agreement (TCA) between the EU and UK will have a significant impact on the pharmaceutical and medical device sectors, particularly in the context of regulation. Companies in both sectors need to review their existing arrangements to see if adjustments are required as a result of the reduced regulatory recognition between the EU and UK under the TCA. A number of the key changes and impacts are summarized below.

Medical devices and IVDs

The TCA does not cover medical devices nor in vitro diagnostic medical devices (IVDs). Consequently, manufacturers, authorized representatives, importers, and distributors operating in the EU and UK must now comply with two regulatory regimes.

UK: Following the UK Medicines and Healthcare products Regulatory Agency (MHRA)'s guidance, Great Britain will continue to recognize the CE marking and CE certificates of Conformity issued by EEA based Notified Bodies until 30 June 2023. After this date, a new route to market culminating in a UKCA mark will replace the CE mark.

In Northern Ireland, EU medical devices legislation will continue to apply. Subject to various grace periods, all medical devices or IVDs placed on the UK market must be registered with the MHRA. Manufacturers are required to either have a legal presence in the UK or to appoint a UK-based responsible person.

EU: Manufacturers of medical devices or IVDs for the EU market that have a UK authorized representative or notified body need to switch to

an authorized representative or notified body in the EU.

Medicines

The TCA provides for the mutual recognition of GMP inspections by competent authorities in the EU and UK, and for the exchange and acceptance of official GMP documents. However, this framework does not extend to other key regulatory areas such as mutual recognition of batch release certification or GCP inspections.

UK: The MHRA will recognize QP certification for batch release conducted in an “approved country,” which includes EEA member states for products placed on the UK market before January 2023. UK-based entities must appoint a “Responsible Person for import” to perform checks on the imported medicinal products.

EU: Final batch certification and subsequent release decisions for the EU can no longer occur in the UK. Marketing authorizations for EU member states that include a UK batch release site need to be varied to include a batch release site within the EU.



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Legal 500 UK, 2020

Changes in regulatory landscapes in Russia

Simplified procedures for obtaining Marketing Authorizations (MA)

A new simplified procedure for obtaining an MA extends to 36 types of medical devices, including medical masks and respirators. The simplified procedure allows obtaining MA without submitting results of any trials/tests. If no request is issued by the regulator, MA will be issued within five business days. The applicant for MA must complete trials/tests after receipt of MA.

The simplified procedure for obtaining MA for medicines that are, for instance, intended for prevention and treatment of diseases that pose a danger to others, is also available.

Online sale of over-the-counter medicines

Online sale of over-the-counter medicines has been legalized in Russia. There is also an initiative to allow selling prescription drugs online.

Tightening liability for sale of counterfeit and substandard medicines

More severe administrative and criminal liability (including suspension of company's activities and imprisonment up to 12 years) has been introduced to mitigate the risks caused by the online sale of medicines.

Track & trace system

In July 2020, the track & trace marking of medicines became obligatory in Russia.

Patent linkage

The Russian PTO promises a prompt launch of the register of APIs protected by patents. The procedure for obtaining MA also provides the requirement to indicate in application information on IP rights that are used in the medicines and valid in Russia.

Softening restrictions of state procurement of foreign medicines

Stimulation of local production of medicines and medical devices remains high on the agenda of the Russian regulator. In 2020, limits of the approach focused on import substitution became evident, which resulted in a new trend to soften restrictions relating to state procurement of foreign medicines. We see additional softening of these restrictions in Russia in 2021.



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The United States

Biden Administration impact on life sciences and health care

President Biden's top priority is to end the raging COVID-19 public health and economic crises. In his first days in office, Biden signed 12 executive orders to solidify federal coordination and support for an equitable pandemic response and recovery, increase vaccine and testing supply and access, and revitalize the country's public health infrastructure. He also encouraged the Department of Health and Human Services to create a special enrollment period for the Affordable Care Act's Exchanges and to spend US\$50 million on related outreach and education efforts.

But, recognizing that legislation will be needed to accomplish some of his goals, President Biden has reached out to Congress to pass a bipartisan COVID relief package that includes a national program to speed up the distribution and administration of COVID-19 vaccines across the country, funding to hire 100,000 new public health workers for testing and tracing, measures to address supply shortages, support for development and distribution of new treatments, and reductions in the cost of insurance premiums. Republicans in Congress uniformly rejected this proposal, however, despite calls from some Republican governors to "go big." In response, Congressional Democrats

are preparing to use the reconciliation process to pass a bill along party lines. This process could drag on for weeks, but we expect Democrats will ultimately be able to pass a bill.

Additional legislation later this year could include other health care proposals. These are most likely to be ideas with some Republican support, such as measures to lower drug prices, increase health insurance tax credits for lower income Americans, or incentives to convince hold-out states to expand Medicaid eligibility, instead of large-scale overhauls, such as a public option plan or Biden's "Medicare for More" proposal, which would lower the eligibility age to 60.



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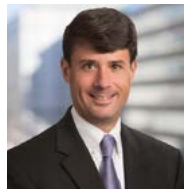


Biden’s potential use of the Defense Production Act

At the outset of the pandemic last spring, one of the key tools that the U.S. government invoked to address supply chain issues and to procure products was the Defense Production Act (DPA). The DPA provides the government with a broad set of authorities to influence domestic industry in the interest of national defense, including the authority to: (1) issue “rated orders” to commercial suppliers, and (2) allocate materials and facilities to further these needs. DPA rated orders generally go to the “head of the line” as compared with existing commercial orders.

The Trump Administration utilized the DPA on multiple occasions, issuing rated orders for COVID-19 vaccine, PPE, and ventilators. The Biden Administration has made clear that it also is committed to utilizing DPA authorities, and that it will aim to approach DPA use more holistically and strategically. It already has announced initiatives to accelerate domestic production, both up and down the supply chain – to cover production of vaccines, therapeutics, and COVID-19 tests, as well as needed raw materials and components (e.g., glass vials and needles).

Indeed, strategic use of the DPA requires analysis of the various – and potentially significant – impacts from all angles, including effects on international trade/supply chain and public health in the broadest sense. As DPA rated orders prioritize government orders above all others, they have the potential to impact supply contracts with foreign governments. For example, any delay of COVID-19 vaccines obligated under existing contracts could well be met with foreign retaliation, including restrictions on exports to the U.S. of supplies and raw materials needed for vaccine manufacture. Additionally, DPA orders could have ripple effects on drug and device manufacture across-the-board in terms of shortages or delays in manufacture of products needed to treat other critical diseases. Balancing these various concerns will need to be front and center in any successful DPA strategy.



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“Buy American” response to the pandemic

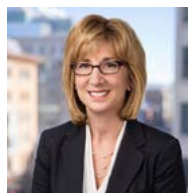
As the COVID-19 pandemic has progressed, legitimate concerns have been raised about U.S. dependency on drugs, devices, raw materials, and supplies manufactured abroad. While the need for vaccines, treatments, tests, and PPE has come into sharp focus, and has been addressed in the short term through Operation Warp Speed contracting and emergency procurement under the DPA, the broader need to enhance U.S. manufacturing infrastructure to support domestic availability of all critical medicines and inputs has become increasingly clear.

In 2020, the Trump Administration took steps toward “onshoring” U.S. manufacturing of drugs and medical devices with a focus on strengthening preferences for U.S. products in government procurements. Trump issued a much-anticipated “Buy American” Executive Order in August 2020, intended to increase and support domestic manufacture and federal government procurement of “essential medicines,” “medical countermeasures,” and “critical inputs” (including API, raw materials, and medical device components), and decrease dependency on non-domestic sources. Legislation has also been introduced to enable the government to take stock of existing supply chains for essential medicines and enhance domestic production.

For its part, just days after the January 2021 inauguration, the Biden Administration directed contracting agencies to focus on strengthening preferences for U.S. products in government procurement, and to consider

products to be identified as domestic based on value-add manufacture and job creation in the United States. President Biden is also expected to issue an executive order calling for a review of critical supply chains to reduce U.S. dependence on imports of materials and equipment.

We expect key government initiatives this year to include continued orders under the DPA, amendment of existing procurement regulations (and possibly statutory changes) to extend stronger domestic preferences in federal procurements, and federal funding and financing initiatives to support domestic manufacturing and capacity development. We can expect the Departments of Health and Human Services (HHS) and Defense (DoD) as well as the White House COVID-19 Response Team to be actively involved in these efforts. In sum, 2021 will likely bring a steady flow of contracting, rulemaking, and legislative activity aimed at supporting and expanding domestic manufacture of pharmaceuticals and devices.



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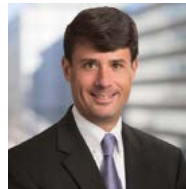


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2021 FDA projections for the medical device industry

Many are looking at 2021 as being active for FDA to re-focus on those items that were put on pause due to the pandemic. Although early priorities will focus on vaccinations and devices still needed during a dissipating pandemic, here are three areas that we believe FDA could make a priority for the medical device industry.

- **Increased enforcement:** 2015 – 2020 has been a period with a significant decrease in CDRH enforcement and Warning Letter issuance. With a new administration and CDRH restructure now complete, the pendulum will likely swing back with a renewed interest on enforcement and ensuring compliance. We could see a repeat in the increase of inspections and enforcement actions that was seen after the recession in 2008/2009. FDA efforts will likely focus on areas of highest risk, including class III products, post-market trends/recalls and new market entrants that have never been inspected. Even those participating in MDSAP could be prioritized and inspected “for cause.”
- **Border scrutiny:** One of the unfortunate results of the pandemic has been the market flooded with inferior products. Many fraudulent and/or otherwise illegal products have been caught due to increased scrutiny by U.S. Customs and FDA. With the lessons learned during the pandemic, increased scrutiny will likely continue leading to increased import detentions and possibly increases in the issuance of import alerts.
- **Regulation of LDTs:** Consistent with recent statements and policies by HHS, 2021 could be the year that FDA seeks to regulate Laboratory Developed Tests (LDTs) through notice-and-comment rulemaking. This could occur without a grant of legislative authority, which has been a barrier that has prevented prior regulatory efforts. Despite HHS’s recent statements indicating that FDA has such authority, we expect to see some back-and-forth before it is settled as to how FDA will regulate LDTs.



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Chambers USA, 2020

Speeding medical device approval and reimbursement

The Food and Drug Administration (FDA) Breakthrough Devices Program, finalized in 2018, continues to gain traction, with the numbers of requests and devices granted this designation steadily increasing. While the benefits for the FDA clearance/approval process are attractive, the primary driver seems to be the reimbursement benefits, which are of substantial interest to investors driving innovation.

The program is intended to speed development and review of devices which provide for more effective treatment/diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Features of the program include increased interaction with FDA, including mechanisms for quicker interaction like Sprint Discussions, and prioritization of the submission in the review queue.

However, it is becoming apparent that FDA cannot grant breakthrough status to all devices which may be eligible, especially in review groups where most devices would qualify (e.g., cardiovascular). Given the increased competition to obtain breakthrough status, it is critical that companies present their strongest case in their application. Key considerations include the timing of the breakthrough request in the development program, and justification for meeting the eligibility factors, especially showing the device is reasonably expected to be “more effective” than the standard of care.

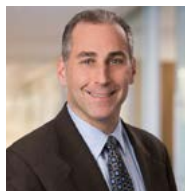
Obtaining breakthrough device designation has tangible benefits from a Medicare coverage and payment perspective, and perhaps for other payers. Under a recently issued Centers for Medicare & Medicaid Services (CMS) final rule, an FDA designated breakthrough device is eligible for four years of national Medicare coverage from the date of FDA marketing authorization.

From a Medicare payment perspective, having breakthrough designation makes it easier to qualify for special, additional reimbursement. Under Medicare’s inpatient hospital payment system, hospitals may receive extra payment for technologies that qualify for new technology add-on payments (NTAP). An FDA designated breakthrough device is deemed to meet the most difficult two of the three criteria to qualify. Similar, under the Medicare hospital outpatient payment system, devices are eligible for separate payment if they qualify for pass-through status. Breakthrough designation means that the device automatically meets the difficult “substantial clinical improvement” criterion. Thus, breakthrough designation facilitates the ability to obtain these special additional payments.

Given these reimbursement benefits, we only expect competition to increase for breakthrough status in the coming years. For devices which do not qualify for this program, there may be an opportunity to qualify for FDA’s Safer Technologies Program (SteP), which was finalized in January 2021, for devices targeting non-life-threatening conditions; however, there are no similar reimbursement benefits for this program.



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Combination products

Combination products are multicomponent therapeutic systems with feet planted in separate regulatory worlds. Development pipelines are expanding to accommodate increasingly complex, integrated systems. We have been side-by-side with our pioneer clients on charting pathways for novel drug eluting implants, prefilled injectors, complex inhalation systems, and newer drug-biologic therapies.

Classification and jurisdiction based on primary mode of action is often murky. There is an absence of clarity and consistency in determining which products may be reviewed under a single New Drug Application (NDA) or Biologics License Application (BLA), and which types of products may require a device 510(k) or Premarket Approval (PMA). The divide between CDER and CDRH on clinical trial design, endpoints, and outcomes among closely related combination products – where some are directed to CDER and some to CDRH – creates even more uncertainty.

Meanwhile, FDA has widened its lens for what constitutes a combination product, and in some cases has indicated that components previously regulated as containers may be considered device constituents of a combination product. This has been jarring for companies with GMP compliance cultures who may be less fluent in device quality standards.

The patent and exclusivity landscape for combination products has also changed markedly in the last few years. For drug-device combination products with a device primary mode of action, the 21st Century Cures Act now applied Hatch-Waxman requirements to the premarket review process. Patent certification

and drug exclusivity provisions, including orphan drug exclusivity, can be read onto the device clearance and approval process. On the drug side, one immediate issue is whether FDA will take steps to limit listing of “device-only” patents in the Orange Book. The newly enacted “Orange Book Transparency Act of 2020” gives legislative backing to the process FDA began in June 2020 seeking feedback on current patent listing practices.

Finally, 2020 saw the FDA abandon a proposed regulatory approach for medical devices referencing drugs that would have allowed devices to be authorized for new uses with already approved drugs without the participation of the drug sponsor. The question of mutually conforming labeling is a thorn for device sponsors who are seeking the use of approved drugs, and a solution to the “cross-labeling” problem remains elusive.



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Complex generics

In the brackish waters between drugs and biologics lies a diverse class of innovative drug products with an important common denominator: they are difficult to copy. Referred to in the EU as “non-biologic, complex drugs,” and called “complex generics” by FDA, the original generic drug laws did not contemplate these products.

Complex generics include (1) Complex Active Ingredients, such as low molecular weight heparin, peptides, nanoparticle iron, complex mixtures, natural source products, (2) Complex Formulations, such as liposomes, microspheres, copolymers, (3) Complex Routes of Delivery/ Locally Acting Drugs, and (4) Complex Drug-Device Combinations.

Under the Drug Competition Action Plan and GDUFA II, FDA is authorized to invest substantial research dollars into solving the problem of adapting the generic drug approval system to fit these complex substances. In 2020, FDA established the Center for Research on Complex Generics at the University of Michigan and the University of Maryland.

Complex generics can be inordinately difficult to manufacture and characterize. In addition to pharmacokinetic studies, they may require extensive in vitro, pharmacodynamic, clinical and other data. The question is whether these kinds of data are capable of showing “sameness” and bioequivalence; and whether FDA has the authority to review the data under a generic drug application. Unlike the biosimilars pathway –

which contains an expectation that uncertainties between the test and reference products will be addressed with new clinical data – for complex generics there is no such provision.

In addition to establishing “sameness” for inherently complex substances – particularly natural source products and synthetic peptides – many complex products (e.g., combination products and long acting depots) raise bioequivalence study issues. FDA has been working on a variety of in vitro models to relieve generics from having to conduct lengthy in vivo studies, but the validity of these models remains unresolved.

These types of products have gained attention from high end generic sponsors, who see an opportunity to enter as a lone generic, or a lone 505(b)(2) competitor, where the norm for most generics is to enter as one of many in a crowded field.



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Latin America

Public procurement of health inputs

Procurement reform has been a top priority from the outset of the current Mexican administration. This has become a more pressing issue in the context of the COVID-19 pandemic.

After a fast-track procedure, an amendment to the Federal Law of Acquisitions, Leasing and Public Sector Services (Procurement Law) was published on 12 August 2020. This amendment is aimed to except from the application of said statute the procurement of health inputs (e.g., medicines) and services carried out by public entities through international intergovernmental bodies under collaboration schemes that have been agreed upon.

The result is a significant game changer for the suppliers of the pharmaceutical industry. The traditional legal framework for public procurement is no longer applicable, but instead, the rules of the specific international bodies apply. Although international entities have more sophisticated rules and less red tape in their internal procedures, such rules are likely to impact the way complaints can be filed. In addition, international entities may not have independent supervising bodies to solve bidders' claims.

Aimed at compliance with the requirement of having a collaboration scheme before conducting a procurement through an international entity, the Institute of Health for Welfare (Instituto de Salud para el Bienestar) (INSABI) entered into an agreement with the United Nations Office for Project Services (UNOPS). As a result, the procurement of medicines is now carried out through the UNOPS under a consolidated scheme. Consolidation activities started several years ago, and they involve grouping together the needs of several public health entities.

The new procurement system has posed significant challenges to the industry, from approaching the authorities to the formalities and requirements that are now applicable to participate in a tender or for obtaining a direct award. These processes have resulted in the need for advice that is both novel and speedy.



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Medicinal use of cannabis: A reality in Mexico

After several years and the granting of several extensions given to the Congress by the Supreme Court of Justice, finally on 12 January, 2021, the first statute for formally regulating the medicinal use of cannabis in Mexico was enacted.

The Regulations to the General Health Law for the Sanitary Control of the Production, Research and Medicinal Use of Cannabis and its Pharmacological Derivatives, have as main purpose the harmonization of the applicable legal framework with respect to the amendments to the General Health Law and the Federal Criminal Code regarding cannabis matters.

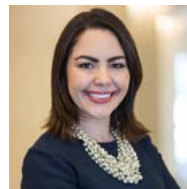
With the publication of this new statute, different activities such as the: (i) growing, (ii) production; (iii) pharmacological and medical research, (iv) manufacture, (v) importation, (vi) exportation, and (vii) marketing of cannabis and its pharmacological derivatives for preventive and therapeutic purposes will be now permitted in Mexico.

Even though the regulations do not cover products with agronomic and industrial purposes, such as the control of products with large industrial uses containing cannabis derivatives of less than 1 percent of THC (e.g., food, cosmetic products, etc.), this new legal framework is a big step forward for the regulation of cannabis and the access to the population to new and innovative treatment alternatives, representing a momentum for the pharmaceutical industry and cannabis producers for investing in new jurisdictions and new areas of treatment.

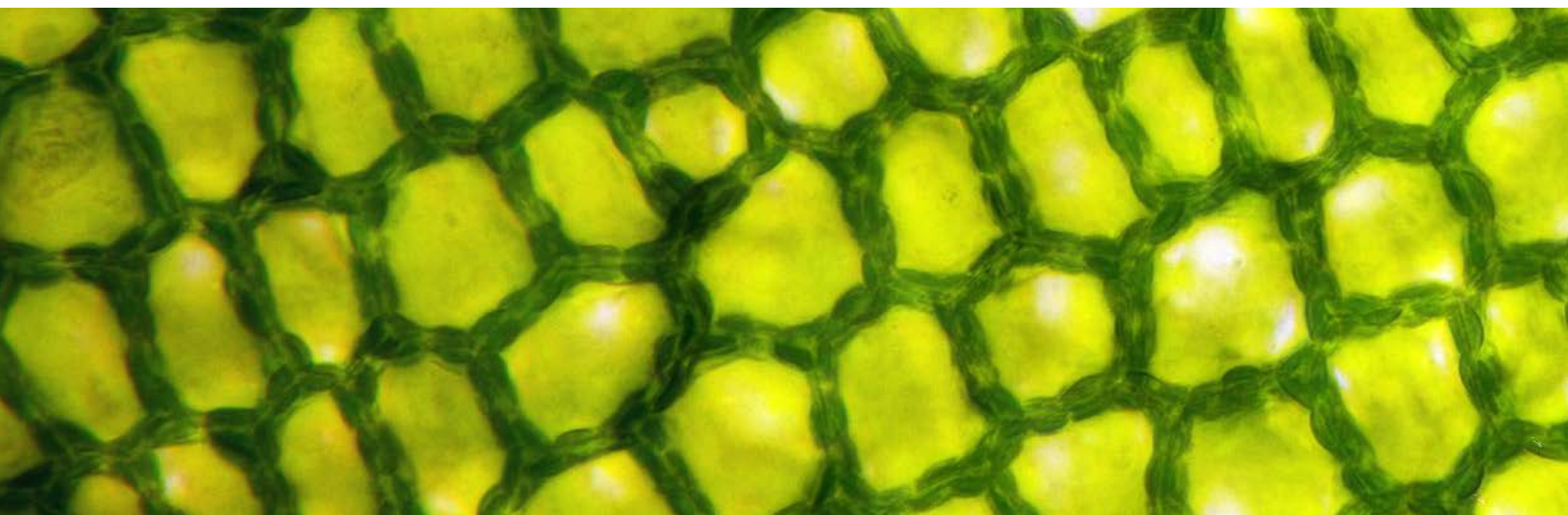
For now, the main challenge is the correct and efficient implementation of the provisions of the regulations by the Health, Economy, Customs and Agricultural authorities in Mexico, for pursuing a successful and innovative framework.



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Regulation of digital health

Discussions around the urgency in evolving in the way in which health care services need to be regulated and rendered have risen due to the COVID-19 pandemic. Technology, AI, non-traditional devices (e.g., wearable bands and fitness devices) have become key elements for the need to render distance health services for improving health quality, cover more of the population, and enhance and facilitate diagnostics and treatments in Mexico.

Both private and public sectors engaged in the rendering of health care services are currently demanding a more comprehensive and clearer legal framework that allows stakeholders to work under more solid and well-structured regulations that fit within the current health needs and resources.

Both federal and state governments have implemented provisional policies for promoting the rendering of health care services through electronic means due to the COVID-19 pandemic. This has resulted into an increasing number of legislative initiatives

aimed to transitioning into a health legal framework adequate to the current needs and circumstances, towards fostering telehealth and digital health technologies in Mexico.

Digital health and telemedicine are not specifically regulated as such by the current sanitary legal framework, but are subject to compliance with the general principles and requirements for rendering face-to-face traditional health care services. We predict new developments in the regulation of telehealth, AI, alternative and innovative health solutions and, in general, for the rendering of health care services, diagnostics and treatments through electronic means, are likely to come in the short and midterm.

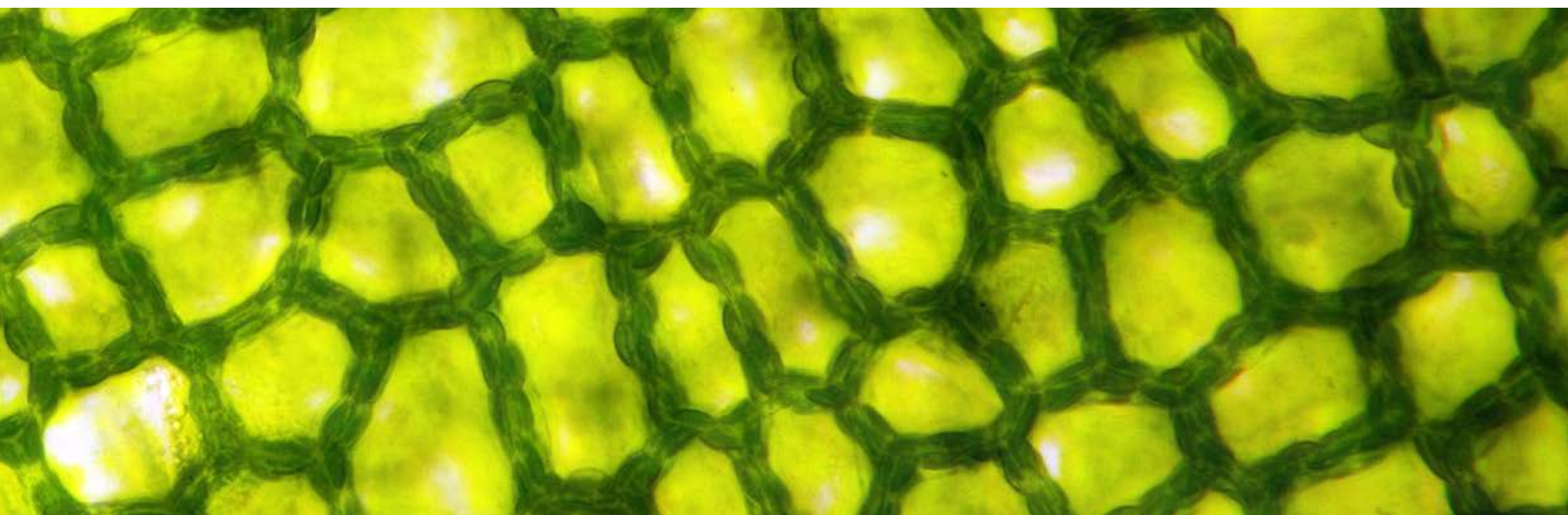
The use of new technologies is a trend that private and public companies in the life sciences and health care sector are eager to seize upon, as they continue to advocate for a governmental public policy change that better promotes digital health and telemedicine in Mexico.



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Anti-corruption efforts and enforcement actions in Brazil

The enactment of the Brazilian anticorruption legislation in 2014 (known as the Brazilian Clean Company Act – Law No. 12,846/2013) has brought significant changes with respect to measures against corruption in Brazil. Brazilian authorities have been drawing their attention and efforts to combat corruption, big-rigging, and other unlawful conduct against renowned companies and individuals.

The major and most important federal anti-corruption investigation known as Operation Car Wash has played a huge role in Brazil, as billions of reais were recovered, thousands of individuals were arrested, hundreds of companies were convicted, and innumerable international agreements have been entered into. Ever since the release of Operation Car Wash, Brazilian authorities have also focused their attention and efforts to fight unlawful conduct carried out within the life science and health care industries.

Significant anti-corruption investigations such as Mafia of Prosthetics, Operation Pacemaker, and Operation Resonance, among others, carried out in Brazil, are examples of relevant and significant investigations conducted by the Brazilian authorities with a focus on the health industry, with the extensive cooperation of international authorities, including the U.S. Department of Justice. Individuals and companies that have been investigated and prosecuted in connection with those investigations were accused of making improper payments and paying kickbacks to HCPs with the intent of influencing them to use medical devices, including stents, orthoses, and prostheses, among other unlawful conduct.

Brazilian public authorities have continued to focus their efforts on the health industry during the COVID-19 pandemic. As a result of the pandemic, some emergency measures were approved by the

Congress which included the flexibilization of rules related to the public procurement laws with respect to purchase of goods by hospitals to deal with the pandemic. Brazilian public authorities remained vigilant in detecting, investigating, and prosecuting wrongdoings and commenced several investigations throughout Brazil concerning the overpricing of materials, the lack of public bids, fraudulent bids, and deviations of public resources, such as the Operations Desvid-19, Virus Infection, and Olet.

As a positive note, compliance policies and procedures have become a norm in Brazilian business operations in view of the enforcement of the new anticorruption law and change in culture. Brazilian companies and multinationals with branches in Brazil have been enhancing their compliance programs including with respect to controls over employees and third-party providers, the provision of more training or undertaking risk assessments. Also, the public administration has begun demanding proof of a compliance program when bidding out for hiring of goods or services from the private sector. A strong compliance culture is a key factor to prevent corruption and this cultural change has come to stay in Brazil.



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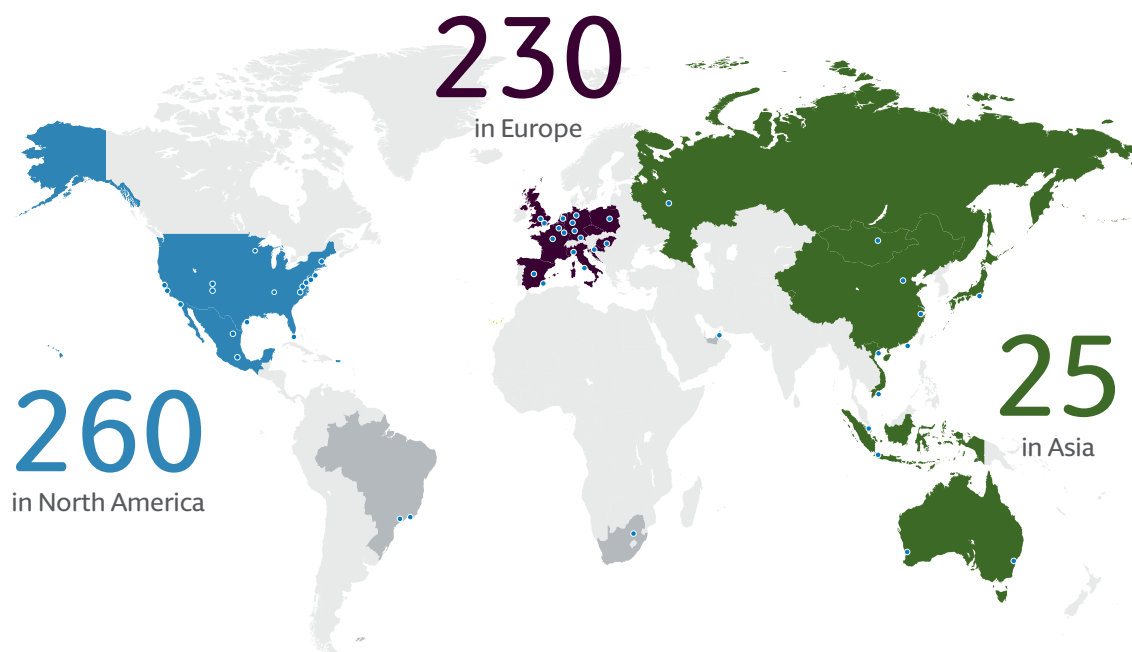
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Get in Touch

Life Sciences and Health Care Horizons provides only a snapshot of some issues the industry will face in 2021. Our team is focused on tackling these issues to provide our clients around the globe with valuable and innovative solutions to their most complex challenges — present and future.

To learn more about our team or any of the issues covered, please contact any of the authors in this publication, or one of the partners you regularly work with at Hogan Lovells.

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