Life Sciences

As the legal matters confronting our life science clients are varied, so are the skill sets we employ. DLA Piper's life sciences team comprises lawyers with legal, scientific and medical knowledge who understand the complexity of the business and regulatory environments in which our clients operate.

The challenges facing today's biotechnology and medical device companies are greater than ever. For companies to take promising therapies from the laboratory to the market, they must protect those therapies from IP, regulatory and reputational risks. Furthermore, the last few years have seen increasing pressure from many sides: demand for greater shareholder return, loss of key revenue streams due to patent expiration or generic challenges, fierce competition in key therapeutic areas, pricing pressures from health care payors, increased government regulation beyond core safety issues, rising costs of R&D, challenges in maximizing return in emerging markets and aggressive government enforcement action.

Our life sciences sector team is one of the largest and most active of any law firm. Operating as one team across more than 30 jurisdictions, we combine subject matter experience with considerable knowledge of the sector, including the scientific, medical, regulatory, commercial and enforcement environments facing our biopharmaceutical, medical device, research and diagnostics clients.

DLA Piper's team includes award-winning lawyers practicing litigation, compliance and investigations, IP strategy and enforcement, M&A, licensing and distribution and clinical trial advice. They also support clients across all other areas needed to address risk, including government affairs, environmental law, import/export, tax, real estate and employment law. Many of our lawyers are former sector professionals, many have PhDs or other advanced degrees in the life sciences field and others are former government officials or prosecutors.

Recognizing that our clients' needs vary, we rapidly organize and customize our client service teams, whether for a large pharmaceutical company, a mid-sized medical device client or a development-stage biotech company. These teams are supported by international and local practitioners to efficiently meet the demands of the matter.

Our cutting-edge staffing, budgeting and billing systems, created specifically to assist our global life science clients, ensure that our teams deliver value in addition to great results.

Our life sciences team helps clients solve their biggest challenges every day. Examples of our experience include:

- Conducting a sensitive investigation in China
- Negotiating a complex multi-country distribution deal in Latin America

KEY CONTACTS

Marco de Morpurgo
Partner
Rome
T: +39 06 68 880 1
marco.demorpurgo@dlapiper.

Andrew P. Gilbert
Partner
New Jersey (Short Hills)
T: +1 973 520 2553
andrew.gilbert@dlapiper.com

Matt Holian
Partner
Boston
T: +1 617 406 6009
matt.holian@dlapiper.com

RELATED SERVICES

- Antitrust and Competition
- Corporate
- Employment
- FDA
- Intellectual Property and Technology
- International Tax Counsel
- Litigation, Arbitration and Investigations
- Real Estate
- Tax

RELATED SECTORS

- Digital Health

- Acting as National Counsel on a mass tort in the US
- Helping sell or acquire a major business asset
- Advising on implementation of transparency laws or the impact of other new legislation
- Devising a risk mitigation plan for a key product
- Negotiating a large vaccine contract with a global NGO
- Counselling on a multi-jurisdictional clinical trial
- Advising on the downsizing of employees in Europe
- Supporting global business conduct and compliance functions
- Outsourcing critical R&D or IT functions
- Devising an IP strategy for a promising new therapy
- Negotiating a worldwide licensing and collaboration deal
- Protecting a blockbuster drug in patent litigation

INSIGHTS

Publications

Preliminary injunction granted in Cal Chamber lawsuit concerning acrylamide Prop 65 warning

1 April 2021

California's Eastern District federal court found that Prop 65's acrylamide warning requirement was likely unconstitutional and preliminarily enjoined new lawsuits alleging failure to warn for acrylamide exposure in food and beverages.

Patent eligibility in bioinformatics: Federal Circuit affirms rejection of computerized haplotype phasing claims

31 March 2021
Yet another hurdle for inventors in the growing field of bioinformatics and computational biology.

The Pharmaceutical Corner

30 March 2021
The opinion may render functional claiming more difficult, but functional claims that follow its guidance may still have an important role to play in pharmaceutical patents.

Understanding the USPTO guidance on patenting AI technologies

30 March 2021
The USPTO guidance opens the door for applicants to obtain patent protection for their AI technologies.

United States imposes significant new export controls and sanctions on Russia and China

23 March 2021

Reflecting a further hardening of US foreign policy and national security policy positions with those two countries.

California Prop 65: OEHHA proposes changing popular short-form warning

3 February 2021
Businesses selling products in California that utilize short-form Proposition 65 warnings may have to be re-label yet again or risk enforcement actions.

Telehealth's impact on low-income communities

3 March 2021

Ray Williams and Kirsten Axelsen are joined by Dr. Benson Hsu of the University of South Dakota Sanford School of Medicine for a frank discussion on disparities to engaging with telehealth and ways to better serve low income communities.

Expectations for white collar enforcement under the Biden Administration

18 February 2021
Six key areas where the Biden Administration may focus its enforcement efforts.

Corruption Perceptions Index 2020 - a regional perspective

11 February 2021

Last week Transparency International launched the 2020 edition of its Corruption Perceptions Index (CPI), which ranks 180 countries and territories by their perceived levels of public sector corruption, according to experts and business people, using a scale of zero to 100 (100 being very clean and zero being highly corrupt).

The Qualified Maquiladora Approach Agreement has been renewed: Implications for multinationals' transfer pricing

26 January 2021
US-based multinationals using the maquiladora structure to manufacture goods in Mexico are taking note.

Israel Group News January 2021

19 January 2021
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

No Surprises Act creates new model for commercial payors and providers

7 January 2021

The act contains consumer protection and transparency requirements that may fundamentally change health payor and provider operations.

Supporting the health of your health system

4 January 2021
Helping you tend to healthcare system wellness throughout the business life cycle.

Boardroom Brexit: What the deal means for business

31 December 2020
BOARDROOM BREXIT

Welcome to this last edition of Boardroom Brexit, marking the end of the negotiations and the agreement of a new trade deal, the UK-EU Trade and Cooperation Agreement (TCA). In this edition, we summarise the impact of the deal on all aspects of business operations in one place – please use the hyperlinks below to help you navigate the report.

Boardroom Brexit: What the deal means for trade in goods

31 December 2020
BOARDROOM BREXIT

What will the Trade and Cooperation Agreement mean for tariffs and quotas, rules of origin, technical barriers to trade, customs and product standards

---

Boardroom Brexit: What the deal means for trade in services

31 December 2020
BOARDROOM BREXIT

The TCA has substantial sectoral coverage, including professional and business services (e.g. legal, auditing, architectural services), delivery and telecommunication services, computer-related and digital services, financial services, research and development services, most transport services and environmental services.

The EEOC breaks its silence on the COVID-19 vaccine

22 December 2020
Some of the most important questions answered by the EEOC's guidance.

The Pharmaceutical Corner

22 December 2020
A precedential decision with potentially far-reaching impacts for future Hatch-Waxman litigation and generic-product launches.

Landmark artificial intelligence legislation advances toward becoming law

16 December 2020
AI OUTLOOK

An overview of the key AI initiatives and funding set out in the defense bill.

Navigating risk and compliance in government contracts M&A

14 December 2020
Webinar now available: government contracts and pre-closing diligence.

Silver linings for FCA defendants in new HHS Working Group

11 December 2020
The US Department of Health and Human Services is launching the Working Group to better protect taxpayer funds and deter "would-be fraudsters."

FDA seeks feedback on industry best practices for medical device cybersecurity communications

9 December 2020
The agency emphasizes the evolving responsibility of medical device manufacturers to promptly, clearly communicate cybersecurity issues to patients and healthcare providers.

CMS, OIG finalize Stark and AKS overhaul – paving the way for value-based care

25 November 2020
We highlight some of the most important ways in which HHS followed through on its ideas from 2019, as well as the instances where they pivoted in reaction to public comments.

HHS-OIG issues alert warning pharmaceutical and device manufacturers about the kickback risks of speaker programs

24 November 2020
Key details and takeaways.

The US Hemp Production Handbook

4 November 2020
A concise, high-level overview for businesses that are currently or are considering operating in this growing market.

Vaping and COVID-19: Plausibility and causality

26 October 2020
In a courtroom, assertions must be analyzed in the context of tort law.

China signs off on PRC Biosecurity Law: What this means for industry players in China

21 October 2020
The Biosecurity Law establishes a comprehensive framework replacing the current somewhat piecemeal legislation.

Germany’s New Foreign Direct Investments (FDI) Act took effect on 11 October 2020

19 October 2020
In addition to the intended amendments to the Foreign Trade and Payments Act Germany’s Federal Government on 20 May 2020 has decided on a bill that broadens the scope and the scrutiny with regard to foreign investments.

China Enforces Tax Collection on Employees Working for Chinese-invested Enterprises Overseas

16 October 2020
With the recent IIT reform in 2019, and the introduction of a number of implementation rules (particularly the tax policy on overseas income), it appears the China tax authorities are taking a harder stance on how overseas income derived by China tax residents will be taxed in China, starting with Chinese expatriates working for Chinese state-owned enterprises.

COVID-19 – Galvanising your business against supply chain and customer insolvency risk

7 October 2020
The risk of unforeseen counterparty customer or supplier financial distress and failure amidst the on-going challenges for businesses from COVID-19 means that pre-emptive legal and operational protections against the risk of heavy financial loss or business disruption from customer/supplier failure are more valuable than ever.

Israel Group News October 2020

7 October 2020
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

Mass layoffs and collective redundancies guide

6 October 2020
As COVID-19 continues to impact the global economy in unprecedented ways, companies that have had to scale back or shut down operations are bracing for what the next few months will bring, and what this means for their workforces. In this guide, we examine key considerations for employers looking to make permanent reductions in force across APAC.

Coronavirus Resource Center: Our global repository of insights and events

30 September 2020
A central repository for our reports and commentary on the legal and regulatory concerns arising from the pandemic.

New CFIUS regulations change mandatory filing requirements and increase the importance of US export controls

30 September 2020
The new rule modifies the criteria that trigger a mandatory filing with CFIUS, potentially subjecting more transactions to mandatory CFIUS review.

Philadelphia grows privacy capabilities with a new arrival

30 September 2020
Ronald Plesco, an internationally known information security and privacy lawyer, has joined our Philadelphia office.

The Pharmaceutical Corner

30 September 2020
In this inaugural column, we look at the implications of IPR and PGR proceedings in Hatch Waxman litigation.

California on the verge of instituting new deidentification requirements, broader research exemptions for health data

23 September 2020
AB 713 has an emergency clause that means it will go into immediate effect once the governor signs it.

Four years later, federal court upholds convictions but harshly criticizes off-label prosecutions

23 September 2020
The decision will likely draw attention both in the First Circuit and beyond.

Digital Therapeutics - evolution and entry into mainstream healthcare

18 September 2020
Research undertaken by DLA Piper's Life Sciences sector in conjunction with The Lawyer seeks to understand the current developments in the field of digital therapeutics, looking at key questions that need to be addressed if these products are to become mainstream components of health systems across the world.

PREP Act immunity: federal courts weigh in

4 September 2020
The decisions suggest PREP Act immunity may apply broadly to manufacturers but may be more limited for hospitals, nursing homes, healthcare providers and others.

Details of the second tranche of Hong Kong’s Employment Support Scheme released

24 August 2020
On 18 August 2020 the Hong Kong government announced details surrounding the second tranche of the Employment Support Scheme. While the majority of the rules surrounding the second tranche remain largely the same as the first tranche, there are new penalties for employers who have fallen foul of a number of nebulous terms.

Release of exposure draft legislation for major reforms to Australia’s Foreign Investment Framework

10 August 2020

Many governments around the world have been strengthening their laws relating to foreign investment. Australia is no exception to this development and has just released proposed sweeping reforms to its foreign investment regime. In this article, we provide a high level

overview of the key proposed amendments and our thoughts on how some of those proposals are likely to affect foreign investment into Australia.

For the healthcare industry, seeking to incentivize restocking of elective surgery supplies may lead to civil and criminal risk

6 August 2020
Discounts and incentives may have unforeseen consequences under certain federal anti-bribery laws.

New Executive Order forecasts permanent telehealth funding changes

5 August 2020
The Order implies a possible mechanism for making telehealth changes in spite of statutory confines and signals to Congress to take further action to permanently expand telehealth access in the Medicare program.

Vlog series: How to raise equity capital during the Coronavirus pandemic (UK)

4 August 2020
The first half of 2020 has seen an unprecedented volume of activity by companies raising capital through follow-on equity offerings on the London Stock Exchange in response to the Coronavirus pandemic. There have been over 140 equity issues on the London Stock Exchange's main market or AIM since 20 March 2020 raising more than GBP14 billion.

HHS extends COVID-19 public health emergency declaration, preserving major Medicare changes (for now)

27 July 2020
The PHE declaration is an important prerequisite for certain major emergency measures the government has deployed to help address the pandemic.

Momentum builds for permanent expansions in federal telehealth policy

21 July 2020
Recent legislative proposals and administrative initiatives suggest that the federal government may be moving to make permanent certain emergency fixes to the telehealth regulatory landscape.

Hong Kong Government increases statutory entitlement for maternity leave

16 July 2020

On 10 October 2018, the Chief Executive stated in her policy address that the government proposed to increase the statutory maternity leave entitlement from ten to 14 weeks.

Israel Group News July 2020

8 July 2020
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

The legal challenges facing the vaping industry in the EU/UK and the US: An overview and a look ahead

7 July 2020
Notes as the industry matures.

CMS proposed rule aims to encourage value based purchasing for drugs, now open for comment

6 July 2020
The rule is intended to spur the development of contractual arrangements between insurers and biopharma companies that rely on the observed value from medicines in exchange for payment.

Clinical trials during the COVID-19 pandemic: A global guide

2 July 2020
The consequences of the COVID-19 pandemic continue to develop dynamically. Some countries are beginning to ease lockdown measures, whilst other retain or even impose new restrictions. The situation continues to impact the ability to conduct clinical trials on a global scale. Pharmaceutical companies need to address even more challenges to ensure the continuity of trials on human medicines.

A go-to firm for defending patent cases

30 June 2020
Recognition from *Law360*

Atlanta expands privacy capabilities

30 June 2020
Lael Bellamy's arrival bolsters our data protection, privacy and security capabilities throughout the firm.

Changes to Hong Kong anti-discrimination legislation

30 June 2020
Anti-discrimination laws in Hong Kong have undergone a series of changes over the past few years.

Coronavirus Resource Center: Our global repository of insights and events

30 June 2020
A central repository for our reports and commentary on the legal and regulatory concerns arising from the pandemic.

Hatch-Waxman Litigation 101: The Orange Book and the Paragraph IV Notice Letter

30 June 2020
A few of the key issues that must be addressed before a Hatch-Waxman suit is filed.

Intellectual property rights are a renewed focus as the world looks beyond a global viral outbreak

30 June 2020
A few key IP-related considerations for companies, whether they are seeking to expand into new markets or looking to preserve their place in an existing market.

Northern California bolsters telecom and regulatory practice

30 June 2020
Regulatory and telecom attorney Kristin Jacobson has joined our Northern California office in Sacramento.

Washington, DC grows technology capabilities with two new arrivals

30 June 2020
Marius Domokos and Justin Ilhwan Park have joined our Washington, DC practice.

First emerging technologies identified and controlled for export in the EAR

26 June 2020
The designation also makes these a "critical technology," giving CFIUS jurisdiction over foreign investments in US businesses that engage with these items.

Therapies for COVID-19: Two major developments

25 June 2020
The developments, one negative and one positive, involve widely available medications.

CFIUS encourages public to provide tips and referrals

24 June 2020
The new webpage encourages tips and referrals about non-notified deals, violations of CFIUS mitigation measures, and other matters that raise national security risk.

Australia tightens rules on foreign investment

17 June 2020
In this article we summarise the tax-related developments from early June 2020, as Australia takes a more stringent approach towards compliance procedures involving foreign investments.

US-based pharmaceutical manufacturing in response to COVID-19: new manufacturers face risks

3 June 2020

A rush to develop a new company to begin manufacturing is fraught with risk.

Preparing for global class actions arising from COVID-19

28 May 2020
The risk to companies of global and cross-border class action and collective redress proceedings is rising.

Chinese and other emerging market companies listed in the US face increased scrutiny from Congress and Nasdaq

27 May 2020
Within a span of two days, the US Senate, House and Nasdaq each took steps to safeguard investors in the US capital markets.

CFIUS proposes export control-based reforms to its mandatory filing program

22 May 2020
Details of the proposed modifications and their practical impact.

Coronavirus testing and contact tracing: House Democrats' HEROES Act provides US$75 billion to support testing and tracing to monitor and suppress COVID-19 transmission

21 May 2020
A major element for a successful, large-scale contact tracing program is data management and technology, and technology partners will play a major role in modifying existing systems as well as developing new data interfaces.

Helping patients during the pandemic

14 May 2020
Some important considerations for biopharma manufacturers.

[UPDATED] Therapies for COVID-19: What is in the pipeline?

11 May 2020
As of May 8, 2020, there are over 1,300 clinical trials investigating potential therapies for COVID-19, of which nearly 800 are interventional trials.

SCOTUS unanimous – willfulness not a prerequisite to a profits award under the Lanham Act

8 May 2020
The Supreme Court resolves a decades-long circuit split.

US takes action to abate tariffs and duties in wake of COVID-19

8 May 2020
US importers may consider navigating the various tariff exemptions and deferrals in several ways.

Coronavirus: Changes to rules governing meetings and the execution of company documents (Australia)

7 May 2020

Certain requirements in the *Corporations Act 2001* (Cth) (**Corporations Act**) relating to shareholders meetings, and document signatures, are not compatible with public health requirements for social distancing during the coronavirus pandemic. In order to facilitate these important corporate functions during this period, on May 6, 2020 the Australian Federal Government introduced the Corporations (Coronavirus Economic Response) Determination (No. 1) 2020.

This determination modifies the legislative requirements regarding meetings and execution of company documents. These changes come into force on 6 May 2020, and will expire after six months, on 5 November 2020.

Latest round of CMS COVID-19 waivers includes telehealth expansion and other billing flexibilities

7 May 2020
Congress is permitting dramatic expansion of telehealth coverage for the duration of the public health emergency. These are the latest developments.

Life Sciences Top of Mind: COVID-19 sector insights

7 May 2020
Top COVID-19 considerations for the life sciences sector.

Protecting AI technologies through patents: A US guide

7 May 2020
A strong patent portfolio developed around a company's artificial intelligence innovations is an important asset.

COVID-19: New York and Other Northeast Council states take phased approach to reopening economy

6 May 2020
These developments raise a number of immediate questions and considerations for businesses operating in the region.

Is subject matter jurisdiction under the Hatch-Waxman Act expanding?

6 May 2020
Can non-Orange Book patents be asserted?

Coronavirus: Directors' duties and making decisions in a crisis (Australia)

4 May 2020

Directors need to carefully consider the risks of the COVID-19 outbreak within their business, given its impact on the global economy. As many now face significant, and increasing, cash flow pressure, directors should carefully consider their actions in the context of the legal framework.

In this new guide we have set out the practical steps directors should be taking to protect their company and its business going forwards.

Israel Group News May 2020

4 May 2020

ISRAEL GROUP NEWS

Providing access to valuable business resources in real time.

Post-COVID-19: What to expect in the "next normal"

30 April 2020

Issues that are front of mind, based on an informal survey of some of the largest companies and most influential global business leaders.

HHS clarifies PREP Act immunity for COVID-19-related activities

28 April 2020

These immunity provisions may provide significant protection to manufacturers, distributors, and others engaged in COVID-19-related efforts.

US telehealth update: New federal guidance to state Medicaid agencies suggests more coverage is coming

27 April 2020

A powerful signal that CMS is ready to support targeted interventions in favor of telehealth.

Connected care funding for healthcare providers from the CARES Act

24 April 2020

New funding to promote and support telehealth.

Coronavirus: State Attorneys General take action against alleged price gouging in personal protection equipment sales

21 April 2020

State Attorneys General coast to coast are taking aggressive action.

Opening Up America Again Guidelines signal relaxation in elective surgery restrictions

20 April 2020

For healthcare providers as they evaluate how the Opening Up America Again Guidelines pertain to their respective practices.

Clinical trials during the COVID-19 pandemic: A global guide

17 April 2020

The unprecedent situation resulting from the COVID-19 pandemic impacts the ability to conduct clinical trials on a global scale.

Pharmaceutical companies need to address multiple challenges to ensure the continuity of trials on human medicines.

CMS regulatory waivers relax supervision and other requirements in an effort to address staff shortages caused by rising COVID-19 cases

16 April 2020
These changes are effective immediately.

Immediate COVID-19 relief to Medicare providers arrives… with conditions

16 April 2020

For eligible Medicare providers who continue to suffer economic losses stemming from the pandemic, this program is welcome, but it comes with detailed conditions.

Paradigm Change in Germany’s Foreign Direct Investments (FDI) Law

14 April 2020
Germany’s FDI rules so far had a reputation of not being very strong. In the past few years, only three transactions have been prohibited. This is set to change under a new bill.

COVID-19: New York State provides new guidance on essential businesses

13 April 2020
The Guidelines raise a number of immediate questions and considerations for New York businesses.

Coronavirus: Overview of healthcare funding stimulus and policy provisions in the CARES Act (United States)

10 April 2020
Among numerous health policy provisions in the CARES Act is one allowing BARDA to partner with private sector companies on R&D.

EU Antitrust Framework for the coordination of essential coronavirus COVID-19 products and services

10 April 2020
ANTITRUST AND COMPETITION: NOVEL ISSUES IN A POST-CORONAVIRUS WORLD

On 8 April 2020 the Commission published a Temporary Framework for the antitrust assessment of increased business cooperation between competitors in response to coronavirus COVID-19. The aim is to reduce shortages for essential products and services.

Families First Coronavirus Response Act – Health emergency leave and exempted health care providers

10 April 2020
The temporary health emergency leave measures include a key carveout for "Health Care Providers" and "Emergency Responders."

US $2T stimulus COVID-19 package includes significant R&D funding

10 April 2020

A summary of R&D funding in the CARES Act broken out by federal departments and agencies.

UK government to provide additional financial support measures for mid-market business impacted by COVID-19

9 April 2020
On 3 April 2020 the Chancellor announced a new scheme for larger companies, with the creation of the new Coronavirus Large Business Interruption Loan Scheme (CLBILS) to ensure that more firms are able to benefit from government-backed support during this difficult time.

COVID-19: Tort immunity for vaccines and antivirals – lessons from the swine flu of 1976

8 April 2020

While the common goal is to quickly develop countermeasures to combat COVID-19, it is important to consider the potential legal and reputational risks.

European Commission proposes one-year postponement of MDR application date

8 April 2020
Following an informal heads-up on 25 March 2020, today the European Commission adopted a proposed regulation to postpone by one year the date of application of the Medical Devices Regulation (Regulation (EU) 2017/745, “MDR”). If enacted, the Medical Device Directive (Directive 93/42/EEC) and implementing legislation of the EU member states will continue to apply as far as they have not yet been amended.

Contract analysis in a crisis: flowcharts

7 April 2020
Flowcharts providing considerations for analyzing commercial contracts in the context of the COVID-19 pandemic through a logical process flow that can serve as a practical checklist.

Coronavirus - Mitigating supply chain and customer insolvency risk (Canada)

7 APR 2020
The on-going impact of the COVID-19 outbreak could have a significant impact on your global supply and customer chains.

Cost-cutting considerations in the time of COVID-19 (Part 3 – employment issues outside the US)

7 April 2020

A deeper dive into various cost-saving measures and their viability for employers outside the US.

FCA publishes guidance on UK mortgage “payment holidays” relating to COVID-19

7 April 2020

Following an announcement by the UK government on 17 March 2020, the Financial Conduct Authority (FCA) has published guidance for participants in the residential mortgages sector, setting out their expectations in respect of payment holidays that are to be offered to customers experiencing financial difficulties arising from the COVID-19 outbreak.

HHS issues notification of enforcement discretion under HIPAA for certain uses and disclosures by business associates

7 April 2020

This announcement permits business associates to share personal health information with public health authorities and agencies in accordance with HIPAA exceptions as part of COVID-19 relief efforts.

A balance between the government, the private sector and the needs of the people: Invocation of rarely used provisions to ensure public safety during the COVID-19 pandemic

6 April 2020

The Defense Production Act, compulsory licensing and march-in rights are means for authorizing the government to step in and assert rights against private companies.

COVID-19 and the "essential business" designation: Practical guidance for businesses that fall in the gray area between "essential" and "non-essential"

6 April 2020

Certain frequently asked questions as well as practical guidance.

COVID-19 emergency declaration allows Centers for Medicare & Medicaid Services to issue 1135 waivers, 1915(c) waivers and changes to survey and audit processes

6 April 2020

Issued in a public health emergency, the waivers help ensure healthcare items and services are available for individuals enrolled in Social Security Act programs.

Coronavirus: Supplier due diligence for vetting Chinese medical suppliers for quality, safety, fair pricing and anti-corruption compliance

6 April 2020

Some key risks, and potential solutions to reduce cross-border operational risks.

Coronavirus: The Defense Production Act's authorities and limitations in the fight against COVID-19

6 April 2020

The DPA has significant implications for companies receiving a direct order from the President and for the subcontractors and

suppliers behind them; meanwhile, recent legislation has created procurement opportunities under the DPA.

[UPDATED] As device industry veterans and newcomers step up to the line, FDA swiftly adjusts regulatory hurdles for personal protective equipment during the COVID-19 pandemic

6 April 2020
A high level overview of the FDA's tiered, risk-based approach to masks, face shields and respirators based on developments to date.

CARES Act may offer relief for medical practices, but raises questions for private equity-backed practice management companies

3 April 2020
Medical practices and practice management companies are urged to consider options under the CARES Act.

CARES Act waivers from CMS provide additional flexibility for telehealth services and relief from certain Stark Law liabilities (United States)

3 April 2020
This latest relief further expands healthcare practitioners' ability to reach patients through telehealth, an important tool for addressing patient needs while reducing in-person contact.

Beyond social distancing: What employers need to know to keep their workplaces safe and manage privacy obligations in the face of COVID-19

2 April 2020
Guidance from OSHA, EEO and CDC to help employers seeking to protect the health, safety and privacy of their on-site employees.

Coronavirus: Cybersecurity considerations for your newly remote workforce (United States)

31 March 2020

Cyber risk management involves balancing the productivity of a workforce with ensuring confidentiality, integrity and availability of the company’s own systems and data, as well as that of their supply chain.

Importing critical healthcare supplies during the COVID-19 pandemic: Recent US developments

31 March 2020

Practical guidance is critical to help importers of medical products efficiently navigate legal and regulatory hurdles so that admissible products with the potential to safeguard patients' health and well-being may be granted entry into US markets as expeditiously as possible.

Are you ready for CCPA class action litigation?

30 March 2020
Many businesses may not have fully contemplated the major data breach class action litigation risk created by the California

Consumer Privacy Act.

Top franchise developments of 2019

30 March 2020

Two top franchise developments in 2019 stand out from the rest.

Coronavirus: DHS Response to COVID-19 - What US Employers Need to Know

29 March 2020
Key questions and answers related to the new DHS guidance.

COVID-19 prompts CMS to give new flexibility to participants in Medicare Quality Programs

25 March 2020
In light of COVID-19, participants in the Medicare Quality Payment Program will have extra time to report some quality metrics and can temporarily suspend other tracking and reporting activities altogether.

Coronavirus: Competition and regulatory measures in Ireland

25 March 2020
ANTITRUST AND COMPETITION: NOVEL ISSUES IN A POST-CORONAVIRUS WORLD

An unprecedented challenge calls for unprecedented measures. The competition and regulatory world has reacted rapidly to the challenge of COVID-19 with bold legal solutions. We discuss how EU and Irish regulators are responding with support for business, exploring the relaxation of competition laws and adopting temporary measures for merger review.

Coronavirus: Cyber hygiene practices

25 March 2020
While the world is responding to the coronavirus disease 2019 (COVID-19), and individuals are increasingly focused on personal hygiene and social distancing, augmenting cyber hygiene efforts at home and at work are increasing in importance too.

Coronavirus: Employee furloughs, reductions-in-force and similar temporary cost-saving measures (Part 2 – Employment issues outside the US)

25 March 2020
A general overview of key employment issues to consider outside of the US in light of COVID-19.

Coronavirus: Employee furloughs, reductions-in-force and similar temporary cost-saving measures in the US - Part 1

25 March 2020
Key employment-related issues for US-based employers in relation to cost-saving measures due to COVID-19.

Hotels and hospitals may find new partnerships to solve for bed capacity issues and vacancies

25 March 2020
The impacts of COVID-19 upon the hospitality sector as well as hospital systems and the healthcare industry have been sudden and dramatic.

CMS Emergency Preparedness Rule: Planning during COVID-19 (United States)

24 March 2020

As healthcare providers continue to face a variety of challenges during the coronavirus disease 2019 (COVID-19) pandemic, healthcare providers and suppliers should be aware of the Centers for Medicare and Medicaid Services Emergency Preparedness Rule and its resources.

Coronavirus: Several state and local governments issue “shelter in place” orders (United States)

23 March 2020
Between March 17 and 22, state and local governments have promulgated at least a dozen “Stay-at-Home” / “Shelter-at-Home”-type Orders. This alert provides details on a number of state and local government orders.

90-day deferral for US federal income tax payments

20 March 2020
Those who decide to defer their federal tax payments will be able to do so on a penalty-free and interest-free basis, with penalties and interest beginning to accrue for payments submitted after July 15, 2020.

Potential paths forward amidst the challenges to COVID-19 therapeutic and vaccine development; collaboration and communication among clinical trial stakeholders takes on heightened importance (United States)

20 March 2020

In a March 19, 2020, briefing and press release, the US Food and Drug Administration outlined ways that existing regulatory options may make it possible to expedite access to therapeutics and vaccines with the potential to treat or prevent coronavirus disease 2019 (COVID-19).

COVID-19: The benefits of US chapter 11 relief in a time of economic crisis

19 March 2020
Highlighting some of the most significant benefits of US chapter 11 for companies facing severe challenges under the current circumstances.

Coronavirus: business resilience and continuity planning

19 March 2020
Prudent companies understand that their response to the COVID-19 pandemic should be consistent with their business resilience plans.

Coronavirus: Congress passes revised paid leave law (United States)

18 March 2020
Congress passed a revised version of The Families First Coronavirus Response Act requiring employers with fewer than 500 employees to provide COVID-19-related paid sick and family leave to eligible employees.

Telehealth update: COVID-19 prompts emergency Medicare coverage and other seismic shifts (United States)

18 March 2020
Multiple federal agencies have issued regulatory waivers and released additional funding to loosen the constraints on telehealth services and encourage widespread adoption.

Coronavirus: Congress expected to pass expanded paid leave (United States)

16 March 2020
The paid leave requirements in the current version of the Families First Coronavirus Response Act.

Coronavirus: federal and state tax relief (United States)

16 March 2020
Congress and state legislatures and administrative agencies are working hard to provide necessary tax relief for those affected by the coronavirus disease (COVID-19) pandemic.

Coronavirus (COVID-19): ten practical steps for global employers, right now (Global)

13 March 2020
These steps are not based on laws of any one jurisdiction but rather are designed to provide a global employer with themes to consider, understanding that what may be suitable for each employer may vary greatly depending on the employer's unique circumstances.

HIPAA and the coronavirus (United States)

13 March 2020
Key questions businesses may consider asking.

Life sciences market remains strong despite uncertainty in an election year

11 March 2020
The current state of life sciences financing – thoughts from the JPMorgan panel

Defending your supply chain against coronavirus COVID-19 (United States)

9 March 2020

An action plan that companies can implement to make strategic decisions related to potential supply chain disruptions.

Europe initiates regulations on artificial intelligence; industry presented with opportunity to provide inputs

5 March 2020
AI OUTLOOK

The White Paper on AI initiates a process that could potentially establish the world's first far-reaching regulatory framework for AI.

Healthcare market proves strong as investors embrace new technological advancements

3 March 2020

Takeaways from the JPMorgan panel, "Healthcare M&A Exits: Who's Buying, What Are They Buying, and Why?"

FTC issues 6(b) orders to tech companies − healthcare companies could be next

14 February 2020
The agency seeks information on unreported acquisitions with the goal of deepening its understanding of the competitive tech sector landscape.

White House proposes doubling artificial intelligence budget

13 February 2020
AI OUTLOOK

Lawmakers now have the opportunity to debate and amend the budget proposal in the upcoming appropriations process.

An update on the impact of the coronavirus on business in Singapore

12 February 2020

Due to the evolving 2019- nCoV acute respiratory disease (the COVID-19) situation, the Ministry of Health (the MOH) and the Ministry of Manpower (the MOM) have, since January 2020, issued advisories which employers will need to be aware of. In particular, the MOH and MOM have, since our last update on February 12 2020, updated and issued new advisories due to the increased risk of importation of COVID-19 into Singapore.

Wasica v. Schrader: IPR estoppel can include system prior art – key takeaways

11 February 2020
This case raises a few interesting points for practitioners and companies involved in patent litigations and IPRs.

DLA Piper's Dylan Kennett joins panel debate at the Cannabis Investor Summit in Odense, Denmark

11 February 2020
On January 28, Dylan Kennett, Senior Associate in DLA Piper's corporate team and co-lead of our Global Cannabis practice, joined a panel debate at the Cannabis Investor Summit in Odense, Denmark. DLA Piper is proud to be a partner on this summit hosted by Invest in Odense, Invest in Denmark and Novo Nordisk Engineering (NNE).

Hong Kong Government introduces mandatory quarantine measures

11 February 2020

On 9 February 2020, the number of deaths due to the rapidly spreading coronavirus in Mainland China officially surpassed the figure seen during the 2002/2003 SARS epidemic.

Numerous governments have been implementing restrictions barring entry to those with recent travel history through Mainland China, including Singapore, Japan, Australia and the United States. Following pressure from public health workers, the Hong Kong Government has now followed suit and has begun a mandatory two-week quarantine for anyone arriving from Mainland China.

How to resume business amid the coronavirus outbreak (China)

11 February 2020

As reported in our previous article, China has extended its Chinese New Year holiday and work suspension period as a result of the novel coronavirus outbreak which has now infected more than 40,000 people around the world.

This is a summary of the Back to Work Day and compensation for working before Back to Work Day in key cities and provinces across China.

Israel Group News February 2020

10 February 2020

ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, coming events and more.

APAC employment issues arising out of the Coronavirus (AsiaPac)

31 January 2020

On 29 January 2020, the number of confirmed cases of the rapidly spreading coronavirus in Mainland China officially surpassed the figure seen during the 2002/2003 SARS epidemic.

Multinationals with local operations around the APAC region have been significantly affected. As staff return to the office following the Chinese New Year holiday period, businesses are now considering what they can do to minimise any risk to health and safety and support staff through this challenging period where anxiety and uncertainty is rife, whilst at the same time complying with their employment obligations and maintaining business continuity. Putting in place detailed business and contingency plans and ensuring careful communications with staff to address key topics and concerns is key, as is keeping such plans and communications under frequent review given the fluidity of the current situation.

This alert considers some of the key issues that HR and business leaders should be considering across the APAC region.

Harsher penalties on discriminatory employment practices in Singapore

29 January 2020

The Fair Consideration Framework was updated in January 2020 to impose harsher penalties on employers found to be engaging in discriminatory practices such as by favouring the hiring of foreigners over Singaporeans.

China extends holidays for workers amid coronavirus outbreak (China)

28 January 2020
Learn about how the widely publicised corona virus outbreak affects business in Greater China.

EU MDCG issues new guidance on Cybersecurity for medical devices

27 January 2020
On 7 January 2020, the EU Medical Device Coordination Group published new guidance to help manufacturers fulfil all relevant cybersecurity requirements in Annex I to the new Medical Device Regulations (Regulations 2017/745 on medical devices and 2017/746 on in vitro diagnostic medical devices).

Broad's CRISPR/Cas9 patent EP2771468 revoked by the European Patent Office

17 January 2020
In the ongoing CRISPR patent battle, the European Patent Office has upheld the earlier EPO Opposition Division ruling revoking Broad Institute's European patent EP2771468.

Iran nuclear deal: the launch of the ‘Dispute Resolution Mechanism’ and the ‘potential snapback’ of UN and EU sanctions

17 January 2020
This week, France, Germany and Britain have triggered the Dispute Resolution Mechanism against Iran under the Joint Comprehensive Plan of Action (JCPOA). Will this process lead to the re-imposition of UN and EU sanctions on Iran?

New regulations reinforce CFIUS's expanded role with respect to foreign investments in the United States

16 January 2020
The new CFIUS regulations become effective on February 13, 2020.

Top of Mind: Life Sciences

16 January 2020
Eight big topics that life sciences businesses have been thinking about and how DLA Piper has been covering those stories.

The almost free US-Japan Trade Agreement is now in effect

9 January 2020
This trade agreement reduces or eliminates US customs duties on numerous goods.

White House issues guidelines for regulatory and non-regulatory approaches to artificial intelligence

8 January 2020
AI OUTLOOK

Michael Kratsios, Chief Technology Officer of the United States, called the new initiative the "first of its kind" − the first "binding document" for how government agencies will regulate emerging AI technology.

Supporting the health of your health system

6 January 2020
Guidance to help tend to healthcare system wellness throughout the business life cycle.

Artificial intelligence software tools tested for demographic impact

20 December 2019
A NIST report quantifying demographic differences in nearly 200 face recognition algorithms found “empirical evidence for the existence of a wide range of accuracy.”

CCPA Rescue Kit arrives amid new privacy law change

19 December 2019
A series of integrated compliance offerings to help businesses begin the journey of compliance with this important new privacy bill.

Street art raises novel copyright issues – or does it?

19 December 2019

Is street art less entitled to copyright protection than are traditional art forms?

EU launches preparatory work for a global sanctions regime for human rights violations

17 December 2019
On 9 December 2019, High Representative/Vice-President of the European Union Josep Borrell announced that the Foreign Affairs Council has agreed with strong consensus to start the preparatory work for a global sanctions regime to address serious human rights violations.

Upcoming 12/31 deadline to comment on CMS and OIG proposed rule changes under the Stark Law and Anti-Kickback Statute

16 December 2019

The two highly consequential proposals are poised to change how HHS approaches fraud and abuse enforcement in federal healthcare programs.

Announcing DLA Piper's MDL Benchmark Database

9 December 2019

Comprehensive and systematic analyses of MDL procedures and practices.

What starts the avalanche? Earlier triggers for life sciences mass torts in the era of big data and social media

9 December 2019

The bar for safety issues to lead to claims that ultimately result in mass tort litigation has never been lower.

Israel Group News November 2019

18 November 2019

In this issue, IP considerations in augmented reality and virtual reality, plus our global activities, latest publications, coming events and more.

DC policymakers working to stay ahead of – or keep up with – AI innovations

4 November 2019

AI OUTLOOK

The inaugural issue of *AI Outlook* reviews the latest developments around AI in Washington and discusses what these bills and trends mean for business.

Plaintiff attorney advertising in pharmaceutical and medical device litigation: addressing the risk of harm to the public

29 October 2019

Law firm advertising about pharmaceutical and medical device litigation is receiving heightened regulatory scrutiny.

CMS and OIG release most expansive changes to the fraud and abuse laws in over a decade

18 October 2019

The proposed changes are part of the HHS Regulatory Sprint, which seeks to remove regulatory barriers to care coordination and value-based care.

Food and Beverage News and Trends

14 October 2019

FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, is it time to revise food standards of identity? Plus vaping, alcohol labels, and a potential commissioner for the FDA.

The Russian Supreme Court clarifies intellectual property legislation

30 Sep 2019

Clarifications from the Supreme Court have a significant impact on the further development of court practice in Russia.

The CBD problem: searching for a legal pathway for CBD in foods and supplements

20 September 2019

The current state of the laws and regulations in the US, and potential pathways to a resolution.

Treasury Department proposes regulations comprehensively implementing FIRRMA and reforming CFIUS national security review

19 September 2019

The proposed regulations affect non-controlling investments involving critical technologies, critical infrastructure, and sensitive personal data; and transactions involving real estate near sensitive national security facilities.

Australian Taxation Office publishes important guidance on cross-border tax measures

29 August 2019
In this article we analyse guidance published by the Australian Taxation Office on important Australian international tax measures that affect foreign investments in Australian structures and other cross-border transactions.

Israel Group News August 2019

7 August 2019
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, coming events and more.

The learned intermediary doctrine in the WebMD era

1 August 2019

Our US medical system continues to put the physician between the medication or treatment and the patient for a reason.

Announcing Accelerate's newly updated market data

25 July 2019
Data may be filtered by time period, transaction volume, transaction type and, in some cases, industry vertical.

Biomarker-based cancer diagnostics: German pricing regulator sets high validation and reimbursement standards for novel diagnostic methods

10 July 2019

On 20 June 2019, for the first time, the German Federal Joint Committee (FJC − Gemeinsamer Bundesausschuss / G-BA), the highest decision-making body of the joint self-government of physicians, dentists, hospitals and statutory health insurance funds (SHI − gesetzliche Krankenversicherung / GKV) in Germany, made the resolution that a specific biomarker-based test to support the treatment

decision for or against adjuvant chemotherapy, i. e. after primary surgery, in certain breast cancer patients may be reimbursed by the SHIs.

Major developments in class action litigation for 2018 – 2019

18 June 2019
A top-level look at class action litigation for 2018-2019 and a look at trends, issues, and strategies that businesses face in the months to come.

In *Albrecht*, US Supreme Court narrows implied preemption of failure-to-warn claims, finds preemption is legal issue for judge, not jury

21 MAY 2019
The *Albrecht* decision clarifies and substantially narrows the scope of preemption under the *Wyeth v. Levine* "clear evidence" standard.

Bellwether trials in MDL proceedings – guidance for transferee judges

16 MAY 2019

Practical considerations for transferee judges establishing and implementing bellwether protocols in MDL proceedings.

Intellectual Property and Technology News (Asia Pacific) May 2019

15 MAY 2019
INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS

Intellectual Property and Technology News (Asia Pacific) is our biannual publication designed to report on worldwide development in intellectual property and technology law, offering perspectives, analysis and visionary ideas.

First Circuit reverses course on its first-to-file rule

9 MAY 2019

First Circuit law on the first-to-file rule is evolving in a way that could have significant consequences for False Claims Act defendants.

Israel Group News May 2019

9 MAY 2019
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, coming events and more.

The cybersecurity of digital medical devices: higher technological capabilities, higher likelihood of liability

8 MAY 2019

To prepare for potential new regulatory requirements, medical device manufacturers should take this opportunity to assess their

compliance with HIPAA and FDA's Draft Guidance, then complete a Risk Management Plan.

California Proposition 65 lists two chemicals, PFOA and PFOS, found in a number of consumer products

12 DEC 2018

Given Prop 65's active and litigious enforcers, companies doing business in California that suspect their products may cause an exposure to PFOA/PFOS should consider compliance options now.

California court's narrow Prop 65 coffee ruling should not be misinterpreted

9 APR 2018

A careful understanding of the narrow basis of the ruling is important for coffee consumers and for all manner of product-based companies doing business in California.

New glyphosate decision forces Prop 65 to reckon with federally accepted science

7 MAR 2018
This outcome will likely put wind in the sails of industry groups and individual companies challenging the science behind other Prop 65 listings.

Precarious steps: patent eligibility for healthcare IT

26 SEP 2016

Three recent Federal Circuit decisions, along with new updates from the USPTO, offer guidance on which steps to take in patenting healthcare IT-related inventions.

Stop them in their tracks: key points in seeking a preliminary injunction against medical device infringers

22 SEP 2016

Three considerations to bear in mind when bringing or defending a preliminary injunction motion in a medical device infringement case.

Is your cybersecurity upgrade FDA reportable?

28 SEP 2016

Draft guidance lends insight into the way the FDA may apply existing postmarket regulatory requirements to evolving cybersecurity-related technological issues.

Supreme Court Corner: Q1 2016

29 MAR 2016
Two cases to watch.

Are IPRs impacting the pharmaceutical industry?

9 JUN 2015
Choosing between IPRs and district court litigation

Supreme Court Corner - Q1 2015

24 MAR 2015

Recent decisions and cases to watch

Intellectual Property and Technology News (United States), Issue 23, Q3 2014

10 SEP 2014

INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS

Our Intellectual Property and Technology News reports on worldwide developments in IP and technology law, offering perspectives, analysis and visionary ideas.

Substitution allowed? State biosimilars laws are evolving

10 SEP 2014
Biosimilar products have not yet reached the US market, but debates on the laws and regulations that will govern them have been raging for some time

Supreme Court Corner - Q3 2014

10 SEP 2014
A review of cases relevant to IPT decided or argued before the Court during Q3

DOJ dismisses last of the drug trafficking charges against FedEx: two key takeaways

5 JUL 2016
A sudden about-face from the DOJ.

Ten tips for generating a life sciences brand name

19 NOV 2015

The proliferation of brands, combined with the PR and financial consequences of a potential rebrand in the event of infringement, has made selecting a trademark trickier than ever. Christina Martini and Virginia Wolk Marino report.

Distributing patent rights between affiliates: guidelines to support enforcement rights around the world

16 NOV 2015

Considering a few issues at the outset when rights are distributed between Parent and Affiliate (or between multiple affiliates) may avoid difficulties in the future when a company wants to enforce patent rights.

Wellness innovators take note: FDA reveals risk-based approaches to the regulation of health IT and mobile medical apps

2 FEB 2015

With these draft guidance documents, FDA indicates it will not take enforcement action in connection with low-risk general wellness products and establishes a new risk-based approach to medical device accessories

---

Revenue pressure climbs for skilled nursing facilities − what does this mean for healthcare REITs?

3 JUN 2015
Healthcare REITs must be mindful of the challenges they may face due to changes in the healthcare environment

---

SEC begins Dodd-Frank rulemaking with new open process

28 Jul 2010

EVENTS

Previous

The current state of life sciences financing

2 March 2021 | 3:00 - 4:00 EST
Webinar

Communication and information sharing in support of healthcare for vulnerable populations

22 February 2021
Webinar

EDPB recommendations for safeguarding data transfers after Schrems II

19 November 2020
Webinar

Planning for an Uncertain World

16 November 2020
TECHLAW EVENT SERIES

Webinar

Women in Science and Technology Conference

29 October 2020 | 5:30 - 7:30 p.m. AST
Webinar

2020 BioHealth Capital Region Virtual Forum

19 October 2020 | 4:30 - 5:00 EDT
Webinar

Considerations for drug pricing and demonstrating value in a post-pandemic environment

5 August 2020 | 12:00 – 1:00 ET
Webinar

TechLaw

31 July 2020
TECHLAW EVENT SERIES

Webinar

TechLaw

5 March 2020
TECHLAW EVENT SERIES

Sydney

TechLaw

3 March 2020
TECHLAW EVENT SERIES

Melbourne

J.P. Morgan Healthcare Conference

14 January 2020
J.P. MORGAN HEALTHCARE CONFERENCE

San Francisco

J.P. Morgan Healthcare Conference

13 January 2020

J.P. MORGAN HEALTHCARE CONFERENCE

Attorney-client privilege and work product protection for in-house life sciences lawyers

10 September 2019
Webinar

TopCo liability panel

25 JUN 2019
London

BIO's 2019 International Convention

3 - 6 JUN 2019
Philadelphia

Medical Device Happy Hour

15 MAY 2019
San Diego

NEWS

Leading trial lawyer Lyn Pruitt joins DLA Piper, along with Adria Conklin and Mary Catherine Way

25 March 2021
DLA Piper announced today that nationally recognized trial lawyer Lyn Pruitt has joined the firm's Litigation and Regulatory practice, along with Adria Conklin and Mary Catherine Way.

Geoffrey Levitt joins DLA Piper's Litigation and Regulatory practice as co-chair of Life Sciences and Health Policy and Regulatory group

22 March 2021
DLA Piper announced today that Geoffrey Levitt has joined the firm's Litigation and Regulatory practice as co-chair of the Life Sciences and Health Policy and Regulatory group.

DLA Piper advises Piper Sandler & Co. as placement agent in US$175 million PIPE for Alpha Healthcare Acquisition Corp.

2 March 2021
DLA Piper represented Piper Sandler & Co. as placement agent in a US$175 million private investment in public equity (PIPE)

transaction for Alpha Healthcare Acquisition Corp.

DLA Piper advises Piper Sandler & Co. as sole book-running manager in connection with US$92 million common stock offering by Infinity Pharmaceuticals

2 March 2021
DLA Piper represented Piper Sandler & Co. as sole book-running manager in connection with the US$92 million public offering of common stock of Infinity Pharmaceuticals, a clinical-stage biotechnology company.

DLA Piper advises NuVasive in its acquisition of Simplify Medical

1 March 2021
DLA Piper represented NuVasive, Inc., in its recent acquisition of Simplify Medical, a privately held company and developer of the Simplify Cervical Artificial Disc for cervical total disc replacement (cTDR).

DLA Piper advises Haemonetics in its acquisition of Cardiva Medical

21 January 2021
DLA Piper represented Haemonetics Corporation (NYSE: HAE), a global medical technology company focused on delivering innovative medical solutions to drive better patient outcomes, in its acquisition of Cardiva Medical, Inc., an industry-leading manufacturer of vascular closure systems based in Santa Clara, California, for US$475 million at closing and up to an additional US$35 million in contingent consideration based on sales growth.

DLA Piper advises Histogen in its US$14 million upsized public offering

6 January 2021
DLA Piper advised Histogen, Inc., in its public offering of 11,600,000 shares of common stock, pre-funded warrants to purchase up to 2,400,000 shares of common stock and warrants to purchase up to an aggregate of 14,000,000 shares of common stock at a price of US$1.00 per share.

DLA Piper advises Arlington Capital Partners in majority investment in Everest Clinical Research Corporation

21 December 2020
DLA Piper represented Washington, DC-based private equity firm Arlington Capital Partners in its investment in Everest Clinical Research Corporation, a leading contract research organization providing a comprehensive suite of mission-critical clinical research services to the worldwide pharmaceutical, biotechnology and medical device industries across Phase I-IV trials.

DLA Piper advises Locanabio in its US$100 million Series B financing

15 December 2020
DLA Piper represented Locanabio, an RNA-targeting gene therapy company focused on developing life-changing therapies for patients with severe neurodegenerative, neuromuscular and retinal diseases, in its recent US$100 million Series B financing led by Vida Ventures.

DLA Piper advises Otsuka America Pharmaceutical in its purchase of the assets of Proteus Digital Health

26 August 2020

DLA Piper represented Otsuka America Pharmaceutical, Inc. in connection with its stalking horse bid to purchase substantially all of the assets of Proteus Digital Health, Inc., including its ingestible and wearable sensor technology.

Former Congressman Jim Greenwood joins DLA Piper as senior policy advisor, adding significant strength to growing life sciences policy and regulatory group

4 August 2020
DLA Piper announced today that former US Representative Jim Greenwood has joined the firm's Litigation and Regulatory practice as a senior policy advisor based in Washington, DC.

DLA Piper advises Liquidia in its acquisition of RareGen and its US$75 million follow-on offering

6 July 2020
DLA Piper represented Liquidia Technologies, Inc. in its acquisition of RareGen, LLC.

DLA Piper advises Haemonetics in its sale of US blood donor management software to the GPI Group

12 June 2020
DLA Piper represented Haemonetics Corporation in its sale of certain blood donor management software assets within its Blood Center business unit to the GPI Group.

DLA Piper represents Axogen in dismissal of securities class action lawsuit

22 April 2020
DLA Piper represented Axogen, Inc. in the dismissal of a securities class action lawsuit filed in the US District Court for the Middle District of Florida.

DLA Piper obtains confirmation of plan for Valeritas in first coronavirus-related chapter 11 case

8 June 2020
DLA Piper represented medical device company Valeritas Holdings Inc. in its chapter 11 case in the United States Bankruptcy Court for the District of Delaware.

DLA Piper advises Iovance Biotherapeutics in its US$604 million common stock offering

4 June 2020
DLA Piper represented Iovance Biotherapeutics, a late-stage biotechnology company developing novel T cell-based cancer immunotherapies (tumor-infiltrating lymphocyte, TIL and peripheral-blood lymphocyte, PBL), in a US$603.7 million underwritten public offering.

DLA Piper advises NuVasive in its US$400 million convertible senior notes offering

3 June 2020
DLA Piper advised NuVasive, Inc. in its offering of US$400 million aggregate principal amount of 1.00% convertible senior notes due 2023.

Jeffrey Selman joins DLA Piper's Corporate practice in Northern California

29 May 2020
DLA Piper announced today that Jeffrey Selman has joined the firm's Corporate practice as a partner in Northern California, based in the Silicon Valley and San Francisco offices.

DLA Piper advises Stratos Genomics in its acquisition by Roche

26 May 2020
DLA Piper represented Seattle-based Stratos Genomics, an early-stage sequencing technology company, in its acquisition by biotechnology company Roche.

DLA Piper advises Luminex in its US$260 million convertible senior notes offering

18 May 2020
DLA Piper advised Luminex Corporation, an Austin-based company that develops, manufactures and sells proprietary biological testing technologies and products, in its offering of US$260 million aggregate principal amount of 3.00% convertible senior notes due 2025.

DLA Piper advises Immunomedics in its US$483 million follow-on offering

15 May 2020
DLA Piper represented Immunomedics, Inc., a leading biopharmaceutical company in the area of antibody-drug conjugates, in its recent US$483 million follow-on offering of common stock.

DLA Piper lawyers and practices ranked in latest Chambers edition

8 May 2020
DLA Piper today announced that the firm received 172 lawyer rankings and 71 practice rankings in *Chambers USA*'s 2020 guide.

DLA Piper announces partnership promotions for 2020

30 April 2020

DLA Piper is proud to announce that 67 lawyers have been promoted to its partnership. The promotions are effective as of April 1, 2020 in the United States and May 1, 2020 for EMEA and Asia Pacific. The promotions have been made across many of the firm's practice areas in 35 different offices throughout 13 countries.

Across the firm's practices globally, Corporate saw the largest intake of new partners with 19 promotions, followed by Litigation and Regulatory with 15. Intellectual Property and Technology and Finance and Projects had ten and eight promotions respectively, while there were six in Real Estate. Tax and Employment both had four, and there was one in Restructuring.

DLA Piper advises Haemonetics in its acquisition of enicor GmbH

8 April 2020
DLA Piper represented Haemonetics Corporation (NYSE: HAE) in its acquisition of enicor GmbH, a Munich, Germany-based privately held manufacturer of a whole blood coagulation testing system known as ClotPro.

Carole Bellis joins DLA Piper's Corporate practice in Northern California

17 March 2020
DLA Piper announced today that Carole Bellis has joined the firm's Corporate practice as a partner in Northern California.

DLA Piper lawyers named Acritas Stars

10 March 2020

Acritas has named over 200 DLA Piper lawyers as 2020 Acritas Stars. Now in its fourth year, Acritas Stars highlights the stand-out lawyers in private practice as nominated by clients around the world. More than 3,000 senior in-house counsel feed into the nomination process to give a comprehensive view of highly recommended lawyers across the globe.

DLA Piper advises NuVasive in its $450 million convertible senior notes offering and credit agreement amendment

5 March 2020
DLA Piper advised NuVasive, Inc. in its offering of US$450 million aggregate principal amount of 0.375% convertible senior notes due 2025.

Ellen Scordino, Susan Krumplitsch and April Abele Isaacson join DLA Piper's Patent Litigation practice in Northern California and Boston

4 February 2020
DLA Piper announced today that Ellen Scordino, Susan Krumplitsch and April Abele Isaacson have joined the firm's Patent Litigation practice and Life Sciences sector.

DLA Piper advises AiCure in US$24.5 million Series C financing

18 November 2019

DLA Piper is pleased to announce that AiCure chose the firm to represent AiCure in its US$24.5 million Series C financing.

Michael Sitzman joins DLA Piper's Intellectual Property and Technology practice in Northern California

4 November 2019

DLA Piper announced today that Michael Sitzman has joined the firm's Intellectual Property and Technology practice as a partner in Northern California, based in the San Francisco office.

DLA Piper advises Plexium in US$28 million Series A financing

18 October 2019

DLA Piper represented Plexium, a San Diego-based emerging biotechnology company whose proprietary platform, DELPhe, enables cell-based phenotypic screening of DNA-encoded libraries in nanoliter volumes, in its US$28 million Series A financing.

DLA Piper advises Insilico Medicine on successful Series B funding

17 October 2019

DLA Piper advised Insilico Medicine, a pioneer in next-generation artificial intelligence technology for drug discovery, on a successful US$37 million Series B funding round to commercialize the validated generative chemistry and target identification technology.

Edward Hanover to join DLA Piper’s Litigation practice in Northern California

26 August 2019
DLA Piper announced today that Edward Hanover will join the firm's Litigation practice as a partner in Northern California based in the Silicon Valley office.

DLA Piper partner Andrew Hoffman named to the *Daily Journal*'s Top 40 Under 40 list

16 August 2019

DLA Piper is pleased to announce that Andrew Hoffman, a partner in the firm's Litigation practice, has been named to the *Daily Journal*'s 2019 Top 40 Under 40 list honoring young California lawyers across a range of practice areas.

DLA Piper advises Adaptive Biotechnologies in its US$345 million IPO

2 July 2019

July 2, 2019 – DLA Piper represented Seattle-based Adaptive Biotechnologies Corporation in its US$345 million initial public offering.

DLA Piper represents Locana in US$55 million Series A financing

23 MAY 2019

DLA Piper represented Locana, Inc. in a US$55 million round of Series A financing led by ARCH Venture Partners, with participation from existing investors Temasek and Lightstone Ventures.

DLA Piper announces launch of Artificial Intelligence practice

14 MAY 2019

DLA Piper announced today the launch of its Artificial Intelligence practice, which will focus on assisting companies as they navigate the legal landscape of emerging and disruptive technologies, while helping them understand the legal and compliance risks arising from the creation and deployment of AI systems.

DLA Piper lawyers and practices ranked in latest Chambers edition

30 APR 2019

DLA Piper today announced that 158 of the firm's lawyers and 64 of its practices were ranked in *Chambers USA*'s 2019 guide.

DLA Piper lawyers and practices ranked in latest Chambers edition

30 APR 2019

DLA Piper today announced that 158 of the firm's lawyers and 64 of its practices were ranked in *Chambers USA*'s 2019 guide.

Carl Wessel joins DLA Piper's Litigation practice in Washington, DC

22 APR 2019

DLA Piper announced today that Carl Wessel has joined the firm's Litigation practice as a partner in Washington, DC.

K. Randolph Peak joins DLA Piper's Healthcare sector and Corporate practice in Dallas

17 APR 2019

DLA Piper announced today that K. Randolph Peak has joined the firm's Healthcare sector and Corporate practice as a partner in Dallas.

Sustainability and ESG

Sustainability is a core business issue in the life sciences sector, given its central role in addressing systemic global challenges including pandemics, access to medicine, and climate change. Creating new and sustainable value depends upon connecting stakeholder experiences with business outcomes – from patients to health workers, as well as wider health sector players. Boards must focus on more personalized healthcare and specialized services, leveraging technology in product development and patient care, and fostering trust on key issues like transparency of clinical trials, use of health and patient data, product quality and safety, and the environmental and social impacts across product life-cycles.

A number of sustainability-related themes affect businesses operating in the life sciences sector:

- **Access and affordability:** Addressing unmet healthcare needs, increasing access to affordable essential medicines and strengthening health systems around the world are all fundamental to social and economic progress. The coronavirus disease 2019 (COVID-19) has further highlighted the importance of the life sciences sector in addressing these challenges.
- **Digital transformation:** The use of AI, machine learning, automation and other digital technologies is transforming the global life sciences landscape. The application of AI, robotics and cloud services has paved the way to innovative, effective and cost-efficient therapy discoveries and the development of preventative and wellness-focused consumer wearables, personalized telemedicine services and remote patient monitoring. This digital transformation is expected to continue as more than 50 percent of health consumers support the use of AI and robotics to improve health outcomes.
- **Transparency and access in clinical trials:** Stakeholders increasingly expect transparency in clinical trials and wider access to trial data for scientific exchange and research. There is a bright spotlight on participant safety and privacy. Businesses are demanding more effective information sharing to enable informed decision-making and consent, along with post-trial access to results. Technology and collaborative partnerships with patient and health worker groups enable wider representative demographic populations to participate in clinical trials.
- **Trust and ethical use of data:** Vast amounts of valuable health data are generated through health and wellness apps, digital or

automated diagnostics, cloud-based patient records and other medical devices. There is also a growing number of stakeholders with access to this data, including healthcare providers, health workers, insurers, governments and app developers. A key expectation within the life sciences sector is that data to improve health outcomes will continue along the path of increased accessibility while also ensuring its ethical use and the protection of individuals' privacy.

- **Patient-centered services and more personalized healthcare:** The changing priorities of health consumers and professionals are leading to a greater focus on the patient experience, from prevention and wellness to diagnosis and management of disease. Technology gives health consumers greater control over prevention and management of disease and provides health professionals access to better data to track and monitor their patients.
- **Net-zero decarbonization:** In striving to decarbonize the economy, businesses are implementing commitments to Science Based Targets, increasing energy efficiency and reducing carbon output, decreasing dependency on fossil fuels and increasing the use of renewables. The implementation of these initiatives is creating operational efficiencies, optimizing processes and reducing costs across the sector.
- **Sustainable sourcing, product life-cycles and a circular economy:** Stakeholders demand greater transparency across product life-cycles, businesses make commitments to net-zero decarbonization and business model innovation is driven by circular economy concepts. Underpinned by an increasingly complex transnational regulatory landscape, these developments are changing the way raw materials are sourced; how products are designed, manufactured, packaged, sold, reused or recycled; how waste and hazardous material is treated; and how wider environmental and social impacts relating to issues like emissions, plastics, water use, biodiversity loss, labor conditions and community impacts are managed.
- **Product safety and quality:** Fake or substandard medicines lead to hundreds of thousands of deaths each year. Drug safety, along with protecting health consumers from counterfeit medicines and drug diversion, are integral to ensuring public health and maintaining trust and confidence in the life sciences sector.
- **Business ethics:** There is increasing stakeholder attention, including from regulators and policymakers and also from providers of capital, on transparency and ethics in business dealings with healthcare providers and medical practitioners for the sale and use of products, as well as in relation to lobbying and advocacy activities. The way in which businesses respond to these expectations can have a direct impact upon their reputation and ultimately upon their license to operate.

To discuss the implications of these issues for your business, please contact our ESG leaders.

DLA PIPER

Life Sciences

As the legal matters confronting our life science clients are varied, so are the skill sets we employ. DLA Piper's life sciences team comprises lawyers with legal, scientific and medical knowledge who understand the complexity of the business and regulatory environments in which our clients operate.

The challenges facing today's biotechnology and medical device companies are greater than ever. For companies to take promising therapies from the laboratory to the market, they must protect those therapies from IP, regulatory and reputational risks. Furthermore, the last few years have seen increasing pressure from many sides: demand for greater shareholder return, loss of key revenue streams due to patent expiration or generic challenges, fierce competition in key therapeutic areas, pricing pressures from health care payors, increased government regulation beyond core safety issues, rising costs of R&D, challenges in maximizing return in emerging markets and aggressive government enforcement action.

Our life sciences sector team is one of the largest and most active of any law firm. Operating as one team across more than 30 jurisdictions, we combine subject matter experience with considerable knowledge of the sector, including the scientific, medical, regulatory, commercial and enforcement environments facing our biopharmaceutical, medical device, research and diagnostics clients.

DLA Piper's team includes award-winning lawyers practicing litigation, compliance and investigations, IP strategy and enforcement, M&A, licensing and distribution and clinical trial advice. They also support clients across all other areas needed to address risk, including government affairs, environmental law, import/export, tax, real estate and employment law. Many of our lawyers are former sector professionals, many have PhDs or other advanced degrees in the life sciences field and others are former government officials or prosecutors.

Recognizing that our clients' needs vary, we rapidly organize and customize our client service teams, whether for a large pharmaceutical company, a mid-sized medical device client or a development-stage biotech company. These teams are supported by international and local practitioners to efficiently meet the demands of the matter.

Our cutting-edge staffing, budgeting and billing systems, created specifically to assist our global life science clients, ensure that our teams deliver value in addition to great results.

Our life sciences team helps clients solve their biggest challenges every day. Examples of our experience include:

- Conducting a sensitive investigation in China
- Negotiating a complex multi-country distribution deal in Latin America
- Acting as National Counsel on a mass tort in the US
- Helping sell or acquire a major business asset
- Advising on implementation of transparency laws or the impact of other new legislation
- Devising a risk mitigation plan for a key product
- Negotiating a large vaccine contract with a global NGO
- Counselling on a multi-jurisdictional clinical trial
- Advising on the downsizing of employees in Europe
- Supporting global business conduct and compliance functions
- Outsourcing critical R&D or IT functions
- Devising an IP strategy for a promising new therapy
- Negotiating a worldwide licensing and collaboration deal
- Protecting a blockbuster drug in patent litigation

INSIGHTS

Publications

Preliminary injunction granted in Cal Chamber lawsuit concerning acrylamide Prop 65 warning

1 April 2021

California's Eastern District federal court found that Prop 65's acrylamide warning requirement was likely unconstitutional and preliminarily enjoined new lawsuits alleging failure to warn for acrylamide exposure in food and beverages.

Patent eligibility in bioinformatics: Federal Circuit affirms rejection of computerized haplotype phasing claims

31 March 2021
Yet another hurdle for inventors in the growing field of bioinformatics and computational biology.

The Pharmaceutical Corner

30 March 2021
The opinion may render functional claiming more difficult, but functional claims that follow its guidance may still have an important role

to play in pharmaceutical patents.

Understanding the USPTO guidance on patenting AI technologies

30 March 2021
The USPTO guidance opens the door for applicants to obtain patent protection for their AI technologies.

United States imposes significant new export controls and sanctions on Russia and China

23 March 2021

Reflecting a further hardening of US foreign policy and national security policy positions with those two countries.

California Prop 65: OEHHA proposes changing popular short-form warning

3 February 2021
Businesses selling products in California that utilize short-form Proposition 65 warnings may have to be re-label yet again or risk enforcement actions.

Telehealth's impact on low-income communities

3 March 2021

Ray Williams and Kirsten Axelsen are joined by Dr. Benson Hsu of the University of South Dakota Sanford School of Medicine for a frank discussion on disparities to engaging with telehealth and ways to better serve low income communities.

Expectations for white collar enforcement under the Biden Administration

18 February 2021
Six key areas where the Biden Administration may focus its enforcement efforts.

Corruption Perceptions Index 2020 - a regional perspective

11 February 2021

Last week Transparency International launched the 2020 edition of its Corruption Perceptions Index (CPI), which ranks 180 countries and territories by their perceived levels of public sector corruption, according to experts and business people, using a scale of zero to 100 (100 being very clean and zero being highly corrupt).

The Qualified Maquiladora Approach Agreement has been renewed: Implications for multinationals' transfer pricing

26 January 2021
US-based multinationals using the maquiladora structure to manufacture goods in Mexico are taking note.

Israel Group News January 2021

19 January 2021
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

No Surprises Act creates new model for commercial payors and providers

7 January 2021
The act contains consumer protection and transparency requirements that may fundamentally change health payor and provider operations.

Supporting the health of your health system

4 January 2021
Helping you tend to healthcare system wellness throughout the business life cycle.

Boardroom Brexit: What the deal means for business

31 December 2020
BOARDROOM BREXIT

Welcome to this last edition of Boardroom Brexit, marking the end of the negotiations and the agreement of a new trade deal, the UK-EU Trade and Cooperation Agreement (TCA). In this edition, we summarise the impact of the deal on all aspects of business operations in one place – please use the hyperlinks below to help you navigate the report.

Boardroom Brexit: What the deal means for trade in goods

31 December 2020
BOARDROOM BREXIT

What will the Trade and Cooperation Agreement mean for tariffs and quotas, rules of origin, technical barriers to trade, customs and product standards

---

Boardroom Brexit: What the deal means for trade in services

31 December 2020
BOARDROOM BREXIT

The TCA has substantial sectoral coverage, including professional and business services (e.g. legal, auditing, architectural services), delivery and telecommunication services, computer-related and digital services, financial services, research and development services, most transport services and environmental services.

The EEOC breaks its silence on the COVID-19 vaccine

22 December 2020
Some of the most important questions answered by the EEOC's guidance.

The Pharmaceutical Corner

22 December 2020
A precedential decision with potentially far-reaching impacts for future Hatch-Waxman litigation and generic-product launches.

Landmark artificial intelligence legislation advances toward becoming law

16 December 2020
AI OUTLOOK

An overview of the key AI initiatives and funding set out in the defense bill.

Navigating risk and compliance in government contracts M&A

14 December 2020
Webinar now available: government contracts and pre-closing diligence.

Silver linings for FCA defendants in new HHS Working Group

11 December 2020
The US Department of Health and Human Services is launching the Working Group to better protect taxpayer funds and deter "would-be fraudsters."

FDA seeks feedback on industry best practices for medical device cybersecurity communications

9 December 2020
The agency emphasizes the evolving responsibility of medical device manufacturers to promptly, clearly communicate cybersecurity issues to patients and healthcare providers.

CMS, OIG finalize Stark and AKS overhaul – paving the way for value-based care

25 November 2020
We highlight some of the most important ways in which HHS followed through on its ideas from 2019, as well as the instances where they pivoted in reaction to public comments.

HHS-OIG issues alert warning pharmaceutical and device manufacturers about the kickback risks of speaker programs

24 November 2020
Key details and takeaways.

The US Hemp Production Handbook

4 November 2020
A concise, high-level overview for businesses that are currently or are considering operating in this growing market.

Vaping and COVID-19: Plausibility and causality

26 October 2020
In a courtroom, assertions must be analyzed in the context of tort law.

China signs off on PRC Biosecurity Law: What this means for industry players in China

21 October 2020
The Biosecurity Law establishes a comprehensive framework replacing the current somewhat piecemeal legislation.

Germany’s New Foreign Direct Investments (FDI) Act took effect on 11 October 2020

19 October 2020
In addition to the intended amendments to the Foreign Trade and Payments Act Germany’s Federal Government on 20 May 2020 has decided on a bill that broadens the scope and the scrutiny with regard to foreign investments.

China Enforces Tax Collection on Employees Working for Chinese-invested Enterprises Overseas

16 October 2020
With the recent IIT reform in 2019, and the introduction of a number of implementation rules (particularly the tax policy on overseas income), it appears the China tax authorities are taking a harder stance on how overseas income derived by China tax residents will be taxed in China, starting with Chinese expatriates working for Chinese state-owned enterprises.

COVID-19 – Galvanising your business against supply chain and customer insolvency risk

7 October 2020
The risk of unforeseen counterparty customer or supplier financial distress and failure amidst the on-going challenges for businesses from COVID-19 means that pre-emptive legal and operational protections against the risk of heavy financial loss or business disruption from customer/supplier failure are more valuable than ever.

Israel Group News October 2020

7 October 2020

ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

Mass layoffs and collective redundancies guide

6 October 2020

As COVID-19 continues to impact the global economy in unprecedented ways, companies that have had to scale back or shut down operations are bracing for what the next few months will bring, and what this means for their workforces. In this guide, we examine key considerations for employers looking to make permanent reductions in force across APAC.

Coronavirus Resource Center: Our global repository of insights and events

30 September 2020

A central repository for our reports and commentary on the legal and regulatory concerns arising from the pandemic.

New CFIUS regulations change mandatory filing requirements and increase the importance of US export controls

30 September 2020

The new rule modifies the criteria that trigger a mandatory filing with CFIUS, potentially subjecting more transactions to mandatory CFIUS review.

Philadelphia grows privacy capabilities with a new arrival

30 September 2020

Ronald Plesco, an internationally known information security and privacy lawyer, has joined our Philadelphia office.

The Pharmaceutical Corner

30 September 2020

In this inaugural column, we look at the implications of IPR and PGR proceedings in Hatch Waxman litigation.

California on the verge of instituting new deidentification requirements, broader research exemptions for health data

23 September 2020

AB 713 has an emergency clause that means it will go into immediate effect once the governor signs it.

Four years later, federal court upholds convictions but harshly criticizes off-label prosecutions

23 September 2020

The decision will likely draw attention both in the First Circuit and beyond.

Digital Therapeutics - evolution and entry into mainstream healthcare

18 September 2020
Research undertaken by DLA Piper's Life Sciences sector in conjunction with The Lawyer seeks to understand the current developments in the field of digital therapeutics, looking at key questions that need to be addressed if these products are to become mainstream components of health systems across the world.

PREP Act immunity: federal courts weigh in

4 September 2020
The decisions suggest PREP Act immunity may apply broadly to manufacturers but may be more limited for hospitals, nursing homes, healthcare providers and others.

Details of the second tranche of Hong Kong's Employment Support Scheme released

24 August 2020
On 18 August 2020 the Hong Kong government announced details surrounding the second tranche of the Employment Support Scheme. While the majority of the rules surrounding the second tranche remain largely the same as the first tranche, there are new penalties for employers who have fallen foul of a number of nebulous terms.

Release of exposure draft legislation for major reforms to Australia's Foreign Investment Framework

10 August 2020

Many governments around the world have been strengthening their laws relating to foreign investment. Australia is no exception to this development and has just released proposed sweeping reforms to its foreign investment regime. In this article, we provide a high level overview of the key proposed amendments and our thoughts on how some of those proposals are likely to affect foreign investment into Australia.

For the healthcare industry, seeking to incentivize restocking of elective surgery supplies may lead to civil and criminal risk

6 August 2020
Discounts and incentives may have unforeseen consequences under certain federal anti-bribery laws.

New Executive Order forecasts permanent telehealth funding changes

5 August 2020
The Order implies a possible mechanism for making telehealth changes in spite of statutory confines and signals to Congress to take further action to permanently expand telehealth access in the Medicare program.

Vlog series: How to raise equity capital during the Coronavirus pandemic (UK)

4 August 2020
The first half of 2020 has seen an unprecedented volume of activity by companies raising capital through follow-on equity offerings on the London Stock Exchange in response to the Coronavirus pandemic. There have been over 140 equity issues on the London Stock

Exchange's main market or AIM since 20 March 2020 raising more than GBP14 billion.

HHS extends COVID-19 public health emergency declaration, preserving major Medicare changes (for now)

27 July 2020
The PHE declaration is an important prerequisite for certain major emergency measures the government has deployed to help address the pandemic.

Momentum builds for permanent expansions in federal telehealth policy

21 July 2020
Recent legislative proposals and administrative initiatives suggest that the federal government may be moving to make permanent certain emergency fixes to the telehealth regulatory landscape.

Hong Kong Government increases statutory entitlement for maternity leave

16 July 2020

On 10 October 2018, the Chief Executive stated in her policy address that the government proposed to increase the statutory maternity leave entitlement from ten to 14 weeks.

Israel Group News July 2020

8 July 2020
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

The legal challenges facing the vaping industry in the EU/UK and the US: An overview and a look ahead

7 July 2020
Notes as the industry matures.

CMS proposed rule aims to encourage value based purchasing for drugs, now open for comment

6 July 2020
The rule is intended to spur the development of contractual arrangements between insurers and biopharma companies that rely on the observed value from medicines in exchange for payment.

Clinical trials during the COVID-19 pandemic: A global guide

2 July 2020
The consequences of the COVID-19 pandemic continue to develop dynamically. Some countries are beginning to ease lockdown measures, whilst other retain or even impose new restrictions. The situation continues to impact the ability to conduct clinical trials on a global scale. Pharmaceutical companies need to address even more challenges to ensure the continuity of trials on human medicines.

A go-to firm for defending patent cases

30 June 2020
Recognition from *Law360*

Atlanta expands privacy capabilities

30 June 2020
Lael Bellamy's arrival bolsters our data protection, privacy and security capabilities throughout the firm.

Changes to Hong Kong anti-discrimination legislation

30 June 2020
Anti-discrimination laws in Hong Kong have undergone a series of changes over the past few years.

Coronavirus Resource Center: Our global repository of insights and events

30 June 2020
A central repository for our reports and commentary on the legal and regulatory concerns arising from the pandemic.

Hatch-Waxman Litigation 101: The Orange Book and the Paragraph IV Notice Letter

30 June 2020
A few of the key issues that must be addressed before a Hatch-Waxman suit is filed.

Intellectual property rights are a renewed focus as the world looks beyond a global viral outbreak

30 June 2020
A few key IP-related considerations for companies, whether they are seeking to expand into new markets or looking to preserve their place in an existing market.

Northern California bolsters telecom and regulatory practice

30 June 2020
Regulatory and telecom attorney Kristin Jacobson has joined our Northern California office in Sacramento.

Washington, DC grows technology capabilities with two new arrivals

30 June 2020
Marius Domokos and Justin Ilhwan Park have joined our Washington, DC practice.

First emerging technologies identified and controlled for export in the EAR

26 June 2020
The designation also makes these a "critical technology," giving CFIUS jurisdiction over foreign investments in US businesses that engage with these items.

Therapies for COVID-19: Two major developments

25 June 2020
The developments, one negative and one positive, involve widely available medications.

CFIUS encourages public to provide tips and referrals

24 June 2020
The new webpage encourages tips and referrals about non-notified deals, violations of CFIUS mitigation measures, and other matters that raise national security risk.

Australia tightens rules on foreign investment

17 June 2020
In this article we summarise the tax-related developments from early June 2020, as Australia takes a more stringent approach towards compliance procedures involving foreign investments.

US-based pharmaceutical manufacturing in response to COVID-19: new manufacturers face risks

3 June 2020

A rush to develop a new company to begin manufacturing is fraught with risk.

Preparing for global class actions arising from COVID-19

28 May 2020
The risk to companies of global and cross-border class action and collective redress proceedings is rising.

Chinese and other emerging market companies listed in the US face increased scrutiny from Congress and Nasdaq

27 May 2020
Within a span of two days, the US Senate, House and Nasdaq each took steps to safeguard investors in the US capital markets.

CFIUS proposes export control-based reforms to its mandatory filing program

22 May 2020
Details of the proposed modifications and their practical impact.

Coronavirus testing and contact tracing: House Democrats' HEROES Act provides US$75 billion to support testing and tracing to monitor and suppress COVID-19 transmission

21 May 2020
A major element for a successful, large-scale contact tracing program is data management and technology, and technology partners will play a major role in modifying existing systems as well as developing new data interfaces.

Helping patients during the pandemic

14 May 2020
Some important considerations for biopharma manufacturers.

[UPDATED] Therapies for COVID-19: What is in the pipeline?

11 May 2020
As of May 8, 2020, there are over 1,300 clinical trials investigating potential therapies for COVID-19, of which nearly 800 are interventional trials.

SCOTUS unanimous – willfulness not a prerequisite to a profits award under the Lanham Act

8 May 2020
The Supreme Court resolves a decades-long circuit split.

US takes action to abate tariffs and duties in wake of COVID-19

8 May 2020
US importers may consider navigating the various tariff exemptions and deferrals in several ways.

Coronavirus: Changes to rules governing meetings and the execution of company documents (Australia)

7 May 2020

Certain requirements in the *Corporations Act 2001* (Cth) (**Corporations Act**) relating to shareholders meetings, and document signatures, are not compatible with public health requirements for social distancing during the coronavirus pandemic. In order to facilitate these important corporate functions during this period, on May 6, 2020 the Australian Federal Government introduced the Corporations (Coronavirus Economic Response) Determination (No. 1) 2020.

This determination modifies the legislative requirements regarding meetings and execution of company documents. These changes come into force on 6 May 2020, and will expire after six months, on 5 November 2020.

Latest round of CMS COVID-19 waivers includes telehealth expansion and other billing flexibilities

7 May 2020
Congress is permitting dramatic expansion of telehealth coverage for the duration of the public health emergency. These are the latest developments.

Life Sciences Top of Mind: COVID-19 sector insights

7 May 2020
Top COVID-19 considerations for the life sciences sector.

Protecting AI technologies through patents: A US guide

7 May 2020
A strong patent portfolio developed around a company's artificial intelligence innovations is an important asset.

COVID-19: New York and Other Northeast Council states take phased approach to reopening economy

6 May 2020
These developments raise a number of immediate questions and considerations for businesses operating in the region.

Is subject matter jurisdiction under the Hatch-Waxman Act expanding?

6 May 2020
Can non-Orange Book patents be asserted?

Coronavirus: Directors' duties and making decisions in a crisis (Australia)

4 May 2020

Directors need to carefully consider the risks of the COVID-19 outbreak within their business, given its impact on the global economy. As many now face significant, and increasing, cash flow pressure, directors should carefully consider their actions in the context of the legal framework.

In this new guide we have set out the practical steps directors should be taking to protect their company and its business going forwards.

Israel Group News May 2020

4 May 2020
ISRAEL GROUP NEWS

Providing access to valuable business resources in real time.

Post-COVID-19: What to expect in the "next normal"

30 April 2020
Issues that are front of mind, based on an informal survey of some of the largest companies and most influential global business leaders.

HHS clarifies PREP Act immunity for COVID-19-related activities

28 April 2020

These immunity provisions may provide significant protection to manufacturers, distributors, and others engaged in COVID-19-related efforts.

US telehealth update: New federal guidance to state Medicaid agencies suggests more coverage is coming

27 April 2020

A powerful signal that CMS is ready to support targeted interventions in favor of telehealth.

Connected care funding for healthcare providers from the CARES Act

24 April 2020
New funding to promote and support telehealth.

Coronavirus: State Attorneys General take action against alleged price gouging in personal protection equipment sales

21 April 2020
State Attorneys General coast to coast are taking aggressive action.

Opening Up America Again Guidelines signal relaxation in elective surgery restrictions

20 April 2020
For healthcare providers as they evaluate how the Opening Up America Again Guidelines pertain to their respective practices.

Clinical trials during the COVID-19 pandemic: A global guide

17 April 2020
The unprecedent situation resulting from the COVID-19 pandemic impacts the ability to conduct clinical trials on a global scale. Pharmaceutical companies need to address multiple challenges to ensure the continuity of trials on human medicines.

CMS regulatory waivers relax supervision and other requirements in an effort to address staff shortages caused by rising COVID-19 cases

16 April 2020
These changes are effective immediately.

Immediate COVID-19 relief to Medicare providers arrives… with conditions

16 April 2020

For eligible Medicare providers who continue to suffer economic losses stemming from the pandemic, this program is welcome, but it comes with detailed conditions.

Paradigm Change in Germany's Foreign Direct Investments (FDI) Law

14 April 2020
Germany's FDI rules so far had a reputation of not being very strong. In the past few years, only three transactions have been prohibited. This is set to change under a new bill.

COVID-19: New York State provides new guidance on essential businesses

13 April 2020
The Guidelines raise a number of immediate questions and considerations for New York businesses.

Coronavirus: Overview of healthcare funding stimulus and policy provisions in the CARES Act (United States)

10 April 2020
Among numerous health policy provisions in the CARES Act is one allowing BARDA to partner with private sector companies on R&D.

EU Antitrust Framework for the coordination of essential coronavirus COVID-19 products and services

10 April 2020
ANTITRUST AND COMPETITION: NOVEL ISSUES IN A POST-CORONAVIRUS WORLD

On 8 April 2020 the Commission published a Temporary Framework for the antitrust assessment of increased business cooperation between competitors in response to coronavirus COVID-19. The aim is to reduce shortages for essential products and services.

Families First Coronavirus Response Act – Health emergency leave and exempted health care providers

10 April 2020
The temporary health emergency leave measures include a key carveout for "Health Care Providers" and "Emergency Responders."

US $2T stimulus COVID-19 package includes significant R&D funding

10 April 2020

A summary of R&D funding in the CARES Act broken out by federal departments and agencies.

UK government to provide additional financial support measures for mid-market business impacted by COVID-19

9 April 2020
On 3 April 2020 the Chancellor announced a new scheme for larger companies, with the creation of the new Coronavirus Large Business Interruption Loan Scheme (CLBILS) to ensure that more firms are able to benefit from government-backed support during this difficult time.

COVID-19: Tort immunity for vaccines and antivirals – lessons from the swine flu of 1976

8 April 2020

While the common goal is to quickly develop countermeasures to combat COVID-19, it is important to consider the potential legal and

reputational risks.

European Commission proposes one-year postponement of MDR application date

8 April 2020
Following an informal heads-up on 25 March 2020, today the European Commission adopted a proposed regulation to postpone by one year the date of application of the Medical Devices Regulation (Regulation (EU) 2017/745, “MDR”). If enacted, the Medical Device Directive (Directive 93/42/EEC) and implementing legislation of the EU member states will continue to apply as far as they have not yet been amended.

Contract analysis in a crisis: flowcharts

7 April 2020
Flowcharts providing considerations for analyzing commercial contracts in the context of the COVID-19 pandemic through a logical process flow that can serve as a practical checklist.

Coronavirus - Mitigating supply chain and customer insolvency risk (Canada)

7 APR 2020
The on-going impact of the COVID-19 outbreak could have a significant impact on your global supply and customer chains.

Cost-cutting considerations in the time of COVID-19 (Part 3 – employment issues outside the US)

7 April 2020

A deeper dive into various cost-saving measures and their viability for employers outside the US.

FCA publishes guidance on UK mortgage “payment holidays” relating to COVID-19

7 April 2020
Following an announcement by the UK government on 17 March 2020, the Financial Conduct Authority (FCA) has published guidance for participants in the residential mortgages sector, setting out their expectations in respect of payment holidays that are to be offered to customers experiencing financial difficulties arising from the COVID-19 outbreak.

HHS issues notification of enforcement discretion under HIPAA for certain uses and disclosures by business associates

7 April 2020

This announcement permits business associates to share personal health information with public health authorities and agencies in accordance with HIPAA exceptions as part of COVID-19 relief efforts.

A balance between the government, the private sector and the needs of the people: Invocation of rarely used provisions to ensure public safety during the COVID-19 pandemic

6 April 2020

The Defense Production Act, compulsory licensing and march-in rights are means for authorizing the government to step in and assert rights against private companies.

COVID-19 and the "essential business" designation: Practical guidance for businesses that fall in the gray area between "essential" and "non-essential"

6 April 2020

Certain frequently asked questions as well as practical guidance.

COVID-19 emergency declaration allows Centers for Medicare & Medicaid Services to issue 1135 waivers, 1915(c) waivers and changes to survey and audit processes

6 April 2020

Issued in a public health emergency, the waivers help ensure healthcare items and services are available for individuals enrolled in Social Security Act programs.

Coronavirus: Supplier due diligence for vetting Chinese medical suppliers for quality, safety, fair pricing and anti-corruption compliance

6 April 2020

Some key risks, and potential solutions to reduce cross-border operational risks.

Coronavirus: The Defense Production Act's authorities and limitations in the fight against COVID-19

6 April 2020

The DPA has significant implications for companies receiving a direct order from the President and for the subcontractors and suppliers behind them; meanwhile, recent legislation has created procurement opportunities under the DPA.

[UPDATED] As device industry veterans and newcomers step up to the line, FDA swiftly adjusts regulatory hurdles for personal protective equipment during the COVID-19 pandemic

6 April 2020
A high level overview of the FDA's tiered, risk-based approach to masks, face shields and respirators based on developments to date.

CARES Act may offer relief for medical practices, but raises questions for private equity-backed practice management companies

3 April 2020
Medical practices and practice management companies are urged to consider options under the CARES Act.

CARES Act waivers from CMS provide additional flexibility for telehealth services and relief from certain Stark Law liabilities (United States)

3 April 2020
This latest relief further expands healthcare practitioners' ability to reach patients through telehealth, an important tool for addressing patient needs while reducing in-person contact.

Beyond social distancing: What employers need to know to keep their workplaces safe and manage privacy obligations in the face of COVID-19

2 April 2020
Guidance from OSHA, EEO and CDC to help employers seeking to protect the health, safety and privacy of their on-site employees.

Coronavirus: Cybersecurity considerations for your newly remote workforce (United States)

31 March 2020

Cyber risk management involves balancing the productivity of a workforce with ensuring confidentiality, integrity and availability of the company’s own systems and data, as well as that of their supply chain.

Importing critical healthcare supplies during the COVID-19 pandemic: Recent US developments

31 March 2020

Practical guidance is critical to help importers of medical products efficiently navigate legal and regulatory hurdles so that admissible products with the potential to safeguard patients' health and well-being may be granted entry into US markets as expeditiously as possible.

Are you ready for CCPA class action litigation?

30 March 2020
Many businesses may not have fully contemplated the major data breach class action litigation risk created by the California Consumer Privacy Act.

Top franchise developments of 2019

30 March 2020

Two top franchise developments in 2019 stand out from the rest.

Coronavirus: DHS Response to COVID-19 - What US Employers Need to Know

29 March 2020
Key questions and answers related to the new DHS guidance.

COVID-19 prompts CMS to give new flexibility to participants in Medicare Quality Programs

25 March 2020
In light of COVID-19, participants in the Medicare Quality Payment Program will have extra time to report some quality metrics and can

temporarily suspend other tracking and reporting activities altogether.

Coronavirus: Competition and regulatory measures in Ireland

25 March 2020

ANTITRUST AND COMPETITION: NOVEL ISSUES IN A POST-CORONAVIRUS WORLD

An unprecedented challenge calls for unprecedented measures. The competition and regulatory world has reacted rapidly to the challenge of COVID-19 with bold legal solutions. We discuss how EU and Irish regulators are responding with support for business, exploring the relaxation of competition laws and adopting temporary measures for merger review.

Coronavirus: Cyber hygiene practices

25 March 2020

While the world is responding to the coronavirus disease 2019 (COVID-19), and individuals are increasingly focused on personal hygiene and social distancing, augmenting cyber hygiene efforts at home and at work are increasing in importance too.

Coronavirus: Employee furloughs, reductions-in-force and similar temporary cost-saving measures (Part 2 – Employment issues outside the US)

25 March 2020

A general overview of key employment issues to consider outside of the US in light of COVID-19.

Coronavirus: Employee furloughs, reductions-in-force and similar temporary cost-saving measures in the US - Part 1

25 March 2020

Key employment-related issues for US-based employers in relation to cost-saving measures due to COVID-19.

Hotels and hospitals may find new partnerships to solve for bed capacity issues and vacancies

25 March 2020

The impacts of COVID-19 upon the hospitality sector as well as hospital systems and the healthcare industry have been sudden and dramatic.

CMS Emergency Preparedness Rule: Planning during COVID-19 (United States)

24 March 2020

As healthcare providers continue to face a variety of challenges during the coronavirus disease 2019 (COVID-19) pandemic, healthcare providers and suppliers should be aware of the Centers for Medicare and Medicaid Services Emergency Preparedness Rule and its resources.

Coronavirus: Several state and local governments issue “shelter in place” orders (United States)

23 March 2020

Between March 17 and 22, state and local governments have promulgated at least a dozen “Stay-at-Home” / “Shelter-at-Home”-type

Orders. This alert provides details on a number of state and local government orders.

90-day deferral for US federal income tax payments

20 March 2020
Those who decide to defer their federal tax payments will be able to do so on a penalty-free and interest-free basis, with penalties and interest beginning to accrue for payments submitted after July 15, 2020.

Potential paths forward amidst the challenges to COVID-19 therapeutic and vaccine development; collaboration and communication among clinical trial stakeholders takes on heightened importance (United States)

20 March 2020

In a March 19, 2020, briefing and press release, the US Food and Drug Administration outlined ways that existing regulatory options may make it possible to expedite access to therapeutics and vaccines with the potential to treat or prevent coronavirus disease 2019 (COVID-19).

COVID-19: The benefits of US chapter 11 relief in a time of economic crisis

19 March 2020
Highlighting some of the most significant benefits of US chapter 11 for companies facing severe challenges under the current circumstances.

Coronavirus: business resilience and continuity planning

19 March 2020
Prudent companies understand that their response to the COVID-19 pandemic should be consistent with their business resilience plans.

Coronavirus: Congress passes revised paid leave law (United States)

18 March 2020
Congress passed a revised version of The Families First Coronavirus Response Act requiring employers with fewer than 500 employees to provide COVID-19-related paid sick and family leave to eligible employees.

Telehealth update: COVID-19 prompts emergency Medicare coverage and other seismic shifts (United States)

18 March 2020
Multiple federal agencies have issued regulatory waivers and released additional funding to loosen the constraints on telehealth services and encourage widespread adoption.

Coronavirus: Congress expected to pass expanded paid leave (United States)

16 March 2020
The paid leave requirements in the current version of the Families First Coronavirus Response Act.

Coronavirus: federal and state tax relief (United States)

16 March 2020
Congress and state legislatures and administrative agencies are working hard to provide necessary tax relief for those affected by the coronavirus disease (COVID-19) pandemic.

Coronavirus (COVID-19): ten practical steps for global employers, right now (Global)

13 March 2020
These steps are not based on laws of any one jurisdiction but rather are designed to provide a global employer with themes to consider, understanding that what may be suitable for each employer may vary greatly depending on the employer's unique circumstances.

HIPAA and the coronavirus (United States)

13 March 2020
Key questions businesses may consider asking.

Life sciences market remains strong despite uncertainty in an election year

11 March 2020
The current state of life sciences financing – thoughts from the JPMorgan panel

---

Defending your supply chain against coronavirus COVID-19 (United States)

9 March 2020

An action plan that companies can implement to make strategic decisions related to potential supply chain disruptions.

Europe initiates regulations on artificial intelligence; industry presented with opportunity to provide inputs

5 March 2020
AI OUTLOOK

The White Paper on AI initiates a process that could potentially establish the world's first far-reaching regulatory framework for AI.

Healthcare market proves strong as investors embrace new technological advancements

3 March 2020

Takeaways from the JPMorgan panel, "Healthcare M&A Exits: Who's Buying, What Are They Buying, and Why?"

FTC issues 6(b) orders to tech companies − healthcare companies could be next

14 February 2020
The agency seeks information on unreported acquisitions with the goal of deepening its understanding of the competitive tech sector landscape.

White House proposes doubling artificial intelligence budget

13 February 2020
AI OUTLOOK

Lawmakers now have the opportunity to debate and amend the budget proposal in the upcoming appropriations process.

An update on the impact of the coronavirus on business in Singapore

12 February 2020

Due to the evolving 2019- nCoV acute respiratory disease (the COVID-19) situation, the Ministry of Health (the MOH) and the Ministry of Manpower (the MOM) have, since January 2020, issued advisories which employers will need to be aware of. In particular, the MOH and MOM have, since our last update on February 12 2020, updated and issued new advisories due to the increased risk of importation of COVID-19 into Singapore.

Wasica v. Schrader: IPR estoppel can include system prior art – key takeaways

11 February 2020
This case raises a few interesting points for practitioners and companies involved in patent litigations and IPRs.

DLA Piper's Dylan Kennett joins panel debate at the Cannabis Investor Summit in Odense, Denmark

11 February 2020
On January 28, Dylan Kennett, Senior Associate in DLA Piper's corporate team and co-lead of our Global Cannabis practice, joined a panel debate at the Cannabis Investor Summit in Odense, Denmark. DLA Piper is proud to be a partner on this summit hosted by Invest in Odense, Invest in Denmark and Novo Nordisk Engineering (NNE).

Hong Kong Government introduces mandatory quarantine measures

11 February 2020

On 9 February 2020, the number of deaths due to the rapidly spreading coronavirus in Mainland China officially surpassed the figure seen during the 2002/2003 SARS epidemic.

Numerous governments have been implementing restrictions barring entry to those with recent travel history through Mainland China, including Singapore, Japan, Australia and the United States. Following pressure from public health workers, the Hong Kong Government has now followed suit and has begun a mandatory two-week quarantine for anyone arriving from Mainland China.

How to resume business amid the coronavirus outbreak (China)

11 February 2020

As reported in our previous article, China has extended its Chinese New Year holiday and work suspension period as a result of the novel coronavirus outbreak which has now infected more than 40,000 people around the world.

This is a summary of the Back to Work Day and compensation for working before Back to Work Day in key cities and provinces across China.

Israel Group News February 2020

10 February 2020

ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, coming events and more.

APAC employment issues arising out of the Coronavirus (AsiaPac)

31 January 2020

On 29 January 2020, the number of confirmed cases of the rapidly spreading coronavirus in Mainland China officially surpassed the figure seen during the 2002/2003 SARS epidemic.

Multinationals with local operations around the APAC region have been significantly affected. As staff return to the office following the Chinese New Year holiday period, businesses are now considering what they can do to minimise any risk to health and safety and support staff through this challenging period where anxiety and uncertainty is rife, whilst at the same time complying with their employment obligations and maintaining business continuity. Putting in place detailed business and contingency plans and ensuring careful communications with staff to address key topics and concerns is key, as is keeping such plans and communications under frequent review given the fluidity of the current situation.

This alert considers some of the key issues that HR and business leaders should be considering across the APAC region.

Harsher penalties on discriminatory employment practices in Singapore

29 January 2020
The Fair Consideration Framework was updated in January 2020 to impose harsher penalties on employers found to be engaging in discriminatory practices such as by favouring the hiring of foreigners over Singaporeans.

China extends holidays for workers amid coronavirus outbreak (China)

28 January 2020
Learn about how the widely publicised corona virus outbreak affects business in Greater China.

EU MDCG issues new guidance on Cybersecurity for medical devices

27 January 2020
On 7 January 2020, the EU Medical Device Coordination Group published new guidance to help manufacturers fulfil all relevant cybersecurity requirements in Annex I to the new Medical Device Regulations (Regulations 2017/745 on medical devices and 2017/746 on in vitro diagnostic medical devices).

Broad's CRISPR/Cas9 patent EP2771468 revoked by the European Patent Office

17 January 2020
In the ongoing CRISPR patent battle, the European Patent Office has upheld the earlier EPO Opposition Division ruling revoking Broad Institute's European patent EP2771468.

Iran nuclear deal: the launch of the ‘Dispute Resolution Mechanism’ and the ‘potential snapback’ of UN and EU sanctions

17 January 2020
This week, France, Germany and Britain have triggered the Dispute Resolution Mechanism against Iran under the Joint Comprehensive Plan of Action (JCPOA). Will this process lead to the re-imposition of UN and EU sanctions on Iran?

New regulations reinforce CFIUS's expanded role with respect to foreign investments in the United States

16 January 2020
The new CFIUS regulations become effective on February 13, 2020.

Top of Mind: Life Sciences

16 January 2020
Eight big topics that life sciences businesses have been thinking about and how DLA Piper has been covering those stories.

The almost free US-Japan Trade Agreement is now in effect

9 January 2020
This trade agreement reduces or eliminates US customs duties on numerous goods.

White House issues guidelines for regulatory and non-regulatory approaches to artificial intelligence

8 January 2020
AI OUTLOOK

Michael Kratsios, Chief Technology Officer of the United States, called the new initiative the "first of its kind" − the first "binding document" for how government agencies will regulate emerging AI technology.

Supporting the health of your health system

6 January 2020
Guidance to help tend to healthcare system wellness throughout the business life cycle.

Artificial intelligence software tools tested for demographic impact

20 December 2019
A NIST report quantifying demographic differences in nearly 200 face recognition algorithms found “empirical evidence for the existence of a wide range of accuracy.”

CCPA Rescue Kit arrives amid new privacy law change

19 December 2019
A series of integrated compliance offerings to help businesses begin the journey of compliance with this important new privacy bill.

Street art raises novel copyright issues – or does it?

19 December 2019

Is street art less entitled to copyright protection than are traditional art forms?

EU launches preparatory work for a global sanctions regime for human rights violations

17 December 2019
On 9 December 2019, High Representative/Vice-President of the European Union Josep Borrell announced that the Foreign Affairs Council has agreed with strong consensus to start the preparatory work for a global sanctions regime to address serious human rights violations.

Upcoming 12/31 deadline to comment on CMS and OIG proposed rule changes under the Stark Law and Anti-Kickback Statute

16 December 2019

The two highly consequential proposals are poised to change how HHS approaches fraud and abuse enforcement in federal healthcare programs.

Announcing DLA Piper's MDL Benchmark Database

9 December 2019

Comprehensive and systematic analyses of MDL procedures and practices.

What starts the avalanche? Earlier triggers for life sciences mass torts in the era of big data and social media

9 December 2019

The bar for safety issues to lead to claims that ultimately result in mass tort litigation has never been lower.

Israel Group News November 2019

18 November 2019

In this issue, IP considerations in augmented reality and virtual reality, plus our global activities, latest publications, coming events and more.

DC policymakers working to stay ahead of – or keep up with – AI innovations

4 November 2019
AI OUTLOOK

The inaugural issue of *AI Outlook* reviews the latest developments around AI in Washington and discusses what these bills and trends mean for business.

Plaintiff attorney advertising in pharmaceutical and medical device litigation: addressing the risk of harm to the public

29 October 2019
Law firm advertising about pharmaceutical and medical device litigation is receiving heightened regulatory scrutiny.

CMS and OIG release most expansive changes to the fraud and abuse laws in over a decade

18 October 2019

The proposed changes are part of the HHS Regulatory Sprint, which seeks to remove regulatory barriers to care coordination and value-based care.

Food and Beverage News and Trends

14 October 2019

FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, is it time to revise food standards of identity? Plus vaping, alcohol labels, and a potential commissioner for the FDA.

The Russian Supreme Court clarifies intellectual property legislation

30 Sep 2019

Clarifications from the Supreme Court have a significant impact on the further development of court practice in Russia.

The CBD problem: searching for a legal pathway for CBD in foods and supplements

20 September 2019

The current state of the laws and regulations in the US, and potential pathways to a resolution.

Treasury Department proposes regulations comprehensively implementing FIRRMA and reforming CFIUS national security review

19 September 2019

The proposed regulations affect non-controlling investments involving critical technologies, critical infrastructure, and sensitive personal data; and transactions involving real estate near sensitive national security facilities.

Australian Taxation Office publishes important guidance on cross-border tax measures

29 August 2019
In this article we analyse guidance published by the Australian Taxation Office on important Australian international tax measures that affect foreign investments in Australian structures and other cross-border transactions.

Israel Group News August 2019

7 August 2019
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, coming events and more.

The learned intermediary doctrine in the WebMD era

1 August 2019

Our US medical system continues to put the physician between the medication or treatment and the patient for a reason.

Announcing Accelerate's newly updated market data

25 July 2019
Data may be filtered by time period, transaction volume, transaction type and, in some cases, industry vertical.

Biomarker-based cancer diagnostics: German pricing regulator sets high validation and reimbursement standards for novel diagnostic methods

10 July 2019

On 20 June 2019, for the first time, the German Federal Joint Committee (FJC − Gemeinsamer Bundesausschuss / G-BA), the highest decision-making body of the joint self-government of physicians, dentists, hospitals and statutory health insurance funds (SHI − gesetzliche Krankenversicherung / GKV) in Germany, made the resolution that a specific biomarker-based test to support the treatment decision for or against adjuvant chemotherapy, i. e. after primary surgery, in certain breast cancer patients may be reimbursed by the SHIs.

Major developments in class action litigation for 2018 – 2019

18 June 2019
A top-level look at class action litigation for 2018-2019 and a look at trends, issues, and strategies that businesses face in the months to come.

In *Albrecht*, US Supreme Court narrows implied preemption of failure-to-warn claims, finds preemption is legal issue for judge, not jury

21 MAY 2019
The *Albrecht* decision clarifies and substantially narrows the scope of preemption under the *Wyeth v. Levine* "clear evidence" standard.

Bellwether trials in MDL proceedings – guidance for transferee judges

16 MAY 2019

Practical considerations for transferee judges establishing and implementing bellwether protocols in MDL proceedings.

Intellectual Property and Technology News (Asia Pacific) May 2019

15 MAY 2019

INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS

Intellectual Property and Technology News (Asia Pacific) is our biannual publication designed to report on worldwide development in intellectual property and technology law, offering perspectives, analysis and visionary ideas.

First Circuit reverses course on its first-to-file rule

9 MAY 2019

First Circuit law on the first-to-file rule is evolving in a way that could have significant consequences for False Claims Act defendants.

Israel Group News May 2019

9 MAY 2019

ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, coming events and more.

The cybersecurity of digital medical devices: higher technological capabilities, higher likelihood of liability

8 MAY 2019

To prepare for potential new regulatory requirements, medical device manufacturers should take this opportunity to assess their compliance with HIPAA and FDA's Draft Guidance, then complete a Risk Management Plan.

California Proposition 65 lists two chemicals, PFOA and PFOS, found in a number of consumer products

12 DEC 2018

Given Prop 65's active and litigious enforcers, companies doing business in California that suspect their products may cause an exposure to PFOA/PFOS should consider compliance options now.

California court's narrow Prop 65 coffee ruling should not be misinterpreted

9 APR 2018

A careful understanding of the narrow basis of the ruling is important for coffee consumers and for all manner of product-based companies doing business in California.

New glyphosate decision forces Prop 65 to reckon with federally accepted science

7 MAR 2018
This outcome will likely put wind in the sails of industry groups and individual companies challenging the science behind other Prop 65 listings.

Precarious steps: patent eligibility for healthcare IT

26 SEP 2016

Three recent Federal Circuit decisions, along with new updates from the USPTO, offer guidance on which steps to take in patenting healthcare IT-related inventions.

Stop them in their tracks: key points in seeking a preliminary injunction against medical device infringers

22 SEP 2016

Three considerations to bear in mind when bringing or defending a preliminary injunction motion in a medical device infringement case.

Is your cybersecurity upgrade FDA reportable?

28 SEP 2016

Draft guidance lends insight into the way the FDA may apply existing postmarket regulatory requirements to evolving cybersecurity-related technological issues.

Supreme Court Corner: Q1 2016

29 MAR 2016
Two cases to watch.

Are IPRs impacting the pharmaceutical industry?

9 JUN 2015
Choosing between IPRs and district court litigation

Supreme Court Corner - Q1 2015

24 MAR 2015

Recent decisions and cases to watch

Intellectual Property and Technology News (United States), Issue 23, Q3 2014

10 SEP 2014

INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS

Our Intellectual Property and Technology News reports on worldwide developments in IP and technology law, offering perspectives,

analysis and visionary ideas.

Substitution allowed? State biosimilars laws are evolving

10 SEP 2014
Biosimilar products have not yet reached the US market, but debates on the laws and regulations that will govern them have been raging for some time

Supreme Court Corner - Q3 2014

10 SEP 2014
A review of cases relevant to IPT decided or argued before the Court during Q3

DOJ dismisses last of the drug trafficking charges against FedEx: two key takeaways

5 JUL 2016
A sudden about-face from the DOJ.

Ten tips for generating a life sciences brand name

19 NOV 2015

The proliferation of brands, combined with the PR and financial consequences of a potential rebrand in the event of infringement, has made selecting a trademark trickier than ever. Christina Martini and Virginia Wolk Marino report.

Distributing patent rights between affiliates: guidelines to support enforcement rights around the world

16 NOV 2015

Considering a few issues at the outset when rights are distributed between Parent and Affiliate (or between multiple affiliates) may avoid difficulties in the future when a company wants to enforce patent rights.

Wellness innovators take note: FDA reveals risk-based approaches to the regulation of health IT and mobile medical apps

2 FEB 2015

With these draft guidance documents, FDA indicates it will not take enforcement action in connection with low-risk general wellness products and establishes a new risk-based approach to medical device accessories

Revenue pressure climbs for skilled nursing facilities − what does this mean for healthcare REITs?

3 JUN 2015
Healthcare REITs must be mindful of the challenges they may face due to changes in the healthcare environment

SEC begins Dodd-Frank rulemaking with new open process

28 Jul 2010

EVENTS

Previous

The current state of life sciences financing

2 March 2021 | 3:00 - 4:00 EST
Webinar

Communication and information sharing in support of healthcare for vulnerable populations

22 February 2021
Webinar

EDPB recommendations for safeguarding data transfers after Schrems II

19 November 2020
Webinar

Planning for an Uncertain World

16 November 2020
TECHLAW EVENT SERIES

Webinar

Women in Science and Technology Conference

29 October 2020 | 5:30 - 7:30 p.m. AST
Webinar

2020 BioHealth Capital Region Virtual Forum

19 October 2020 | 4:30 - 5:00 EDT
Webinar

Considerations for drug pricing and demonstrating value in a post-pandemic environment

5 August 2020 | 12:00 – 1:00 ET
Webinar

TechLaw

31 July 2020
TECHLAW EVENT SERIES

Webinar

TechLaw

5 March 2020
TECHLAW EVENT SERIES

Sydney

TechLaw

3 March 2020
TECHLAW EVENT SERIES

Melbourne

J.P. Morgan Healthcare Conference

14 January 2020
J.P. MORGAN HEALTHCARE CONFERENCE

San Francisco

J.P. Morgan Healthcare Conference

13 January 2020
J.P. MORGAN HEALTHCARE CONFERENCE

Attorney-client privilege and work product protection for in-house life sciences lawyers

10 September 2019
Webinar

TopCo liability panel

25 JUN 2019
London

BIO's 2019 International Convention

3 - 6 JUN 2019

Philadelphia

Medical Device Happy Hour

15 MAY 2019
San Diego

NEWS

Leading trial lawyer Lyn Pruitt joins DLA Piper, along with Adria Conklin and Mary Catherine Way

25 March 2021
DLA Piper announced today that nationally recognized trial lawyer Lyn Pruitt has joined the firm's Litigation and Regulatory practice, along with Adria Conklin and Mary Catherine Way.

Geoffrey Levitt joins DLA Piper's Litigation and Regulatory practice as co-chair of Life Sciences and Health Policy and Regulatory group

22 March 2021
DLA Piper announced today that Geoffrey Levitt has joined the firm's Litigation and Regulatory practice as co-chair of the Life Sciences and Health Policy and Regulatory group.

DLA Piper advises Piper Sandler & Co. as placement agent in US$175 million PIPE for Alpha Healthcare Acquisition Corp.

2 March 2021
DLA Piper represented Piper Sandler & Co. as placement agent in a US$175 million private investment in public equity (PIPE) transaction for Alpha Healthcare Acquisition Corp.

DLA Piper advises Piper Sandler & Co. as sole book-running manager in connection with US$92 million common stock offering by Infinity Pharmaceuticals

2 March 2021
DLA Piper represented Piper Sandler & Co. as sole book-running manager in connection with the US$92 million public offering of common stock of Infinity Pharmaceuticals, a clinical-stage biotechnology company.

DLA Piper advises NuVasive in its acquisition of Simplify Medical

1 March 2021
DLA Piper represented NuVasive, Inc., in its recent acquisition of Simplify Medical, a privately held company and developer of the Simplify Cervical Artificial Disc for cervical total disc replacement (cTDR).

DLA Piper advises Haemonetics in its acquisition of Cardiva Medical

21 January 2021

DLA Piper represented Haemonetics Corporation (NYSE: HAE), a global medical technology company focused on delivering innovative medical solutions to drive better patient outcomes, in its acquisition of Cardiva Medical, Inc., an industry-leading manufacturer of vascular closure systems based in Santa Clara, California, for US$475 million at closing and up to an additional US$35 million in contingent consideration based on sales growth.

DLA Piper advises Histogen in its US$14 million upsized public offering

6 January 2021
DLA Piper advised Histogen, Inc., in its public offering of 11,600,000 shares of common stock, pre-funded warrants to purchase up to 2,400,000 shares of common stock and warrants to purchase up to an aggregate of 14,000,000 shares of common stock at a price of US$1.00 per share.

DLA Piper advises Arlington Capital Partners in majority investment in Everest Clinical Research Corporation

21 December 2020
DLA Piper represented Washington, DC-based private equity firm Arlington Capital Partners in its investment in Everest Clinical Research Corporation, a leading contract research organization providing a comprehensive suite of mission-critical clinical research services to the worldwide pharmaceutical, biotechnology and medical device industries across Phase I-IV trials.

DLA Piper advises Locanabio in its US$100 million Series B financing

15 December 2020
DLA Piper represented Locanabio, an RNA-targeting gene therapy company focused on developing life-changing therapies for patients with severe neurodegenerative, neuromuscular and retinal diseases, in its recent US$100 million Series B financing led by Vida Ventures.

DLA Piper advises Otsuka America Pharmaceutical in its purchase of the assets of Proteus Digital Health

26 August 2020
DLA Piper represented Otsuka America Pharmaceutical, Inc. in connection with its stalking horse bid to purchase substantially all of the assets of Proteus Digital Health, Inc., including its ingestible and wearable sensor technology.

Former Congressman Jim Greenwood joins DLA Piper as senior policy advisor, adding significant strength to growing life sciences policy and regulatory group

4 August 2020
DLA Piper announced today that former US Representative Jim Greenwood has joined the firm's Litigation and Regulatory practice as a senior policy advisor based in Washington, DC.

DLA Piper advises Liquidia in its acquisition of RareGen and its US$75 million follow-on offering

6 July 2020
DLA Piper represented Liquidia Technologies, Inc. in its acquisition of RareGen, LLC.

DLA Piper advises Haemonetics in its sale of US blood donor management software to the GPI Group

12 June 2020

DLA Piper represented Haemonetics Corporation in its sale of certain blood donor management software assets within its Blood Center business unit to the GPI Group.

DLA Piper represents Axogen in dismissal of securities class action lawsuit

22 April 2020
DLA Piper represented Axogen, Inc. in the dismissal of a securities class action lawsuit filed in the US District Court for the Middle District of Florida.

DLA Piper obtains confirmation of plan for Valeritas in first coronavirus-related chapter 11 case

8 June 2020
DLA Piper represented medical device company Valeritas Holdings Inc. in its chapter 11 case in the United States Bankruptcy Court for the District of Delaware.

DLA Piper advises Iovance Biotherapeutics in its US$604 million common stock offering

4 June 2020
DLA Piper represented Iovance Biotherapeutics, a late-stage biotechnology company developing novel T cell-based cancer immunotherapies (tumor-infiltrating lymphocyte, TIL and peripheral-blood lymphocyte, PBL), in a US$603.7 million underwritten public offering.

DLA Piper advises NuVasive in its US$400 million convertible senior notes offering

3 June 2020
DLA Piper advised NuVasive, Inc. in its offering of US$400 million aggregate principal amount of 1.00% convertible senior notes due 2023.

Jeffrey Selman joins DLA Piper's Corporate practice in Northern California

29 May 2020
DLA Piper announced today that Jeffrey Selman has joined the firm's Corporate practice as a partner in Northern California, based in the Silicon Valley and San Francisco offices.

DLA Piper advises Stratos Genomics in its acquisition by Roche

26 May 2020
DLA Piper represented Seattle-based Stratos Genomics, an early-stage sequencing technology company, in its acquisition by biotechnology company Roche.

DLA Piper advises Luminex in its US$260 million convertible senior notes offering

18 May 2020
DLA Piper advised Luminex Corporation, an Austin-based company that develops, manufactures and sells proprietary biological testing technologies and products, in its offering of US$260 million aggregate principal amount of 3.00% convertible senior notes due 2025.

DLA Piper advises Immunomedics in its US$483 million follow-on offering

15 May 2020
DLA Piper represented Immunomedics, Inc., a leading biopharmaceutical company in the area of antibody-drug conjugates, in its recent US$483 million follow-on offering of common stock.

DLA Piper lawyers and practices ranked in latest Chambers edition

8 May 2020
DLA Piper today announced that the firm received 172 lawyer rankings and 71 practice rankings in *Chambers USA*'s 2020 guide.

DLA Piper announces partnership promotions for 2020

30 April 2020

DLA Piper is proud to announce that 67 lawyers have been promoted to its partnership. The promotions are effective as of April 1, 2020 in the United States and May 1, 2020 for EMEA and Asia Pacific. The promotions have been made across many of the firm's practice areas in 35 different offices throughout 13 countries.

Across the firm's practices globally, Corporate saw the largest intake of new partners with 19 promotions, followed by Litigation and Regulatory with 15. Intellectual Property and Technology and Finance and Projects had ten and eight promotions respectively, while there were six in Real Estate. Tax and Employment both had four, and there was one in Restructuring.

DLA Piper advises Haemonetics in its acquisition of enicor GmbH

8 April 2020
DLA Piper represented Haemonetics Corporation (NYSE: HAE) in its acquisition of enicor GmbH, a Munich, Germany-based privately held manufacturer of a whole blood coagulation testing system known as ClotPro.

Carole Bellis joins DLA Piper's Corporate practice in Northern California

17 March 2020
DLA Piper announced today that Carole Bellis has joined the firm's Corporate practice as a partner in Northern California.

DLA Piper lawyers named Acritas Stars

10 March 2020

Acritas has named over 200 DLA Piper lawyers as 2020 Acritas Stars. Now in its fourth year, Acritas Stars highlights the stand-out lawyers in private practice as nominated by clients around the world. More than 3,000 senior in-house counsel feed into the nomination process to give a comprehensive view of highly recommended lawyers across the globe.

DLA Piper advises NuVasive in its $450 million convertible senior notes offering and credit agreement amendment

5 March 2020
DLA Piper advised NuVasive, Inc. in its offering of US$450 million aggregate principal amount of 0.375% convertible senior notes due

2025.

Ellen Scordino, Susan Krumplitsch and April Abele Isaacson join DLA Piper's Patent Litigation practice in Northern California and Boston

4 February 2020
DLA Piper announced today that Ellen Scordino, Susan Krumplitsch and April Abele Isaacson have joined the firm's Patent Litigation practice and Life Sciences sector.

DLA Piper advises AiCure in US$24.5 million Series C financing

18 November 2019

DLA Piper is pleased to announce that AiCure chose the firm to represent AiCure in its US$24.5 million Series C financing.

Michael Sitzman joins DLA Piper's Intellectual Property and Technology practice in Northern California

4 November 2019

DLA Piper announced today that Michael Sitzman has joined the firm's Intellectual Property and Technology practice as a partner in Northern California, based in the San Francisco office.

DLA Piper advises Plexium in US$28 million Series A financing

18 October 2019

DLA Piper represented Plexium, a San Diego-based emerging biotechnology company whose proprietary platform, DELPhe, enables cell-based phenotypic screening of DNA-encoded libraries in nanoliter volumes, in its US$28 million Series A financing.

DLA Piper advises Insilico Medicine on successful Series B funding

17 October 2019

DLA Piper advised Insilico Medicine, a pioneer in next-generation artificial intelligence technology for drug discovery, on a successful US$37 million Series B funding round to commercialize the validated generative chemistry and target identification technology.

Edward Hanover to join DLA Piper’s Litigation practice in Northern California

26 August 2019
DLA Piper announced today that Edward Hanover will join the firm's Litigation practice as a partner in Northern California based in the Silicon Valley office.

DLA Piper partner Andrew Hoffman named to the *Daily Journal*'s Top 40 Under 40 list

16 August 2019

DLA Piper is pleased to announce that Andrew Hoffman, a partner in the firm's Litigation practice, has been named to the *Daily Journal*'s 2019 Top 40 Under 40 list honoring young California lawyers across a range of practice areas.

DLA Piper advises Adaptive Biotechnologies in its US$345 million IPO

2 July 2019

July 2, 2019 – DLA Piper represented Seattle-based Adaptive Biotechnologies Corporation in its US$345 million initial public offering.

DLA Piper represents Locana in US$55 million Series A financing

23 MAY 2019

DLA Piper represented Locana, Inc. in a US$55 million round of Series A financing led by ARCH Venture Partners, with participation from existing investors Temasek and Lightstone Ventures.

DLA Piper announces launch of Artificial Intelligence practice

14 MAY 2019

DLA Piper announced today the launch of its Artificial Intelligence practice, which will focus on assisting companies as they navigate the legal landscape of emerging and disruptive technologies, while helping them understand the legal and compliance risks arising from the creation and deployment of AI systems.

DLA Piper lawyers and practices ranked in latest Chambers edition

30 APR 2019

DLA Piper today announced that 158 of the firm's lawyers and 64 of its practices were ranked in *Chambers USA'*s 2019 guide.

DLA Piper lawyers and practices ranked in latest Chambers edition

30 APR 2019

DLA Piper today announced that 158 of the firm's lawyers and 64 of its practices were ranked in *Chambers USA'*s 2019 guide.

Carl Wessel joins DLA Piper's Litigation practice in Washington, DC

22 APR 2019

DLA Piper announced today that Carl Wessel has joined the firm's Litigation practice as a partner in Washington, DC.

K. Randolph Peak joins DLA Piper's Healthcare sector and Corporate practice in Dallas

17 APR 2019

DLA Piper announced today that K. Randolph Peak has joined the firm's Healthcare sector and Corporate practice as a partner in Dallas.

Sustainability and ESG

Sustainability is a core business issue in the life sciences sector, given its central role in addressing systemic global challenges including pandemics, access to medicine, and climate change. Creating new and sustainable value depends upon connecting stakeholder experiences with business outcomes – from patients to health workers, as well as wider health sector players. Boards must focus on more personalized healthcare and specialized services, leveraging technology in product development and patient care, and fostering trust on key issues like transparency of clinical trials, use of health and patient data, product quality and safety, and the environmental and social impacts across product life-cycles.

A number of sustainability-related themes affect businesses operating in the life sciences sector:

- **Access and affordability:** Addressing unmet healthcare needs, increasing access to affordable essential medicines and strengthening health systems around the world are all fundamental to social and economic progress. The coronavirus disease 2019 (COVID-19) has further highlighted the importance of the life sciences sector in addressing these challenges.
- **Digital transformation:** The use of AI, machine learning, automation and other digital technologies is transforming the global life sciences landscape. The application of AI, robotics and cloud services has paved the way to innovative, effective and cost-efficient therapy discoveries and the development of preventative and wellness-focused consumer wearables, personalized telemedicine services and remote patient monitoring. This digital transformation is expected to continue as more than 50 percent of health consumers support the use of AI and robotics to improve health outcomes.
- **Transparency and access in clinical trials:** Stakeholders increasingly expect transparency in clinical trials and wider access to trial data for scientific exchange and research. There is a bright spotlight on participant safety and privacy. Businesses are demanding more effective information sharing to enable informed decision-making and consent, along with post-trial access to results. Technology and collaborative partnerships with patient and health worker groups enable wider representative demographic populations to participate in clinical trials.
- **Trust and ethical use of data:** Vast amounts of valuable health data are generated through health and wellness apps, digital or automated diagnostics, cloud-based patient records and other medical devices. There is also a growing number of stakeholders with access to this data, including healthcare providers, health workers, insurers, governments and app developers. A key expectation within the life sciences sector is that data to improve health outcomes will continue along the path of increased accessibility while also ensuring its ethical use and the protection of individuals' privacy.
- **Patient-centered services and more personalized healthcare:** The changing priorities of health consumers and professionals are leading to a greater focus on the patient experience, from prevention and wellness to diagnosis and management of disease. Technology gives health consumers greater control over prevention and management of disease and provides health professionals access to better data to track and monitor their patients.
- **Net-zero decarbonization:** In striving to decarbonize the economy, businesses are implementing commitments to Science Based Targets, increasing energy efficiency and reducing carbon output, decreasing dependency on fossil fuels and increasing the use of renewables. The implementation of these initiatives is creating operational efficiencies, optimizing processes and reducing costs across the sector.
- **Sustainable sourcing, product life-cycles and a circular economy:** Stakeholders demand greater transparency across product life-cycles, businesses make commitments to net-zero decarbonization and business model innovation is driven by circular economy concepts. Underpinned by an increasingly complex transnational regulatory landscape, these developments are changing the way raw materials are sourced; how products are designed, manufactured, packaged, sold, reused or recycled; how waste and hazardous material is treated; and how wider environmental and social impacts relating to issues like emissions, plastics, water use, biodiversity loss, labor conditions and community impacts are managed.
- **Product safety and quality:** Fake or substandard medicines lead to hundreds of thousands of deaths each year. Drug safety, along with protecting health consumers from counterfeit medicines and drug diversion, are integral to ensuring public health and maintaining trust and confidence in the life sciences sector.

- **Business ethics:** There is increasing stakeholder attention, including from regulators and policymakers and also from providers of capital, on transparency and ethics in business dealings with healthcare providers and medical practitioners for the sale and use of products, as well as in relation to lobbying and advocacy activities. The way in which businesses respond to these expectations can have a direct impact upon their reputation and ultimately upon their license to operate.

To discuss the implications of these issues for your business, please contact our ESG leaders.