



## Healthcare

The healthcare industry around the world is intricate and evolving. Healthcare laws and regulations affect all companies at some level. The healthcare industry is among the most highly regulated in the world, and all employers must comply with the medical privacy protections and healthcare benefits afforded their employees. Multinational companies must navigate sometimes quite divergent payment and reimbursement regimes and the pharmaceutical and medical device approval rules of multiple national governments, as well as regional and international requirements. Healthcare providers are subject to the licensing and oversight rules of every jurisdiction in which they do business.

Our lawyers represent healthcare clients all around the world. We live and work where our clients live and work. And we work together across our offices throughout Asia Pacific, Europe, the Middle East and the United States, combining global strategy with local implementation.

We counsel the healthcare industry in these areas:

- Antitrust and competition
- Project finance
- Healthcare transactional
- Healthcare fraud and compliance
- Health insurance and managed care
- Healthcare regulatory
- Healthcare technology
- Employment
- Payment reimbursement disputes
- Pensions
- Personal injury and product liability litigation
- Privacy
- Professional liability and litigation
- Restructuring

### INSIGHTS

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## Publications

### Israel Group News January 2021

19 January 2021

#### [ISRAEL GROUP NEWS](#)

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

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### When a threat actor strikes: Legal considerations and challenges in a ransomware attack

21 December 2020

Evidence suggests that having employees working remotely significantly increases the risk of a successful ransomware attack.

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### Israel Group News October 2020

7 October 2020

#### [ISRAEL GROUP NEWS](#)

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

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### Israel Group News July 2020

8 July 2020

#### [ISRAEL GROUP NEWS](#)

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

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### Therapies for COVID-19: Two major developments

25 June 2020

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

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### 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.

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### Helping patients during the pandemic

14 May 2020

Some important considerations for biopharma manufacturers.

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### [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.

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### **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.

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### **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.

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### **Life Sciences Top of Mind: COVID-19 sector insights**

7 May 2020

Top COVID-19 considerations for the life sciences sector.

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### **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.

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### **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.

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### **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.

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### **Connected care funding for healthcare providers from the CARES Act**

24 April 2020

New funding to promote and support telehealth.

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### **Coronavirus: reopening businesses – compliance risks**

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24 April 2020

Companies looking to reopen are urged to do so in compliance with varying, changing government restrictions to avoid longer term liabilities that could potentially outweigh short term gains

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### **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.

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### **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.

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

17 April 2020

The unprecedented 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.

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### **CMS issues temporary waivers to allow hospital services to be provided in community-based locations and clarifies the applicability of EMTALA for locations outside of the hospital**

16 April 2020

These waivers permit patients to be triaged to a variety of community-based locales.

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### **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.

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### **FCC now accepting applications for CARES Act telehealth grants**

16 April 2020

To ensure as many applicants as possible receive funding, the FCC noted it does not anticipate awarding more than \$1 million to any single applicant.

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### **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.

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## **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.

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## **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.

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## **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."

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## **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.

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## **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.

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## **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.

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## **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.

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## **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.

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## **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.

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## **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.

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## **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.

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## **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.

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## **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.

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**[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.

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**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.

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**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.

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**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.

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**DOJ increases scrutiny of nursing home industry**

1 April 2020

DOJ is doubling down on its commitment to investigate and prosecute allegations of elder abuse and of substandard quality of care.

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**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.

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

31 March 2020

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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.

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### **Coronavirus: State Attorneys General and the New COVID-19 Stimulus**

30 March 2020

With the president's signature on March 27, 2020, the government passed into law the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), the largest economic stimulus package in American history. Passed in response to the coronavirus disease 2019 (COVID-19) pandemic, the CARES Act will have an enduring impact on the country for years to come, particularly so for the industries and businesses eligible for stimulus relief funds. The massive scale of the CARES Act immediately calls to mind questions about how the government will respond in its attempt to prevent fraud, waste, and abuse in carrying out the stimulus.

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### **Top franchise developments of 2019**

30 March 2020

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

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### **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.

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### **OCR issues guidance on permitted health information sharing to protect US law enforcement and first responders**

27 March 2020

HIPAA-covered entity may, under certain circumstances, disclose protected health information about an individual who has been infected with, or exposed to, SARS-CoV-2 or COVID-19 without an individual's authorization.

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### **Teledentistry update: Navigating teledentistry during the COVID-19 pandemic (United States)**

27 March 2020

As part of its efforts to mitigate the spread of the COVID-19 pandemic, on March 18, 2020, the American Dental Association provided essential guidance on emergency vs. nonemergency dental care and the use of teledentistry.

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### **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.

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## **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.

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## **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.

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## **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.

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## **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.

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## **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.

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## **US HHS-OCR Clarifies Waiver of HIPAA Sanctions for Telehealth Services during COVID-19**

24 March 2020

On March 20, 2020, the Office for Civil Rights (OCR) at the US Department of Health and Human Services (HHS) issued FAQs to follow its Notice of Enforcement Discretion (notification). The FAQs address several questions and clarify OCR's intended broad application, including that the notification has no expiration date; rather, OCR will issue a new notice to the public when it is no longer available.

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## **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-

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at-Home"-type Orders. This alert provides details on a number of state and local government orders.

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### **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.

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### **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).

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### **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.

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### **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.

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### **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.

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### **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.

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### **Coronavirus: federal and state tax relief (United States)**

16 March 2020

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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.

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### **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.

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### **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.

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### **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?

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### **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.

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### **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.

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### ***Alice* uncertainty: curiouser and curiouser**

24 July 2019

The Federal Circuit declines to follow USPTO guidance on subject matter eligibility, instead following its own precedent.

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### **Supreme Court Corner Q1 2019**

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11 APR 2019

In celebration of the 10th anniversary of IPT News, we note that 10 years ago, in the first quarter of 2009, Bernard L. Bilski filed his petition in the landmark *Bilski v. Kappos*, 561 U.S. 593 (2010), forever shaping the patentability of business methods.

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### Top of Mind: Litigation

20 MAR 2019

In this issue, our coverage of 10 big topics businesses have been thinking about this quarter.

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### 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.

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### First Lady and nutrition: USDA and FDA propose sweeping food labeling and marketing regulations

27 FEB 2014

Today, First Lady Michelle Obama and the Food and Drug Administration released two long-awaited proposed regulations that would for the first time in 20 years make significant changes to the nutrition information found on food and dietary supplement labels.

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### Food safety from farm to fork: FDA publishes proposed rules aiming to ensure the safety and security of the food supply

24 JAN 2013

The proposed rules lay the foundation of the prevention-based, modern food safety system envisioned in the FSMA and have wide-ranging effects on many industries, including every link in the global food supply chain.

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## EVENTS

### [Previous](#)

#### The US Election and the Race for a Vaccine: A Roundtable Discussion with Gregory Zuckerman

21 December 2020

Webinar

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#### Health tech market midst and post COVID-19

14 September 2020

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Webinar

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## NEWS

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### **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.

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