FDA

DLA Piper's FDA practice provides strategic counseling and advocacy for our pharmaceutical, medical device, dietary supplement, biologics, and diagnostics and clinical laboratory clients on a wide range of matters involving the FDA and other government agencies, from clinical development and marketing authorization strategies to post-marketing compliance. Our attorneys combine an understanding of agency practice, science, policy, and bioethics with practical strategies to meet business objectives and mitigate risk in an increasingly complex regulatory and enforcement environment.

We counsel clients in administrative and judicial enforcement actions and other proceedings involving the Food and Drug Administration (FDA), Federal Trade Commission (FTC), Drug Enforcement Administration (DEA), US Department of Justice (DOJ) and other federal and state agencies.

RELATED SERVICES

- International Trade, Regulatory and Government Affairs

CAPABILITES

Strategic Regulatory Advice and Counseling

We advise clients at all stages of the regulatory lifecycle, on matters including:

- Developing marketing authorization strategies and navigating the FDA processes for conventional drugs, biologics and biosimilars, and medical devices, as well as evaluating classification issues and potential regulatory pathways for combination and borderline products (food v. drug, conventional food v. dietary supplement, human tissue v. biologic, cosmetic v. device), and the business implications of product positioning on the choice of regulatory pathway
- Crafting life cycle management strategies for small molecule pharmaceuticals and large molecule biological products under the Hatch-Waxman Amendments and the Biologics Price Competition and Innovation Act (BPCIA)
- Planning and executing product development activities in compliance with Good Clinical Practice requirements
- Providing post-market compliance counseling with respect to adverse event and medical device reporting, corrections, removals, and recalls, Phase IV study obligations, and changes to product labeling or design
- Reviewing proposed promotional materials and activities to identify and mitigate regulatory risks
- Facilitating quality system and cGMP compliance by recommending and tailoring strategies for companies throughout the supply chain, from API manufacturers to contract manufacturers, specification developers, and marketers of finished products (including “virtual” companies)
- Actively assisting companies to prepare for and respond to questions raised during FDA inspections and to respond to Form 483 Observations and Warning Letters

- Engaging with regulators to seek clarification, resolve disagreements, and address improper agency actions through both informal interactions, formal administrative procedures and, where necessary or advantageous, though federal court Administrative Procedure Act litigation.

Cross-Agency And Cross-Border Regulatory Advice

Members of FDA-regulated industries also must be aware of and comply with ancillary federal, state, and international laws that affect their ability to operate. We advise on issues including wholesale distribution and similar state permit or license requirements; regulation of clinical laboratories under the Clinical Laboratory Improvement Amendments (CLIA) and state laboratory licensure requirements; and state consumer protection laws.

We also work closely with DLA Piper's global Life Sciences sector colleagues in our offices around the world to address regulatory questions whose implications do not end at the US border. DLA Piper is well positioned to provide coordinated advice and multi-jurisdictional surveys, with the benefit of local perspective.

Transactions

FDA insight is critical to a variety of corporate transactions involving FDA-regulated products and companies − from commercial agreements, to M&A transactions, to private company financings, to IPOs. We support clients by applying the broad FDA knowledge that is essential for effective due diligence and for creating risk mitigation and management strategies. Our work includes:

- Reviewing and analyzing contract manufacturing, supply and distribution agreements relevant to regulatory compliance provisions and documentation of responsibility
- Conducting regulatory due diligence to identify risks in connection with product development and marketing authorization strategies, promotional and advertising practices, quality system and good manufacturing practices, adverse event reporting, recalls and other product safety concerns, and federal and state registration and licensure
- Drafting and tailoring regulatory representations and warranties and other risk allocation provisions in M&A agreements, including asset, stock, and membership interest purchase agreements
- Advising on transition, integration, and other post-closing matters in connection with M&A transactions, including transfer of regulatory authorizations.

Litigation Matters, Investigations, and Risk Assessments

We provide strategic advice for clients in litigation and pre-litigation matters implicating FDA legal and regulatory concerns. We also provide support on matters ranging from product liability cases involving state failure-to-warn claims and manufacturing issues, to investigations and litigation initiated pursuant to the False Claims Act and federal Anti-Kickback Statute.

We also assist in proactive compliance reviews, internal investigations, and litigation and enforcement risk assessments on topics related to compliance with FDA standards, industry standards, and internal policies and procedures, such as:

- Clinical trial compliance
- Pharmacovigilance
- Promotion and advertising
- Social media and internet communications

EXPERIENCE

- A global pharmaceutical company in a confidential matter before the FDA involving eligibility for New Chemical Entity (NCE) Exclusivity
- A private equity client on FDA compliance issues faced by an acquisition target medical device company; also advised the company on corrective action plans post-acquisition
- Achieved reversal of FDA decision to refuse to file a new drug application in confidential pre-litigation advocacy before the

FDA Chief Counsel's Office

- The promotional review committee of a major pharmaceutical company, as regulatory counsel with responsibility for prescription anti-infective, cardiovascular, pain, and women's health drug products
- Provided successful regulatory strategy for a third-party-initiated OTC switch of a blockbuster prescription drug
- Managed the legal, regulatory, and public relations aspects of a major nationwide recall of roasted tree nuts shellnuts, engaged and directed scientific experts in conducting the internal root-cause investigation, and negotiated terms and conditions of a recall with FDA and California Department of Health officials, with no warning letter or additional enforcement actions taken
- On behalf of a top-10 global pharmaceutical company, prevailed in a contested citizen petition proceeding involving the scope of coverage of the three-year Hatch-Waxman new clinical study exclusivity
- On behalf of a pharmaceutical company, through confidential negotiation with FDA and public advocacy strategies, achieved the market withdrawal of unapproved prescription drug products being unlawfully marketed in competition with the client's approved product
- On behalf of a research-based pharmaceutical company, served as FDA counsel in a successful US Supreme Court case broadening the scope of the FDA research exemption to patent infringement under the Hatch-Waxman Amendments (*Merck KGaA v. Integra Life Sciences*)
- On behalf of a national wine industry trade association, drafted and filed a Supreme Court amicus brief in a successful Constitutional challenge to state law restrictions on interstate mail-order delivery of wine (*Granholm v. Heald*)
- On behalf of two leading orphan drug patient advocacy groups, drafted a Supreme Court amicus brief in a case striking down state law restrictions on the use of physician prescribing data by pharmaceutical companies for marketing purposes (*IMS v. Vermont*)

INSIGHTS

Publications

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.

Food and Beverage News and Trends

17 September 2020
FOOD AND BEVERAGE NEWS AND TRENDS

First-ever consent decree under FSMA, plus new egg rules, new grape variety names, carrot cake without carrots, smoked almonds without smoking.

Food and Beverage News and Trends

27 August 2020
FOOD AND BEVERAGE NEWS AND TRENDS

USDA to hold virtual meeting on Salmonella contamination, egg producer charged with price gouging in the pandemic, plus vegan butter, fish, jams, and the onion recall expands again.

Food and Beverage News and Trends

10 August 2020

FOOD AND BEVERAGE NEWS AND TRENDS

FDA announces new food safety blueprint, plus cell-cultured meat, bioengineered foods, soda, onions and a white candy bar, a court says, is white.

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.

Therapies for COVID-19: Two major developments

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

[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.

Food and beverage COVID-19 regulatory updates

1 May 2020
Ongoing commentary and guidance from US regulators.

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.

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.

US CPSC advises consumers certain recall remedies may be unavailable due to COVID-19 – four key takeaways

15 April 2020

Guidance will evolve as the pandemic develops, and CPSC-regulated firms are encouraged to consider these actions.

FDA COVID-19 updates for the food and beverage industry

13 April 2020

FOOD AND BEVERAGE NEWS AND TRENDS

FDA issues guidance to serve as a food safety resource during the COVID-19 pandemic, plus other late-breaking developments in the food and beverage sector.

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.

[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.

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.

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 and food – FDA position (United States)

19 March 2020

For help considering potential impacts of FDA touchpoints.

COVID-19: As diagnostic companies and laboratories ask “how can I help?” FDA responds with unprecedented regulatory flexibility, seeking to achieve more rapid testing capacity in the US

18 March 2020
Options expand for life science, healthcare and other stakeholders.

Food and Beverage News and Trends

7 February 2020
FOOD AND BEVERAGE NEWS AND TRENDS

Virginia moves to define "milk," court overturns Kansas ag-gag law, plus vanilla, glyphosate, and Hep A back in the news.

Food and Beverage News and Trends

24 January 2020
FOOD AND BEVERAGE NEWS AND TRENDS

Appeals court strikes down Missouri alcohol advertising rules on free speech grounds; USDA loosens school lunch nutrition rules; plus news of salads, e-cigarettes, serving sizes, and a new dietary fiber

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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.

Food and Beverage News and Trends

11 December 2019
FOOD AND BEVERAGE NEWS AND TRENDS

Nomination of new FDA head advances, plus rose chocolate, meat wars, cage-free hens, and the last near-beer state.

Food and Beverage News and Trends

15 November 2019
FOOD AND BEVERAGE NEWS AND TRENDS

The FDA addresses the future of food safety, plus labels for plant-based “meat”; vapes in the news; and cotton… for dinner?

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.

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.

President Trump sounds the death knell for "regulation by guidance"

10 October 2019

Two Executive Orders effectively end the controversial practice.

Food and Beverage News and Trends

23 September 2019

FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, USDA publishes hog slaughterhouse rule, flavored e-cigarettes in the news, plus vegetarian meat, chocolate milk, bottle sizes, sugary snacks.

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.

Food and Beverage News and Trends

18 July 2019

FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, lawsuits fight state meat-labeling laws, call for cancer warning on alcohol, high court strikes down Tennessee alcohol sales statute, plus bison, blood pressure, beverage taxes, best if used by.

Food and Beverage News and Trends

21 June 2019
FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, FDA settles suit on deadlines for reporting on high-risk foods, TTB announces new "Conditional Approval" process for alcohol labels, plus PFAS, biotech, added sugars, frozen food recalls.

Food and Beverage News and Trends

10 June 2019
FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, Sharpless pledges continuity, fruit juice linked to higher mortality, court OKs mobile vendor rule, plus kombucha, palcohol, salt, SNAP.

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.

Food and Beverage News and Trends

10 MAY 2019
FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, Q1 food recalls down, FDA bolsters oversight of biologically modified animals, Texas approves to-go beer sales from breweries, Louisiana bans cauliflower "rice."

Food and Beverage News and Trends

26 APR 2019
FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, go-slow approach urged for salt reduction plan, developments in state alcohol regulation, and sweeteners in the news

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Food and Beverage News and Trends

15 APR 2019
FOOD AND BEVERAGE NEWS AND TRENDS

In this issue: Three more states move to prohibit use of term "meat" for cell-cultured products, and when is rice not rice?

Food and Beverage News and Trends

1 APR 2019
FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, livestock groups ask for change in regulation of genetically engineered animals, state legislatures ponder alcohol laws.

Food and Beverage News and Trends

19 MAR 2019
FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, Dietary Guidelines panel to hold first meeting, new acting director for FDA, states look at their alcohol laws.

Arizona Supreme Court's *Conklin* decision calls into question viability of *Stengel* claims

26 FEB 2019
The decision creates a promising foothold for defendants seeking to dismiss state-based failure-to-warn claims involving PMA devices.

Explainability: where AI and liability meet

25 FEB 2019
Makers and users of AI face a new and interesting problem: what is the acceptable tradeoff between explanation and accuracy?

Food and Beverage News and Trends

21 FEB 2019
FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, FDA moves against false claims for dietary supplements, court grants injunction against city law on sugary-drink ads.

Congress begins new session with scrutiny of drug pricing near the top of the agenda

1 FEB 2019
The cost of prescription medications and therapies has quickly emerged as one of the top priorities of lawmakers on both sides of the Capitol.

Food and Beverage News and Trends

25 JAN 2019
FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, FDA continues crucial food surveillance, shutdown hamstrings craft brewers, plus news about meat, whiskey, and Tennessee's alcohol retail law.

Supreme Court hears oral argument in *Fosamax*: key takeaways

8 JAN 2019
None of the justices indicated a desire to upset the *Wyeth v. Levine* framework.

Food and Beverage News and Trends

4 JAN 2019
FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, FDA head chides e-cigarette makers, USDA announces GMO labeling rules, grocery manufacturers implement new use-by labeling, plus: beer.

Food and Beverage News and Trends

19 DEC 2018
FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, one source of romaine outbreak identified, guidance for California alcohol retailers in aftermath of fires

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Food and Beverage News and Trends

3 DEC 2018
FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, Senate holds confirmation hearings for top food safety post; new labeling and advertising rules aim to reduce burden on alcohol industry

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Device manufacturers have a little over a year to prepare for the first state law regulating the security of Internet of Things devices

27 NOV 2018

California law will require manufacturers of most Internet of Things and Bluetooth connected devices to implement one or more "reasonable security features" by January 1, 2020.

Food and Beverage News and Trends

19 NOV 2018
FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, FDA plans new restrictions on e-cigarettes, FDA and USDA announce details on joint regulation of cell-cultured

meats, Chicago voters say yes to plastic straw ban, more.

Food and Beverage News and Trends

26 OCT 2018

FOOD AND BEVERAGE NEWS AND TRENDS

In this issue, Walmart food safety executive joins FDA, redefining "healthy," revisiting standards of identity, more.

Artificial Intelligence: from diagnostic programs to sex robots - unresolved liability questions

24 OCT 2018

Could AI develop to a point where a jury can be persuaded to blame the product, but not the manufacturer?

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.

FDA's new menu labeling and vending machine requirements: 10 key answers for food businesses

2 DEC 2014

The new requirements apply nationwide and preempt existing state laws

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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.

Offering healthcare solutions at consumers' fingertips? What you should know about FDA regulation of mobile medical apps

10 OCT 2013

When may a label say “gluten free”? Get ready to comply with FDA’s final rule

9 SEP 2013

FRAN*CAST*

Events

Previous

Law Over Lunch

17 September 2019
Washington

BIO's 2019 International Convention

3 - 6 JUN 2019
Philadelphia

NEWS

DLA Piper advises Digital Force Technologies in strategic partnership with DC Capital Partners

29 September 2020
DLA Piper represented Digital Force Technologies (DFT) in its formation of a strategic partnership with DC Capital Partners.

Campos Mello Advogados opens Brasilia office, launches Government Affairs practice with addition of two new partners

16 September 2020
Campos Mello Advogados today announced the opening of the firm's new Brasilia office, as well as the arrival of new partners Carolina Caiado and Paulo Renato Barroso, who will lead the firm's new Government Affairs practice.

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 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.

Jonathan Haray appointed to board of Washington Lawyers' Committee for Civil Rights and Urban Affairs

20 February 2020

Jonathan Haray, a partner in DLA Piper's Washington, DC office, has been appointed to the board of directors of the Washington Lawyers' Committee for Civil Rights and Urban Affairs.

DLA Piper hosts General James Mattis in Washington, DC

27 January 2020

On January 23, 2020, General James Mattis, senior counselor at The Cohen Group, addressed DLA Piper's employees in Washington, DC. DLA Piper maintains a longstanding strategic alliance with The Cohen Group.

Frank Ryan discusses the trade war with Yahoo Finance

9 Sep 2019

Highlight: "Where we are right now is in a political phase in this debate, and... we need to get to a practical phase," says @DLA_Piper's Frank Ryan on the trade war. "The sooner we get stability for major multinationals in China regarding IP protection, the better off we'll be." pic.twitter.com/u0ykzF8m89

— Yahoo Finance (@YahooFinance) September 9, 2019

General James Mattis to join the Cohen Group

9 Sep 2019
General James Mattis will join The Cohen Group as a Senior Counselor in October, the firm announced today.

Paul Hemmersbaugh joins DLA Piper's Litigation practice as chair of Transportation Regulatory group

3 September 2019

DLA Piper announced today that Paul Hemmersbaugh has joined the firm's Litigation practice as a partner and chair of its

transportation regulatory and litigation group, in Washington, DC.

Tony Samp joins DLA Piper as policy advisor in Washington, DC

10 July 2019

DLA Piper announced today that Tony Samp has joined the firm's Government Affairs practice as a policy advisor in Washington, DC.

DLA Piper announces partnership promotions for 2019

1 APR 2019

DLA Piper is proud to announce that 77 lawyers have been promoted to its partnership. The promotions are effective as of April 1, 2019 in the United States and May 1, 2019 for EMEA and Asia Pacific. The promotions were made across many of the firm's practice areas in 43 different offices throughout 20 countries.

DLA Piper hosts leading business and diplomacy conference

14 MAR 2019
DLA Piper's London office has hosted the Annual Conference of the International Diplomatic and Business Exchange (IBDE).

Paul Tiburzi named to the *Daily Record*'s 2019 Influential Marylanders list

1 FEB 2019

DLA Piper is pleased to announce that Paul Tiburzi, chair of the firm's Maryland Public Policy and Administrative Law practice, was named to the *Daily Record*'s 2019 Influential Marylanders list.

Dean Fealk named honorary senator of German economy

6 DEC 2018

DLA Piper is pleased to announce that Dean Fealk has been named an honorary senator of the German economy (Senat Der Wirtschaft) in recognition of his efforts to strengthen transatlantic relations by leading trade, investment and innovation initiatives between Germany and California.
