October 22, 2025

FOOD AND DRUG ADMINISTRATION DEVELOPMENTS WEBINAR

GIBSON DUNN

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WELCOME & OPENING REMARKS

01

Our Speakers

Jonathan M. Phillips
Partner / Washington, D.C.

Jonathan Phillips is a partner in the Washington, D.C. office of Gibson, Dunn & Crutcher, where he is a member of the firm's litigation department and Co-Chair of the FDA and Health Care Practice Group and False Claims Act/Qui Tam Defense Practice Group. A former DOJ Trial Attorney, his practice focuses on FDA and health care enforcement, compliance, and litigation, as well as other white collar enforcement matters and related litigation. Mr. Phillips is ranked nationally as a leading False Claims Act practitioner by Chambers USA.

Katlin McKelvie
Partner / Washington, D.C.

Katlin McKelvie is a partner in the Washington, D.C. office of Gibson, Dunn & Crutcher and Co-Chair of the firm's Food and Drug Administration (FDA) and Health Care Practice Group. With over two decades of experience in food and drug law, including as Deputy General Counsel of the Department of Health and Human Services (HHS), Katlin advises clients on complex regulatory and policy issues associated with FDA regulation of food, drugs, medical devices, and cosmetics.

John D. W. Partridge
Partner / Denver

John Partridge, a Co-Chair of Gibson Dunn's FDA and Health Care Practice Group and Chambers-ranked white collar defense and government investigations lawyer, focuses on government and internal investigations, white collar defense, and complex litigation for clients in the life science and health care industries, among others. John has particular experience with the Anti-Kickback Statute, the False Claims Act, the Foreign Corrupt Practices Act, and the Federal Food, Drug, and Cosmetic Act, including defending major corporations in investigations pursued by the U.S. Department of Justice (DOJ) and the U.S. Securities and Exchange Commission (SEC).

Gustav W. Eyler
Partner / Washington, D.C.

Gustav W. Eyler is a partner in the Washington, D.C. office of Gibson, Dunn & Crutcher. He is Co-Chair of the firm's Consumer Protection and FDA and Health Care Practice Groups, and he is a member of the White Collar Defense and Privacy Practice Groups. An experienced litigator and a former Director of the U.S. Department of Justice's Consumer Protection Branch, he defends companies and individuals in government investigations and enforcement actions and counsels clients on the design and implementation of compliance programs.

AGENDA

01	Welcome & Opening Remarks
02	FDA and DOJ Enforcement Upheaval
03	Direct-to-Consumer (DTC) Drug Advertising Crackdown
04	Most-Favored-Nation Pricing Executive Order Implications
05	Make America Healthy Again (MAHA) Initiative
06	FDA Inspections & Compliance
07	FDA Priorities on Drug Regulation
08	FDA Deregulation

FDA AND DOJ ENFORCEMENT UPHEAVAL

02

FDA Reforms and Restructuring

- **The President and HHS Secretary have announced orders and initiatives aimed at reforming FDA, including:**
  - 10-to-1 Regulatory Reform and RFI Initiative
  - Regulatory Relief to Promote Domestic Production of Critical Medicines
  - Reducing Anticompetitive Regulatory Barriers
- **HHS and DOGE also have sought to restructure FDA, including by:**
  - Reducing FDA's workforce by at least 3,500 employees
  - Closing regional office and consolidating offices across centers
  - Seeking to create a Federal Food Safety Agency under USDA
- **The ongoing government shutdown is impacting FDA operations**

DOJ Reforms and Restructuring

- **Significant reduction in DOJ headcount and deemphasis on corporate and regulatory enforcement**
  - 7% reduction in force; almost entire budget dedicated to violent and drug crime and immigration
- **Executive Order – Fighting Overcriminalization in Federal Regulations**
  - Seeks to prevent "abuse and weaponization" of criminal regulatory offenses against "unwitting individuals" who lack the "privileges [of] large corporations"
  - "Criminal enforcement of criminal regulatory offenses is disfavored" and "should focus on matters where a putative defendant is alleged to have known his conduct was unlawful"
- **Restructuring of DOJ's Consumer Protection Branch**
  - Civil attorneys and work rebranded as Civil Division's Enforcement and Affirmative Litigation Branch
  - Criminal prosecutors and authorities merged with Criminal Division's Fraud Section
    - New Health and Safety Unit and Market, Government, and Consumer Fraud Unit established
      - Health and Safety Unit will oversee all Food Drug and Cosmetic Act investigations and prosecutions
      - But "sale and lease back" of certain criminal prosecutors and authorities to Civil Division EAL Branch
- **Government shutdown is substantially affecting DOJ efforts**

Enforcement Implications

Most FDA-regulated companies currently have fewer federal enforcement risks because of reduced FDA and DOJ resources and shifted priorities

BUT political leadership is quick to engage;

And agencies are willing to act aggressively against products or services deemed detrimental by the Trump Administration.

Examples:

- Scrutiny of a potential link between acetaminophen use by pregnant women and autism
- Criticism and investigation of "ultra-processed" foods and color additives
- Investigation of drugs and practices used in the provision of gender-affirming care to minors
- Issuance of warning and untitled letters for direct-to-consumer prescription drug ads
- Investigation of products reportedly linked to outbreaks

AND states are seeking to fill the regulatory and enforcement gap.

Examples:

- States are enacting laws pursuing litigation related to ultra-processed foods
- Texas is investigating baby food manufacturers for allegedly dangerous levels of heavy metals
- Democratic states are launching a Governors Public Health Alliance

Strategic Considerations

- **Intelligence as to agency considerations in high-risk areas is critical**
  - Companies should monitor statements of key agency officials and regulatory developments
  - Assess state developments and consumer class actions for potential enforcement trends
  - Anticipate likely enforcement areas and move assertively to reduce risks while planning for action

- **When in the crosshairs of an enforcement initiative, act proactively**
  - Engage crisis management, public relations, and political experts
  - Work with legal teams to ensure activities occur under attorney-client privilege
  - Do not rely on administrative processes – anticipate press-conference rulemaking
  - Prepare for swift legal and media action

DIRECT-TO-CONSUMER (DTC) DRUG ADVERTISING CRACKDOWN

03

Direct-to-Consumer (DTC) Drug Advertising Crackdown

- **New initiative announced jointly by the White House, HHS, and FDA on September 9, 2025**
- **FDA "will aggressively deploy its available enforcement tools" and use AI as part of proactive surveillance and review of advertising**
- **Key aspects of advertising targeted include:**
  - DTC content that may "mislead the public about the risks and benefits, encourage medications over lifestyle changes, inappropriately intervene in the physician-patient relationship, and advantage expensive drugs over cheaper generics"
  - Focus on broadcast and social media platforms, as well as healthcare provider (HCP)-directed materials, including websites and conference booths
- **FDA's three-part approach on taking action on DTC advertising:**
  - "Cease and desist" letters for allegedly violative advertising: issued to both manufacturers of approved drugs and compounding pharmacies, for alleged violations of the FDCA and FDA regulations across a wide variety of media (e.g., TV ads, newsletters to HCPs, conference booths)
  - "Dear Pharmaceutical Company" letters instructing holders of marketing applications to comply with FDCA and FDA regulatory requirements
  - Forthcoming rulemaking on "adequate provision" regulation

How Companies Can Prepare

1

Prospective and retrospective review of advertising and promotion

2

Prepare for future enforcement pushes

- Promotional communications involving "paid consultants," influencers
- Presentation of risk, efficacy
- Pre-approval promotion

3

Consider potential defenses

- First Amendment
- Administrative Procedure Act

MOST-FAVORED-NATION PRICING EXECUTIVE ORDER IMPLICATIONS

04

The Most-Favored-Nation Pricing EO (and Background)

First Trump Administration

- Nov. 2020 Interim Final Rule implementing MFN CMMI model for Part B drugs
- Barred on procedural grounds by several federal courts

Biden Administration

- Inflation Reduction Act of 2022
- Required HHS to negotiate prices for certain Part D drugs and then Part B drugs
- Negotiations result in maximum fair price
- Challenges to the IRA pricing program have been unsuccessful to date

Second Trump Administration

- May 12, 2025 EO aimed at securing MFN pricing
- Instructed HHS and other agencies to take certain actions to compel progress
- E.g., HHS rulemaking; DOJ/FTC enforcement; Commerce/USTR review; FDA steps
- July 31, 2025 letters to 17 manufacturers included specific demands

FDA

- Potential revocation and modification of approvals for drugs that "may be unsafe, ineffective, or improperly marketed"
- Certification to Congress to support personal importation of prescription drugs under FDCA § 804(j)

Recent MFN-Related Developments

- President Trump's July 2025 letters demanded four types of "**binding commitments**" from 17 manufacturers:

1 – MFN pricing (all Medicaid patients)	**2 – MFN launch prices in US (all payers)**	**3 – Repatriation of ex-U.S. additional revenues**	**4 – MFN-prices sales via Direct-to-Consumer (DTC) and/or Direct-to-Business (DTB) channels**

- The letters said that if manufacturers refused, the Administration would use "**every tool in [its] arsenal**"
- Since then, multiple manufacturers have announced DTC sales channels
- And two manufacturers (Pfizer and AstraZeneca) have announced agreements to provide their drugs at MFN prices to state Medicaid programs, launch drugs at guaranteed MFN prices, repatriate increased ex-U.S. revenues, and invest in U.S. manufacturing and R&D

Implications of the Most-Favored-Nation Pricing Order for FDA Regulation and Enforcement

- **Companies should prepare for FDA actions intended to increase pressure to agree to MFN pricing**
  - Actions under explicit consideration include revocation/modification of approvals and certification for personal importation
  - Other actions are also possible, including increased inspection scrutiny, delays in application reviews, scrutiny of advertising/labeling, and targeted enforcement actions
- **Proactive preparation and development of strategies is important, including:**
  - Evaluating any potential APA or other arguments a company can raise against an adverse FDA action
  - Using both formal (e.g., comments to proposed rules) and informal (e.g., lobbying key Administration officials) channels to advance positions
  - Leveraging internal and external resources for crisis management, internal investigations, responding to enforcement actions, and managing public relations

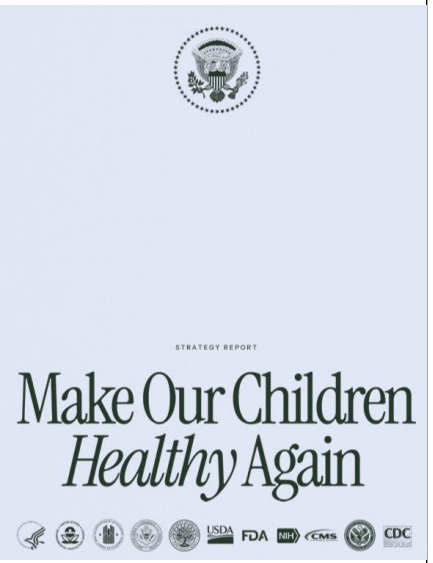
MAKE AMERICA HEALTHY AGAIN (MAHA) INITIATIVE

05

Make America Healthy Again (MAHA) Initiative Developments

- **Movement led by HHS Secretary Robert F. Kennedy, Jr., focused on reforms to food, medical products, and more**
- **In February 2025, President Trump established the MAHA Commission to advise on "the childhood chronic disease crisis," and help develop a strategy in response**
- **In May 2025, the MAHA Commission published the MAHA Report, which focused on various causes of the crisis, including:**
  - The shift to so-called ultra-processed foods;
  - The cumulative load of chemicals in the environment;
  - A "crisis of childhood behavior;" and
  - The "overmedicalization" of children

Make America Healthy Again (MAHA) Initiative Developments (cont.)



- **In September 2025, the MAHA Commission published the MAHA Strategy, which outlines FDA-related priorities, including:**
  - Focus on perceived over-prescription of medications to children.
  - Mental health diagnosis and prescription working group, which will evaluate prescription and "over-prescription" trends, which will inform NIH research and FDA-directed label updates.
  - NIH and FDA investigation of opportunities to strengthen use of "repurposed drugs" for chronic disease and facilitate pathways for FDA approval
  - Increased scrutiny from FDA, HHS, FTC, and DOJ on direct-to-consumer prescription drug advertising, particularly by social media influencers and DTC telehealth companies.
  - Eliminating burdens on product development, including increased use of non-animal testing and facilitating development and use of personal health and digital health tools, as well as regenerative medicine.

MAHA Focus on Food Policy

- **So-called "ultra-processed foods" (UPFs) are a core concern for the MAHA movement, because of their perceived depleted nutrient levels, increases to caloric intake, and inclusion of food additives**
- **In July 2025, FDA and the U.S. Department of Agriculture (USDA) published a request for information to inform a definition of "UPF"**
  - Agencies focused on a multi-faceted approach that accounts for food ingredients, processing steps, and nutritional and other attributes of food
  - An official definition could have far-reaching implications, including possible impact on food labeling or manufacturing requirements and on what foods are eligible for the National School Lunch Program (NSLP) and nutrition assistance programs
- **FDA is also taking other steps to address food ingredients and additives, including:**
  - Planning to propose a rule to end a process by which manufacturers self-affirm that the ingredients used in their food products are "generally recognized as safe" (GRAS)
  - Working to phase out petroleum-based synthetic dyes, and to approve natural color additives
  - Planning to finalize front-of-package nutrition labeling rule

Broader Implications

- **MAHA focus on UPFs in private litigation**
  - Assertion that UPFs are addictive and heavily marketed to children
  - Motion to dismiss for failure to state a claim granted in *Martinez v. Kraft Heinz* (E.D. Pa.), motion to amend is currently pending; other lawsuits may also test these theories
- **States also are taking action**
  - California is adopting official definitions of UPF and banning UPFs from school lunches,
  - Texas and Louisiana enacting their own labeling and warning requirements for certain food additives
  - Important for companies to monitor state attorney general (AG) enforcement trends and state law developments
- **Companies should evaluate strategies in the event of adverse regulatory or enforcement actions with respect to UPFs, including:**
  - First Amendment challenges to requirements or restrictions on labeling and advertising
  - Administrative Procedure Act challenges

GENERAL INSPECTIONS & COMPLIANCE

06

Areas of Focus

- **In the medical products space, foreign facilities and clinical trial operations have become a target—just as FDA and the Trump Administration have rolled out programs to incentivize medical product companies to move operations domestically**
  - Increased use of unannounced inspections at foreign manufacturing facilities
  - General correspondence to Chinese third-party testing firms for data integrity issues in testing to support premarket device submissions
  - Review of clinical trials that send American citizens' living cells to China and other "hostile countries" for genetic engineering and re-infusion
- **As discussed earlier, DTC prescription drug advertising is reemerging as a focus for FDA enforcement actions (untitled and warning letters)**
- **Food safety and traceability continue to be a priority for FDA**
  - Top citations (2009-2026) in food inspections focus on compliance with good manufacturing practice (GMP), preventive controls, and foreign supplier verification program (FSVP) requirements

How Companies Can Prepare

Expect an increase in inspection frequency for foreign establishments across all product areas

Given FDA's limited resources, it is possible that routine, periodic inspections may become less frequent and for-cause inspections and re-inspections of facilities with voluntary or official action indicated may be prioritized

Prompt, thorough, and responsive responses to inspection observations and enforcement actions will be crucial

FDA PRIORITIES ON DRUG REGULATION COME INTO FOCUS

07

FDA PreCheck Program

- **FDA PreCheck program to promote domestic production of critical medicines**
  - Response to Executive Order, “Regulatory Relief to Promote Domestic Production of Critical Medicines”
  - Two-phase program designed to facilitate the construction and approval of new domestic manufacturing facilities
  - Designed to facilitate construction of US manufacturing sites through more frequent agency communication at early stages (e.g., design, construction, pre-production) and streamlining of CMC section development for applications through meetings and FDA feedback.
  - Public meeting held in September 2025
  - In October 2025, FDA announced a pilot prioritization program for review of generics who test and manufacture products in the United States

Commissioner's National Priority Voucher Program

FDA Rolling Out "Commissioner's National Priority Voucher" (CNPV) Program: Intended to allow companies "aligned with U.S. national priorities" to accelerate application review.

- Unlike other priority review voucher programs, **not expressly authorized by statute**; FDA claims its authority for CNPV stems from its general authority to implement the FDCA.
- Benefits include **faster review times (to just 1-2 months), enhanced communication during review process, multidisciplinary team-based evaluation, and potential for accelerated approval.**
- New guidance and FAQs published in July 2025:
- Eligibility requires alignment with one or more of five Program Priorities: **addressing a US public health crisis; delivering innovative cures with "transformative impact"; addressing a large unmet public health need; onshoring drug development and manufacturing to advance health interests and strengthen US supply chain resiliency; and increasing affordability.**
- If granted, CNPV expires within two years from receipt from FDA
- Last week, FDA announced 9 voucher recipients, and anticipates announcing another group of recipients in the coming months
- FDA had announced intent to select no more than 5 initial participants in the first year

Rare Disease Evidence Principles (RDEP) Process

- In September 2025, FDA announced the Rare Disease Evidence Principles (RDEP) process **for sponsors to get guidance from FDA to support approval for rare diseases**
- Approval process may be based on a single adequate and well-controlled study in conjunction with robust confirmatory evidence
- Sponsors may apply at any time prior to launch of a pivotal trial
- **Therapies must target a very small, rare disease population or subpopulation** (generally fewer than 1,000 patients in the United States facing rapid deterioration in function leading to disability or death, for whom no adequate alternatives exist
- Drugs approved using this process **may face additional postmarketing requirements to further ensure safety and effectiveness**

Release of Complete Response Letters (CRLs)

- **"Radical Transparency" and Disclosure of Complete Response Letters (CRLs) for Now-Approved Drugs:**
  - Complete response letters typically have not been publicly released, and FDA has stated previously that it lacks legal authority to release them
  - In July 2025, FDA started publishing hundreds of CRLs for drugs now approved
  - In September 2025, FDA announced it will release future CRLs promptly after issuance to sponsors and issued almost 100 previously unpublished CRLs associated with pending or withdrawn applications

FDA
DEREGULATION

08

Deregulatory Efforts

FDA has started to implement deregulatory efforts, including by proposing to revoke 52 "obsolete" standards of identity for foods, with agency's analysis of over 250 standards of identity "ongoing"

- The White House issued an EO stating that, **for every new regulation a federal agency has issued, it must identify at least 10 existing rules to be repealed**, and asking agencies to identify regulations that:
  - Are unconstitutional or raise constitutional difficulties, such as overreach by the federal government
  - Are based on unlawful delegations of authority, "anything other than the best reading" of the statute
  - Impose significant costs on private parties that are not outweighed by public benefits
  - Harm the national interest by "significantly and unjustifiably impeding," e.g., technological innovation, research and development, economic development
  - Impose undue burdens on small business and impede private enterprise and entrepreneurship
- OMB guidance to agencies leaves certain implementation questions unanswered
- HHS published a request for information asking for deregulatory proposals and opened a docket for public comment, which closed in July
- Impact of deregulatory efforts on use of "podium policy" over regulations, guidance

How Companies Should Approach Deregulation

Consider informal avenues for engaging regulators with deregulatory proposals. When assessing whether to propose or oppose a potential deregulatory path, companies should consider many factors that may pull in different directions, including:

The public relations impact of the company challenging a particular type of regulation

The potential benefits of possible deregulation, including greater flexibility and lower compliance costs and enforcement risks

The potential drawbacks, including lack of certainty for industry and the potential reduction of barriers to entry

Questions?

Upcoming October Programs

2025/2026 White Collar Webcast Series

Date and Time	Program	Registration Link
Thursday, October 23, 2025 **9:00 AM – 10:00 AM PT** **12:00 PM – 1:00 PM ET**	**An Examination of Whistleblower Regimes** In this webinar, we will explore the evolution of global whistleblower regimes across the world, including across the United States and Europe. We will discuss new initiatives we have seen in 2025, the protections that have been afforded whistleblowers and companies under these regimes, and how companies can take steps to ensure they are complying with their statutory obligations while mitigating enforcement risk. **Presenters**: Michael Diamant, Sophia Hansell, Katharina Humphrey, Poonam Kumar, Greta Williams	Event Details