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DOJ's Consumer Protection Branch Releases Second Annual Recent Highlights Report

Client Alert | May 15, 2023

On April 28, 2023, the U.S. Department of Justice's Consumer Protection Branch (CPB) released its second annual Recent Highlights Report.[1] The Report describes the Branch and its role at DOJ, and it reviews significant litigation and resolutions that occurred in 2022. Gibson Dunn will discuss the Report and other developments related to the Consumer Protection Branch in a complimentary webcast on Wednesday, May 31, from 12:00 p.m. to 1:00 p.m. EDT. ***You may register for the webcast* here**. The below alert also summarizes key aspects of the Report.

Consistent with last year's publication,[2] the Report again highlights CPB's growth, both in terms of its size and its widening scope of criminal and civil actions. With well more than 200 people (including more than 110 prosecutors), the Branch is the fastest-growing enforcement component at the Department of Justice. Indeed, the Branch currently is onboarding a large number of new prosecutors and would receive further enhancement through the President's recent budget request.[3]

The Report also showcases CPB's expanding relationships with agency partners. Those partners include various law enforcement agencies and consumer protection regulators, including the U.S. Food and Drug Administration (FDA), the Federal Trade Commission (FTC), the Drug Enforcement Administration (DEA), the Consumer Product Safety Commission (CPSC), and the National Highway Traffic Safety Administration (NHTSA), among others. Working with these partners, the Branch is expanding the use of criminal and civil penalty authorities to new enforcement spaces.

The Report flags several enforcement trends. With regard to **consumer health and safety**, it is clear that the Branch is dedicating particular attention to opioids, dietary supplements, tobacco products, and food safety.[4] The Branch also is notably focused on distributors of regulated products, with the Report describing actions and investigative efforts to hold distributors—defined in the Report as including e-commerce and social media companies—accountable for "allowing" products "to get into the [wrong] hands."

As to **consumer fraud and deceptive practices**, the Report emphasizes the continuing expansion of the Branch's partnership with the FTC, especially in civil penalty actions, which the Branch litigates on behalf of the FTC. With the FTC now referring to the Branch dozens of civil-penalty actions a year, the litigation of such actions has become a huge component of the Branch's work and reflects a significant shift in how FTC-related actions are litigated. The Report also describes the Branch's ongoing commitment to prosecuting schemes that target the elderly and other vulnerable populations.

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The Report describes CPB's work in three main areas: consumer health and safety enforcement, consumer fraud and deceptive practices enforcement, and the defense of

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federal consumer protection agencies. It also discusses new corporate compliance policies.

Consumer Health and Safety Enforcement

The Report highlights CPB's work in enforcing the Federal Food, Drug, and Cosmetic Act (FDCA) and in combating the opioid epidemic. In the FDCA context, the Branch remains active in pursuing criminal and civil cases involving misbranded and adulterated drugs, medical devices, dietary supplements, biologics, food, and tobacco. The Report calls particular attention to the Branch's resolution of a long-running civil action involving cigarette marketing that will result in corrective statements being published at approximately 200,000 retail locations throughout the country. The Report also reviews the Branch's enforcement efforts involving unapproved nicotine products, unlawful dietary supplements, adulterated infant formula and other food, and misbranded drugs and medical devices. Food safety is an enforcement area emphasized in the Report, which states that the Branch is "[w]orking closely with the FDA and CDC" to pursue "civil and criminal actions against companies and individuals who fail to maintain sanitary facilities, distribute tainted food products, or make significant misrepresentations to customers or the public." The Report also continues a trend of statements by the Branch highlighting its work to address clinical triad fraud,[5] with the Report describing multiple prosecutions advanced and convictions secured for alleged conduct related to the falsification of results, records, and other information.

The Report also notes the Branch's strengthened efforts to combat the opioid epidemic. These efforts include nationwide civil actions under the Controlled Substances Act (CSA) related to the distribution and dispensing of prescription drugs. The efforts also include new actions to address the sharp rise in overdose deaths due to counterfeit pills laced with fentanyl. As noted in the Report:

> "[T]he Branch has broadened its efforts to pursue corporate bad actors facilitating the manufacture, distribution, or sale of counterfeit pills. This includes investigating e-commerce sites and social media platforms that may be allowing traffickers to sell counterfeit pills to teens and young adults. Further, the Branch is investigating companies that may be allowing precursor chemicals and equipment to get into the hands of drug trafficking organizations."

These "counterfeit pill initiatives" rely on the potential application of various provisions of the CSA and other laws that have not been frequently utilized. But that approach is consistent with the Branch's work in prior years to use novel enforcement pathways in cases involving diverted prescription opioids, misbranded drugs, and hazardous products.

Further, the Report includes an interesting call out to the Branch's work with CPSC and NHTSA. While no enforcement actions with those agencies are highlighted in the Report, their reference reflects increased collaboration with both agencies, especially with respect to criminal enforcement efforts.

Consumer Fraud and Deceptive Practice Enforcement

In the consumer fraud space, the Report notes a continued focus on transnational and complex consumer fraud schemes, as well as the enforcement of statutes administered by the FTC.

The Report makes clear that the Branch is continuing to collaborate more with the FTC, especially to advance actions seeking civil penalties for FTC rules or order violations. Under the FTC Act, the FTC must refer all actions seeking civil penalties to the Department of Justice for litigation. CPB receives and handles those referrals. In the wake of the Supreme Court's decision in *AMG Capital Management*,[6] the FTC has increased dramatically the number of civil penalty referrals sent to the Branch. In fact, the Branch

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now receives dozens of referrals annually, requiring more than 40,000 hours of personnel time to litigate last year.

Highlighted in the Report are a $275 million judgment against a video game developer for allegedly collecting personal information in violation of Children's Online Privacy Protection Act, and a $150 million civil penalty judgment against a social media company for allegedly failing to comply with data privacy provisions of a prior FTC order. The Report also notes that the Branch filed the first case under the FTC's "Made in the USA" rule, multiple telemarketing cases, and other actions for unfair or deceptive practices. In addition, the Report highlights a case in which the Branch combined claims that a product violated both an FTC rule and the FDCA's misbranding provisions—a combining of claims only possible because of the FTC's referral of civil penalty actions to the Branch.

The Report also reviews CPB's continued work fighting scams that target or disproportionately affect the elderly, immigrants, veterans, and vulnerable populations. That work includes the Branch's coordination of global fraud-fighting efforts through the Department's Transnational Elder Fraud Strike Force, which Attorney General Garland expanded to cover twenty federal districts.

Defensive Litigation

The Report includes a robust section discussing CPB's enhanced efforts and capabilities to defend consumer protection agencies against challenges to their actions brought under the U.S. Constitution and the Administrative Procedure Act. Such challenges often involve the authorization or denial of medical device or drug approvals, the issuance of public health guidance, or product recalls. Some highlights noted in the Report include the Branch's defense of the FDA's orders denying marketing authorization for e-cigarette products, and its defense of the FDA in cases related to COVID-19 vaccines and treatments. Although not mentioned in the Report due to ongoing litigation, the Branch is also defending the FDA in challenges involving the drug mifepristone. The Branch's defensive litigation work has expanded substantially over the past year and remains a space to watch.

Corporate Compliance

All of the Branch's enforcement efforts will be informed by its new voluntary self-disclosure and monitor-selection policies, which we detailed in a previous alert in March of this year.[7] Those policies signal a desire to incentivize self-disclosure directly to CPB and to impose independent monitors more frequently. The Report explains that the policies are overseen by CPB's Corporate Compliance and Policy Unit, which "helps to craft and enforce corporate resolutions," including by working to "assess compliance programs, craft resolution terms, and ensure that defendants follow the compliance and reporting provisions of resolutions."[8]

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The Report makes clear that CPB remains one of the Department of Justice's most active enforcers, using its unique ability to employ criminal and civil authorities to bring actions across a wide range of areas. Gibson Dunn has deep familiarity with CPB and experience in navigating actions involving it. We stand ready to assist clients engaging with the Branch.

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[1] *United States Department of Justice Consumer Protection Branch*, "Recent Highlights" (Apr. 2023), available at https://www.justice.gov/d9/2023-04/CPB%20Highlights.pdf.

[2] *United States Department of Justice Consumer Protection Branch*, "Recent Highlights" (Apr. 2022), available at https://www.justice.gov/file/1490441/download.

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[3] *See* https://www.whitehouse.gov/wp-content/uploads/2023/03/jus_fy2024.pdf.

[4] *See also* United States Department of Justice, "Deputy Assistant Attorney General Arun G. Rao Delivers Remarks at the Food & Drug Law Institute's (FDLI) 2021 Enforcement, Litigation and Compliance Conference" (Dec. 7, 2022), available at https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-arun-g-rao-delivers-keynote-address-food-and-drug-law.

[5] *See e.g.* United States Department of Justice, "Deputy Assistant Attorney General Arun G. Rao Delivers Remarks at the Food & Drug Law Institute's (FDLI) 2021 Enforcement, Litigation and Compliance Conference" (Dec 9, 2021), available at https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-arun-g-rao-delivers-remarks-food-drug-law-institute-s.

[6] *AMG Capital Management, LLC, et al. v. Federal Trade Commission*, 593 US _ (2021).

[7] *See* Client Alert, Gibson Dunn, DOJ's Consumer Protection Branch Announces New Corporate Enforcement Policies (March 28, 2023), https://www.gibsondunn.com/doj-consumer-protection-branch-announces-new-corporate-enforcement-policies/.

[8] *United States Department of Justice Consumer Protection Branch*, "Recent Highlights" (Apr. 2023), at 36, available at https://www.justice.gov/d9/2023-04/CPB%20Highlights.pdf.

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Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding the issues discussed in this update. Please contact the Gibson Dunn lawyer with whom you usually work in the firm's FDA and Health Care, Privacy, Cybersecurity and Data Innovation, or White Collar Defense and Investigations practice groups, or the authors:

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