



RECENT HIGHLIGHTS

Consumer Protection Branch
United States Department of Justice

FOREWORD

2021 marked the 50th anniversary of the Consumer Protection Branch. Following that milestone, I am pleased to present the Branch's first-ever report highlighting its recent work for consumers.

Initially established in 1971 as the Consumer Affairs Section of the Department of Justice's Antitrust Division, the Consumer Protection Branch over the past five decades has moved Divisions, changed names, and grown to an organization of more than 200 people. Today, the Branch's nearly 100 attorneys, embedded federal agents, investigators, and staff handle both criminal and civil cases throughout the country to protect consumers' health, safety, economic security, and identity integrity. Branch personnel also defend the Food and Drug Administration, the Consumer Product Safety Commission, and other federal agencies against challenges to their programs and decisions.

The Branch achieved record results in 2021 and the months preceding it, filing actions against more than 200 defendants, handling 55 defensive cases, entering into more than 50 corporate resolutions, and securing judgments or settlements involving more than \$6.38 billion in monetary amounts.¹ This work included actions responding to the ongoing opioid epidemic and COVID-19 pandemic, drug and device hazards, pathogen outbreaks, youth smoking, and product harms, as well as fraud and deception affecting the elderly, recent immigrants, and other vulnerable populations. The Branch's efforts also included the use of new legal tools, including criminal provisions of the Consumer Product Safety Act, civil sections of the Controlled Substances Act, and numerous statutes and rules administered by the Federal Trade Commission. In all of its work, the Branch partnered with United States Attorney's Offices, other Department components, and law-enforcement agencies.

The dedicated personnel of the Consumer Protection Branch have achieved exceptional results despite extraordinary challenges. Furthering the Branch's unique mission with skill and drive, they proudly have marked a half-century of progress. Looking forward, I am confident that they will continue to advance important actions to safeguard consumers.

Gustav Eyler
 Director
 Consumer Protection Branch
 April 2022²

Justice Department Establishes A Section on Consumer Affairs

"The Justice Department announced today the establishment of a Consumer Affairs Section in its Antitrust Division The aim is to strengthen enforcement of consumer protection laws and give consumers 'a focal point for complaints,' according to a statement issued by Attorney General John N. Mitchell."

-The New York Times

¹ This report calculates figures starting from the beginning of the 2021 fiscal year and ending on December 31, 2021. Certain imposed monetary amounts remain subject to ongoing legal proceedings.

² Thanks to Assistant Director John Claud, Civil Division Counsel Cristen Handley, and Senior Systems Analyst Jim Murphy for their exceptional work in preparing this report.

RESULTS AT A GLANCE

CPB's investigative and litigation efforts between October 2020 and December 2021 led to more than:



\$6.38b

Monetary amounts in resolutions and judgments³



96

Individuals and corporations charged⁴



112

Individuals and corporations sued in civil enforcement actions



67

Individuals convicted



17

Corporate guilty pleas



5

Corporate deferred prosecution agreements



29

Corporate civil resolutions



55

Defensive cases litigated



48

Federal districts with actions filed

³ Reflects the monetary amounts payable to the United States or victims imposed through judgments or resolutions secured by CPB action. Payments associated with actions parallel to CPB actions are not counted. Certain imposed monetary amounts were suspended in accordance with Department policies or remain subject to ongoing legal proceedings, including the monetary terms of the criminal resolution with Purdue Pharma LP. *See infra* at 9.

⁴ 79 individuals charged; 17 corporations charged. These numbers exclude sealed cases and actions associated with the 2021 Money Mule Initiative, *see infra* at 19. Defendants are presumed innocent until proven guilty beyond a reasonable doubt in a court of law.

SENIOR LEADERSHIP

Civil Division Leadership

Brian Boynton, *Principal Deputy Assistant Attorney General*

Brian joined the Department of Justice from a large national law firm in 2021 as the Principal Deputy Assistant Attorney General in the Civil Division. He previously served at the Department from late 2014 through early 2017, first as a Deputy Assistant Attorney General in the Office of Legal Counsel and then as a Counselor to Attorney General Loretta E. Lynch. Brian clerked on the U.S. Court of Appeals for the District of Columbia Circuit and on the U.S. District Court for the Northern District of California.

Arun Rao, *Deputy Assistant Attorney General*

Arun joined the Department of Justice in 2021 as the Deputy Assistant Attorney General for CPB. He previously served at the Department from 2007 to 2017, first as an Assistant U.S. Attorney in the Western District of Tennessee and later as Chief of the Southern Division of the U.S. Attorney's Office for the District of Maryland. He also served as a Deputy Associate Counsel in the Office of the White House Counsel from 2012 to 2013. He clerked on the U.S. Court of Appeals for the Sixth Circuit.

CPB Senior Management

Gustav Eyster, *Director*

Gus joined the Consumer Protection Branch as its Director in 2017. He previously served as a Counselor to the Attorney General and as a prosecutor in the Criminal Division's Fraud Section and the U.S. Attorney's Office for the District of Maryland. Gus also worked in private practice at a law firm in Washington, D.C., served as a counsel to the U.S. Senate Judiciary Committee, and clerked on the U.S. Court of Appeals for the Third Circuit.

Amanda Liskamm, *Principal Deputy Director*

Amanda joined the Branch in 2021 as Principal Deputy Director. Amanda has served in numerous leadership roles in the Department, including as Deputy Assistant Attorney General in the Criminal Division, Chief of Staff at the DEA, Associate Deputy Attorney General and Director of Opioid Enforcement and Prevention Efforts in the Office of the Deputy Attorney General, and as an Assistant U.S. Attorney in the Central District of California.

Richard Goldberg, *Deputy Director*

Rich joined the Branch in 1999 through the Attorney General's Honors Program. He became a Deputy Director in 2019, having previously served as a Senior Counsel for Complex Litigation and an Assistant Director. Rich oversees the Branch's consumer fraud and deception work, including criminal and civil actions to combat schemes affecting older Americans, immigrants, servicemembers, and consumers' data privacy. Rich also coordinates the Department's Transnational Elder Fraud Strike Force and co-chairs the Global Antifraud Enforcement Network.

Alan Phelps, *Deputy Director*

Alan joined the Branch in 2001 through the Attorney General's Honors Program. He became a Deputy Director in 2019, having previously served as a Senior Counsel for Complex Litigation and an Assistant Director. Alan supervises the Branch's consumer health and safety work, including criminal and civil enforcement actions under various statutes. He clerked on the U.S. Court of Appeals for the Third Circuit.

CPB ASSISTANT DIRECTORS

Consumer Health and Safety

Allan Gordus joined CPB in 2000 from a law firm in Missouri. He supervises civil and criminal enforcement of the Federal Food, Drug, and Cosmetic Act (FDCA) and the Consumer Product Safety Act.

Matt Lash joined CPB in 2011 from a law firm in Washington, D.C. He supervises consumer health and safety matters, including criminal and civil enforcement actions related to drugs, medical devices, food safety, and the opioid epidemic.

Clint Narver joined CPB in 2015 from the FDA's Office of the Chief Counsel, where he served as an Associate Chief Counsel. His work focuses on criminal FDCA enforcement. Clint previously worked at two law firms in Washington, D.C., and clerked on the U.S. Court of Appeals for the Ninth Circuit.

Catherine Dick joined CPB in 2021 from the U.S. Attorney's Office in Maryland. She is CPB's Criminal Trial Coordinator and supervises criminal FDCA cases. She previously served in the Criminal Division's Fraud Section and Organized Crime and Gang Section. Cassie clerked on the U.S. District Court for the District of Columbia.

Consumer Fraud

Josh Burke joined CPB in 2007 through the Attorney General's Honors Program. He supervises consumer fraud matters with a focus on criminal prosecutions of fraud schemes targeting the elderly, immigrants, and other vulnerable populations.

Lisa Hsiao joined CPB in 2010 from a law firm in Washington, D.C., where she was a partner. She supervises cases seeking civil penalties and other relief for allegations of consumer protection laws involving false advertising, data privacy violations, telemarketing violations, and other deceptive and unfair practices.

Jacqueline Blaesi-Freed joined CPB in 2015 through the Attorney General's Honors Program. She supervises consumer fraud matters and assists with the Department's elder fraud efforts and Money Mule Initiative. Jackie clerked on the U.S. Court of Appeals for the Tenth Circuit and the Kansas Supreme Court.

Defensive Litigation

Hilary Perkins joined CPB in 2019 from a law firm in Washington, D.C. She oversees CPB's defensive litigation practice and advises on policy matters. Hilary clerked on the U.S. Court of Appeals for the Fifth Circuit.

Specialized Units

John Claud joined CPB in 2008 from a law firm in Washington, D.C. John supervises CPB's Corporate Compliance and Policy Unit and also supervises FDCA criminal and civil enforcement actions.

Vincent Shuler joined CPB in April 2019 as an Assistant Director, having served as a military lawyer and retired from the U.S. Army. He supervises consumer fraud matters related to schemes targeting servicemembers, veterans, and their families. Vincent also oversees the Branch's Administration and Litigation Support Unit.

Adam Lyons joined CPB in 2020, having previously litigated complex matters in the Civil Division's National Courts Section and in private practice. He supervises consumer fraud matters and leads CPB's Special Matters Unit.

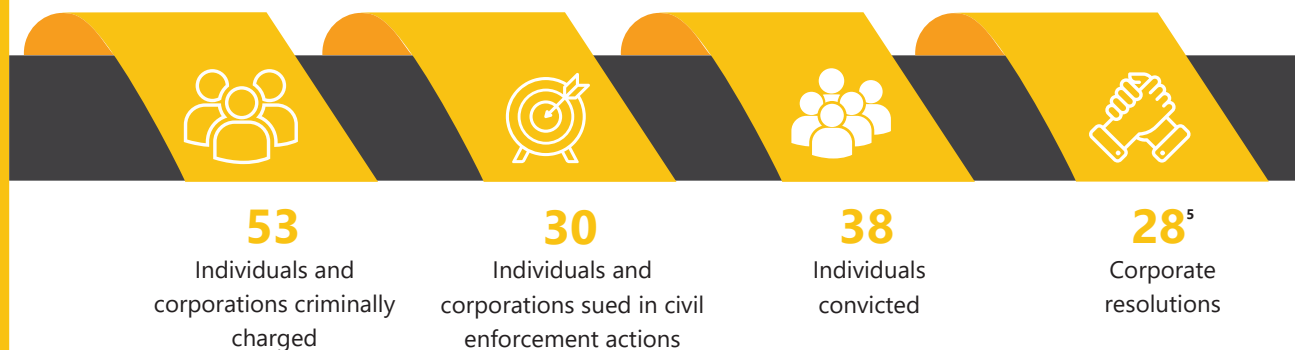
CONSUMER HEALTH AND SAFETY

CPB leads Department of Justice efforts to protect consumers from unlawful products. Charged with enforcing the Federal Food, Drug, and Cosmetic Act (FDCA), CPB works closely with the Food and Drug Administration (FDA) to investigate and litigate a wide range of criminal and civil matters involving adulterated and misbranded drugs, medical devices, food, dietary supplements, biologics, and tobacco products. Matters advanced by CPB often involve allegations of clinical trial fraud, pathogen outbreaks, unapproved marketing claims, and use of illicit ingredients. Much of CPB's recent work in the FDCA space has involved misbranded and adulterated drugs and medical devices (including test kits and personal protective equipment) sold as purported treatments or cures for COVID-19. CPB attorneys routinely seek injunctions to protect consumers from ongoing harm while pursuing parallel criminal sanctions, and they often collaborate on matters with attorneys from the Fraud Sections of the Civil and Criminal Divisions.

CPB also partners with the Drug Enforcement Administration (DEA) and U.S. Attorney's Offices to combat the nation's opioid abuse epidemic. This work includes filing nationwide civil and criminal actions against manufacturers, distributors, chain pharmacies, and executives alleged to have contributed to the epidemic. CPB also brings local-impact cases against individual prescribers, pharmacists, and other entities engaged in the diversion of prescription opioids. In addition, CPB is focused on addressing the harm from counterfeit pills laced with fentanyl and other substances, seeking to stem the pathways by which those pills—or ingredients and equipment necessary to their manufacture—are sold. In conducting this work, CPB relies on state-of-the-art data-analysis and evidence-review tools, a robust support staff, and a dedicated group of agents and investigators.

To protect consumers' health and safety, CPB also leads efforts to enforce statutes administered by the Consumer Product Safety Commission (CPSC) and the National Highway Traffic Safety Administration (NHTSA). Having recently brought the first-ever criminal prosecutions under the Consumer Product Safety Act (CPSA), CPB attorneys and partner U.S. Attorney's Offices are working closely with both CPSC and NHTSA to advance assertive enforcement actions related to dangerous products and failures to report defects or hazards.

CPB's recent Consumer Health and Safety efforts led to more than:



⁵ These resolutions include 16 criminal pleas, three deferred prosecution agreements, and nine civil consent decrees or judgments.

Significant Actions – Consumer Health and Safety



Drugs, Medical Devices, and Dietary Supplements

United States v. Fresenius Kabi Oncology, Ltd. (D. Nev.). In March 2021, Indian drug manufacturer Fresenius Kabi Oncology Limited (FKOL) was sentenced to pay \$50 million in fines and forfeiture after pleading guilty to concealing and destroying records prior to an FDA plant inspection. According to court documents, FKOL owned and operated a manufacturing plant in Kalyani, West Bengal, India, that manufactured active pharmaceutical ingredients used in various cancer drug products distributed to the United States. Prior to an FDA inspection of the Kalyani facility, FKOL management directed employees to remove certain records from the premises and to delete other records from computers that would have revealed FKOL was manufacturing drug ingredients in contravention of the FDCA.

United States v. Avanos Medical, Inc. (N.D. Tex.). In July 2021, Avanos Medical, Inc., a U.S.-based multinational medical device corporation, entered into a deferred prosecution agreement (DPA) with CPB, the Criminal Division's Fraud Section, and the U.S. Attorney's Office for the Northern District of Texas to resolve criminal charges related to the company's fraudulent misbranding of surgical gowns. Certain Avanos employees falsely labeled gowns manufactured by the company as providing the current highest level of protection against fluid and virus penetration when they knew that the gowns did not meet that standard. With this false labeling, Avanos made false representations to hospitals and other customers about the gowns' safety, including to at least one health care provider who sought assurances before procuring the gowns for use by medical professionals handling the 2014 Ebola outbreak. As part of the resolution, Avanos agreed to pay a total criminal monetary amount of \$22,228,000, consisting of a victim compensation payment of \$8,939,000, a criminal monetary penalty of \$12,600,000, and a disgorgement payment of \$689,000.

United States v. AMARC Enterprises, et al. (S.D. Cal.). In August 2021, a federal court ordered AMARC Enterprises and its owner to stop distributing unapproved and misbranded drugs and adulterated animal drugs. The government alleged that AMARC sold and distributed products called "Poly-MVA" and "Poly-MVA for Pets" that defendants claimed in online posts—including posts featuring third-party content—could cure, mitigate, treat or prevent disease, including cancer. The defendants' Poly-MVA products were not generally recognized as safe and effective by qualified experts to do any of those things.

United States v. Bolos, et al. (E.D. Tenn.). In December 2021, following a month-long trial, a federal jury convicted Peter Bolos of conspiracy to commit health care fraud, multiple counts of mail fraud, and felony misbranding of a medication. Bolos and his 16 co-conspirators conspired to defraud pharmacy benefit managers, such as Express Scripts and CVS Caremark, by billing for fraudulent prescriptions. As a co-owner of a pharmacy, Bolos purchased bogus prescriptions from a telemedicine company, knowing that those prescriptions were not issued under valid doctor-patient relationships. He and his co-defendants then shipped medications from compounding pharmacies they owned to thousands of unsuspecting patients across the country, all without collecting the required co-pays. Bolos and his co-conspirators billed over \$900 million to private and public insurers, collecting over \$174 million of those invoices. In addition to securing convictions against Bolos and his co-defendants, CPB and the U.S. Attorney's Office for the Eastern District of Tennessee obtained seven corporate guilty pleas. Sterling Knight Pharmaceuticals, LLC, ULD Wholesale Group, LLC, Tanith Enterprises, LLC, Alpha-Omega Pharmacy, LLC, Germaine Pharmacy, Inc., and ERX Consultants, LLC, dba Zoetic Pharmacy, and HealthRight, LLC, each agreed in pleading guilty to implement substantial enhanced compliance measures and, collectively, to pay more than \$50 million in fines, forfeiture, and restitution.

United States v. Boccuzzi, et al. (S.D. Fla.). In December 2021, a federal jury in Fort Lauderdale convicted James Boccuzzi of one count of conspiracy to defraud the FDA and one count of conspiracy to distribute controlled substances. Boccuzzi was the 11th defendant convicted in connection with Blackstone Labs, LLC, a Boca Raton company that sold millions of dollars of products falsely labeled as dietary supplements. The trial followed a years-long investigation into Blackstone that showed that the company and its executives conspired to defraud the FDA and to manufacture and distribute research chemicals and anabolic steroids that were controlled substances under the Designer Anabolic Steroid Control Act. The co-conspirators quickly sold off other Blackstone products containing certain stimulants after they received an FDA warning letter notifying them that the products were unlawful to sell as dietary supplements. Multiple other corporate and individual defendants pleaded guilty and were sentenced in the run-up to trial, including both Blackstone Labs and Ventech Labs. The defendants collectively have been ordered to pay nearly \$9 million in restitution, forfeiture, and fines.



Opioids

United States v. Indivior Solutions, Inc. (W.D. Va.). In November 2020, Indivior Solutions was sentenced to pay \$289 million in criminal penalties in connection with its guilty plea to making false statements related to the safety of its opioid-addiction-treatment drug, Suboxone Film. Indivior's parent companies, Indivior, Inc. and Indivior, PLC, also agreed in a resolution with CPB and the U.S. Attorney's Office for the Western District of Virginia to enhanced compliance and reporting measures. The former CEO and medical director of those companies were fined and sentenced to terms of imprisonment and home confinement, respectively. In total, payments made by Indivior companies and executives, along with payments made under a 2019 resolution with Indivior's former parent company, Reckitt Benckiser Group, PLC, exceeded \$2 billion.

United States v. Purdue Pharma, LP (D. N.J.). In November 2020, Purdue Pharma, LP admitted guilt for its role in the nation's opioid abuse crisis. Consistent with its plea agreement with CPB and the U.S. Attorney's Offices for the Districts of New Jersey and Vermont, Purdue pleaded guilty to conspiring to defraud the United States by impeding the lawful function of the DEA; conspiring to aid and abet violations of the FDCA by facilitating the dispensing of opioids without a legitimate medical purpose; and conspiring to violate the Federal Anti-Kickback Statute by making payments to doctors and an electronic health records company to induce the writing of more prescriptions for Purdue's products. In conjunction with its guilty plea, Purdue agreed to the largest penalties ever levied against a pharmaceutical manufacturer, including a criminal fine of \$3.544 billion and an additional \$2 billion in criminal forfeiture. The company also agreed to cease operating in its current form and to convert through bankruptcy to a public benefit company or similar entity. Payment of the agreed-to fine is subject to ongoing bankruptcy proceedings, and Purdue's plea agreement anticipates crediting against the forfeiture amount up to \$1.775 billion for funds paid to support state and local opioid-abatement programs.

United States v. Walmart, Inc., et al. (D. Del.). In a complaint filed in December 2020, attorneys from CPB and four U.S. Attorney's Offices alleged on behalf of the United States that Walmart unlawfully dispensed controlled substances from pharmacies it operated across the country and unlawfully distributed controlled substances to those pharmacies. The complaint alleges that this unlawful conduct resulted in hundreds of thousands of Controlled Substances Act (CSA) violations. The complaint seeks civil penalties and injunctive relief. Litigation is ongoing.

United States v. Bacaner, et al. (M.D. Fla.). In February 2021, attorneys from CPB and the U.S. Attorney's Office for the Middle District of Florida filed on behalf of the United States a civil complaint against the owners of a Tampa-area clinic and pharmacy. The complaint alleged that Dr. Tobias Bacaner, Theodore Ferguson II, Timothy Ferguson, Paragon Community Healthcare, Inc., and Cobalt Pharmacy, Inc., ignored obvious signs of abuse or diversion when issuing and filling opioid prescriptions. The complaint also alleged that drug toxicity played a role in the deaths of several individuals who received controlled substances from the defendants. The United States secured preliminary injunctive relief to prevent the physician and pharmacy defendants from writing or filling controlled-substance prescriptions during the pendency of the case, which remains ongoing.

United States v. Shaffer Pharmacy, et al. (N.D. Ohio). In June 2021, pursuant to a consent judgment and permanent injunction, an Ohio judge enjoined Shaffer Pharmacy, along with pharmacist-owner Thomas Tadsen and pharmacist Wilson Bunton, from dispensing certain opioid prescriptions, including combination opioid and benzodiazepine prescriptions. The order also mandates that the defendants undergo periodic comprehensive reviews of their dispensing practices to ensure compliance with the order and the CSA. The consent decree includes a \$375,000 civil penalty and resolves a civil complaint alleging that the defendants repeatedly dispensed highly addictive and highly abused prescription opioids while ignoring obvious indications of drug diversion. The case was handled by attorneys from CPB and the U.S. Attorney's Office for the Northern District of Ohio.



COVID-19

United States v. Nepute, et al. (E.D. Mo.). In April 2021, CPB attorneys filed a complaint against Eric Anthony Nepute and Quickwork, LLC, doing business as Wellness Warrior, in the first enforcement action brought under the COVID-19 Consumer Protection Act, as well as Sections 5(a) and 12 of the Federal Trade Commission Act (FTC Act). Enacted in December 2020, the COVID-19 Consumer Protection Act prohibits deceptive acts or practices associated with the treatment, cure, prevention, mitigation, or diagnosis of COVID-19. The defendants allegedly advertised that their vitamin D and zinc nutritional supplements could prevent or treat COVID-19, without competent or reliable scientific evidence to support their claims. Further, the defendants allegedly advertised without scientific support that their supplements were equally or more effective therapies for COVID-19 than the currently available vaccines. The complaint seeks civil penalties and injunctive and other equitable relief to stop the defendants from continuing to make deceptive advertising claims. The CPB litigation team obtained preliminary injunctive relief prohibiting defendants from continuing to make their unsubstantiated claims, and defeated defendants' motions to dismiss. Litigation is ongoing.

United States v. Brandenburg (W.D. Wis.). In June 2021, Steven R. Brandenburg, a pharmacist, was sentenced to three years in prison for tampering with COVID-19 vaccine doses at the hospital where he worked. According to court documents, Brandenburg purposefully removed a box of COVID-19 vaccine vials manufactured by Moderna from a hospital refrigeration unit during two successive overnight shifts, then returned them after they had spoiled. Brandenburg stated that he was skeptical of vaccines. Fifty-seven of the spoiled vaccines were administered before Brandenburg's actions were discovered.

United States v. Parris (D.D.C.). In August 2021, Christopher Parris pleaded guilty to conspiracy to commit wire fraud related to the fraudulent sale of purported personal protective equipment (PPE). During the height of the pandemic in 2020, Parris offered to sell to the Department of Veterans Affairs (VA) scarce PPE that he did not possess or have any means to procure, including 3M-brand N95 respirator masks. He attempted to obtain an upfront payment of \$3.075 million from the VA, even though he knew at the time that he had no access to the promised masks or ability to deliver the promised masks. In total, Parris claimed to be able to fill orders for hundreds of millions of dollars, and he sought orders in excess of \$65 million for the non-existent PPE. Parris is awaiting sentencing.

United States v. Xlear, Inc., et al. (D. Utah). In October 2021, CPB attorneys brought a civil enforcement action against Xlear, Inc. and Nathan Jones for alleged violations of FTC Act Sections 5(a) and 12 and the COVID-19 Consumer Protection Act. According to the complaint, the defendants advertised that their saline nasal spray product could prevent or treat COVID-19, without competent or reliable scientific evidence to support their claims. Further, the defendants allegedly made deceptive statements about several scientific studies to bolster their unproven claims. The complaint seeks civil penalties, injunctive relief, and other equitable monetary relief. Litigation is ongoing.

United States v. Natural Solutions Foundation, et al. (D. N.J.). In December 2021, a federal court permanently enjoined a New Jersey organization, Ralph Fucetola, and Dr. Rima Laibow from distributing unapproved and misbranded drugs touted as COVID-19 treatments. The government alleged that Natural Solutions Foundation, Fucetola, and Dr. Laibow distributed a “nano silver” solution product that they claimed would prevent, treat, or cure COVID-19. But Silver is not generally recognized as safe and effective by qualified experts to prevent, treat, or cure COVID-19, and the defendants’ claims were not supported by credible scientific evidence or studies. The defendants agreed to a consent decree of permanent injunction and instituted a recall for their nano silver products.



Consumer Product Safety

United States v. Walter Kidde Portable Equipment, Inc. (M.D.N.C.). In January 2021, the Kidde company agreed to pay \$12 million in civil penalties to settle allegations that it failed timely to notify the CPSC about a product defect. The complaint accompanying the settlement alleged that Kidde significantly underreported to the CPSC the scope and nature of a defect to certain of its fire extinguishers that could have caused the products to fail to discharge during a fire emergency and failed to report immediately to the CPSC information concerning nozzles detaching from fire extinguishers.

United States v. Pharmicare, Inc., et al. (D. P.R.). In September 2021, two companies and their owner agreed in a consent decree to stop importing children’s toys until implementing remedial measures, including hiring an independent product safety coordinator. According to the government’s complaint, defendants imported children’s products containing illegal levels of lead or phthalates and products that failed to meet various safety or labeling requirements.

United States v. Gree Electric Appliances, Inc. of Zhuhai, et al. (C.D. Cal.). In October 2021, in the first corporate criminal enforcement action ever brought under the CPSA, Gree Electric Appliances, Inc. of Zhuhai (Gree Zhuhai), a global appliance manufacturer headquartered in Zhuhai, China, and Hong Kong Gree Electric Appliances Sales Co., Ltd. (Gree Hong Kong) entered into a DPA with CPB and the U.S. Attorney's Office for the Central District of California to resolve a felony charge for failing timely to notify the CPSC that millions of dehumidifiers they sold to U.S. consumers were defective and could catch fire. The companies' subsidiary, Gree USA, also agreed to plead guilty to the same felony charge. Under the terms of the DPA, Gree Zhuhai and Gree Hong Kong agreed to a \$91 million penalty and to pay restitution for any uncompensated victims of fires caused by the companies' defective dehumidifiers. Gree Zhuhai and Gree Hong Kong also agreed to enhanced compliance and reporting measures, including the retention of an independent compliance expert. The former CEO and chief administrative officer of Gree USA were also charged with multiple felony counts related to their failure to notify the CPSC about the defective dehumidifiers.



Clinical Trial Fraud

United States v. Villaman-Bencosme, et al. (S.D. Fla.). In March 2021, Dr. Yvelice Villaman-Bencosme was sentenced to 63 months in prison after pleading guilty to one count of conspiracy to commit wire fraud for her role in a scheme to falsify clinical trial data. Villaman-Bencosme was a licensed medical doctor who served as the primary investigator for clinical trials purportedly conducted at Unlimited Medical Research, one of many companies hired to conduct a clinical trial designed to investigate the safety and efficacy of an asthma medication in children between the ages of four and eleven. Villaman-Bencosme admitted that she falsified medical records to make it appear as though pediatric subjects made scheduled visits to Unlimited Medical Research, took study drugs as required, and received checks as payment. Lisett Raventos, a study coordinator at Unlimited Medical Research, and Maytee Lledo, a receptionist at Villaman-Bencosme's private medical practice, also pleaded guilty to conspiracy to commit wire fraud and were sentenced to 30 months and 14 months in prison, respectively. In a separate case, Olga Torres, a co-owner of Unlimited Medical Research, pleaded guilty to obstructing an FDA regulatory inspection concerning the asthma study conducted by Villaman-Bencosme. Torres is scheduled to be sentenced in April 2022. One remaining defendant, Jessica Palacio, who was also a study coordinator at Unlimited Medical Research, is set for trial in a separate case.

United States v. Navarro, et al.; United States v. Valdes, et al.; United States v. Rico, et al. (S.D. Fla.). In June 2021, Eduardo Navarro, a nurse practitioner and sub-investigator at Tellus Clinical Research, and Nayade Varona, an assistant study coordinator at Tellus, pleaded guilty to their participation in a conspiracy to falsify clinical trial data. As part of their plea agreements, Navarro and Varona admitted that they agreed with one another and others to falsify data in medical records in connection with two clinical trials intended to evaluate a treatment for irritable bowel syndrome. Navarro was sentenced to 46 months in prison, and Varona was sentenced to 30 months in prison. Four additional defendants—including the principal investigator of clinical trials and the chief executive officer—were indicted in connection with the scheme. One of those defendants, study coordinator Duniel Tejeda, pleaded guilty to conspiracy to commit mail and wire fraud in October 2021, and was sentenced to 30 months in prison. Two other Tellus employees have been charged with related conduct in an additional case, with trials scheduled in 2022. Data falsified by Tellus Clinical Research employees is alleged to have been submitted to at least three pharmaceutical manufacturers for use in drug development and approval applications.



Food Safety

United States v. Kruse (W.D. Tex.). In October 2020, a Texas grand jury charged the former president of ice cream manufacturer Blue Bell Creameries, LP with seven counts of wire fraud and conspiracy to commit wire fraud in connection with an alleged scheme to cover up the company's sales of listeria-tainted ice cream in 2015. Blue Bell Creameries previously pleaded guilty to two misdemeanor counts of distributing adulterated ice cream products and was sentenced to pay \$17.25 million in fines and forfeiture—the largest-ever criminal penalty following a conviction in a food safety case.

United States v. Valley Processing, Inc., et al. (E.D. Wash.). In January 2021, a federal court enjoined Valley Processing, Inc., along with the company's owner and president, Mary Ann Bliesner, from preparing, processing, or distributing adulterated juice or other food products in violation of the FDCA. The company formerly supplied millions of juice servings used in school lunch programs. Court documents alleged that the defendants processed juice under grossly insanitary conditions, failed to adhere to relevant food safety standards, and distributed to the public newer juice mixed with older, potentially contaminated juice.

United States v. AffinityLifestyles.com, Inc. (D. Nev.). In June 2021, a federal court enjoined AffinityLifestyles.com, Inc. and Real Water, Inc., along with company officers Brent A. Jones and his son, Blain K. Jones, from preparing, processing, or distributing adulterated and misbranded bottled water in violation of the FDCA. While the companies marketed their products as a healthy alternative to tap water, the government alleged that the products in fact consisted of municipal tap water that the defendants processed with various chemicals in violation of current good manufacturing practices, relevant food safety standards, and hazard prevention measures. According to court filings submitted by attorneys from CPB and the U.S. Attorney's Office for the District of Nevada, the FDA received information that at least five children experienced acute non-viral hepatitis resulting in acute liver failure after drinking the defendants' products.

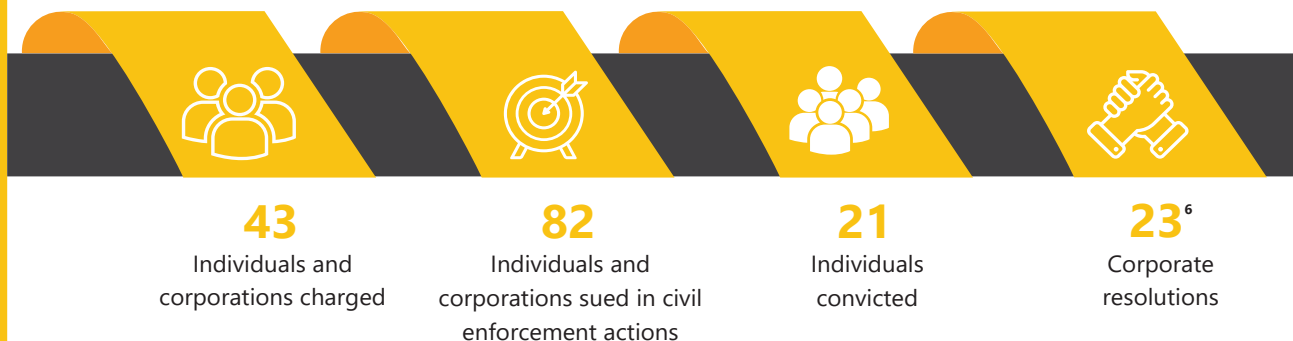
CONSUMER FRAUD

CPB is a leader in investigating and prosecuting consumer fraud, with substantial experience in tackling multi-district and transnational fraud schemes. CPB also handles all Department of Justice litigation under statutes administered by the Federal Trade Commission (FTC) that protect consumers from unfair and deceptive conduct.

CPB devotes considerable resources to stopping scams that disproportionately target or affect older Americans, recent immigrants, veterans, and other vulnerable populations. Prominent in this work is CPB's coordination of the Department's Transnational Elder Fraud Strike Force, which combats foreign-based scams with resources from CPB, U.S. Attorney's Offices, the U.S. Postal Inspection Service, FBI, FinCEN, and other law-enforcement agencies. CPB personnel also support the Strike Force's efforts by co-chairing the Global Anti-Fraud Enforcement Network and maintaining strong partnerships with foreign law enforcement. In addition, CPB prosecutors have led the Department in convicting individuals responsible for schemes targeting Spanish speakers, and they have held to account corporations and executives that have knowingly facilitated fraud schemes. Through the Department's Servicemembers and Veterans Initiative, CPB also prosecutes fraud schemes that target the men and women who defend America, bringing actions against product-marketing, debt-relief, and identity-theft scams.

CPB's work enforcing statutes administered by the FTC involves complex civil and criminal litigation. CPB litigates actions referred by the FTC seeking civil penalties for violations of the Children's Online Privacy Protection Act, the Fair Credit Reporting Act, the Restore Online Shoppers' Confidence Act, the Telemarketing Sales Rule, and other FTC-administered orders and provisions of law. These actions increasingly involve claims related to the acquisition, use, and transfer of consumers' personal information. CPB also advances criminal actions based on investigative referrals from the FTC, and it collaborates regularly with the Department's Antitrust Division on enforcement and interagency initiatives.

CPB's recent Consumer Fraud efforts led to more than:



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These resolutions include one criminal plea, two deferred prosecution agreements, and 20 civil consent decrees or judgments.

Significant Actions – Consumer Fraud



Elder Fraud

United States v. Epsilon Data Management, LLC (D. Colo.). In January 2021, Epsilon Data Management entered into a DPA with CPB and the U.S. Attorney’s Office for the District of Colorado to resolve an information charging the company with one count of conspiracy to commit mail fraud. One of the largest marketing companies in the world, Epsilon admitted through the DPA that, from July 2008 through July 2017, certain of its employees knowingly sold information associated with more than 30 million American consumers to clients engaged in fraudulent mass-mailing schemes, many of which targeted elderly victims. The DPA required a payment of \$150 million, with \$127.5 million allocated for compensating victims. The DPA also included substantial compliance and reporting measures. One former vice president of the company has pleaded guilty, and two other former executives have been charged with various felony offenses.

United States v. Newman (D. Conn.). Norman Newman pleaded guilty in April 2021 to conspiracy to commit mail and wire fraud. Newman was a former senior vice president at Macromark, Inc., which previously pleaded guilty to conspiracy to commit mail and wire fraud for providing lists of potential victims to multiple fraudulent mass-mailing schemes and admitted to causing victim losses exceeding \$9.5 million. In pleading guilty, Newman admitted to knowingly assisting clients in obtaining victim lists for deceptive mass-mailing campaigns. Those clients sent fraudulent letters that falsely appeared to be personalized and tricked consumers into paying fees for promised cash prizes and “psychic services.” Another former Macromark senior vice president also previously pleaded guilty in the case. Newman will be sentenced in 2022. CPB prosecutors partnered on the case with the U.S. Attorney’s Office for the District of Connecticut.

United States v. KBM Group, LLC d/b/a/ iBehavior (D. Colo.). In June 2021, KBM Group, LLC entered into a DPA with CPB and the U.S. Attorney’s Office for the District of Colorado to resolve an information charging the company with conspiracy to commit mail fraud. KBM Group employees knowingly facilitated numerous elder fraud schemes over a decade through the sale of consumer information from its “iBehavior” database to the perpetrators of those schemes. The DPA provided for \$33.5 million in victim compensation and an \$8.5 million criminal fine. KBM Group also agreed to implement significant compliance and reporting measures.

United States v. Runner (E.D.N.Y.). Patrice Runner was extradited from Spain on an indictment alleging that he operated a mail-fraud scheme that defrauded over one million victims of over \$180 million. For more than a decade, Runner and his co-conspirators sent letters to millions of U.S. consumers purporting to be from two well-known French psychics who, according to the letters, had visions that the recipients had opportunities to attain great wealth. In reality, the purported senders had no actual role in sending the letters. Runner and his co-conspirators obtained the names of victims by renting and trading mailing lists with other fraud schemes. Runner remains in prison awaiting trial.

United States v. Ingram, et al. (S.D. Cal.). Eight defendants were indicted in August 2021 with a racketeering conspiracy for their alleged roles in a scheme to defraud elderly Americans. Victims received phone calls from individuals claiming to be a family member or friend of the victim. The callers alleged that victims' relatives were in legal trouble and needed money to pay for bail, medical expenses for car accidents, or to prevent additional charges from being filed against them. Members of the racketeering enterprise also impersonated attorneys and employees of security and courier services. Victims paid thousands to tens of thousands of dollars to the scheme. Two defendants pleaded guilty to racketeering conspiracy in March 2022. CPB prosecutors are working on this case with the U.S. Attorney's Office for the Southern District of California.

United States v. Cotter, et al. (S.D. Fla.). In October 2021, CPB attorneys filed a civil action on behalf of the United States seeking to enjoin an individual and five companies from facilitating a technical-support fraud scheme. In an unprecedented collaborative effort, India's Central Bureau of Investigation took actions in parallel with the filing against corporate and individual participants located in Delhi, Noida, Gurgaon, and Jaipur. According to the United States' complaint, the scheme used pop-up messages that falsely appeared to be security alerts from Microsoft or another well-known company. The messages fraudulently claimed that the consumers' computers were infected by a virus. When victims called the listed number, they were connected to India-based call centers and convinced to pay for hundreds of dollars of unnecessary services and software. The court entered a permanent injunction against the defendants.



Fraud Targeting Spanish-Speaking Americans

United States v. Campuzano, et al. (S.D. Fla.). At various times in 2021, seven Peruvian nationals were convicted of conspiracy to commit mail and wire fraud for operating a series of call centers that they ran in Peru from 2011 through 2018. The defendants supervised call centers where callers falsely threatened Spanish-speaking victims in the United States with legal consequences for failing to pay for and accept delivery of products the victims never ordered. Many of the victims were recent immigrants, elderly, or otherwise vulnerable. The callers posed as lawyers, court officials, federal agents, and representatives of a "minor crimes court," and they threatened the victims with imprisonment and immigration consequences to convince them to pay illusory fees. All seven defendants were sentenced to prison terms ranging from 88 months to 110 months.

United States v. Adrianzen (S.D. Fla.). In May 2021, Angel Adrianzen was sentenced to 121 months in prison for conspiring with call-center operators to threaten and defraud Spanish-speaking U.S. consumers. Adrianzen's co-conspirators falsely threatened victims with court proceedings, negative marks on their credit reports, imprisonment, or immigration consequences if they did not pay for purportedly delivered products. Adrianzen received victims' payments despite knowing that the call centers used fraudulent and extortionate tactics. Adrianzen was also convicted of, and sentenced for, two counts of possessing child pornography for images found on his computer and cell phone during the investigation of the fraud scheme.



Telemarketing and Robocall Violations

United States, et al. v. DISH Network, LLC (C.D. Ill.). In December 2020, after years of litigation and a loss at trial, DISH Network, LLC agreed to pay \$210 million for placing millions of illegal robocalls. DISH paid the United States \$126 million for violating the Telemarketing Sales Rule (TSR) and the Federal Trade Commission Act, the largest penalty ever paid to resolve telemarketing violations under the Act, exceeding the total penalties paid to the United States by all prior violators of the TSR. DISH agreed to pay the four states who joined the United States' lawsuit as co-plaintiffs a total of \$84 million. The post-trial order had already imposed robust compliance measures, including restrictions on DISH's future telemarketing activities, submitting telemarketing compliance materials to the Department and the FTC, and providing compliance reports upon request.

United States v. Rhodes (D. Mont.). In September 2021, the Department filed suit to recover a \$9.9 million penalty imposed by the Federal Communications Commission on Scott Rhodes, who allegedly spoofed nearly 5,000 illegal robocalls with falsified caller ID information. The unlawful calls included highly inflammatory messages and targeted communities across the country with xenophobic, racist, and anti-Semitic rhetoric. Litigation is ongoing.



Deceptive Practices and Data-Privacy Violations

United States v. Just In Time Tickets, Inc., et al.; United States v. Concert Specials, Inc., et al.; United States v. Cartisim Corp., et al. (E.D. N.Y.). In the first enforcement actions under the Better Online Ticket Sales Act, CPB and the U.S. Attorney's Office for the Eastern District of New York filed complaints against three companies and their principals for circumventing Ticketmaster's bot-prevention measures to buy thousands of tickets that they then resold, earning millions of dollars in profits. In January 2021, the court issued stipulated orders that imposed significant injunctive relief and required defendants to pay \$3.6 million in civil penalties.

United States v. Vivint Smart Home, Inc. (D. Utah). In May 2021, the court issued a stipulated order imposing a permanent injunction against home security company Vivint and ordering it to pay \$15 million in civil penalties and \$5 million in consumer redress. The complaint alleged that Vivint failed to implement an Identity Theft Prevention Program, allowed its sales representatives to obtain credit reports of unsuspecting consumers without their knowledge or consent, and sold false debt to buyers or debt collectors in violation of the Fair Credit Reporting Act (FCRA) and the FTC's Red Flags Rule. The civil penalties award is the most ever awarded for alleged FCRA violations.

United States v. MyLife.com, Inc., et al. (C.D. Cal.). Represented by CPB attorneys, the United States sued MyLife.com, Inc. and its founder and CEO, alleging that the company sold subscriptions to its consumer background reporting service using deceptive marketing tactics, including falsely implying that individuals had criminal or sexual offense records. The company also allegedly failed to disclose material terms and locked consumers into subscriptions that automatically renewed and were difficult to cancel. In October 2021, the court granted partial summary judgment for the United States, finding that MyLife's deceptive marketing practices violated the FTC Act. The court further determined that injunctive relief was appropriate for those violations and indicated that it would eventually order defendants to pay consumer redress. In a stipulated order entered in December 2021, defendants agreed to settle the case by submitting to robust injunctive relief—including a ban on automatically renewing subscriptions—and a judgment to pay \$21 million in consumer redress.

United States v. OpenX Technologies, Inc. (C.D. Cal.). In December 2021, the court entered a stipulated order requiring online advertising platform OpenX Technologies, Inc. to pay a \$2 million civil penalty and to comply with injunctive measures to ensure its compliance with the Children’s Online Privacy Protection Act and the FTC Act. The complaint resolved by the stipulated order alleged that OpenX’s platform, which connects website and mobile application publishers with advertisers, collected and maintained location data and other personal information from children under 13 without parental notice or consent and facilitated the use of that data for targeted advertising on hundreds of child-directed apps.

United States v. Dinh, et al. (M.D. Fla.). In December 2021, a federal court permanently enjoined three residents of Vietnam from operating a pandemic-related scam that targeted American consumers. The defendants operated more than 300 websites that fraudulently purported to sell products in the United States that became scarce during the pandemic, including hand sanitizer and disinfectant wipes. Thousands of victims paid for items marketed through the website, but received nothing. The defendants also listed fraudulent contact information on the website, which caused unaffiliated individuals and businesses to receive numerous complaints from victims who had been defrauded. CPB attorneys partnered with the U.S. Attorney’s Office for the Middle District of Florida to bring the case.



Servicemembers and Veterans Fraud

United States v. Boling, et al. (W.D. Tex.). In August 2021, the second of five indicted co-conspirators, Fredrick Brown, was sentenced to 151 months in prison after pleading guilty to one count of conspiracy to commit wire fraud and one count of conspiracy to commit money laundering. The transnational conspiracy in which Brown participated targeted more than 3,300 members of the U.S. military community and resulted in at least \$1.5 million in victim losses. The conspiracy used personal identifying information stolen from a military health records database in a complex benefits and bank fraud scheme. Three defendants remain detained overseas. CPB prosecutors are handling the case with the U.S. Attorney’s Office for the Western District of Texas.

United States v. Kohn, et al. (D. S.C.). In December 2021, one of three co-defendants pleaded guilty in a case involving an alleged \$300 million investment fraud and ponzi scheme. According to the indictment, the defendants ran a ponzi scheme that victimized more than 2,600 pension holders, including many U.S. veterans. The pensioners made monthly payments to a co-defendant company called Future Income Payments (FIP) in exchange for a lump sum payment or loan. FIP then solicited investors to purchase “structured cash flows,” which were the pensioners’ monthly pension payments, and promised the investors a rate of return between 6.5% and 8%. FIP diverted new investor funds flowing into the business to fund payments to earlier investors in order to keep the scheme operational. CPB attorneys are working with the U.S. Attorney’s Office for the District of South Carolina on the matter. Trial is expected in 2022.



Money Mule Efforts

Every year, foreign fraudsters steal billions of dollars from victims, but much of that money does not pass directly from the victim to the perpetrator. Instead, it passes through bank accounts of individuals located in the United States who have agreed to receive money from strangers and forward it. These individuals—often referred to as money mules—are sometimes complicit in the fraud. Others, however, may have first encountered the fraud scheme not as a complicit participant, but rather as a victim. Money mules facilitate consumer fraud schemes such as lottery fraud and romance scams, as well as schemes targeting pandemic relief funds and businesses.

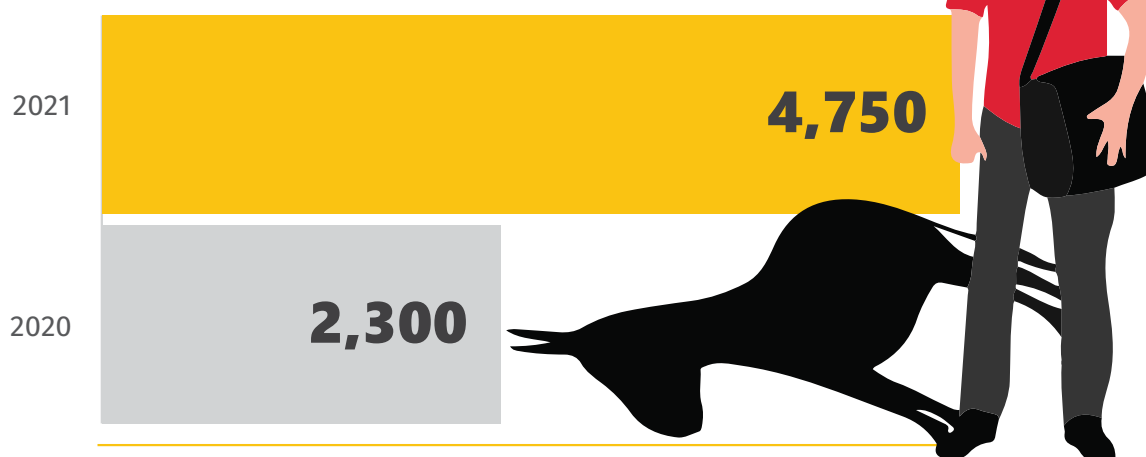
Law enforcement turns to a range of tools to disrupt money mules' unlawful conduct, including criminal prosecution, civil and administrative actions, and warning letters. In 2021, CPB, in partnership with U.S. Attorney's Offices, the FBI, and U.S. Postal Inspection Service, led a ten-week, multi-agency effort to stop money mule activity. The effort—referred to as the Department's Money Mule Initiative—included actions in every state in the country. Agencies took action against approximately 4,750 individuals, including by issuing 4,670 warning letters, 11 civil or administrative actions, and 30 criminal charges. Additionally, a host of federal agencies engaged in public outreach about how fraudsters use and recruit money mules, signs of money mule activity, and steps that should be taken if someone has unknowingly facilitated fraud by moving money.

CPB attorneys and U.S. Attorney's Office partners also brought a number of actions against money mule networks outside of the 2021 Money Mule Initiative. For instance, in September 2021, CPB attorneys secured an indictment against four California-based defendants for their alleged roles in laundering fraud proceeds stored on gift cards. According to the indictment, the defendants obtained more than 5,000 gift cards funded with proceeds from government-imposter and technical-support fraud schemes and then converted those gift cards to cash by purchasing and returning merchandise. CPB collaborates with members of the retail and financial-services industries to identify and prevent such conduct.

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ACTIONS TAKEN

The 2021 Money Mule Initiative involved twice as many actions as the 2020 Money Mule Initiative.



DEFENSIVE LITIGATION

In addition to its affirmative enforcement work, CPB maintains a robust docket of litigation in federal district courts defending actions of the FDA, CPSC, and other consumer-protection agencies. These cases include challenges to agency actions under the U.S. Constitution, the Administrative Procedure Act (APA), and other statutes and regulations. Prevailing in these cases allows our agency partners to conduct their important work for American consumers. Much of the recent efforts of CPB attorneys have focused on defending FDA's authorization of COVID-19 vaccines and its actions related to electronic nicotine delivery systems.

Significant Cases

MediNatura, Inc. v. FDA (D.D.C.). In July 2021, plaintiff voluntarily dismissed its lawsuit against FDA after the D.C. Circuit affirmed the district court's denial of plaintiff's motion for a preliminary injunction. Plaintiff challenged FDA's withdrawal of an enforcement discretion policy for homeopathic drugs and the agency's addition of plaintiff's products to an import alert. The D.C. Circuit agreed with the district court that plaintiff's challenge to FDA's withdrawal of the policy was not likely to succeed on the merits, and the addition of plaintiff's products to an import alert was not final agency action.

Ipsen Biopharms., Inc. v. Becerra (D.D.C.). In September 2021, a federal district court granted summary judgment to FDA in a challenge to the agency's refusal to regulate plaintiff's drug as a "biological product." Plaintiff argued that its drug satisfied FDA's recently adopted definition of a "protein" or, in the alternative, was analogous to a protein, and should therefore be regulated as a biological product. The court held that it lacked subject-matter jurisdiction because the company's alleged injuries were too speculative to establish Article III standing.

Arbor Pharmaceuticals v. Becerra, et al. (N.D. Ga.). In November 2021, a federal district court granted summary judgment to FDA in a challenge to the agency's determination that the original formulation of plaintiff's drug was not withdrawn for reasons of safety or effectiveness. Plaintiff claimed that it withdrew its drug due to safety concerns raised by FDA, which would bar approval of generic versions of the drug, but FDA disagreed, concluding that plaintiff's drug still could be safely marketed. The court held that it lacked subject-matter jurisdiction because the company failed to establish Article III standing. The court further held that, even if plaintiff had established standing, FDA's determination should be upheld because it was reasonable and consistent with the relevant statutory authority.

Children's Health Defense v. FDA (E.D. Tenn.). In November 2021, a federal district court in Tennessee granted FDA's motion to dismiss a challenge to FDA's licensing of Pfizer's "Comirnaty" COVID-19 vaccine and FDA's emergency use authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine. Plaintiffs alleged that FDA's concurrent approval of the Comirnaty vaccine and continuation of the EUA for the Pfizer-BioNTech vaccine was unlawful under the FDCA and the APA. The court found that plaintiffs failed to establish Article III standing and dismissed the case for lack of subject-matter jurisdiction, while simultaneously denying plaintiffs' motion for a preliminary injunction.

SPECIALIZED UNITS

Three specialized units of the Consumer Protection Branch support its litigation work.

The Corporate Compliance and Policy Unit (CCP) helps to craft and enforce corporate resolutions, advises on FDCA matters, and engages with the broad range of policy and training issues implicated by the Branch's work. With respect to corporate resolutions, CCP attorneys assess compliance programs and help craft resolution terms, including evaluating whether to impose an independent monitor. They also have primary responsibility for ensuring that defendants follow the compliance and reporting provisions of resolutions. In addition, to carry out the Branch's responsibility to ensure uniform and balanced application of the FDCA, CCP attorneys consult with U.S. Attorney's Offices on all criminal investigations and prosecutions involving a possible FDCA charge that are not worked jointly by Branch prosecutors.⁷ In handling this work, CCP attorneys collaborate closely with prosecution teams and FDA agency counsel. CCP attorneys also routinely advise on draft regulations and guidance related to consumer interests, serve on Department and interagency policy committees, provide crime-victim assistance, conduct outreach to industry and community groups, and lead the Branch's training efforts.

The Special Matters Unit, established in 2021, handles issues related to privilege and legal ethics that arise in Branch investigations and cases. Unit attorneys assist in the collection and processing of evidence, as well as conduct filter reviews and litigation involving assertions of privilege. They also collaborate frequently with other Department personnel to ensure consistent approaches in developing areas of the law, and they provide regular trainings and guidance for the Branch.

The Administration and Litigation Support Unit handles all of the Branch's resource and staffing needs, coordinating the Branch's dedicated corps of investigators, federal support personnel, and contractors, as well as managing hiring and critical administrative tasks. Unit personnel have been extraordinarily busy during the pandemic, helping to ensure that the Branch maintains the support and services needed to advance its mission.



Society Freed Through Justice, by George Biddle, 1936. Located Inside the Robert F. Kennedy Department of Justice Building.

⁷ See Justice Manual 4-8.200 – Federal Food, Drug, and Cosmetic Act Litigation (requiring notification and consultation with CPB “[u]pon opening any criminal investigation involving a possible violation of the FDCA”).