April 2024

Recent Highlights

Consumer Protection Branch

United States Department of Justice

Introduction

Established in 1971, the Department of Justice's Consumer Protection Branch leads efforts to protect Americans' health, safety, economic security, and identity integrity.

The Branch, which is comprised of more than 100 attorneys (as well as a dedicated team of paralegals, investigators, and contract personnel) works diligently to advance complex investigations into significant violations of consumer protection and fraud laws in a broad range of areas.

In 2023, the Branch pursued criminal and civil actions that helped to ensure the safety of critical food and medication relied upon by consumers across the country. The Branch also investigated and prosecuted domestic and international fraudsters who stole from vulnerable victims, as well as multinational corporations that engaged in unfair and deceptive practices.

In addition to civil and criminal enforcement actions, the Branch defended partner agencies, including the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC), in district court litigation. The Branch shared its expertise in government-wide working groups and engaged with consumers, industry, and law enforcement around the world.

To learn more about the Branch's efforts, visit its website at https://www.justice.gov/civil/consumer-protection-branch.

This publication provides insight into some of the Branch's recent accomplishments, none of which would be possible without assistance from partner agencies and law enforcement. The Branch especially benefits from the knowledge and expertise of the many U.S. Attorneys' Offices that partner with the Branch on challenging matters of national significance.

Contents

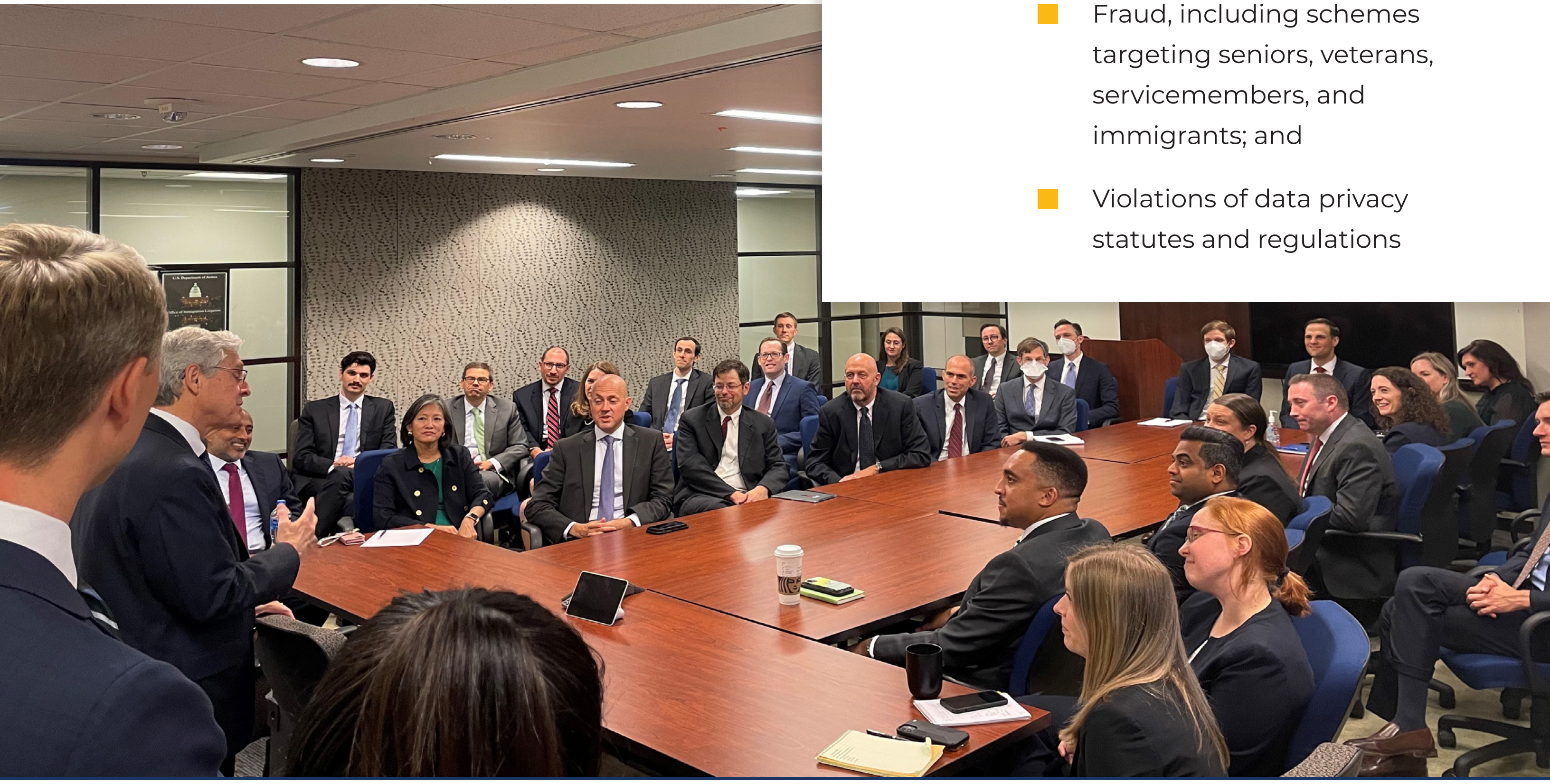
The Consumer Protection Branch

In Brief

Comprised of 200 attorneys, paralegals, investigators, and contractors

Brings criminal and affirmative civil enforcement actions to protect consumers by pursuing misconduct involving:

- Unsafe food and drugs;
- Opioids;
- Fraud, including schemes targeting seniors, veterans, servicemembers, and immigrants; and
- Violations of data privacy statutes and regulations



Defends partner agencies, including the FDA, the FTC, and the Consumer Product Safety Commission (CPSC)

Works closely with a wide range of federal agency and law enforcement partners

The Consumer Protection Branch's

Portfolio and Partners

The Branch is responsible for a wide variety of criminal and civil enforcement matters, including matters implicating statutes administered by the FDA, the FTC, the CPSC, and certain statutes administered by the Department of Transportation's National Highway Transportation Safety Administration (NHTSA). The Branch's efforts are made possible through collaboration with other Department components and federal and state consumer protection and law enforcement agencies, as well as with an embedded team of U.S. Postal Inspectors, supported by analysts and victim service specialists.

The Branch's affirmative enforcement falls into two categories. First, the Branch protects consumers' health and safety by advancing matters involving unlawful conduct related to prescription medications, opioids, counterfeit pills and substances, medical devices, food, dietary supplements, tobacco, and consumer products. Second, the Branch protects consumers' economic security and identity integrity by advancing criminal and civil matters involving consumer fraud and unlawful business practices. The Branch brings actions against perpetrators of fraud schemes impacting seniors, immigrants, veterans, servicemembers, and vulnerable populations. The Branch is also responsible for civil actions against businesses and individuals engaging in deceptive and abusive acts and practices, including conduct impacting consumers' privacy interests.

Separately, the Branch defends against challenges to government programs and policies in consumer-related areas, including actions of the FDA, the FTC, and the CPSC. These cases typically involve constitutional, statutory, and administrative challenges to statutes, agency actions, and executive decisions.

The Branch also plays a crucial role in policymaking initiatives related to consumer protection by engaging with intra-agency and interagency working groups, advancing the development of novel investigative tools and litigation strategies, and advising law enforcement partners across the country. The Branch further helps law-enforcement partners and consumers by offering trainings and engaging in outreach to the public, industry, and other governmental partners.

Civil Division

Leadership

Brian M. Boynton, *Principal Deputy Assistant Attorney General*

Brian joined the Department of Justice on January 20, 2021, as the Principal Deputy Assistant Attorney General in the Civil Division. Prior to rejoining the Department, Brian was a partner at Wilmer Cutler Pickering Hale and Dorr LLP in Washington, D.C. 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. Prior to that service, Brian had been the Vice Chair of the Government and Regulatory Litigation Group at WilmerHale, where he practiced from 2002 through 2014.

Arun G. Rao, *Deputy Assistant Attorney General*

Arun joined the Department of Justice in 2021 as the Deputy Assistant Attorney General for the Branch. He 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.

The Consumer Protection Branch's

Management

Senior Leadership

Amanda N. Liskamm, *Director*

Amanda joined the Branch in 2021 and has served in numerous leadership roles in the Department, including as Acting Deputy Assistant Attorney General in the Criminal Division, Associate Deputy Attorney General and Director of Opioid Enforcement and Prevention Efforts in the Office of the Deputy Attorney General, Chief of Staff at the Drug Enforcement Administration, Deputy Chief of Litigation in the Narcotic and Dangerous Drug Section in the Criminal Division, and as an Assistant U.S. Attorney.

Anthony J. Nardozzi, *Senior Deputy Director, Criminal Chief*

Anthony joined the Branch in 2022, having served in leadership roles and as a trial attorney in the Department's Narcotic and Dangerous Drug Section. Since joining the Branch, he has supervised civil and criminal health and safety matters, including matters arising from the opioid epidemic. In 2024, Anthony was appointed as a Senior Deputy Director and Criminal Chief overseeing all of the Branch's criminal enforcement.

Lisa Hsiao, *Senior Deputy Director, Civil Chief*

Lisa joined the Branch in 2010 from a law firm in Washington, D.C., where she was a partner. She has supervised cases seeking civil monetary penalties and other relief for violations of consumer protection laws, including those regulating advertising, privacy, telemarketing, and other deceptive and unfair practices. In 2024, Lisa was appointed as a Senior Deputy Director and Civil Chief overseeing all of the Branch's civil enforcement.

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 enforcement efforts related to consumer fraud and deceptive acts and practices. 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 after serving as an Assistant Director. He supervises the Branch's work in consumer health and safety.

Assistant Directors

Lory D. Alexander joined the Branch in 2019 as a contractor and moved into the role of Assistant Director in 2023. She oversees the Branch Support Unit.

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

Catherine Dick joined the Branch in 2021 from the U.S. Attorney's Office in Maryland. She oversees the Branch's training and trial strategy. She also supervises criminal health and safety cases. She previously served in the Criminal Division's Fraud Section and Organized Crime and Gang Section.

Zach Dietert joined the Branch in 2020 and litigated a variety of consumer protection cases, including civil enforcement under the FTC Act, the Children's Online Privacy Protection Act (COPPA), the Restore Online Shoppers' Confidence Act (ROSCA), and the Telemarketing Sales Rule (TSR). He supervises civil and criminal health and safety matters, including matters arising from the opioid epidemic.

Rachael Doud joined the Branch in 2021 from the U.S. Attorney's Office for the Southern District of New York. She supervises cases seeking civil monetary penalties and other relief for violations of consumer protection laws, including those regulating advertising, privacy, and telemarketing, and other deceptive and unfair practices. She also supervises the Branch's civil opioid matters.

Timothy Finley joined the Branch in 2010 from a law firm where he was a partner. He supervises consumer fraud matters and assists with the Department's elder fraud efforts and Money Mule Initiative.

Allan Gordus joined the Branch 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 (CPSA).

Ross Goldstein joined the Branch in 2008. He supervises civil and criminal enforcement related to medical products and coordinates CPB's "rapid response" to newly emerging situations. Prior to joining the Branch, he worked in private practice in Washington, D.C.

Adam Lyons joined the Branch in 2020, having worked previously as a litigator of complex matters in the Civil Division's National Courts Section and in private practice. He oversees the Complex Matters Unit and supervises consumer health and safety matters.

Clint Narver joined the Branch 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.

Hilary Perkins joined the Branch in 2019 from a law firm in Washington, D.C. She supervises the Branch's defensive litigation practice.

Patrick Runkle joined the Branch in 2009 through the Attorney General's Honors Program. He supervises consumer health and safety matters, including criminal and civil enforcement actions related to drugs, medical devices, food safety, and the opioid epidemic.

Gabriel Scannapieco joined the Branch in 2016 from a law firm in Chicago. He supervises health and safety cases, as well as cases seeking civil monetary penalties and other relief for violations of consumer protection laws.

Vincent Shuler joined the Branch in 2019, having served as a military lawyer. He supervises consumer fraud matters related to schemes targeting servicemembers, veterans, and their families. He also supervises the paralegal and investigator teams.

J. Matt Williams joined the Branch in 2019 from the U.S. Attorney's Office for the District of Columbia. He supervises consumer fraud matters with a focus on criminal prosecutions of transnational fraud schemes impacting older adults, immigrants, and vulnerable populations.

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

Consumer Health and Safety

The Branch leads Department of Justice efforts to protect consumers from unlawful products. Charged with enforcing the Federal Food, Drug, and Cosmetic Act (FDCA), the Branch 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 and medical devices, food, dietary supplements, biologics, and tobacco products, including e-cigarettes and vaping products. Matters advanced by the Branch often involve allegations of clinical trial fraud, pathogen outbreaks, unapproved marketing claims, and use of illicit ingredients. Branch attorneys frequently seek injunctions to protect consumers from ongoing harm and pursue criminal sanctions to punish and deter misconduct.

The Branch also leads efforts, undertaken in partnership with U.S. Attorney's Offices around the country as well as law enforcement agencies, to combat the nation's opioid epidemic. This work includes civil and criminal actions to hold corporate actors accountable for contributing to the epidemic, including prescription opioid manufacturers, distributors, national chain pharmacies, and their executives. In close coordination with DEA, the Branch also brings local-impact cases against individual prescribers, pharmacists, and other entities and people engaged in the diversion of prescription opioids. In addition, given the sharp rise in overdose deaths from counterfeit pills laced with fentanyl, the 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. The Branch is using every tool at its disposal to hold accountable bad actors contributing to the opioid crisis.

The Branch also leads efforts to enforce statutes administered by the CPSC and works with multiple components within the Department of Transportation's NHTSA on issues related to automobiles. Branch attorneys work closely with both CPSC and NHTSA to advance enforcement actions related to dangerous products and failures to report defects or hazards.

The CPSA requires manufacturers, distributors, and retailers of consumer products to report "immediately" to the CPSC information that reasonably supports the conclusion that a product contains a defect that could create a substantial product hazard or creates an unreasonable risk of serious injury or death. The Branch works closely with the CPSC to hold accountable manufacturers that put profits over the safety of consumers. Prompt reporting of potentially dangerous defects in or problems with products is vital to impactful and immediate consumer protection.

Branch Secured Historic, First-Ever Corporate Criminal Convictions Under the Consumer Product Safety Act

United States v. Gree Electric Appliances, Inc. of Zhuhai, et al. (C.D. Cal.)
United States v. Chu and Loh (C.D. Cal.)

A Chinese appliance manufacturer and two subsidiaries agreed to resolve criminal charges for failing to notify the CPSC that millions of dehumidifiers they sold to U.S. consumers were defective and posed fire hazards. The resolutions were the first corporate criminal enforcement actions ever brought under the CPSA.

In January 2023, Gree USA, Inc., the U.S. subsidiary, pleaded guilty to a felony violation of the CPSA and was later sentenced to pay a $500,000 criminal fine. Gree Electric Appliances, Inc. of Zhuhai (Gree Zhuhai), headquartered in Zhuhai, China, and Hong King Gree Electric Appliances Sales Co., Ltd. (Gree Hong Kong) previously entered into a deferred prosecution agreement (DPA) in connection with the same felony charge. Under the terms of the DPA, Gree Zhuhai and Gree Hong Kong agreed to a $91 million penalty and restitution for any uncompensated victims of fires caused by the companies' defective dehumidifiers. Gree Zhuhai and Gree Hong Kong also agreed to implement enhanced compliance and reporting measures.

In November 2023, a jury convicted two corporate executives of Gree USA of conspiracy and failure to report information related to the defective dehumidifiers. According to the indictment, Chu was part owner and chief administrative officer of Gree USA and another corporation in California that distributed and sold to retailers for consumer purchase dehumidifiers that were made by Gree Zhuhai. Loh was part owner and chief executive officer of the same two corporations.

The indictment alleged that as early as September 2012, Chu, Loh, and their companies received multiple reports that their Chinese dehumidifiers were defective, dangerous, and could catch fire. They also allegedly knew that they were required to report this product safety information to the CPSC immediately. Despite their knowledge of consumer complaints of dehumidifier fires and test results showing defects in the dehumidifiers, the indictment alleged that Chu and Loh failed to disclose their dehumidifiers' defects and hazards for months while they continued to sell their products to retailers for resale to consumers.

Branch Filed Complaint Against Manufacturer for Delay in Reporting Dangerous Awning Covers

United States v. SunSetter Products LP (D. Ma.)

In April 2023, the Branch filed a complaint against SunSetter Products alleging that the company delayed reporting a hazardous defect involving protective vinyl covers for its outdoor, retractable awnings. According to the complaint, SunSetter knew that when bungee tie-downs securing its protective awning covers were removed, the retractable awnings could spring open unexpectedly with enough force to strike consumers and cause them to fall and suffer death or serious injury. Between 2012 and 2017, SunSetter received fourteen reports of its motorized awnings springing open, which resulted in several injuries and one death. Despite notice of these incidents, the company did not report the problems with its awning covers to the CPSC until October 2017. The complaint seeks injunctive relief.

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

With more than 84,000 Americans dying annually from prescription drug and synthetic opioid overdoses, the Department of Justice is committed to using every available tool to prevent overdose deaths and hold accountable those responsible for the opioid crisis. The Branch is on the front lines of the Department's fight, pursuing criminal and civil actions against entities and individuals across the prescription opioid supply chain. Additionally, the Branch is pursuing both criminal and civil actions targeting companies involved in the manufacture and distribution of chemicals and equipment used to create counterfeit pills laced with fentanyl.

The Branch is aided in its work by its expertise in enforcing the Controlled Substances Act (CSA) and the FDCA, as well as by its experience with complicated and multi-district litigation. The Branch's strong relationships with U.S. Attorneys' Offices, the Criminal Division, the DEA, and the FDA also position it well to coordinate actions and advise Department leadership on policies and initiatives. Through dedicated effort, the Consumer Protection Branch aims to help stem the opioid crisis by ensuring that opioids are not diverted and abused.

Federal Court Ordered Puerto Rico Pharmaceutical Distributor to Pay $12 Million in Connection with Alleged Failure to Report Suspicious Orders of Pharmaceutical Drugs and Other Controlled Substance Violations

United States v. Droguería Betances, LLC (D.P.R.)

In October 2023, the Branch filed a complaint and consent decree to curb the distribution of suspicious orders of opioids. In its complaint, the United States alleged that Betances failed to notify the DEA of orders for opioids and other controlled substances distributed to pharmacy customers that were suspicious given unusual patterns such as size and frequency, and that Betances also failed to routinely report opioid distributions to the DEA. The complaint described that Betances failed to report at least 655 suspicious orders for fentanyl and at least 113 suspicious orders for oxycodone. The complaint further alleged that Betances failed to report its distribution transactions to the DEA, including all of Betances' distributions of Schedule II opioids from May 2017 to July 2018.

A federal court entered the consent decree in November 2023. The order requires the distributor to pay $12 million over five years in annual payments, with $10.2 million in the form of civil penalties and $1.8 million in civil forfeiture. The consent decree also requires the distributor to make extensive improvements to its compliance programs, including the implementation of improved procedures and systems for detecting and reporting suspicious orders to the DEA and for conducting due diligence reviews of pharmacy customers.

Branch Secured Permanent Injunction Against Pharmacist for Controlled Substances Act Violations

United States v. Zarzamora Healthcare LLC, et al. (W.D. Tex.)

In October 2023, a federal court ordered a San Antonio pharmacy and its pharmacist-owner to pay a $275,000 civil penalty and imposed restrictions related to the dispensing of opioids and other controlled substances. The complaint, brought under the CSA, alleged that Jitendra Chaudhary unlawfully dispensed controlled substance prescriptions at Rite-Away Pharmacy & Medical Supplies #2, which was operated by a company Chaudhary partially owned, Zarzamora Healthcare. The complaint alleged that the defendants ignored numerous “red flags” of abuse or diversion when filling opioid prescriptions and that one patient even died from toxic effects of fentanyl within nine days of Rite-Away filling the patient’s prescription for that drug.

Tobacco

The Branch has long partnered with the FDA and other public health agencies to enforce laws relating to the sale and marketing of tobacco products.

Court Ordered Distributor to Pay $7 Million in Connection with Misleading Marketing Claims

United States v. Connors, et al. (M.D. Fla.)

In July 2023, a federal court ordered the distributor of “Smoke Away” products to pay more than $7 million in consumer redress and a $500,000 civil penalty to resolve allegations the distributor violated the Opioid Addiction Recovery Fraud Prevention Act of 2018 and the FTC Act in connection with the marketing and sale of Smoke Away products as a quick, effective, and easy way to quit smoking. According to the complaint, Michael Connors and several of his companies made misleading and unsubstantiated claims on websites and social media platforms that Smoke Away tablets, pellets, and homeopathic sprays eliminate nicotine cravings and withdrawal symptoms and enable consumers to quit smoking quickly, easily, and permanently, which were not supported by competent and reliable scientific evidence. The complaint also alleged that although the FTC entered into a settlement in 2005 with Connors and one of his then-existing companies concerning the advertising of Smoke Away products, Connors nevertheless continued to violate the FTC Act by making unsubstantiated health claims about Smoke Away products. In addition to the monetary judgment and civil penalty, the 2023 stipulated order includes injunctive relief that prohibits, among other things, the defendants from advertising and selling smoking cessation products, and imposes two decades of recordkeeping and reporting obligations.

Branch Filed Complaint Seeking Injunction Against Individuals Selling Unauthorized Vaping Products

United States v. Fitzgerald and Allen (M.D. Fla.)

In December 2023, the Branch filed a complaint against two individuals doing business as Vape Junkie Ejuice alleging that they were manufacturing, selling, and distributing vaping products without FDA authorization. According to the complaint, the FDA previously warned the defendants about their violative conduct and that they sold products without FDA authorization. The FDA further warned the defendants that continued violations could lead to enforcement action, including requests for injunctive relief. The Branch’s complaint sought a permanent injunction prohibiting the defendants from continuing to sell illegal vaping products, and in March 2024, a federal court entered two consent decrees of permanent injunction resolving the matter.

Branch Resolved Complaints Against Three Companies Selling Unauthorized Vaping Products

United States v. Lucky’s Convenience & Tobacco, LLC, et al. (D. Kan.)
United States v. Morin Enterprises, Inc., et al. (D. Minn.)
United States v. Super Vape’z LLC, et al. (W.D. Wash.)

In 2022, the Branch filed complaints against several companies and related individuals to stop the illegal manufacture and sale of unauthorized vaping products. The complaints alleged that the defendants manufactured and sold vaping products without FDA authorization and continued to do so despite receiving warning letters from the FDA that they were violating the law. In January and February 2023, federal courts entered consent decrees of permanent injunction against Kansas-based

Lucky's Convenience & Tobacco and two of its owners; Minnesota-based Morin Enterprises and its owner; and Washington-based Super Vape'z and its owners. The injunctions prohibit the defendants from continuing to sell illegal vaping products.

Food Safety

The Branch plays a key role in protecting the safety of America's food supply chain. Working closely with the FDA and the Centers for Disease Control (CDC), the Branch pursues civil and criminal actions against companies and individuals for failing to maintain sanitary facilities, distributing tainted food products, and making significant misrepresentations to customers or the public.

Branch Secured Record Criminal Penalty Following Conviction of Company and Employee Related to Insanitary Plant Conditions Linked to Salmonellosis Outbreak

United States v. Kerry Inc. (C.D. Ill.)
United States v. Chermala (C.D. Ill.)

In March 2023, Kerry was sentenced after pleading guilty to a misdemeanor count of distributing adulterated cereal marketed as Kellogg's Honey Smacks. Kerry manufactured Kellogg's Honey Smacks cereal under insanitary conditions at a facility in Illinois, and its distribution of the cereal led to a salmonellosis outbreak in 2018. In pleading guilty, the company agreed to pay a criminal fine and forfeiture amount totaling $19.228 million—which was the largest criminal penalty following a criminal conviction for food safety violations. Kerry's former Director of Quality Assurance, Ravi Chermala, who oversaw the sanitation programs at various Kerry facilities, previously pleaded guilty to three misdemeanor counts of causing violations of the FDCA, and in June 2023 Chermala was sentenced to one year of probation.

Drugs, Devices, and Dietary Supplements

The Branch investigates and litigates a wide range of violations of the FDCA. The Branch's investigations include drug and medical device manufacturers selling adulterated and misbranded products, as well as fraudsters selling fake cures or counterfeit pharmaceuticals. The Branch also brings enforcement actions against manufacturers and importers of dietary supplements and ingredients that create a safety risk to consumers. The Branch uses both criminal and civil tools to tackle conduct by a range of industry players, including physicians, drug compounders, pharmaceutical companies, and manufacturers and sellers of dietary supplements.

Pharmaceutical Manufacturer Enjoined from Making and Selling Adulterated Drugs

United States v. Pharmasol Corp., et al. (D. Ma.)

In December 2023, a federal court enjoined a Massachusetts company and its president from manufacturing and distributing adulterated drugs in violation of the FDCA. According to the complaint, Pharmasol manufactured and processed prescription and over-the-counter drugs, including Lexette, which is used to treat itching, redness, and swelling of skin, and Dexamethasone, which is used to relieve arthritis inflammation. The Branch alleged that the company failed to notify its customers about defects in its finished products, failed to establish a procedures for responding to complaints despite receiving 533 customer complaints relating to defects in its drug products within a 12-month period, and failed to adequately clean and maintain its equipment. The consent decree of permanent injunction requires the defendants to stop manufacturing, processing, labeling, holding, or distributing adulterated drugs and to recall all adulterated prescription drugs the company manufactured or distributed on or after February 10, 2022.

Former Employee of Medical Device Manufacturer Pleaded Guilty and Was Sentenced for Forging FDA Documents that Led to Illegal Sale of Medical Devices

United States v. Stoll (E.D. Pa.)

In July 2023, Peter Stoll, III pleaded guilty for his role in the distribution of medical devices without FDA clearance. Stoll pleaded guilty to one felony count of violating the FDCA by causing the introduction of misbranded and adulterated medical devices into interstate commerce. Stoll was a regulatory affairs specialist at a medical device manufacturer in Pennsylvania and was responsible for shepherding two of the company's devices through the FDA's 510(k) clearance process. In pleading guilty, Stoll admitted that he never submitted any 510(k) documents to the FDA regarding the ELAN-4 Air Drill, a high-speed surgical drill used for bone cutting, sawing, and drilling; and the JS Series SterilContainer S2, a reusable sterilization container for medical instruments. Instead, Stoll created two false letters that purported to show that the FDA had granted clearance to sell the devices. As a result, the company illegally sold tens of thousands of dollars' worth of medical devices throughout the United States. Stoll was later sentenced to one year in prison and was ordered to pay $122,836 in restitution.

Former CEO Pleaded Guilty for Causing the Distribution of Adulterated and Misbranded Medical Devices Intended to Treat Migraine Headaches

United States v. Wright (D. Utah)

In February 2023, Mark Wright pleaded guilty for his role in the distribution of adulterated and misbranded medical devices. Wright pleaded guilty to misdemeanor charges of causing the introduction of misbranded and adulterated devices into interstate commerce. Wright was the CEO of a medical device manufacturer in Utah that sold a SphenoCath device intended to treat migraine headaches by administering nerve blocks to the sphenopalatine ganglion (SPG), a collection of nerves located in the midface of the skull. In pleading guilty, Wright admitted that the company did not seek FDA clearance or approval to distribute the device for this intended use and did not conduct any investigational studies about the device's safety and effectiveness. Instead, Wright and the company continued to market the SphenoCath with the intention that it be used to treat migraine headaches by administering SPG nerve blocks, and Wright provided healthcare providers with marketing materials and unsolicited directions for this unapproved use. Wright was later sentenced to 24 months of probation and ordered to pay a $5,000 fine.

Clinical Trial Fraud

Clinical trials of investigational drugs are necessary for the government and pharmaceutical companies to determine whether a drug for which a company may seek FDA approval is safe and effective. The FDA relies on the truthfulness and accuracy of clinical trial data to make regulatory decisions about the approval of new drugs, with the goal of ensuring that all FDA-approved drugs are safe and effective for their approved uses. Unscrupulous clinical research personnel who fabricate or falsify clinical trial data can adversely and materially impact the FDA's decisions concerning drug approval and thereby put patients at risk. The Branch has charged and secured convictions of numerous individuals, including licensed medical professionals and clinical support staff, in connection with clinical trial fraud schemes.

Florida Doctor Sentenced for False Representations to the FDA in Clinical Trials

United States v. Valdes, et al. (S.D. Fla.)

A defendant associated with Tellus Clinical Research, Inc., a medical research firm based in Miami, was sentenced in August 2023 after a jury convicted him of making a false statement in connection with clinical trials intended to evaluate irritable bowel syndrome. According to evidence presented at trial, during a 2016 FDA inspection of Tellus Clinical Research, Martin Valdes, the clinic's principal investigator, falsely represented that he had personally performed physical exams of certain research subjects. Dr. Valdes was sentenced to time served and one year of supervised release.

Medical Clinic Owner and Pharmacy Technician Received Multi-Year Sentences for Falsifying Clinical Trials Data

United States v. Montalvo Villa, et al. (S.D. Fla.)

In December 2023, the owner of a medical clinic in Miami and a pharmacy technician were sentenced for their roles in a clinical trial fraud scheme that included the falsification and fabrication of clinical trial data related to an investigational drug intended to treat Clostridium difficile-associated diarrhea. Miguel Angel Montalvo Villa and Ivette Maria Portela Martinez were convicted by a jury of one count of conspiracy to commit wire fraud and one count of wire fraud. Montalvo Villa was a co-owner, president, and CEO of AMB Research Center Inc., a medical clinic located in Miami that conducted clinical trials of new drugs for pharmaceutical companies and sponsors. Portela Martinez was an employee who served as recruiter, site manager, data entry specialist, and pharmacist. Montalvo Villa also was convicted of making a false statement to a regulatory investigator with the FDA. Montalvo Villa was sentenced to 71 months in prison and Portela Martinez to 46 months in prison.

Activities of the Justice Department, by Louis Bouche, 1941.
Located inside the Robert F. Kennedy Department of Justice Building.

Consumer Fraud and Deceptive Acts and Practices

The Branch is a leader in investigating and prosecuting consumer fraud, with substantial experience in tackling multi-district and transnational fraud schemes. The Branch also handles civil litigation under statutes and rules that protect consumers from unfair and deceptive conduct and are administered by the FTC.

The Branch devotes considerable resources to stopping scams that target or disproportionately affect older adults, immigrants, veterans, and vulnerable populations. Prominent in this work is the Branch's coordination of the Department's Transnational Elder Fraud Strike Force, which combats foreign-based scams with resources from CPB, U.S. Attorneys' Offices, the U.S. Postal Inspection Service, the Federal Bureau of Investigation (FBI), and other law enforcement agencies. As part of that effort, Branch personnel are building and maintaining strong partnerships with foreign law enforcement, including by co-chairing the Global Anti-Fraud Enforcement Network.

In addition to prosecuting fraudsters, Branch prosecutors have held to account corporations and executives that have knowingly facilitated fraud schemes. Through the Department's Servicemembers and Veterans Initiative, the Branch also prosecutes fraud schemes that target the men and women who defend America, bringing actions against product-marketing, debt-relief, and identity-theft scams.

The Branch's work enforcing statutes and rules administered by the FTC involves complex civil and criminal litigation. The Branch litigates actions referred by the FTC seeking civil penalties for violations of the FTC Act, the COPPA, the ROSCA, the TSR, the Fair Credit Reporting Act, 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. The Branch also advances criminal actions based on investigative referrals from the FTC.

Consumer Fraud

The Branch has long sought to combat fraud schemes that target specific populations, including older adults, Spanish-speaking consumers, and servicemembers—especially large-scale fraud schemes that target hundreds or even thousands of potential victims. In pursuing the perpetrators of these schemes, the Branch is not deterred by international borders and works collaboratively with foreign law enforcement to disrupt the infrastructure of these schemes and to bring to justice perpetrators, no matter where they may reside. The Branch also seeks to ensure that those who knowingly facilitate schemes by providing, for instance, the names of potential victims or technology and payment infrastructure, are held responsible for their misconduct. In addition, the Branch works to protect consumers from odometer fraud, which the NHTSA estimates results in consumer losses in the United States of more than $1 billion annually.

Elder Fraud

Branch Obtained Conviction of Canadian Man in Decades-Long Multimillion-Dollar Psychic Mass-Mailing Fraud

United States v. Runner (E.D.N.Y.)

In June 2023, a jury convicted a Canadian man, Patrice Runner, of perpetrating a decades-long fraud scheme that stole more than $175 million from victims, many of whom were elderly and vulnerable. According to evidence presented at trial, Runner operated a mass-mailing fraud scheme from 1994 through November 2014 by sending letters to millions of U.S. consumers that were purportedly individualized, personal communications from “psychics.” Runner’s fraudulent letters promised recipients an opportunity to achieve great wealth and happiness with the psychic’s assistance in exchange for payments. Runner was convicted of conspiracy to commit mail and wire fraud, eight counts of mail fraud, four counts of wire fraud, and conspiracy to commit money laundering. He was found not guilty on four counts of mail fraud. Runner faces a maximum penalty of 20 years in prison on each count.

Lottery Fraud, Mass-Mailing, and Prize Notifications Schemes

Fraudsters located overseas call U.S. consumers purporting to have good news: that the consumer has won a lottery and just needs to pay the taxes and fees to claim it. But victims that pay do not receive the promised check or prize. Instead, they receive additional calls from fraudsters claiming that even more money is needed before the prize can be claimed. Some of these schemes originate in Jamaica. As part of its international fraud efforts, the Branch—working closely with the U.S. Postal Inspection Service—has dedicated substantial time and resources to disrupting these schemes by identifying and acting against U.S.-based actors, as well as by prosecuting and bringing to justice those based in Jamaica who orchestrate the schemes and target U.S. consumers.

United States v. Oakley (M.D. Pa.)

In November 2023, a Jamaican national, Damone Oakley, was sentenced to 192 months in prison for his role in a fraudulent sweepstakes scheme targeting elderly victims in the United States. Oakley was extradited to the United States in 2022 and pleaded guilty in July 2023 to two counts of mail fraud and two counts of wire fraud. Victims throughout the United States received mailings, text messages, or phone calls in which they were falsely told that they had won millions of dollars and luxury vehicles in a sweepstakes but first needed to pay taxes and fees to claim their winnings. Oakley used a variety of names, including “Officer Alex Logan” and “Officer Stan Valentine.” Victims sent money directly to Oakley and to intermediaries who then transmitted the victim’s money to Oakley. In addition to sending cash or wire transfers, victims were directed to purchase electronics, jewelry, and clothing and to have the purchased items shipped to Oakley through mail forwarding services in Florida.

United States v. Stewart (W.D.N.C.)

After extradition to the United States, Antony Stewart, a Jamaican national, pleaded guilty in August 2023 to one count of conspiracy to commit mail and wire fraud in connection with a fraudulent Jamaica-based lottery scheme targeting elderly victims in the United States. Stewart admitted that he called elderly Americans and falsely told the victims they won money and other prizes in a sweepstakes or lottery but first needed to pay fees and taxes to claim their winnings. Victims were instructed on how to send their money, including through money transmitter services, wire transfers, and the mail, and were instructed to whom the money should be sent. Stewart contacted victims repeatedly for as long as they could be persuaded to send additional money.

United States v. Castro, et al. (D. Nev.)

Three men were sentenced for perpetrating a prize-notification scheme that stole more than $10 million from elderly and vulnerable victims. Mario Castro was sentenced to 240 months in prison, Miguel Castro was sentenced to 235 months in prison, and Jose Luis Mendez was sentenced to 168 months in prison. In April 2023, a jury found the three men guilty of conspiracy to commit mail fraud and multiple individual counts of mail fraud. According to evidence presented at trial, the defendants and other co-conspirators printed and mailed millions of fraudulent prize notices that led their victims to believe that they could claim a large cash prize if they paid a fee of about $20 to $25. Victims who paid fees did not receive anything of value but instead were bombarded with more fraudulent prize notices from the defendants.

United States v. Del Rio (D. Nev.)

In November 2023, Edgar Del Rio was sentenced to 51 months in prison for his role in a scheme involving the mailing of fraudulent prize notices to thousands of victims. Del Rio previously pleaded guilty to conspiracy to commit mail fraud. From 2010 to 2018, Del Rio and his co-conspirators stole over $10 million from elderly and vulnerable victims by sending fraudulent prize notices stating the victims won a large cash prize that could be claimed by paying a fee. Three other co-conspirators also pleaded guilty: Andrea Burrow, who was sentenced to 36 months in prison; Patti Kern, who was sentenced to 24 months in prison; and Sean O’Connor, who was sentenced to three years of probation. Three other participants—Mario Castro, Miguel Castro, and Jose Luis Mendez—were convicted following a jury trial in 2023 and received sentences of 240 months, 235 months, and 168 months, respectively, in prison.

United States v. Novis and Denkberg (E.D.N.Y.)

In August 2023, Sean Novis and Gary Denkberg were sentenced to 90 and 66 months, respectively, in prison for their roles in a mass-mailing fraud scheme that tricked thousands of victims, many of whom were elderly, into providing the defendants with money by falsely promising prizes. A jury previously convicted the defendants of charges related to this scheme. Evidence presented at trial showed that, from January 2003 to September 2016, Novis and Denkberg mailed millions of prize notices that falsely represented that the victims had been specifically chosen to receive a large cash prize and would receive the prize if they paid a fee. Victims who paid the requested fee, however, did not receive the promised cash prize. Although the notices appeared to be personalized correspondence, they were merely mass-produced, boilerplate documents that were bulk mailed to recipients whose names and addresses were on mailing lists. Novis also was ordered to forfeit $60 million and Denkberg to forfeit $19 million.

Officials from the Branch, the FBI, and India’s CBI met in New Delhi. From left to right: Dawn Rizzo (Assistant Legal Attaché, FBI); Richard Goldberg (Deputy Director, Department of Justice, Consumer Protection Branch); Jason Feldman (Trial Attorney, Department of Justice, Consumer Protection Branch); Kevin Gallagher (Supervisory Special Agent, FBI, Washington Field Office); Suhel Daud (Legal Attaché, FBI); CBI official; Arun Rao (Deputy Assistant Attorney General, Department of Justice, Civil Division); Rachel Yurkovich (Management and Program Analyst, FBI); Lovjit Curran (Assistant Legal Attaché, FBI); Ronald Miller (Special Agent, FBI, Washington Field Office).

Deputy Assistant Attorney General Rao (front row, center, right), EOCO Deputy Director, Intelligence and Monitoring, Aba Opoku (front row, center, left), Assistant Legal Attaché Justin Nwadiashi (front row, right), and other officials from the Justice Department, FBI and EOCO meet at EOCO headquarters in Accra, Ghana.

Defendants Sentenced in International Inheritance Fraud Scheme

United States v. Neboh, et al. (S.D. Fla.)

In November 2023, five defendants were sentenced for operating a transnational inheritance fraud scheme targeting elderly Americans. Ezennia Peter Neboh was sentenced to 128 months in prison, Iheanyichukwu Jonathan Abraham was sentenced to 90 months in prison, Kennedy Ikponmwosa and Jerry Chucks Ozor were sentenced to 87 months in prison, and Emmanuel Samuel was sentenced to 82 months in prison. The defendants were also required to pay nearly $7 million in restitution.

In 2022, the five co-defendants were charged by sealed indictment and were extradited from the United Kingdom and Spain. The indictment alleged that the co-conspirators sent personalized letters to elderly Americans falsely stating that the victims were entitled to receive a multimillion-dollar inheritance and ultimately induced the victims to pay alleged advance fees and taxes to claim their purported inheritance. A sixth charged defendant, Amos Prince Okey Ezemma, was arrested in 2023 and is scheduled for trial in 2024.

Branch Met with International Partners in India, Ghana, and Togo to Discuss Efforts to Fight Against Fraud

In January 2023, colleagues from the Branch and the FBI met with Central Bureau of Investigation (CBI) colleagues in New Delhi, India, to discuss deepening and expanding efforts to combat cyber-enabled financial crimes and transnational call center fraud. The parties highlighted the continued strengthening of cooperation in combatting these types of crimes and reaffirmed their mutual commitment to continued cooperation in addressing dynamic and evolving technology-based crimes. Recent successful efforts include those to secure the testimony of U.S. victims of call center fraud for use in enforcement proceedings against the alleged perpetrators in India, and the seizure of evidence and arrests of individuals in India allegedly involved in cyber-enabled financial crimes and global telemarketing frauds that were identified, in part, through information provided with the assistance of U.S. law enforcement.

In September 2023, colleagues from the Branch and the FBI also met with various key law enforcement partners in Ghana and Togo to advance the Branch's West Africa Consumer Fraud Initiative to combat fraud schemes originating in western Africa or facilitated by criminal enterprises operating in the region, with a focus on both perpetrators and money launderers. In their meetings in Ghana, the parties discussed strengthening cooperation and collaboration on parallel investigations and providing training assistance. In addition, Branch and FBI officials shared valuable insights and lessons learned related to the investigation and prosecution of cases involving fraud and public corruption. In Togo, the parties discussed the initiation and continuation of joint efforts to combat cyber-enabled fraud originating in or affecting Togo. They focused on aligning priorities and exploring strategies for improving lines of communication and information-sharing mechanisms.

Odometer Fraud

Used Motor Vehicle Dealer Sentenced for Conspiracy to Commit Securities Fraud in Connection with Odometer Tampering Scheme

United States v. Elphic (N.D. Ga.)

A Georgia man, Andrew Elphic, pleaded guilty in July 2023 for his role in falsifying vehicle titles as part of a scheme to roll back odometers on used motor vehicles. According to court documents, between 2011 and 2013, Elphic engaged in a scheme to roll back odometers on at least 305 used motor vehicles and sell them to unsuspecting customers. In October 2023, Elphic was sentenced to 12 months and one day in prison and ordered to pay nearly $628,000 in restitution.

Servicemember Fraud

South Carolina Woman Sentenced for Fraud Conspiracy Targeting Retirees and Military Pension Holders

United States v. Kern (D.S.C.)

In May 2023, Candy Kern pleaded guilty to conspiracy for her role in a nationwide structured cash flow scheme that exploited military veterans in desperate financial straits. From approximately 2012 through 2021, Kern used her law firm to facilitate a fraudulent scheme involving illegal assignment of veterans' benefits. As part of the scheme, numerous individuals and small corporate entities, referred to as Structured Cash Flow (SCF) entities, offered veterans an up-front lump sum payment in exchange for the assignment of the veteran's monthly pension and/or disability payments for a period of time, even though such assignment was illegal under federal law. The SCF entities would then solicit elderly investors to invest in contracts by providing the up-front lump sums under the false pretense that the flow of repayments by veterans would translate into an investment return. Kern's law firm, managed, controlled, and maintained the bank accounts used to route payments from veterans to investors. Kern even used her law firm to file suits against veterans who defaulted. Kern was sentenced in August 2023 to a five-year term of probation and ordered to pay approximately $1.4 million in restitution.

Deceptive Acts and Practices

Unscrupulous business practices harm consumers in many ways, including increasing costs, jeopardizing privacy, and preventing consumers' from making informed decisions about goods and services. The Branch, working in partnership with the FTC, brings cases against such practices under the FTC Act and regulations promulgated by the FTC. These actions generally seek civil monetary penalties and strong injunctive relief aimed at preventing future violations of the law.

Branch Takes Series of Actions to Protect Consumers' Information

Consumers are increasingly concerned by the many ways that companies collect, use, and profit from their public and private data. In 2023, the Branch filed multiple data privacy-related actions to bring companies into compliance with the law, including several actions related to COPPA and its implementing regulation (the COPPA Rule), which regulate how and when companies may collect information from children under 13 years old. These Branch actions obtained substantial monetary penalties and compliance terms to ensure that companies treat consumer data with the care the law requires.

Branch Secured Injunctive Relief and $25 Million Civil Penalty for Alleged Violations of Children's Privacy Law Relating to Alexa

United States v. Amazon.com, Inc., et al. (W.D. Wash.)

In July 2023, Amazon.com, Inc., and its wholly-owned subsidiary Amazon.com Services LLC (collectively, Amazon), agreed to a permanent injunction and a $25 million civil penalty to resolve alleged violations of the COPPA, the COPPA Rule, and the FTC Act relating to Amazon's voice assistant service Alexa. The complaint alleged in part that Amazon retained children's voice recordings indefinitely by default, in violation of the COPPA's requirement that these recordings be retained only as long as reasonably necessary to fulfill the purposes for which they were collected.

Microsoft Agreed to Pay $20 Million Civil Penalty and to Injunctive Relief for Alleged Violations of Children's Privacy Laws Relating to Xbox Live

United States v. Microsoft Corp. (W.D. Wash.)

In June 2023, Microsoft agreed to resolve alleged violations of the COPPA, the COPPA Rule, and the FTC Act relating to its practices for collecting and retaining personal information from children who use Microsoft's Xbox Live service. In a stipulated order, Microsoft agreed to pay $20 million in civil penalties and to injunctive relief. The complaint alleged in part that Microsoft knew that certain users were children but nonetheless continued to collect personal information, such as telephone numbers, before notifying parents of Microsoft's information collection practices and before obtaining parental consent.

Permanent Injunction Imposed on Online Education Platform Company Edmodo, LLC for Alleged Violations of Children's Privacy Law

United States v. Edmodo, LLC (N.D. Cal.)

In June 2023, Edmodo agreed to a permanent injunction and a $6 million civil penalty as part of a settlement to resolve alleged violations of the COPPA, the COPPA Rule, and the FTC Act relating to Edmodo's online educational platform. The Edmodo educational platform, sold to schools throughout the United States, enabled teachers to interface with students, including children under 13 years old, to host virtual class spaces, conduct discussions, share materials, make assignments, and provide quizzes and grades. The complaint alleged that Edmodo collected the personal information of children under 13, and retained it indefinitely, without providing notice to the children's parents or obtaining parental authorization to collect such information. The complaint also alleged that Edmodo used that information to enable third parties to display targeted advertising to students.

Digital Healthcare Platform Ordered to Pay Civil Penalties and Take Corrective Action for Unauthorized Disclosure of Personal Health Information

United States v. GoodRx Holdings, Inc. (N.D. Cal.)

In February 2023, GoodRx Holdings, doing business as GoodRx, GoodRx Gold, GoodRx Care, and Hey Doctor (collectively, GoodRx), agreed to a permanent injunction and a $1.5 million civil penalty to resolve allegations that the company violated the FTC Act and the FTC's Health Breach Notification Rule relating to GoodRx's digital healthcare platform. The complaint alleged that GoodRx disclosed millions of users' personal health information—including details about medications and sensitive health conditions—to third parties without the users' authorization, consent, or knowledge. The complaint also alleged that GoodRx did so despite its repeated assurances that it would protect users' privacy though public policies and advertising.

Branch Secured Injunctive Relief and Civil Penalties for Alleged Funeral Rule and FTC Act Violations

United States v. Funeral & Cremation Group of North America, LLC, et al. (S.D. Fla.)

In April 2023, a federal court ordered Funeral & Cremation Group of North America, Legacy Cremation Services, LLC, and Anthony Damiano to pay $275,000 in civil penalties in connection with their funeral services practices. The court also ordered the defendants to comply with the FTC Act and the FTC's Trade Regulation Rule Concerning Funeral Industry Practices. In its complaint, the Branch alleged that the defendants served as brokers between consumers and third-party funeral and cremation providers that offer funeral services, and that the defendants had misled consumers about the locations where funeral services would be provided and about the ultimate costs of such services. The complaint also alleged that when consumers objected to the pricing practices, defendants refused to provide consumers with the remains of their loved ones until they paid.

Illegal Telemarketing

Illegal telemarketing frustrates Americans and, at times, includes deceptive pitches or outright attempts to defraud. The Branch uses both civil and criminal tools to aggressively pursue those who place and carry illegal telephone traffic.

Branch Participated in Nationwide Initiative to Curtail Illegal Telemarketing Operations

In 2023, the Branch joined other Department components, the FTC, the Federal Communications Commission, and other law enforcement partners in a crackdown on telemarketing operations responsible for billions of illegal calls to American consumers. This initiative, "Operation Stop Scam Calls," targeted telemarketers, including those who use telephone calls to commit fraud, as well as those who facilitate illegal telephone calls. As part of the initiative, the Branch brought nine civil actions in partnership with the FTC, which collectively alleged conduct involving billions of robocalls. Four of these cases involved lawsuits against Voice over Internet Protocol (VoIP) providers that transmitted illegal phone calls. Some of these calls were scams arising from foreign call centers, such as calls by fraudsters pretending to be government agencies or impersonating e-commerce companies. Defendants, as alleged in the government's

Deputy Assistant Attorney General Arun G. Rao announces results of nationwide initiative to curtail telemarketing operations, together with Samuel Levine, Director of the FTC's Bureau of Consumer Protection, and Loyaan Egal, Chief of the FCC's Enforcement Bureau, in July 2023 complaints, continued to transmit illegal calls even after being warned that those calls were scam pitches. These cases also included a resolution with multinational payment processing company Nexway, arising from a lawsuit that alleged that the company processed credit card payments for India-based Tech Live Connect and other foreign clients that committed telemarketing fraud via tech support scams.

Owner of VoIP Company Responsible for Facilitating Fraudulent Robocalls Sentenced for Money Laundering

United States v. Kahen (E.D.N.Y.)

After pleading guilty to money laundering, Jon Kahen was sentenced in December 2023 in connection with his role as the owner and operator of a VoIP company that facilitated and profited from the introduction of fraudulent robocall traffic into the United States. Global Voicecom Inc. (GVI) provided telecommunications services including calling platforms and generation of telephone numbers. GVI's services were used by an India-based VoIP provider to route calls—including calls made by fraudsters impersonating government agents—to the United States. Kahen knew that the Indian-based VoIP provider was using GVI to engage in unlawful activities and that funds from the Indian-based client were proceeds of unlawful activities. Kahen was sentenced to 60 days in prison, ordered to forfeit $176,000, and ordered to pay $216,700 in restitution.

Three Individuals Convicted for Laundering Money Stolen from Scam Victims Through Gift Cards

United States v. Bai, et al. (C.D. Cal.)

In September 2023, a jury convicted three individuals for their roles in laundering proceeds of large-scale consumer fraud schemes through gift card transactions. Blade Bai, Bowen Hu, and Tairan Shi were convicted of conspiracy to launder proceeds of wire fraud. Bai also was convicted of a separate money laundering conspiracy charge. As part of the scheme, the fraudsters engaged in government-imposter scams and tech-support scams whereby telephone scammers instructed victims to purchase gift cards from the retail store Target and provide the scammers with the account numbers and access codes listed on the gift cards. The defendants then distributed the numbers assigned to the gift cards to "runners," who used the funds on the cards at Target stores to purchase consumer electronics, other gift cards, and other items. Through the purchases and other transactions at multiple Target stores, the defendants and their co-conspirators sought to conceal the fact that the gift cards had been originally funded with fraudulent proceeds. Bai, Hu, and Shi were later sentenced to 15 years, 10 years, and 8 years in prison, respectively.

Branch Secured Injunctive Relief and Civil Penalties Against Telecommunications Service Provider for Assisting and Facilitating Illegal Robocalls

United States v. XCast Labs, Inc. (C.D. Cal.)

In December 2023, a court ordered a provider of VoIP services to pay $10 million in civil penalties to resolve allegations that the company violated the TSR by assisting and facilitating illegal telemarketing campaigns. The complaint alleged that XCast Labs provided VoIP services that transmitted billions of illegal robocalls to U.S. consumers, including scam calls that fraudulently claimed to be from government agencies. These robocalls delivered prerecorded marketing messages, and many of them were delivered to numbers listed on the National Do Not Call Registry or were transmitted with "spoofed" caller ID information. Many also failed to truthfully identify the seller of the services being marketed or contained other false or misleading statements to induce purchases. The complaint further alleged that XCast Labs continued to allow its services to transmit these calls even after being alerted to their illegality. In addition to a civil penalty, the stipulated order bans XCast from assisting and facilitating high-risk customers and from providing VoIP services without having ongoing automated procedures in place to block certain telephone calls.

Transportation

The Branch has recently expanded its efforts to protect consumers from unlawful and unsafe products and unfair and deceptive practices in transportation. Branch attorneys and partner U.S. Attorney's Offices are working closely with the Department of Transportation (DOT), including its Office of the Inspector General, its Office of Aviation Consumer Protection, the NHTSA, the Federal Railroad Administration, and the Federal Motor Carrier Safety Administration. The Branch uses its civil and criminal enforcement tools to hold corporations and executives in all areas of transportation accountable and to enforce transportation laws protecting consumers. The Branch's expanding work in this area has affected all modes of transportation, including the airlines, the railroads, and cars and trucks.

Southwest Airlines Agreed to Pay Record $140 Million Civil Penalty for Violations of Consumer Protection Laws During and After 2022 Christmas Holiday Operational Failures

Southwest Airlines Co. (Dept. of Transportation)

During the 2022 holiday season, Southwest Airlines stranded over 2 million of its passengers due to multiple operational failures that resulted in the cancellation of 16,900 flights and stranded over two million passengers. Southwest's treatment of its passengers during these operational failures resulted in numerous violations of federal law, including failures to provide prompt flight status notifications, prompt and proper refunds, and adequate customer service. The Branch assisted DOT and DOT's Office of Aviation Consumer Protection in their investigation and subsequent negotiations with Southwest to remedy Southwest's illegal conduct through a consent order. Southwest ultimately agreed to a consent order that directed Southwest to cease and desist from future similar illegal conduct against consumers and to pay a $140 million civil penalty for its past illegal conduct. This penalty is 30 times larger than any previous DOT penalty for consumer protection violations.

COVID-19 Fraud

Since before the novel coronavirus (COVID-19) was declared a pandemic, the Branch has aimed to prevent fraudsters and unscrupulous companies and individuals from jeopardizing public health by hawking unproven treatments and cures or using the virus as a ploy to defraud consumers, among other misconduct. Over the last several years, these efforts have spanned the Branch's entire portfolio, including matters related to health and safety, consumer fraud and deceptive acts and practices, and defensive cases, which are discussed on page 25.

Branch Defeated Motion to Dismiss Action Against Seller of Deceptively Marketed Herbal Tea Advertised as COVID-19 Treatment

United States v. B4B Earth Tea LLC, et al. (E.D.N.Y.)

The Branch brought a civil enforcement action against two companies, B4B Earth Tea and B4B Corp., and their owner for advertising that an herbal tea product could prevent or treat COVID-19 without competent or reliable scientific evidence to support those claims. According to the complaint, the defendants violated the FDCA, which prohibits selling an unapproved new drug, and the COVID-19 Consumer Protection Act, which prohibits deceptive acts or practices associated with the treatment, cure, prevention, mitigation, or diagnosis of COVID-19. The complaint seeks injunctive relief and civil monetary penalties. In December 2023, the Branch defeated a motion to dismiss the action.

Branch Negotiated Settlement in COVID-19 False Advertising Case

United States v. Nepute, et al. (E.D.Mo.)

In August 2023, after a court awarded partial summary judgment to the government, Eric Nepute agreed to a stipulated order resolving false advertising allegations that Nepute and his company, Quickwork LLC, violated the FTC Act and the COVID-19 Consumer Protection Act by making misleading and unsubstantiated claims that Vitamin D and zinc supplements cured or prevented COVID-19 and were more effective than the available COVID-19 vaccines. The stipulated order requires Nepute to pay an $80,000 civil penalty. The injunction prohibits Nepute from advertising that his supplements can prevent, cure, mitigate, or treat COVID-19 without competent and reliable scientific evidence to support such claims and bans him from misrepresenting the results of COVID-19 research in advertising. He further agreed to pay damages if he engages in prohibited conduct. Quickwork previously agreed to injunctive relief and a civil monetary penalty.

Defensive Practice

The Branch defends certain consumer protection and public health agencies, including the FDA, the FTC, and the CPSC, in district courts throughout the country. This work includes cases challenging, under the U.S. Constitution and the Administrative Procedure Act (APA), agency actions related to food, drugs, medical devices, tobacco, and other consumer products. These cases typically involve complex issues regarding the FDCA, the Tobacco Control Act, the Public Health Service Act, the FTC Act, and the CPSA. The Branch's defense of these matters has allowed our agency partners to conduct their important work in safeguarding the health, safety, economic security, and identity integrity of American consumers.

Branch Secured the Dismissal of Challenge to CPSC Compliance Letters

Jake's Fireworks Inc. v. CPSC, et al. (D. Md.)

Jake's Fireworks received compliance letters from CPSC's Office of Compliance and Field Operations (OCFO) from 2015 to 2019, warning that samples of fireworks imported by Jake's failed to comply with regulations issued under the Federal Hazardous Substances Act. In response, Jake's filed suit challenging OCFO's letters under the APA, and the suit was dismissed in 2020 for lack of final agency action. After further communications with OCFO, Jake's filed a second lawsuit in August 2021, renewing its challenge to the OCFO compliance letters under the APA. In April 2023, the court dismissed Jake's second lawsuit for lack of final agency action, ruling the compliance letters did not represent the consummation of CPSC's decision-making process.

Branch Defeated Preliminary Injunction Motion in Suit Challenging the FDA's Approval of Generic Drug

Vanda Pharmaceuticals Inc. v. FDA, et al. (D.D.C.)

Vanda Pharmaceuticals filed a complaint under the APA asking the Court to vacate FDA's approval of Teva Pharmaceuticals USA, Inc.'s Abbreviated New Drug Application for generic tasimelteon, which is a generic version of Vanda's drug Hetlioz that is used to treat Non-24-Hour Sleep-Wake Disorder. Vanda's label includes Braille and Teva's label does not, and Vanda argued that this difference between the labels violates the requirement that the brand-name and generic labels be the same. Vanda filed a motion for a preliminary injunction, which the Branch opposed. In March 2023, after briefing and oral argument, the court denied Vanda's motion, finding that Vanda had failed to meet its burden to show irreparable harm or that the balance of equities and the public interest favored preliminary relief.

Branch Won Summary Judgment in Challenge to the FDA's Classification of a Product as a Drug Rather Than as a Biological Product

Ipsen Biopharmaceuticals, Inc. v. Becerra, et al. (D.D.C.)

Plaintiff Ipsen Biopharmaceuticals filed a lawsuit challenging the FDA's determination that Ipsen's product is properly classified as a drug rather than as a biological product. Ipsen argued that the FDA erred in finding that the company's product does not qualify as a "protein," and thus, a biological product, under the relevant FDA regulation. In May 2023, the court granted the government's motion for summary judgment, holding that the FDA's decision was reasonable and that it was not contrary to the relevant statute and regulations.

Branch Defended Against Challenges to Government's Tobacco Efforts

Pastel Cartel LLC v. FDA, et al. (W.D. Tex.)

In August 2023, Pastel Cartel filed suit challenging the FDA's refusal to accept its Premarket Tobacco Product Applications for electronic nicotine delivery systems (ENDS) products, including disposable e-cigarettes and e-liquids used in e-cigarettes. Pastel Cartel amended the complaint asserting claims under the APA and the Due Process Clause of the Fifth Amendment, and sought injunctive relief to stay the FDA's "Refuse to Accept" letters pending judicial review. In December 2023, following a hearing on the preliminary injunction, the Court entered an order denying Pastel Cartel's preliminary injunction motion without prejudice.

Magellan Technology, Inc. v. FDA (2d Cir.)

In June 2023, the U.S. Court of Appeals for the Second Circuit issued a published opinion upholding an FDA order denying marketing authorization for Magellan Technology's flavored e-cigarette products. Magellan sought authorization to market e-cigarette products in various flavors, including Blue Razz, Mango, and Pretzel Graham. In denying approval, the FDA concluded that Magellan's evidence was insufficient to show an added benefit to adult smokers relative to tobacco-flavored products and fell short of the robust and reliable evidence needed to demonstrate that any benefit of the products to adult smokers outweighed the risk to youth. Following briefing and oral argument, the Second Circuit rejected arguments that the FDA had changed the relevant evidentiary standard without giving manufacturers fair notice or otherwise acted arbitrarily or capriciously or exceeded its statutory authority in denying Magellan's application.

The Great Hall of the Department of Justice

Emerging Technology

The Branch is leading new efforts to investigate and prosecute crimes involving the use of generative artificial intelligence (AI). Branch prosecutors are leveraging existing relationships with law-enforcement partners and seeking to apply the full range of existing authorities, criminal or civil, to AI-enabled scams. These efforts complement our existing initiatives including elder fraud, romance scams, payment processors, and robocalls. In addition, the Branch is applying its experience in prosecuting criminal facilitators to entities that intentionally provide artificial intelligence capabilities for criminal purposes.

The Branch, through Deputy Assistant Attorney General Rao, also participates in the Deputy Attorney General's Emerging Technology Board, supporting coordination of governance of artificial intelligence and emerging technology issues across the Department.

Alistair Reader is the Branch's Senior Counsel for Emerging Technologies. He develops and leads cases involving advanced technologies, including artificial intelligence, digital advertising, deepfakes, and social media. He also serves as the Branch liaison for emerging technology issues in the Department and with partner agencies, and conducts outreach on emerging technology issues that impact consumers. Alistair joined the Branch in 2016 from the Office of the Massachusetts Attorney General.

Policy & Compliance

The Branch regularly engages with the broad range of policy issues implicated by the Branch's work. These efforts include opining on draft agency regulations and guidance, participating in various working groups, and providing technical assistance on proposed legislation. In addition, because the Branch's work often involves corporations, the Branch has dedicated resources to evaluate corporate compliance programs, develop and enforce post-resolution compliance measures, and ensure that such resolutions are consistent with Department policy.

Shannon Pedersen is the Branch's Senior Counsel of Policy & Compliance. In this role, Shannon facilitates the Branch's engagement on policy matters and develops and leads the Branch's corporate compliance program, including the application of policies related to voluntary self-disclosure and monitor selection. Shannon joined the Branch in 2010 through the Attorney General's Honors Program.

Specialized Units and Resources

Specialized units and resources support the Branch's litigation work.

The Complex Matters Unit 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 and conduct filter reviews and litigation involving assertions of privilege. The Unit also carries out the Branch's responsibility to ensure uniform and balanced application of the FDCA by consulting with U.S. Attorneys' Offices on all criminal investigations and prosecutions involving a possible FDCA charge.

The Branch Support Unit handles all the Branch's resource and staffing needs, coordinating the Branch's dedicated corps of investigators, federal administrative personnel, and contractors, as well as managing hiring and critical administrative tasks. The Branch relies on a dedicated team of contract staff and trained investigators responsible for providing investigative and case support. The team includes attorneys, document analysts, and data specialists who support the Branch's efforts to proactively identify misconduct in a range of its practice areas, including scams impacting older adults and opioids matters.

Voluntary Self-Disclosure and Monitor Selection Policies

As part of the Department's efforts to enhance its corporate crime enforcement efforts, the Branch maintained its Voluntary Self-Disclosure Policy and its Monitor Selection Policy. These policies are published on the Branch's website, https://www.justice.gov/civil/consumer-protection-branch.

Voluntary Self-Disclosure Policy

The Branch's Voluntary Self-Disclosure Policy sets forth the criteria that the Branch uses to determine an appropriate resolution for a company that self-discloses potential violations of federal criminal law within the Branch's purview. Specifically, the policy applies to disclosures involving the manufacture, distribution, sale, or marketing of products regulated by, or conduct under the jurisdiction of, the FDA, the CPSC, the FTC, or the NHTSA, as well as potential misconduct involving failures to report to, or misrepresentations to, those agencies.

Absent aggravating factors, if a company timely and voluntarily self-discloses such matters to the Branch, fully cooperates, and timely and appropriately remediates the conduct, the Branch will not seek a corporate guilty plea for the disclosed conduct. In addition, the Branch will not require the imposition of an independent compliance monitor for a cooperating company that voluntarily self-discloses the relevant conduct if, at the time of resolution, the company also demonstrates that it has implemented and tested an effective compliance program. Additional benefits may be available for disclosures made in relation to a merger or acquisition.

Written disclosures should be made by emailing consumer.disclosure@usdoj.gov. Since the policy was released, the Branch has received multiple disclosures.

Monitor Selection Policy

The Branch's Monitor Selection Procedure sets forth the process used to select an independent compliance monitor in criminal corporate resolutions that require the use of a monitor. For such resolutions, the company nominates monitor candidates taking into consideration, among other things, conflict-of-interest concerns. The Branch interviews the candidates and assesses their qualifications, credentials, and suitability for the monitorship, and recommends the selection of a candidate to the Branch's Standing Committee of the Selection of Monitors, which includes senior Branch management and the Civil Division's Ethics Official. All independent compliance monitors used in the Branch's criminal corporate resolutions require approval by the Standing Committee, the Assistant Attorney General for the Civil Division, the Office of the Associate Attorney General, and the Office of the Deputy Attorney General.