

April 2023



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 composed 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 2022, 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 action, the Branch also defended decisions made by partner agencies, including the FDA and FTC, in district court litigation. Branch personnel lent their expertise to Department and 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 the assistance of its partner agencies and law enforcement organizations. The Branch also benefits greatly from the knowledge and expertise of the many U.S. Attorney's Offices that work collaboratively with the Branch on challenging matters of national significance.

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¹ Some of the criminal and civil cases included in this report are unresolved criminal charges or civil allegations and have not been proven in a court of law. Criminal defendants are presumed innocent until proven guilty beyond a reasonable doubt.

The Consumer Protection Branch **In Brief**



Composed of 200 attorneys, paralegals, investigators, and contractors



Brings criminal and affirmative civil enforcement actions to protect consumers, including by pursuing wrongdoing involving:

- Unsafe food and drugs
- Opioids
- Fraud, including schemes targeting older adults, veterans, and immigrants and
- Violations of data privacy statutes and regulations



Defends actions by our partner agencies



Works closely with a range of federal and law enforcement partners

The Consumer Protection Branch's

Portfolio and Partners

The Branch's affirmative enforcement efforts fall into two categories.

First, the Branch protects consumers' health and safety by advancing matters involving, for example, unlawful conduct related to drugs, including prescription medications, opioids, and counterfeit pills; counterfeit substances; medical devices; food; dietary supplements; tobacco; and consumer products.

Second, the Branch protects consumers' economic security and identity integrity by advancing matters targeting consumer fraud and unscrupulous businesses practices. The Branch brings actions against the perpetrators of fraud schemes impacting older individuals, immigrants, veterans, and vulnerable populations. It also litigates civil cases against business and individuals involved in deceptive and abusive acts and practices, including conduct impacting consumers' privacy interests.

The Branch's affirmative enforcement efforts are possible due to its close relationships with a host of federal agencies, including the Food and Drug Administration (FDA), Federal Trade Commission (FTC), Drug Enforcement Administration (DEA), Consumer Product Safety Commission (CPSC), and National Highway Transportation Safety Administration (NHTSA). The Branch also has an embedded team of U.S. Postal Inspectors, supported by analysts and victim service specialists, and works with a wide range of federal law enforcement including Federal Bureau of Investigation, Drug Enforcement Administration, Homeland Security Investigations, Defense Criminal Investigation Service, U.S. Department of Transportation Office of Inspector General and Office of Odometer Fraud Investigation, U.S. Department of Health and Human Services Office of Inspector General, FDIC Office of Inspector General, among others, including state and local law enforcement.

The Branch defends decisions of partner agencies like the FDA, FTC, and Consumer Product Safety Commission in federal district courts. These cases typically involve constitutional, statutory, and administrative challenges to statutes, agency actions, and executive decisions.

The Branch also plays a crucial role in devising and implementing Department policies and initiatives. This work includes leading and participating in Department and interagency working groups, advancing the use of novel investigative tools and litigation strategies, and advising prosecutors and agents 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 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.

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 as Principal Deputy Director. Amanda 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 an Assistant U.S. Attorney.

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 deceptive acts and practices work. 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.

Consumer Health and Safety Assistant Directors

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 and the Consumer Product Safety Act.

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.

Matt Lash joined the Branch 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.

Anthony J. Nardoizzi joined the Branch in 2022, having served in leadership roles and as a trial attorney in the Department's Narcotic and Dangerous Drug Section. He supervises civil and criminal health and safety matters, including matters arising from the opioid epidemic.

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.

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.

Consumer Fraud and Deceptive Acts and Practices Assistant Director

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.

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, telemarketing, and other deceptive and unfair practices.

Lisa Hsiao joined the Branch in 2010 from a law firm in Washington, D.C., where she was a partner. 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.

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.

Defensive Litigation Assistant Director

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

Specialized Units Assistant Directors

Jacqueline Blaes-Freed joined the Branch in 2015 through the Attorney General's Honors Program. She oversees the Branch's Corporate Compliance and Policy Unit, supervises consumer fraud matters, and assists with the Department's elder fraud efforts and Money Mule Initiative.

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 Unit. She also supervises criminal health and safety cases. She previously served in the Criminal Division's Fraud Section and Organized Crime and Gang Section.

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 Special Matters Unit and supervises consumer health and safety matters.

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



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.



| Opioids

As the Department continues to advance its efforts to confront the opioid crisis and hold accountable those who contributed to it, the Branch is pursuing both criminal and civil actions against entities and individuals across the prescription opioid supply chain. The Branch is leading investigations and cases against multibillion dollar companies, as well as bringing cases against local pharmacies and doctors. The Branch also is seeking to combat the surge of deadly counterfeit pills laced with fentanyl. Its counterfeit pill initiatives are designed to disrupt the sale of certain chemical precursors and equipment, as well as the pills themselves, over e-commerce and social media platforms.

Branch and U.S. Attorney Office Partners File Lawsuit Against AmerisourceBergen Corp. and Subsidiaries

United States v. AmerisourceBergen Corp., et al. (E.D. Pa.)

In December 2022, the Branch and its partners, including the U.S. Attorney's Offices for the District of New Jersey, Eastern District of Pennsylvania, Eastern District of New York, and District of Colorado, filed a civil lawsuit against AmerisourceBergen Corporation and two of its subsidiaries, AmerisourceBergen Drug Corporation and Integrated Commercialization Solutions, LLC (together "AmerisourceBergen"), collectively one of the country's largest wholesale pharmaceutical distributors. The complaint alleged AmerisourceBergen prioritized profits over the well-being of Americans and violated federal law in connection with the distribution of controlled substances to pharmacies and other customers across the country, contributing to the prescription opioid epidemic.

The complaint alleged that over the course of nearly a decade, from 2014 through the present, AmerisourceBergen violated the Controlled Substances Act by failing to report to the DEA hundreds of thousands of suspicious orders of controlled substances as required by law. The complaint alleges that AmerisourceBergen's internal systems to monitor and identify suspicious orders were deeply inadequate, both in design and implementation, and that AmerisourceBergen was aware of significant "red flags" suggesting the existence of diversion of prescription drugs to illicit markets. The complaint seeks civil penalties and injunctive relief.

Branch Secures Court Order Closing Clinic and Requiring Physician and Clinic Owners to Pay Penalty for Alleged Unlawful Opioid Distribution

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

In July 2022, a federal court ordered a pain management clinic to close and directed the clinic's owners and its former physician to collectively pay \$600,000 in civil penalties pursuant to agreed resolutions in a case alleging violations of the Controlled Substances Act. The Branch pursued the case in partnership with the U.S. Attorney's Office for the Middle District of Florida.

The government alleged that Dr. Tobias Bacaner wrote prescriptions for opioids without a legitimate medical purpose and outside the usual course of professional practice while employed at Paragon Community Healthcare, a pain clinic in New Port Richey, Florida. The complaint alleged that Paragon's owners, Theodore Ferguson II and Timothy Ferguson, managed the clinic's operations and profited from the unlawful prescribing while ignoring obvious signs of drug abuse and diversion. The complaint further alleged that Dr. Bacaner and the Fergusons used their jointly owned pharmacy, Cobalt Pharmacy, to unlawfully fill prescriptions issued at Paragon without scrutiny.

The order against Bacaner prohibits him from prescribing, administering, dispensing, or distributing controlled substances, among other restrictions, and requires him to pay \$500,000 in civil penalties. The order also requires Paragon to permanently close; places restrictions on the Fergusons' ability to own or work at entities that administer, dispense, or distribute controlled substances; and requires the Fergusons and Paragon to jointly pay \$100,000 in civil penalties. The defendants also agreed to permanently dissolve Cobalt Pharmacy, which closed shortly before the government filed suit.

Branch Files Action Seeking Permanent Injunction Against Pharmacist for Controlled Substances Act Violations

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

In January 2022, the Branch filed a civil complaint seeking to permanently enjoin a San Antonio-area pharmacy and its owner and pharmacist-in-charge from unlawfully dispensing opioids and other controlled substances. The Branch is pursuing the case in partnership with the U.S. Attorney's Office for the Western District of Texas. The complaint, brought under the Controlled Substances Act, alleges that Jitendra Chaudhary unlawfully filled controlled substance prescriptions at Rite-Away Pharmacy, which was operated by a company Chaudhary partially owned, Zarzamora Healthcare LLC. The complaint alleges that Chaudhary and Rite-Away ignored numerous "red flags," or obvious signs of abuse or diversion, when filling opioid prescriptions. The complaint further alleges that one patient died from toxic effects of fentanyl nine days after Rite-Away filled her prescription for that drug.



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



The Branch has long partnered with the FDA and public health agencies to enforce laws relating to the sale and marketing of tobacco products. This year, the Branch's tobacco-related achievements included resolving the landmark lawsuit that proved tobacco companies defrauded consumers about the danger of smoking, as well as bringing lawsuits against companies and individuals illegally manufacturing and selling a new generation of nicotine delivery systems—vaping or e-cigarette products. Additionally, as discussed on page 33, the Branch is defending the FDA's decisions related to e-cigarette products.

Court Issues Order Requiring Cigarette Companies to Post Corrective Statements, Resolving Historic RICO Tobacco Litigation

United States v. Philip Morris USA Inc., et al. (D.D.C.)

In December 2022, a federal court entered an order imposing the last of several corrective remedies sought by the Department of Justice in connection with a 1999 landmark lawsuit against 11 cigarette companies. That lawsuit alleged that beginning in the 1950s, the companies had misled the American public and concealed information about the harmful effects of smoking. In 2006, a federal court determined that the cigarette companies had defrauded consumers about the health dangers associated with cigarette smoking.

To rectify those misstatements, the remaining defendants—Altria, Philip Morris USA Inc., R.J. Reynolds Tobacco Company, and four cigarette brands owned by ITG Brands LLC—are required to work with approximately 200,000 retail locations that sell their products to display eye-catching, truthful statements related to the following: the adverse health effects of smoking; the addictiveness of smoking and nicotine; the lack of health benefits from cigarettes advertised as light or low tar; cigarette companies' manipulation of cigarette design and composition to ensure optimum nicotine delivery; and the adverse health effects of exposure to secondhand smoke. The corrective statements will be posted beginning in July 2023 and will be in English and, in geographic areas with significant Spanish-speaking populations, also Spanish.

A FEDERAL COURT HAS ORDERED R.J. REYNOLDS TOBACCO & PHILIP MORRIS USA TO STATE:



**Smoking kills, on average,
1,200 Americans. Every day.**

These corrective statements are part of a broader order aimed at preventing the cigarette companies from continuing to engage in fraud and deception. Starting in 2017, the corrective statements also have appeared as newspaper advertisements, in television spots, on cigarette packages, and on the companies' websites and cigarette-brand social media pages.

Branch Files Complaints Against Six Companies Selling Unapproved Vaping Products

Companies manufacturing or importing e-cigarette or vaping products, also called electronic nicotine delivery systems (ENDS), must receive approval from the FDA. In determining whether to approve a product, the agency considers whether the manufacturer or importer has demonstrated that the marketing of a new tobacco product would be appropriate for the protection of public health, including considering the risk and benefits to the population as a whole.

In October 2022, the Branch filed complaints against six companies and related individuals alleging the defendants were manufacturing and selling e-cigarettes and vaping products without FDA approval. These actions are the first seeking to enjoin manufacturers of ENDS products for violations of the premarket review requirements of the FDCA. The six companies, based in Kansas, Minnesota, Arizona, West Virginia, Washington, and Georgia, sold e-liquids, or liquids that contain nicotine and colorings, flavorings, or other ingredients. The FDA inspected and issued warning letters to each defendant company warning the companies that they were violating the law before the Department acted. Within four months after filing the actions, five of the lawsuits were resolved with the defendants agreeing to stop manufacturing and selling the unapproved products. The Branch pursued the actions along with the U.S. Attorney's Offices for the District of Kansas, District of Minnesota, District of Arizona, Southern District of West Virginia, Western District of Washington, and Southern District of West Virginia.



Tobacco Litigation Team receives Civil Division Award.

From left to right, Michael Baer, Principal Deputy Assistant Attorney General Brian M. Boynton, Danial Crane-Hirsch, Meredith Healy, Adam Lyons, Marilyn Neal, James Nelson, Hilary Perkins, Steve Tosini, Leo Wise, Deputy Assistant Attorney General Arun Rao, Deputy Assistant Attorney General Michael Granston. Not pictured Lisa Hsiao and Zachary Dietert.



The Branch is a key component of the infrastructure protecting the safety of the country's food supply chain. Working closely with the FDA and CDC, the Branch pursues civil and criminal actions against companies and individuals who fail to maintain sanitary facilities, distribute tainted food products, or make significant misrepresentations to customers or the public.

Branch Secures a Permanent Injunction Against Abbott Laboratories to Ensure Safety of Its Infant Formula

United States v. Abbott Laboratories, et al. (W.D. Mich.)

In May 2022, the Branch and the U.S. Attorney's Office for the Western District of Michigan filed a complaint and consent decree that helped to mitigate the shortage of infant formula while also protecting public health. In its complaint, the United States alleged that Abbott and several of its executives manufactured powdered infant formula under conditions and using practices that failed to comply with regulations designed to ensure the quality and safety of infant formula, including protection against the risk of contamination from bacteria such as *Cronobacter sakazakii*. The *Cronobacter sakazakii* bacteria can cause deadly sepsis or meningitis in infants. The complaint further alleged that FDA testing of environmental samples taken in February 2022 detected *Cronobacter sakazakii* in the defendants' manufacturing facility.

The consent decree with Abbott Laboratories, which followed an inspection by the FDA, set forth requirements for Abbott to resume manufacturing formula at its facility in Michigan. The consent decree required Abbott to, among other things, retain outside expert assistance to bring its plant into compliance with federal law, develop plans to reduce and control bacterial contamination, and periodically evaluate compliance with the FDCA, regulations, and the consent decree.

Branch Prosecutes Company and Individual for Conduct Related to a Salmonella Outbreak

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

In June 2018, the FDA and CDC linked an ongoing salmonellosis outbreak to Kellogg's Honey Smacks breakfast cereal produced at a Kerry Inc. facility in Gridley, Illinois. The FDA and CDC eventually identified more than 130 cases of salmonellosis related to the cereal, which Kellogg's voluntarily recalled. In October 2022, Ravi Kumar Chermala, Kerry's Director of Quality Assurance until September 2018, pleaded guilty to charges related to his role in Kerry's distribution of cereal linked to the salmonellosis outbreak. In December 2022, the Branch filed an information charging Kerry with one misdemeanor count of introducing adulterated food into interstate commerce. Kerry pleaded guilty to the information on February 3, 2023.

Chermala oversaw the sanitation programs at various Kerry manufacturing plants, including the Gridley facility that manufactured Honey Smacks for Kellogg's. In pleading guilty, Chermala admitted that between June 2016 and June 2018, he directed subordinates to not report certain information to Kellogg's about conditions at the Gridley facility. In addition, Chermala admitted that he directed subordinates at the Gridley facility to alter the plant's program for monitoring for the presence of pathogens in the plant, thereby limiting the facility's ability to accurately detect insanitary conditions. The cases were brought with assistance from the United States Attorney's Office for the Central District of Illinois.

Company and Its Former President Charged with Selling Tainted Fruit Juice

United States v. Bliesner and Valley Processing, Inc. (E.D. Wash.)

In September 2022, a federal grand jury charged Mary Ann Bliesner and her company Valley Processing, Inc. with manufacturing and distributing tainted fruit juice and deceiving customers about the contaminated products. The indictment alleges that the defendants' juice products were made under insanitary conditions and contained potentially harmful levels of contaminants, including arsenic. The defendants also allegedly sold juice products after storing them for years outside, exposed to the elements. The indictment further alleges that Bliesner and Valley Processing failed to register two facilities used to store juice products and lied to inspectors about the existence of those facilities, thereby hindering the FDA's ability to conduct safety inspections. Some of the defendants' product was sold to customers that supplied free or reduced-cost school lunches. The case was brought in partnership with the United States Attorney's Office for the Eastern District of Washington.



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



Drugs, Devices, and Dietary Supplements

The Branch investigates and litigates a wide range of violations of the Food, Drug, and Cosmetic Act. These investigations include legitimate drug and medical device manufacturers selling adulterated and misbranded products, as well as fraudsters selling fake cures or counterfeit pharmaceuticals. The Branch also brings actions against dietary supplement manufacturers and ingredient importers 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.

Branch Prosecutes Texas Physician for Allegedly Tampering with IV Bags Implicated in Death and Patient Injuries

United States v. Ortiz (N.D. Tx.)

In September 2022, Raynaldo Rivera Ortiz Jr., a Texas anesthesiologist, was arrested on charges of tampering with IV bags at a surgical center where he worked. According to court documents, a coworker of Ortiz experienced a medical emergency and died immediately after treating herself for dehydration using an IV bag of saline taken from the surgical center. An autopsy report revealed that she died from a lethal dose of bupivacaine, a nerve blocking agent that is rarely abused but is often used during the administration of anesthesia. According to the complaint, surgical center personnel concluded that this incident and at least 10 others suggested a pattern of intentional adulteration of IV bags used at the surgical center. The complaint alleges that surveillance video from the center's operating room hallway showed Ortiz placing IV bags into the stainless-steel bag warmer shortly before other doctors' patients experienced cardiac emergencies. The case was brought in partnership with the United States Attorney's Office for the Northern District of Texas.

Seven Individuals and Seven Companies Sentenced for Multimillion-Dollar Nationwide Telemedicine Pharmacy Fraud Scheme

United States v. Bolos, et al. (E.D. Tenn.)

In May 2022, the Branch secured sentences against seven individuals and seven corporate entities for their roles in a multimillion-dollar scheme to defraud health insurers and pharmacy benefit managers. According to court documents and evidence presented at trial, the defendants used telemarketers to sell bogus prescriptions to consumers that the defendants filled using pharmacies they owned. The prescriptions were typically for drugs such as pain creams, scar creams, and vitamins. Evidence showed that to obtain the prescriptions, the perpetrators cold-called consumers and deceived them into agreeing to accept the drugs and to provide their insurance information. The defendants then billed private health insurance companies for those prescriptions at significant markups. One of the individual defendants, Peter Bolos, was sentenced to 14 years in prison and ordered to pay nearly \$25 million in restitution.

Individuals and Dietary Supplement Firms Sentenced for Distributing Controlled Substances and Other Hazardous Substances Labelled as Dietary Supplements

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

The Consumer Protection Branch obtained convictions against eight individuals and three companies for their roles in a scheme to illegally distribute anabolic steroids while marketing them as muscle-building dietary supplements. In 2022, four defendants were sentenced, including Phillip Braun, who founded a sports and dietary supplement retailer called Blackstone Labs LLC and was sentenced to 54 months' imprisonment. Blackstone's lead salesman, James Boccuzzi, was sentenced to 51 months in prison in March 2022. Three companies associated with the scheme were ordered to pay restitution.

Branch Files Civil Complaint to Enjoin Beverage Seller That Claimed the Product Could Cure and Treat Certain Illnesses

United States v. Marold (D. Mass.)

In October 2022, the Branch, in partnership with the U.S. Attorney's Office for the District of Massachusetts, filed a civil complaint to enjoin Daniel Marold from distributing a product the government alleged to be an unapproved new drug, a misbranded drug product, and an adulterated food product. According to the complaint, Marold sold various flavors of "Chill6" beverage powder directly to consumers, claiming Chill6 would cure, treat, mitigate, and prevent, among other things, anxiety, insomnia, alcoholism, and post-traumatic stress disorder. The complaint also alleged that Marold's Chill6 contains Phenibut HCl, an unsafe food additive.



Activities of the Department of Justice, by Henry Varnum Poor, 1936.
Located inside the Robert F. Kennedy Department of Justice Building.



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.

Three Defendants Receive Multi-Year Sentences for Falsifying Medical Records in Clinical Trials

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

Three defendants associated with Tellus Clinical Research, a medical research firm based in Miami, were sentenced in 2022 after admitting that they conspired to falsify medical records in connection with clinical trials intended to evaluate various medical conditions, including opioid dependency, irritable bowel syndrome, and diabetic nephropathy. Duniel Tejeda, a project manager and study coordinator, was sentenced to 30 months in prison. Analay Rico, a lead study coordinator, was sentenced to 40 months in prison, and Daylen Diaz, a research assistant and study coordinator, was sentenced to 24 months in prison. Among other things, the defendants admitted that they and their co-conspirators enrolled ineligible subjects in clinical trials, falsified laboratory results, falsified medical records, and falsely represented that subjects were taking the drugs being studied, when in fact they were not. The court also ordered these defendants to pay \$2,134,503.56 in restitution – the full amount of victim losses identified to date. Two other defendants, Eduardo Navarro and Nayada Varona, were previously sentenced to 46 months and 30 months in prison, respectively. Three other defendants are awaiting trial.

Three Defendants Charged for Falsifying Clinical Trial Data

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

In September 2022, three individuals who were associated with a medical clinic based in Miami were charged for knowingly enrolling ineligible subjects in a clinical trial, falsifying subject laboratory results, falsifying subject medical records, and falsely representing that subjects were taking the drug being studied when, in fact, they were not. Miguel Montalvo and Bernardo Garmendia were co-owners of AMB Research Center, where Montalvo also served as a lead study coordinator and Garmendia served as a study coordinator. Ivette Portela worked at AMB Research Center and was a pharmacy technician. AMB Research was paid to test an investigational drug intended to treat with *Colstridium difficile*-associated diarrhea, an infectious disease of the gastrointestinal tract with symptoms that can range from diarrhea to life-threatening damage to the colon.

Each defendant was charged with conspiracy to commit wire fraud and one substantive count of wire fraud. In addition, Montalvo was charged with making a false statement to an FDA regulatory investigator.

Clinical Research Coordinator Convicted for Lying to an FDA Investigator

United States v. Palacio (S.D. Fla.)

In September 2022, a jury convicted a clinical research coordinator, Jessica Palacio, of lying to an FDA regulatory investigator during a 2017 regulatory inspection of her employer. In January 2023, Palacio was sentenced to 36 months in prison. Four co-conspirators had previously pleaded guilty and were sentenced for their roles in the scheme.

According to evidence presented at trial, Palacio worked from 2013 to 2015 as a clinical research coordinator at a clinical trial firm called Unlimited Medical Research (UMR), which was one of many companies hired to conduct a clinical trial on the safety of an asthma medication in children. Palacio was charged with falsifying medical records to make it appear as though pediatric subjects made scheduled visits to UMR, received physical exams from a clinical investigator, and took study drugs as required, when in fact they had not. The indictment alleged that when Palacio was confronted by an FDA regulatory investigator about her role in the clinical trial conducted by UMR, she submitted a false affidavit claiming that she had performed a screening visit of a child subject when she had not. Following trial, the jury found Palacio guilty of both conspiring to commit wire fraud and with making a false statement. The court subsequently granted a defense motion for a judgment of acquittal on the conspiracy charge, but denied a motion for judgment of acquittal as to the false statement charge.

Consumer Fraud and Deceptive 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 Federal Trade Commission (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. Attorney's Offices, the U.S. Postal Inspection Service, the 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 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. 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 bring to justice perpetrators wherever 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.



Elder Fraud

Attorney General Expands Branch-Led Transnational Elder Fraud Strike Force

In October 2022, Attorney General Garland announced the expansion of the Transnational Elder Fraud Strike Force, adding 14 additional U.S. Attorney's Offices. Since 2019, the Strike Force, which is led by the Consumer Protection Branch, and includes various U.S. Attorney's Offices, the FBI, the U.S. Postal Inspection Service, and Homeland Security Investigations, has brought successful cases against the largest and most harmful global elder fraud schemes. The Strike Force works with foreign law enforcement to disrupt criminal enterprises, disable their infrastructure, and bring perpetrators to justice. Expansion of the Strike Force will help to coordinate the Department's ongoing efforts to combat sophisticated fraud schemes that target or disproportionately impact older adults. The expansion has increased the total number of U.S. Attorney's Offices comprising the Strike Force from six to 20, including all of the U.S. Attorneys' Offices in the states of California, Arizona, Texas, Florida, Georgia, Maryland, and New York.

Branch Returns \$77 Million Surrendered by Marketing Companies to Victims, Obtains Resolution with Additional Company

In 2022 the Branch notified approximately 700,000 consumer victims that they were eligible for compensation and returned approximately \$77 million to victims of mass mailing schemes.

The money returned to victims was paid as part of resolutions with two marketing companies, Epsilon Data Management, LLC and KBM Group LLC, that the Branch prosecuted in partnership with the U.S. Attorney's Office for the District of Colorado. Both companies entered into deferred prosecution agreements to resolve allegations they sold consumer data to operators of fraudulent schemes. Victims of these fraud schemes, many of whom were older adults, were targeted with "sweepstakes" or "astrology" solicitations that falsely promised prizes or individualized services if victims paid a fee. Many victims lost thousands of dollars. Epsilon and KBM Group LLC entered into deferred prosecution agreements in January 2021 and June 2021, respectively, that required them to distribute \$127.5 million and \$33.5 million, respectively, to victims of fraud schemes to which Epsilon and KBM Group sold lists of consumer names.

Additionally, in September 2022, Wiland Inc., another marketing company, agreed through a non-prosecution agreement with the Branch and the U.S. Attorney's Office for the District of Colorado to pay \$4.4 million in victim compensation for its acknowledged sale of consumer data to operators of similar fraudulent schemes.

Six Defendants Involved in Grandparent Scam Sentenced for RICO Conspiracy

United States v. Ingram, et al. (S.D. Cal.)

Six defendants charged with racketeering conspiracy for their involvement in an international grandparent scam have been sentenced. Members of the network called older individuals and impersonated a grandchild, other close relative, or friend of the victim. They convinced the victims that their relatives or friends were in legal trouble and needed money to pay for bail, for medical expenses for car accident victims, or to prevent additional charges from being filed. The defendants and their co-conspirators then received money from victims via various means, including in-person pickup, the mail, and wire transfer, and then laundered the proceeds, including using cryptocurrency. Timothy Ingram, personally and through others, directed a network of individuals who picked up money from victims or had victim money sent to their accounts. He was sentenced to 108 months in prison. Anajah Gifford personally picked up money from victims and recruited and directed other members of the conspiracy and was sentenced to 57 months in prison. Jack Owuor, who played a similar role as Gifford, received a 46-month sentence. The Branch prosecuted this case in partnership with the U.S. Attorney's Office for the Southern District of California.



In October 2022, Attorney General Garland hosted a discussion with FBI and USPIS on elder fraud efforts. From left to right FBI Deputy Assistant Director Aaron Tapp, Former Branch Director Gus Eyler, DAAG Arun Rao, USPIS Chief Inspector Gary Barksdale, USPIS Inspector Ashlea Bowens, Attorney General Garland, USPIS Deputy Chief Inspector Craig Goldberg, FBI Deputy Director Paul Abbate, Branch Assistant Director Jackie Blaesi-Freed, DOJ's Elder Justice Coordinator Andy Mao, Branch Director Amanda Liskamm, PDAAG Brian Boynton

Branch Extradites from Jamaica Three Individuals Charged with Lottery Fraud 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 prosecuting and bringing to justice those based in Jamaica who orchestrate the schemes and target U.S. consumers. This year, the Branch extradited three individuals from Jamaica.

United States v. Clarke (S.D. Fla.)

In May 2022, Greg Warren Clarke was extradited from Jamaica to face charges of conspiring to commit mail and wire fraud in connection with a lottery fraud scheme. In August, Clarke pleaded guilty to conspiracy to commit mail fraud and in October, he was sentenced to 36 months in prison. Clarke admitted that he worked with co-conspirators, including Claude Anthony Shaw, to call victims and falsely tell them that they had won over a million dollars in a lottery and needed to pay fees or taxes to claim their winnings. Victims were instructed to send their money through wire transfers or the mail to Shaw and other individuals. Clarke then instructed Shaw to send the victims' money to Clarke in Jamaica, usually through wire transfers. Shaw was previously sentenced to 36 months in prison. The Branch prosecuted this case with assistance from the U.S. Attorney's Office for the Southern District of Florida.

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

In July 2022, Damone Oakley was extradited from Jamaica to face a 16-count indictment charging him with operating a fraudulent sweepstakes scheme targeting older individuals. 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. The indictment alleges that Oakley used a variety of names, including "Officer Alex Logan" and "Officer Stan Valentine." Victims were directed to send money directly to Oakley, as well as to individuals in the United States and elsewhere who served as intermediaries and transmitted the money to Oakley. In addition to sending cash or wire transfers, the indictment alleges that victims were directed to purchase electronics, jewelry, and clothing and to have the purchased items shipped to mail forwarding services in Florida. The Branch is prosecuting this case with the U.S. Attorney's Office for the Middle District of Pennsylvania.

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

In October 2022, Anthony Stewart was extradited from Jamaica, having been charged in a nine-count indictment alleging that Stewart and his co-conspirators enriched themselves through a fraudulent lottery scheme targeting older individuals. Victims throughout the United States received phone calls in which they were falsely informed that they had won cash prizes totaling over \$1 million, but first needed to pay fees to claim their winnings. The indictment alleges that victims were instructed on how to send their money, including through money transmitter services, wire transfers, and the mail, and also were instructed to whom the money should be sent. The indictment further alleges that victims were instructed to purchase electronics and other expensive goods and to send them to Stewart's co-conspirators, who ultimately forwarded the goods and money to Stewart in Jamaica. The Branch is prosecuting this case with the U.S. Attorney's Office for the Western District of North Carolina.

Fraudsters Behind Multi-Million Dollar Prize Notice Scheme Convicted at Trial

United States v. Novis, et al. (E.D.N.Y.)

In May 2022, a jury convicted Sean Novis and Gary Denkberg of charges related to a mass mailing fraud scheme. The jury found that the defendants tricked thousands of victims, many of whom were older individuals, into providing the defendants with money by falsely promising prizes. 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.

Peruvian Brothers Sentenced to More than Seven Years in Prison for Defrauding Thousands of Spanish-Speaking Immigrants

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

In February 2022, two Peruvian nationals previously extradited from Peru were sentenced for operating a series of call centers in Peru that defrauded and threatened Spanish-speaking U.S. residents. Josmell Espinoza Huerta was sentenced to 88 months in prison. Carlos Alberto Espinoza Huerta was sentenced to 102 months.

Both defendants admitted to owning and operating several call centers responsible for defrauding Spanish-speaking U.S. consumers. The defendants and their co-conspirators in Peru called victims—many of whom were recent immigrants from Central America, Mexico, and other Spanish-speaking countries—and fraudulently threatened them with legal consequences if they did not make payments for purportedly delivered products and settlement fees for English-language classes. The defendants and their co-conspirators used false statements and threats to obtain money from victims across the United States by falsely telling the victims that they were required to accept and pay for English-language courses and other educational products and that failure to do so placed them in legal jeopardy. The defendants and their co-conspirators then falsely threatened to have their victims arrested and deported, in order to collect payments from their victims. The Branch prosecuted this case with assistance from the U.S. Attorney's Office for the Southern District of Florida.



Mastermind Behind \$300 Million Ponzi Scheme Sentenced to Ten Years

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

In August 2022, the Branch and the U.S. Attorney's Office for the District of South Carolina secured a 10-year sentence for an individual who had caused more than 2,500 retirees to suffer more than \$310 million in losses and placed more than 13,000 veterans into exploitative loans. For seven years, Scott Kohn and his co-conspirators solicited pensioners experiencing financial distress, most of whom were military veterans, by offering upfront lump-sum payments in exchange for assignment of their rights to monthly pension and disability payments. The transactions were characterized as "sales," but were actually usurious loans with annual interest rates as high as 240%. Kohn then solicited thousands of older adults—using false promises of significant return rates—to purchase "structured cash flows" funded by the pensioners' monthly payments. The scheme collapsed when Kohn could not acquire enough rights to pensions to meet the promised investment returns. Kohn funded a lavish lifestyle with proceeds from his scheme.



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



Unauthorized Debits

Defendant Sentenced for Sophisticated International Scheme to Steal Money from Consumers' Accounts

United States v. Sobel (D. Nev.)

In December 2022, Harold Sobel was sentenced to 42 months in prison for his role in an international criminal enterprise that unlawfully debited money from the bank accounts of U.S. victims. Members of the criminal enterprise created shell companies for the purpose of receiving victim funds and created fake websites for the shell companies that claimed to offer products or services, such as cloud storage. Members then executed unauthorized debits against victims' bank accounts, while falsely representing to banks that the debits were authorized by the victims. In some cases, members of the criminal enterprise caused the accounts used by the criminal enterprise to also make "micro debits" against other bank accounts controlled and funded by or for the criminal enterprise to artificially lower the return rates to levels that conspirators believed would reduce bank scrutiny and thereby lessen the likelihood of closure of the accounts used by the criminal enterprise. Sobel opened bank accounts for the criminal enterprise, including accounts used to fund "micro debits." He also provided support for the activities of the enterprise's call center in Ukraine. The Branch prosecuted this case with the U.S. Attorney's Office for the District of Nevada.

Two Illinois Men Charged in Fraudulent Payment Scheme

United States v. D'Ambrose, et al. (N.D. Ill.)

In December 2022, the Branch secured charges against Michael D'Ambrose and Scott Apgar, who operated a group of payment processing companies that deposited checks on behalf of merchant-clients. The checks typically were "remotely created checks" (RCCs), which were not signed by the account holder whose account was debited. The indictment alleges that D'Ambrose and Apgar deceived banks about the nature of the payment processing companies' business and financial transactions in order to open and maintain bank accounts and to allow for the processing of tens of millions of dollars of RCCs, which were purportedly authorized by consumers.

D'Ambrose and Apgar allegedly used those bank accounts to deposit RCCs on behalf of merchant clients despite warning signs of fraud, including indications that merchant-clients were initiating unauthorized debits from the accounts of purported customers. As alleged in the indictment, the warning signs of fraud included consumer complaints and law enforcement and bank inquiries about unauthorized debits. According to the indictment, D'Ambrose and Apgar fraudulently manipulated the rates of returned deposits associated with the payment processing companies' accounts. They allegedly did so by making small-dollar deposits known as micro-transactions, which increased the volume of deposits in an account, thereby causing the percentage of returned RCCs to appear smaller than it actually was. The defendants also allegedly submitted to banks documents that the defendants knew contained false and fraudulent information about the nature of the payment processing companies' operations. The Branch prosecuted this case with the U.S. Attorney's Office for the Northern District of Illinois.



Deceptive Acts and Practices

Unscrupulous business practices harm consumers in many ways, including by taking money, jeopardizing privacy, and hindering consumers' ability to make informed decisions about goods and services. The Branch, working in partnership with the Federal Trade Commission, brings cases against such practices under the Federal Trade Commission Act and rules promulgated by the Commission. 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 aware of – and often concerned by – the many ways that companies collect, use, and profit from their private information. In 2022, the Branch filed multiple data privacy-related actions to bring companies into compliance with the law, including several actions involving the Children's Online Privacy Protection Act (COPPA) and its implementing regulation (the COPPA Rule), which regulate how and when companies may collect information from children under 13 years old. These actions have sought and obtained substantial monetary penalties, compliance terms, and monitoring conditions to ensure that companies treat private information and its collection with the care the law requires.

Epic Games, Inc., Developer for "Fortnite," Agrees to Pay \$275 Million Penalty and Injunction for Alleged Violations of Children's Privacy Law

United States v. Epic Games, Inc. (E.D.N.C.)

In December 2022, the Branch filed a complaint and proposed settlement requiring Epic Games, maker of the popular video game Fortnite, to pay the largest penalty ever imposed for a violation of COPPA. The settlement was entered by a federal judge in February 2023.

In its complaint, the government alleged that Epic Games designed and marketed Fortnite for use by children and knew that the game collected personal information from children, including their names, email addresses, and identifiers used to keep track of players' progress, purchases, settings, and friends lists. Epic Games failed to notify parents that it was collecting children's personal information or to obtain verifiable parental consent for that collection. The government further alleged that Epic Games maintained default privacy settings that publicly broadcasted child and teen Fortnite players' display names and put children and teens in direct, real-time communication with adult Fortnite players.

The entered order requires Epic Games to pay \$275 million in civil penalties. It also prohibits Epic Games from collecting personal information from children in a manner that violates the COPPA Rule and from using children's personal information that was previously collected unless it obtains verifiable parental consent. Epic Games is also required to maintain default privacy settings that protect children's and teens' privacy. As part of the order and agreement, Epic must also maintain a comprehensive privacy program that protects certain personal information and abide by compliance reporting obligations.

Twitter Agrees to Pay \$150 Million and to Implement Comprehensive Compliance Program to Resolve Alleged Data Privacy Violations

United States v. Twitter, Inc. (N.D. Cal.)

In May 2022, a federal judge entered an order requiring Twitter, Inc. to pay \$150 million in civil penalties and implement robust compliance measures to protect users' data privacy. The order settled allegations that Twitter had violated the FTC Act and an FTC administrative order by misrepresenting how it would make use of users' nonpublic contact information. The government's complaint alleged that Twitter deceived users about the extent to which it maintained and protected the security and privacy of users' nonpublic contact information, including by telling consumers for over five years that

it collected telephone numbers and email addresses for account-security purposes, when in fact it also used that information to help companies send targeted advertisements to consumers.

As part of the settlement agreement, Twitter is required to develop and maintain a comprehensive privacy and information security program, conduct a privacy review with a written report before implementing any new product or service that collects users' private information, and conduct regular testing of its data privacy safeguards. Twitter is also required to obtain regular assessments of its data privacy program from an independent assessor, provide annual certifications of compliance from a senior officer, provide reports after any data privacy incidents affecting 250 or more users, and comply with numerous other reporting and record-keeping requirements. Both the Department and the FTC continue to closely monitor Twitter's compliance with the court order.

Kurbo, Inc. and WW International, Inc. Pay a \$1.5 Million Penalty for Allegedly Collecting Children's Personal Information Without Parental Consent

United States v. Kurbo, Inc., et al. (N.D. Cal.)

In March 2022, the court issued a stipulated order requiring Kurbo, Inc. and WW International, Inc. (formerly Weight Watchers International, Inc.) to pay a civil penalty of \$1.5 million and imposing injunctive relief. In its complaint, the government alleged that the defendants designed and marketed the "Kurbo by WW" mobile application and website for use by children as young as eight years old. The website and application collected sensitive information about children without notifying parents about the collection and obtaining parental consent. The defendants knew that the application and website collected children's personal information, including not only names, telephone numbers, and email addresses, but also other sensitive information like height, weight, food intake, and physical activity. The defendants also collected information enabling them to track devices. The order enjoins the defendants from collecting personal information from children outside the bounds of COPPA, the COPPA Rule, and Section 5 of the FTC Act; prevents them from using previously collected information unless they obtain parental consent; and imposes compliance reporting obligations.

Branch Sues Legacy Cremation Services for Funeral Rule and FTC Act Violations

United States v. Legacy Cremation Services LLC, et al. (S.D. Fla.)

In April 2022, The Branch sued Legacy Cremation Services, LLC; Funeral & Cremation Group of North America, LLC; and Anthony Joseph Damiano alleging violations of the FTC Act and the FTC's Trade Regulation Rule Concerning Funeral Industry Practices. According to the complaint, the defendants, who arrange third-party cremation services, made deceptive statements to consumers about pricing for funeral and cremation services, misrepresented the location where services were to be provided, and wrongfully withheld loved ones' remains. The complaint seeks civil monetary penalties and injunctive relief. In January 2023, the parties reached a settlement of the case in which the defendants agreed to pay \$275,000 in civil penalties and abide by strict injunctive compliance and monitoring measures, including providing consumers with accurate and timely pricing information.

Branch Sues 16 Defendants for Allegedly Deceptive Sales Practices Related to Timeshare "Exit Services"

United States v. Consumer Law Protection, LLC, et al. (E.D. Mo.)

In November 2022, the Branch, together with the FTC, the U.S. Attorney's Office for the Eastern District of Missouri, and the State of Wisconsin, announced a civil enforcement action against 16 individual and corporate defendants for allegedly using deceptive sales practices nationally to sell timeshare "exit services" to senior citizens.

According to the complaint, the defendants promised to help consumers get out of their timeshare contracts in exchange for large fees, but usually failed to deliver on their promises. The complaint alleges that the defendants lured consumers, mostly seniors, to high-pressure sales presentations at hotels and restaurants in multiple states. The defendants' high-pressure sales tactics to induce a captive audience into buying their timeshare exit services included falsely claiming that consumers

could not exit timeshare contracts on their own, that the defendants were affiliated with legitimate companies, and that the consumers' heirs would be stuck with large fees unless they signed the defendants' contracts. The complaint further alleges that the defendants failed to notify consumers of their rights under federal and state law to cancel their contracts with defendants within three business days. According to the complaint, consumers were unfairly pressured and deceived into paying more than \$90 million to the defendant companies for services that were not delivered.

Branch Files Lawsuit and Secures Preliminary Relief Against Credit Repair Company and its CEO

United States v. Turbo Solutions Inc., et al. (S.D. Tx.)

In March 2022, the Branch sued Alexander Miller and his company Turbo Solutions Inc. for unlawful activity in claiming that they could repair consumers' credit. The complaint alleges that the defendants used websites and telemarketing to falsely claim they could improve consumers' credit scores by removing all negative items from consumers' credit reports. For these services, defendants routinely charged thousands of dollars in advance fees for their credit repair services, which are prohibited by law, and did not make required disclosures regarding those services. According to the complaint, the defendants also filed or caused to be filed fake identity theft reports with the FTC. Many consumers allegedly paid the defendants a fee ranging from several hundred dollars to \$1,500, but did not receive the higher credit scores the defendants promised. Due to the extent of the consumer harm and nature of the violations, the Branch, with the assistance of the U.S. Attorney's Office for the Southern District of Texas, sought and was awarded emergency relief and within a month of filing secured an injunction permanently preventing the defendants from unlawful acts related to telemarketing and credit repair.

Branch Files First Action Under "Made in USA" Labeling Rule

United States v. Lithionics Battery, LLC, et al. (M.D. Fla.)

In May 2022, the Branch filed the first case under the FTC's "Made in the USA" rule, which prohibits a company from touting a product as made in the United States unless virtually all of the product, including all significant parts, was made in the U.S.

The action was filed against lithium battery manufacturer Lithionics Battery, LLC and its manager Steven Tartaglia. The government alleged that Lithionics violated the rule by improperly labeling and advertising batteries, battery modules, and battery management systems as "Made in USA," even though key components of the products — including the lithium ion cells that powered the batteries — were imported. The defendants agreed to resolve the allegations by paying \$105,319 in civil penalties and being subject to an injunction prohibiting them from mislabeling their batteries and components containing imported components as "Made in the USA." The defendants are also required to identify customers who purchased their products during a specified time period and to notify those customers that the defendants had been sued for deceptively advertising their products as "Made in USA."



| Illegal Telemarketing

Illegal telephone calls frustrate American consumers and, at times, carry deceptive pitches or even outright attempts to defraud. The Branch is aggressively pursuing those who place and carry illegal telephone traffic, using both civil and criminal tools.

Owner of VoIP Company Responsible for Facilitating Fraudulent Robocalls Pleads Guilty to Money Laundering

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

In September 2022, Jon Kahen pleaded guilty to money laundering in connection with his role as the owner and chief executive officer of a voice-over-internet-protocol (VoIP) company that facilitated and profited from the introduction of fraudulent robocall traffic into the United States. Kahen was the owner and chief executive officer of Global Voicecom, Inc. (GVI), which provided telecommunications services including calling platforms and 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's telecommunication services to engage in unlawful activities and that the funds paid to GVI by this client for continued services constituted the proceeds of unlawful activities.

VoIP Provider Enjoined from Telemarketing Violations and Subjected to Civil Penalties

United States v. VoIP Terminator, Inc., et al. (M.D. Fla.)

In May 2022, two VoIP service providers, VoIP Terminator Inc. and BLMarketing, Inc., and their owner, Muhammed Usman Khan, agreed to a court order resolving allegations that they facilitated tens of millions of illegal telemarketing calls, including some calls to numbers listed on the “Do Not Call” Registry and robocalls that displayed “spoofed” or fake caller ID numbers. The complaint alleges that the illegal calls transmitted by the defendants included recorded messages about air duct cleaning services that purportedly filtered out COVID-19 (preying on consumers’ fears of the virus), as well as messages involving credit card interest rate reduction and tech support scams. The stipulated order bars the defendants from similar misconduct in the future, requires them to screen and monitor customers, and to terminate customers if they are engaged in improper telemarketing activity.



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 34.

Defendant Who Purported to Sell Personal Protection Equipment Sentenced to 244 Months' Imprisonment

United States v. Parris (W.D.N.Y.)

In December 2022, Christopher Parris was sentenced on charges arising from his efforts to defraud the U.S. Department of Veterans Affairs and eight companies in a scheme involving personal protection equipment (PPE) and an unrelated Ponzi scheme. In February and March 2020, Parris purported to broker access to then-scarce PPE, including N95 respirator masks, to medical supply companies and government entities. Parris knowingly misrepresented his access and ability to obtain and deliver the equipment. He sought orders in excess of \$65 million, eventually obtaining upfront payments of approximately \$7.4 million. For his PPE scheme and the unrelated Ponzi scheme, Parris received a sentence of 244 months' imprisonment. The case was prosecuted with the U.S. Attorney's Offices for the Western District of New York and District of Columbia.

Branch Files Action to Stop Deceptive Marketing of Herbal Tea Advertised as COVID-19 Treatment

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

In March 2022, the Branch, together with the FTC and FDA, brought a civil enforcement action against two companies, B4B Earth LLC and B4B Corp., and their owner operator for advertising an herbal tea as a treatment or prevention for COVID-19, without competent scientific evidence to support the 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 treatment, cure, prevention, mitigation, or diagnosis of COVID-19. The complaint seeks injunctive relief and civil monetary penalties. The Branch partnered with the U.S. Attorney's Office for the Eastern District of New York to bring the case.

Branch Secures Permanent Injunction Against Fake CDC COVID-19 Vaccination Card Operation

United States v. Keller (S.D. Ohio)

In May 2022, the Branch and the U.S. Attorney's Office for the Southern District of Ohio secured a permanent injunction against Tiffany Keller, who produced and sold fake CDC COVID-19 Vaccination Cards. According to the complaint, the defendant offered to print and mail fake cards for \$40 per card. Keller agreed to be permanently enjoined from misusing words, symbols, or emblems associated with the Department of Health and Human Services, including by reproducing and selling CDC COVID-19 Vaccination Cards. Should Keller violate the decree, she will be required to pay a civil monetary penalty of approximately \$443,000.

Defendant Who Used COVID-19 to Convince Consumers to Pay Money as a Part of a Pet Scam Sentenced to 21 Months' Imprisonment

United States v. Bobga (W.D. Pa.)

In April 2022, a Cameroonian national who had been extradited from Romania was sentenced to 21 months in prison for his role in a scheme that deceived consumers into paying fees for pets that were never delivered and for using the COVID-19 crisis as an excuse to extract higher fees from victims. Bobga conspired with others to purport to offer pets for sale online. After a consumer purchased a pet, Bobga and his co-conspirators told consumers a transportation company would arrange delivery of the animal. Bobga and other then posed as the transportation company and claimed that more money was needed to deliver the pet, because the pet purportedly had been exposed to COVID-19. The prosecution was brought in partnership with the U.S. Attorney's Office for the Western District of Pennsylvania.



The Great Hall of the Department of Justice

Defensive Practice

The Branch defends certain consumer protection and public health agencies, including the FDA, FTC, and CPSC, in district courts throughout the country. This work includes cases challenging, under the U.S. Constitution and the Administrative Procedure Act, agency actions related to food, drugs, medical devices, tobacco, and other consumer products. These cases typically involve complex issues regarding the Federal Food, Drug, and Cosmetic Act, the Tobacco Control Act, the Public Health Service Act, the Federal Trade Commission Act, and the Consumer Product Safety Act. 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.

Two Appellate Courts Uphold FDA Orders Denying Marketing Authorization for Flavored E-Cigarette Products

The Branch, working collaboratively with the Civil Division's Appellate Staff and Federal Programs Branch, is defending the FDA's decisions regarding the marketing of e-cigarette products. In September 2021, the FDA denied a large number of applications from manufacturers seeking to market flavored e-cigarette products, which are particularly attractive to youth. Dozens of those manufacturers filed petitions for review in courts of appeals across the country. To date, the Branch and other Department components have secured favorable rulings in several circuits that have rejected challenges to the FDA's decisions regarding flavored e-cigarettes.

Prohibition Juice v. FDA (D.C. Cir.)

In July 2022, a unanimous panel of the U.S. Court of Appeals for the District of Columbia Circuit issued a published opinion denying four consolidated petitions for review of FDA orders denying marketing authorization for flavored e-cigarette products. The petitioners sought authorization to market e-cigarette products in various flavors, including Crazy Bubble Grape, Giggle Juice, Pink Burst, Sweet Thang, and Jolly Apple. In denying the petitions, the FDA noted the well-known risks of flavored e-cigarettes to youth and the dramatic increase in youth use of e-cigarettes. The agency concluded that, given the substantial risk to youth, the petitioners needed to provide robust and reliable evidence establishing that flavored e-cigarette products have an added benefit to adult smokers over comparable tobacco-flavored e-cigarette products. The FDA concluded that the petitioners had failed to make the requisite showing and that the petitioners' proposed marketing plans could not decrease the appeal to youth to a sufficient degree to mitigate the concerns regarding youth use.

Following briefing and oral argument, the D.C. Circuit held that the FDA had acted "well within" its statutory authority in comparing the benefits of flavored e-cigarettes, which are especially popular among youth, to the benefits of tobacco-flavored e-cigarettes, which are less attractive to youth. The panel also rejected the petitioners' contention that the FDA orders were arbitrary and capricious and concluded that any error with respect to petitioners' marketing plans was harmless because petitioners had failed to show how consideration of the plans could have changed the agency's decision.

Liquid Labs v. FDA (3d Cir.)

In October 2022, a unanimous panel of the U.S. Court of Appeals for the Third Circuit issued a published opinion upholding an FDA order denying marketing authorization for the petitioner's flavored e-cigarette products. The petitioner sought approval to market eighteen flavored e-liquids, including OG Island Fusion, Berry Au Lait, OG Summer Blue, and Shake. In denying approval, the FDA concluded that the petitioner'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. After full briefing on the merits, the Third 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 authority in denying the petitioner's applications.

Branch Prevails Against Challenges to Government's COVID-19 Efforts

As the Department component primarily responsible for defending actions taken by the FDA, since March of 2020, the Branch's defensive team has represented the agency in cases challenging its decisions related to vaccines and treatments for COVID-19. Such cases have included challenges to vaccine emergency use authorizations and to the agency's efforts to ensure that the public receives truthful information about proposed COVID-19 treatments.

America's Frontline Doctors, Inc., et al. v. United States, et al. (N.D. Al.)

America's Frontline Doctors, a physicians' non-profit, and seven individuals (mainly federal contractors and employees) sued President Biden, the Department of Health and Human Services (HHS), several HHS components, and several senior agency officials asserting statutory and constitutional challenges to the COVID-19 Public Health Emergency Declaration, the COVID-19 vaccine emergency use authorizations, and President Biden's Executive Orders 14042 and 14043 regarding COVID-19 safety measures for federal contractors and employees. The plaintiffs sought a preliminary injunction enjoining enforcement of the Executive Orders, and the Branch opposed the preliminary injunction motion and moved to dismiss the amended complaint for lack of subject matter jurisdiction and failure to state a claim. Had the litigation succeeded, it could have profoundly impacted access to COVID-19 vaccines throughout the country. Shortly after the court heard oral argument, the plaintiffs withdrew their preliminary injunction motion and the parties filed a joint motion to dismiss certain plaintiffs and defendants, which the court granted. The court later dismissed what remained of the case, agreeing with the Branch that the court lacked jurisdiction.

Apter, et al. v. Department of Health and Human Services, et al. (S.D. Tx.)

During the COVID-19 pandemic, the FDA received multiple reports of patients who required medical attention, including hospitalization, after self-medicating with ivermectin products intended for livestock. Drug products containing ivermectin as the active ingredient are approved to treat parasites and certain skin conditions in humans, and the FDA has also approved different ivermectin products to treat certain animals. But ivermectin products have not been approved or authorized to prevent or treat COVID-19, and it could be dangerous for humans to use animal versions of ivermectin, or potentially even human versions, for that purpose. In response, the FDA released a publication entitled "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." The agency also posted several tweets linking to that publication, including a tweet stating, "Hold your horses, y'all. Ivermectin may be trending, but it still isn't authorized or approved to treat COVID-19."

Three doctors who prescribed ivermectin or promoted its use to prevent or treat COVID-19 sued HHS and its secretary, as well as the FDA and its commissioner. They argued that the FDA's statements advising against the use of ivermectin to prevent or treat COVID-19 interfered with their ability to practice medicine. The Branch moved to dismiss, and after briefing and oral argument, the district court dismissed the amended complaint for lack of subject matter jurisdiction.

Antunes v. University of Virginia, et al. (W.D. Va.)

Plaintiff, a nurse who was fired by the University of Virginia Medical Center in November 2021 for refusing vaccination against COVID-19, filed suit against the University of Virginia, HHS, and the FDA, as well as the HHS Secretary and FDA Commissioner in their official capacities. The plaintiff claimed that the COVID-19 vaccine Emergency Use Authorizations did not meet certain statutory requirements and that the FDA's implementation of those authorizations violated her rights under the Equal Protection Clause. The Branch moved to dismiss for lack of subject matter jurisdiction and failure to state a claim. After holding oral argument, the Court granted the Branch's motion to dismiss, finding that the plaintiff lacked standing and had failed to identify a waiver of sovereign immunity.

Branch Secures Order Dismissing Challenge to FDA's Decision to Inform Consumers About Salmonella in Plaintiff's Products

Arrow Reliance Inc. v. Califf, et al. (W.D. Wa.)

Following reports of pets becoming sick, the FDA found salmonella in certain lots of the plaintiff's pet food products and told the plaintiff that unless the company issued a statement of its own and conducted a voluntary recall of the affected products, the FDA would issue a statement alerting the public to the potential danger to pets and humans. The plaintiff sued the FDA and sought a temporary restraining order and preliminary injunction to stop the agency from issuing a public statement. After briefing and oral argument, the Court denied plaintiff's motion and the FDA issued a public statement one day later. The plaintiff then amended its complaint to seek an order requiring the FDA to take down its statement, and the Branch moved to dismiss for lack of subject matter jurisdiction. The court granted the Branch's motion, finding that the FDA's public statement was not "agency action" within the meaning of the Administrative Procedure Act and, alternatively, that the statement was not "final" agency action.

Government Wins Summary Judgment in Challenge to FDA's Award of New Chemical Entity Exclusivity

Sandoz, Inc. v. Becerra, et al. (D.D.C.)

Sandoz, Inc. filed a lawsuit challenging the FDA's award of "new chemical entity" exclusivity to Sanofi for the drug Aubagio. Sandoz argued that the FDA had exceeded its authority under the FDCA and had acted arbitrarily and capriciously. If Sandoz had prevailed on its lead argument, FDA could have been required to significantly alter the way it determines whether a drug will receive new chemical entity exclusivity. The parties filed cross motions for summary judgment on the administrative record. In July 2022, the court granted the government's motion for summary judgment and denied Sandoz's cross motion, finding that FDA had correctly interpreted the Act and properly exercised its authority. The D.C. Circuit later affirmed the judgment of the district court.

Specialized Units and Resources

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

The Trial Strategy and Training Unit develops and delivers high-quality, component-specific training for Branch staff. The Unit also assists teams preparing for trials.

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 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 and document analysts, as well as 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 in opioids matters.

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, the CCP assess compliance programs and help craft resolution terms and ensures that defendants follow the compliance and reporting provisions of resolutions. 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 Unit also opines on draft regulations and guidance.

Voluntary Self-Disclosure and Monitor Selection Policies

As part of the Department's efforts to enhance its corporate crime enforcement efforts, the Branch released 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, CPSC, FTC, or 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.

Disclosures may be made by emailing Consumer.Disclosure@usdoj.gov.

Monitor Selection Policy

The Branch's Monitor Selection Policy 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, amongst other things, conflict-of-interest concerns. The Branch's Corporate Compliance and Policy Unit 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.