

# Federal Enforcement of Pharmaceutical Fraud under the False Claims Act, 2006–2022

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## Abstract

**Context:** The False Claims Act is the US federal government's primary tool for identifying and penalizing pharmaceutical fraud. The Department of Justice uses the False Claims Act to bring civil cases against drug manufacturers that allegedly obtain improper payment from federal programs.

**Methods:** The authors searched the Department of Justice website for press releases published between 2006 and 2022 that announced fraud actions brought against drug companies. They then used the World Health Organization's Anatomical Therapeutic Classification index to identify the classes of prescription drugs implicated in fraud actions.

**Findings:** During fiscal years 2006–2022, payments by six manufacturers amounted to more than 28% of total payments made as a result of federal False Claims Act actions. Nervous system and cardiovascular drugs were the classes of medications most commonly implicated in alleged fraud. Federal officials most frequently alleged that companies improperly promoted nervous system drugs and paid kickbacks to increase revenues from cardiovascular, antineoplastic and immuno-modulating, and alimentary tract and metabolism drugs.

**Conclusions:** Despite frequent pharmaceutical fraud settlements and penalties, incidence of alleged fraud among drug companies remains high. Alternative methods for preventing and deterring fraud could help safeguard our health systems and promote public health, and policy makers should ensure that effective fraud enforcement complements preventive public health regulation.

**Keywords** health care fraud, prescription drugs, public health, False Claims Act, pharmaceutical industry

Fraud, which is generally defined as the knowing deception of others in pursuit of financial gain, is a leading source of wasteful spending in US health care (Shrank et al. 2019). The federal government's primary statutory basis for uncovering and addressing fraud is the civil False Claims

Act (FCA) (Kalb 1999; Kesselheim and Studdert 2008). The FCA authorizes the Department of Justice (DOJ) to penalize fraud and recoup government losses on fraudulent claims for federal money, such as knowingly overcharging Medicare for services, in lawsuits brought on behalf of the federal government. Since DOJ started escalating its enforcement of FCA violations in the 1990s, it has consistently identified health care fraud as the “leading source of the department’s False Claims Act settlements and recoveries” (DOJ 2022; Krause 2002). Among health care entities, pharmaceutical companies topped recent annual DOJ recoveries by dollar amount. DOJ has reached several high-profile FCA settlements with pharmaceutical companies in recent years, including Purdue Pharma’s \$2.8 billion settlement in 2020 relating to its illegal overpromotion of opioid medications (Hoffman and Benner 2020). Overall, the federal government has recovered more than \$57 billion from False Claims Act settlements and judgments since 2006 (DOJ 2023).

How federal officials enforce laws to penalize pharmaceutical fraud has profound implications for public health and the integrity of medical products regulation. Common violations by pharmaceutical manufacturers include the fraudulent reporting of prices to federal payers, payment of kickbacks and inducements to prescribers, causing the government to pay for noncovered uses of therapies, unlawful promotion of drugs for medically unnecessary or unsupported off-label uses, and price-fixing schemes (Almashat et al. 2018). When pharmaceutical manufacturers engage in these deceptive practices, they harm patients through the provision of dangerous care, and they waste taxpayer resources that could be used to provide useful health care to people who need it. Deterring pharmaceutical fraud is therefore a public health priority.

Most civil False Claims Act cases, and the majority of dollars recovered as a result of these actions, involve whistleblowers (also known as *qui tam* relators) with inside knowledge of alleged fraud (DOJ 2023). Whistleblowers can help uncover fraudulent schemes that might otherwise go undetected, helping safeguard taxpayer money and protect consumers (Kesselheim and Studdert 2008). When the federal government intervenes to join a whistleblower-initiated False Claims Act action, whistleblowers receive 15% to 25% of the dollar amount recovered in settlements and judgments. If the federal government declines to intervene and the whistleblower decides to proceed with the lawsuit anyway, whistleblowers receive 25% to 30% of any amount recovered.

DOJ has substantial incentives to bring fraud actions against health care companies. Successful settlements and judgments against bad actors like

Purdue Pharma punish wrongdoers, help deter future problematic behavior, and recover money for the federal budget (Eliason et al. 2021; 42 U.S.C. § 1395i(k)(3)). Manufacturers found liable for FCA violations in 2022 faced fines of up to \$25,076 per violation in addition to three times the dollar amount of damages incurred (28 C.F.R. Sect. 85.5). Depending on the scale of the alleged fraud, an adverse ruling at trial could cost a firm billions of dollars in damages (DOJ 2013). This may help explain why few FCA actions brought against pharmaceutical manufacturers reach the trial stage (Krause 2016). In settlements, manufacturers often agree to corporate integrity agreements (CIAs), programs that establish oversight mechanisms or restructure firms to promote future compliance with federal laws and regulations (HHS OIG 2023a). The effectiveness of these agreements is unclear, however, given repeat settlements by companies subject to CIAs (Wolfe 2013). Firms also settle related criminal actions because a criminal fraud conviction would render them ineligible for payment from federal health care programs (42 U.S.C. § 1320a–7b; 42 U.S.C. § 1320a–7). The threat of exclusion from federal reimbursement may increase manufacturers' willingness to settle fraud cases with terms that allow them to retain their eligibility for Medicare and Medicaid payments (Osborn 2010).

The types of fraud committed by pharmaceutical manufacturers that DOJ actively enforces using the civil False Claims Act, and the drug classes at issue in these actions, remain largely underexplored in the literature (Rodwin 2015). Other scholarship has analyzed the scale and nature of pharmaceutical fraud in the United States, examined the tools at DOJ's disposal to enforce fraud and the agency's incentive to limit stronger sanctions, described off-label marketing litigation, and scrutinized the legal structure of DOJ's fraud enforcement regime (Almashat et al. 2018; Greenman and Greenman 2017; Krause 2016; Rodwin 2015). Understanding the scope of DOJ fraud cases can also help reveal the potential public health benefits of vigorous enforcement in this area (HHS and DOJ 2022). We sought to characterize DOJ's enforcement of pharmaceutical fraud in recent years and identify the classes of drugs at issue.

## Study Data and Methods

### Identification of Federal False Claims Act Enforcement Actions

We conducted a search of DOJ press releases issued between January 1, 2006, and December 31, 2022, to identify settlements and judgments arising from federal False Claims Act actions brought against pharmaceutical

companies. We searched the DOJ website for the terms “False Claims Act” and “drug” and manually reviewed the results. We excluded actions brought against nonmanufacturer entities such as pharmacies or individual providers. Our methodology relies on DOJ issuing press releases describing its involvement in concluded federal fraud actions brought against pharmaceutical manufacturers that generated recoveries for the government. DOJ has considerable incentive to report lucrative settlements and judgments that the agency played a role in obtaining.

Our analysis excludes federal fraud actions in which DOJ declined to intervene on behalf of a whistleblower. This is because DOJ is not likely to issue press releases concerning actions not involving DOJ. Accordingly, this analysis may underestimate the scope of pharmaceutical fraud actions brought under the FCA. DOJ also likely does not issue press releases for unsuccessful FCA actions, namely those that DOJ lost at trial or for which it failed to reach a settlement agreement with a pharmaceutical firm. As a result, this study could not estimate how often DOJ fails or succeeds (defined as reaching settlement deals or judgments and recovering money for the government) in FCA actions.

### Analysis of Concluded FCA Actions

Consistent with previous empirical studies on DOJ health care enforcement policy, we additionally conducted a comprehensive search strategy that included Westlaw, news outlets, and the DOJ’s archives to gather information on enforcement actions (Almashat et al. 2018; Arnold, Stewart, and Beck 2020; Daval, Avorn, and Kesselheim 2022). We cross-checked data across multiple sources whenever possible. One investigator collected the following characteristics from each concluded action: defendant company name, year concluded, whether the action was brought by whistleblowers, federal recovery before whistleblower payments, the type of alleged fraud at issue, whether a CIA was part of the settlement, and the prescription drugs at issue in the action. We adjusted all spending to January 2023 US dollars using the consumer price index for all urban consumers. Some drugs were named in multiple press releases. We recorded these as distinct alleged violations in every instance they were named because the alleged fraud was distinct. For example, DOJ alleged fraud related to the promotion of aripiprazole (Abilify), which Bristol Myers Squibb and Otsuka co-market, in two press releases (DOJ 2007, 2008). Since one press release described fraud allegedly committed by Bristol Myers Squibb and another press release described fraud allegedly committed by Otsuka, we considered these to be distinct violations.

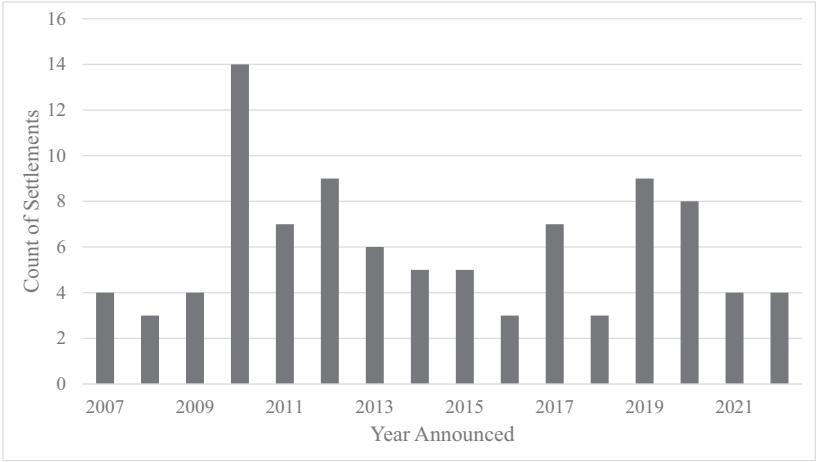
We used the World Health Organization's Anatomical Therapeutic Classification (ATC) index (WHO 2023) to identify the therapeutic classes of prescription drugs. An investigator with clinical expertise manually excluded certain ATC codes because those uses were implausible as a result of the product's formulation. For instance, a 2009 press release detailed how Mylan had allegedly underpaid Medicaid rebates for ibuprofen tablets and other products (DOJ 2009). One of the ATC codes listed in the World Health Organization's index for ibuprofen is "Topical Products for Joint and Muscular Pain"; since ibuprofen tablets are not used topically, we excluded this classification.

## Results

Our search yielded 95 False Claims Act actions brought against pharmaceutical manufacturers that concluded between 2006 and 2022 (fig. 1). DOJ and pharmaceutical companies settled all 95 civil actions before trial. The settlements described in the press releases generated more than \$29 billion in inflation-adjusted recoveries for the federal government before accounting for whistleblower payments (fig. 2). The vast majority (78; 82%) of press releases mentioned one or more actions initiated by a whistleblower. DOJ contemporaneously announced related criminal guilty pleas or deferred criminal prosecution agreements in 31 (33%) cases.

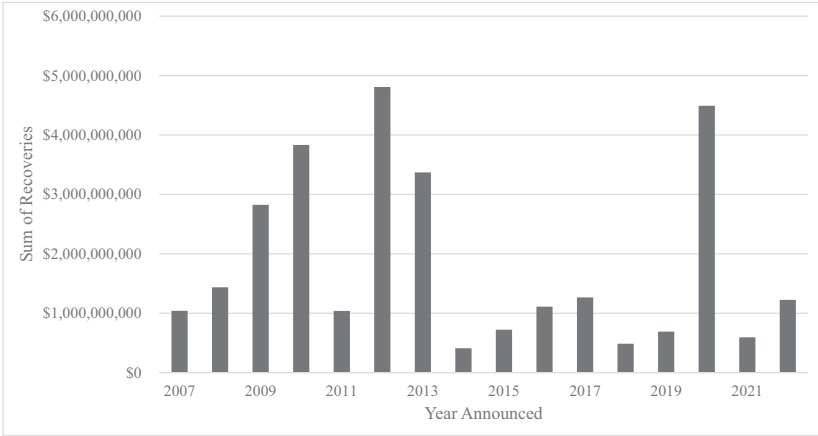
Sixty-five pharmaceutical firms were involved in the settlements, after attributing settlements naming subsidiaries to their parent companies. Six firms and their subsidiaries accounted for 55% of total federal pharmaceutical fraud recoveries after adjusting for inflation: GSK (\$3.4 billion), Purdue Pharma (\$3.2 billion), Pfizer (\$3.1 billion), Johnson & Johnson (\$2.7 billion), Novartis (\$1.8 billion), and Merck (\$1.8 billion) (appendix table 1). Settlement payments by these six companies amounted to 28% of total federal fraud recoveries during fiscal years 2006–2022 (DOJ 2023). GSK, Purdue Pharma, Pfizer, Johnson & Johnson, Novartis, and Merck collectively reached 22 settlements, half of which each involved payments that totaled more than \$400 million. The firms that settled most frequently, including subsidiaries, were Pfizer (six actions), Novartis (six actions), Johnson & Johnson (four actions), AstraZeneca (four actions), and Sanofi (four actions). In 43 (45%) actions, manufacturers agreed to a new CIA; in three (3%) actions, manufacturers extended existing CIAs (fig. 3). The standard term length for such efforts to promote firms' compliance with relevant laws and regulations is five years (HHS OIG 2023b).

We identified 213 drug products implicated in settlements of pharmaceutical fraud actions. The most common first-level classifications were



**Figure 1** Federal fraud settlements involving pharmaceutical manufacturers, 2006–2022.

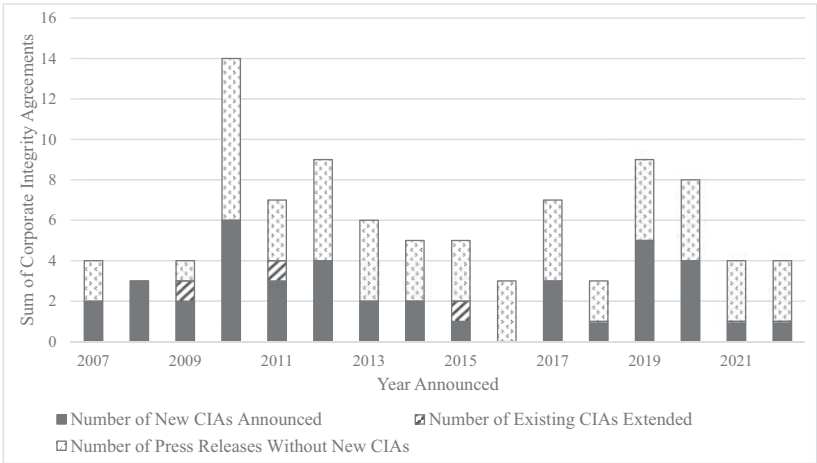
Source: US Department of Justice press releases.



**Figure 2** Totality of federal fraud settlement payments involving pharmaceutical manufacturers.

Note: All values in January 2023 dollars.

Source: US Department of Justice press releases.



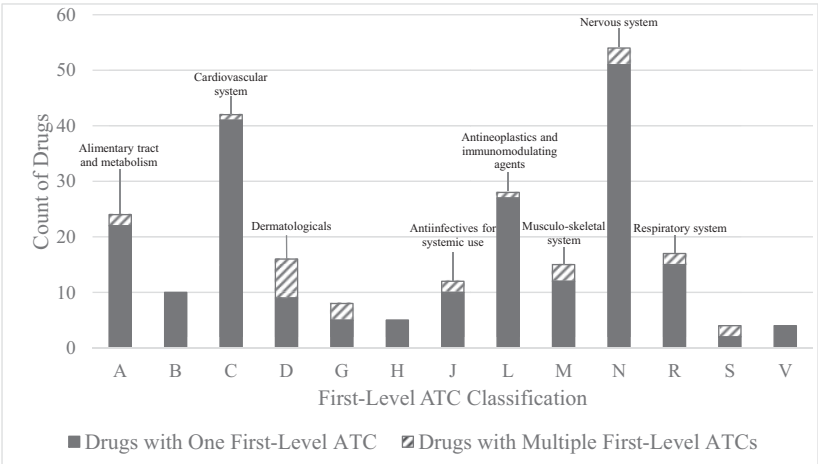
**Figure 3** New or modified corporate integrity agreements in False Claims Act settlements involving pharmaceutical manufacturers, 2006–2022.

*Note:* CIA = corporate integrity agreement.  
*Source:* US Department of Justice press releases.

nervous system drugs (54; 24%), cardiovascular system drugs (42; 19%), antineoplastic and immunomodulating agents (28; 12%), and alimentary tract and metabolism drugs (24; 11%) (fig. 4). Twelve drugs were named in two press releases detailing distinct fraud violations: aripiprazole (Abilify), corticotropin (Acthar), darbepoetin alfa (Aranesp), interferon beta-1a (Avonex), hyoscyamine sulfate extended release, diclofenac sodium, valsartan (Diovan), amlodipine/valsartan (Exforge), ipratropium bromide, aliskiren (Tekturna), natalizumab (Tysabri), and rofecoxib (Vioxx).

### Nervous System

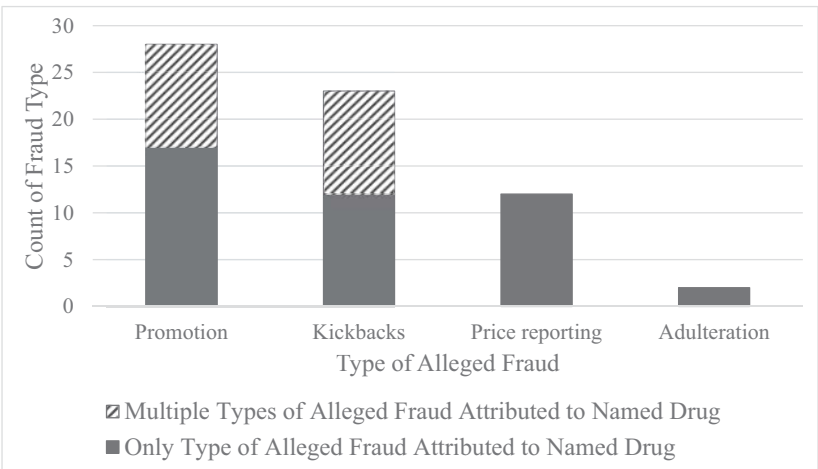
Among the 54 named drugs classified as nervous system products, the most common subclassifications were analgesics (18); psychoanaleptics such as antidepressants, psychostimulants, and antidementia drugs (12); psycholeptics such as antipsychotics and anxiolytics (8); and antiepileptics (7). Promotion for uses not specified on a drug’s labeling or for nonmedically indicated uses was the most common alleged fraud attributed to nervous system products (28 instances), followed by alleged payments in violation of the Anti-Kickback Statute (23 instances) (fig. 5). Settlements related to



**Figure 4** Clinical categories of drugs named in False Claims Act settlements, 2006–2022.

*Note:* ATC=anatomical therapeutic chemical classification, B=blood and blood-forming organs, G=genitourinary system and sex hormones, H=systemic hormonal preparations (excluding sex hormones and insulins), S=sensory organs, V=various. The 12 drugs that were named in two distinct press releases were included twice in this analysis. For example, aripiprazole (Abilify) was named in two press releases and is a nervous system drug, so it counts twice in the nervous system drug column.

*Source:* US Department of Justice press releases.



**Figure 5** Alleged fraud attributed to nervous system drugs, 2006–2022.

*Source:* US Department of Justice press releases.



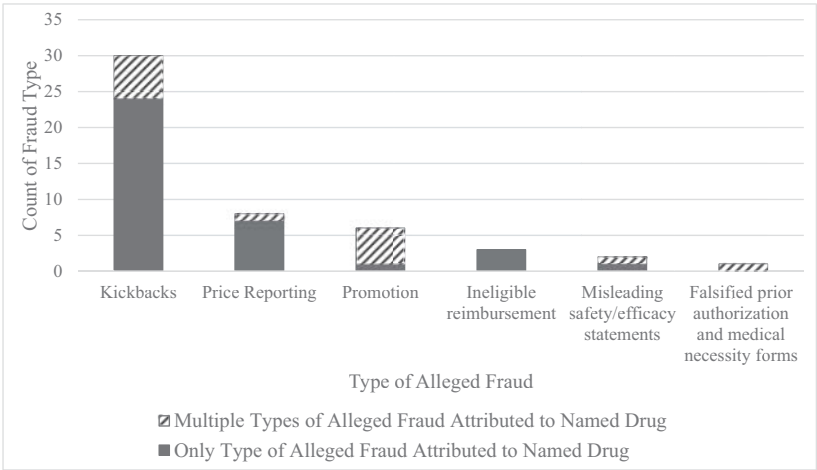
kickback violations primarily concerned payments to clinicians intended to induce additional prescribing, such as speaking fees or meals. An illustrative example of nervous system drug fraud is Johnson & Johnson's 2013 settlement, in which the company resolved claims that it had promoted the atypical antipsychotic risperidone (Risperdal) to "elderly nursing home residents, children and individuals with mental disabilities" regardless of whether patients had schizophrenia, the only condition the US Food and Drug Administration had approved risperidone to treat at the time (DOJ 2013). Although a company study "showed a significant risk of strokes and other adverse events in elderly dementia patients," the company allegedly encouraged physicians to prescribe the drug to treat nonspecific symptoms like agitation in that population.

### Cardiovascular System

The top subcategories of cardiovascular system products named in federal antifraud settlements were agents acting on the renin-angiotensin system (17), lipid-modifying agents (8), and cardiac therapy (7). The predominant type of alleged fraud attributed to cardiovascular products was kickbacks (30 instances) (fig. 6). Alleged violations were primarily inducements to prescribers. Other settlements detailed how companies allegedly used copay foundations to improperly cover copays for Medicare patients using their products, engaged in schemes to fix the price of generic drugs, or misrepresented drug prices or aspects of their products to federal payers to receive more generous reimbursement. A characteristic example of alleged cardiovascular drug fraud is Daiichi Sankyo's 2015 settlement (DOJ 2015). DOJ alleged that the firm paid kickbacks to doctors in the form of speaking fees to induce them to prescribe the antihypertensive drugs olmesartan/amlodipine (Azor), olmesartan (Benicar), and olmesartan/amlodipine/hydrochlorothiazide (Tribenzor), and the cholesterol-lowering agent colesevelam (Welchol).

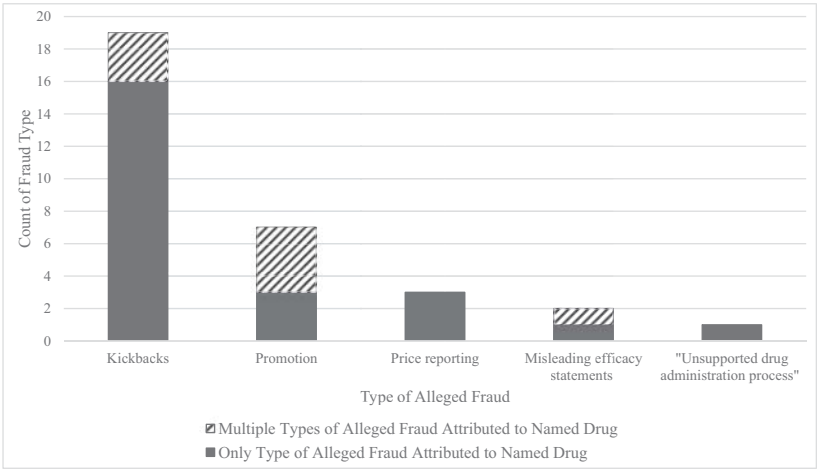
### Antineoplastic and Immunomodulating Agents

Of named antineoplastic and immunomodulating agents, immunosuppressants (15) and antineoplastic agents (10) were the most common drug types, and kickbacks were the most common type of alleged fraud (19 instances) (fig. 7). Most alleged kickback violations (11; 58%) involved companies' use of foundations as conduits to fund the copays of patients. This is perhaps not surprising because many drugs in this class are expensive physician-administered products. A 2018 settlement "alleged that Pfizer



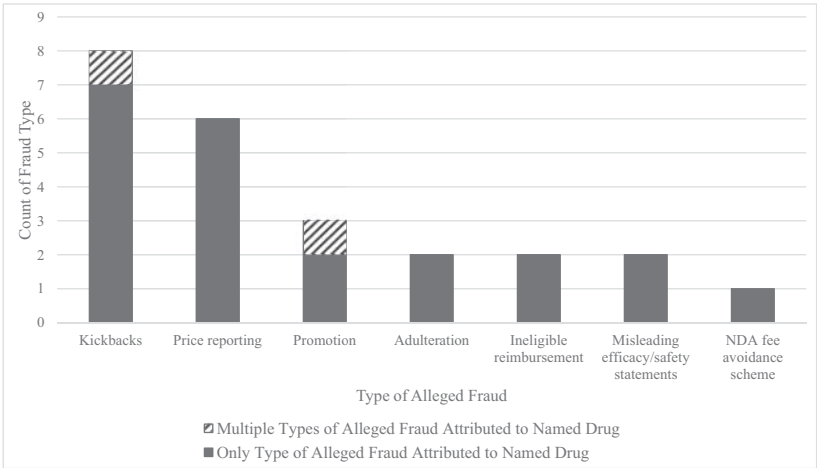
**Figure 6** Alleged fraud attributed to cardiovascular system drugs, 2006–2022.

Source: US Department of Justice press releases.



**Figure 7** Alleged fraud attributed to antineoplastic and immunomodulating agents, 2006–2022.

Source: US Department of Justice press releases.



**Figure 8** Alleged fraud attributed to alimentary tract and metabolism drugs, 2006–2022.

*Note:* NDA=new drug application.  
*Source:* US Department of Justice press releases.

used a foundation as a conduit to pay the copay obligations of Medicare patients taking . . . Sutent and Inlyta, which both treat renal cell carcinoma” (DOJ 2018). All copay foundation settlements were announced in 2018 or later.

**Alimentary Tract and Metabolism**

The most frequently implicated alimentary tract and metabolism products were drugs for gastric acid–related disorders (6) and drugs used in diabetes (5). The most prevalent types of alleged fraud in this class were kickbacks (8 instances) and price reporting (6 instances) (fig. 8). Kickbacks attributed to alimentary tract and metabolism products were primarily inducements to prescribers, such as fraudulent speaker programs and medical education events. Price reporting allegations concerned manufacturers’ misreporting of the prices or classifications of their drugs to federal payers, such as inappropriately classifying a product as a “non-innovator” drug to avoid paying higher Medicaid rebates (DOJ 2009). One example of alleged fraud in this class is GSK’s 2012 settlement, in which the firm resolved allegations that it paid kickbacks to physicians to induce prescriptions of the anti-nausea medication ondansetron (Zofran) and promoted the drug for a use not listed on the product’s FDA-approved label (DOJ 2012).

## Discussion

More than half of all federal pharmaceutical fraud settlement payments from 2006 through 2022 were from six companies (GSK, Purdue, Pfizer, Johnson & Johnson, Novartis, Merck). Some federal fraud actions resolved in this time frame described repeat offenses by the same parent firms, resolving alleged misconduct that implicated a wide array of drug products and therapeutic classes. Nervous system and cardiovascular system drugs were commonly the subject of alleged fraud. DOJ frequently alleged that companies improperly promoted nervous system drugs and paid kickbacks to induce additional prescribing of cardiovascular, antineoplastic and immunomodulating, and alimentary tract and metabolism drugs. The scale of alleged pharmaceutical fraud, including repeated settlements by some large companies, casts doubt on the effectiveness of DOJ's current approach to deterring drug industry fraud and suggests that additional preventive regulations may be necessary to supplement DOJ's efforts.

A small number of repeat defendants paid a disproportionately large share of overall pharmaceutical fraud settlement payments. In many instances, manufacturers or their subsidiaries reached multiple fraud settlements with DOJ, supporting the idea that some large pharmaceutical manufacturers consider the risk of federal fraud payments to be a cost of doing business. As others have noted, companies' profits from misconduct often exceed the penalties DOJ imposes on these firms in fraud settlements (Almashat et al. 2018). Even though a nonzero level of fraud may be consistent with some deterrent effects, the repeated incidence of settlements involving these companies suggests that current antifraud measures do not sufficiently deter companies from engaging in this misconduct. Extending fines or other settlement outcomes to corporate officers in addition to the corporation could enhance deterrent effects, although DOJ has rarely pursued individual responsible corporate officers (Daval, Avorn, and Kesselheim 2022).

The high frequency of settlements implicating nervous system drugs, especially unlawful promotion for off-label or nonmedically indicated uses, illustrates the public health consequences of fraud enforcement policies. Researchers have long recognized overuse of antipsychotic agents and other nervous system drugs as a problem in patient care (Gurwitz, Bonner, and Berwick 2017). We found that manufacturers of psychotropic drugs frequently settled allegations of promoting their products for uses far broader than those listed on products' FDA-approved labeling, potentially contributing to the overuse of these therapies. Companies' improper promotion of antipsychotic drugs likely exacerbated the mortality risks and

other serious adverse events associated with use of these medications, particularly among elderly patients (Huybrechts et al. 2012; Ray et al. 2009; Wang et al. 2005).

Our findings show that DOJ is increasingly pursuing fraud actions aimed at kickback schemes, suggesting a shift in strategy or priorities from previous decades, when cases alleging improper off-label promotion made up the vast majority of settlements. Kickbacks were the most frequently alleged type of fraud in actions concerning cardiovascular system products, antineoplastic and immunomodulating agents, and alimentary tract and metabolism products, with DOJ alleging that manufacturers induced prescribers, copay assistance foundations, and other actors to improperly increase publicly insured patients' use of their products. These inducements interfere with the provider-patient relationship and change clinicians' incentives so that they no longer make medical decisions solely based on patients' needs, contributing to wasteful spending and even bad clinical outcomes (Campbell 2007; Mitchell, Sarpatwari, and Bach 2022). DOJ's heightened attention to kickback violations and pursuit of fewer cases targeting off-label promotion may be a reaction to judicial decisions such as *US v. Caronia* (2012) that recognize robust First Amendment protection of corporate speech. In a post-*Caronia* legal landscape, DOJ may prefer to target kickback violations rather than off-label promotion to avoid the risk of additional adverse rulings on constitutional grounds.

The recent rise of kickback settlements concerning manufacturers' use of third-party foundations to cover Medicare patients' copays, particularly for products used in oncology and to a lesser extent for cardiovascular drugs, is also notable. Such activity helps sustain high drug prices, leading to excess financial costs to the US health system, higher premiums, and decreased use of less expensive alternatives, but it also often helps patients gain access to medicines by lowering their out-of-pocket costs (Ross and Kesselheim 2013; Sinnott et al. 2013).

## Policy Implications

Although public health promotion is not an explicit goal of the False Claims Act, it is notable that federal officials often mentioned protecting patients as a goal or consequence of bringing fraud actions against pharmaceutical manufacturers. In a 2012 press release announcing a settlement, a senior DOJ official stated, "At every level, we are determined to stop practices that jeopardize patients' health, harm taxpayers, and violate the public trust" (DOJ 2012). While protecting public health is an important goal, fraud settlements are not the best way to address systemic failures in

our health care system that put patients at risk. One important limitation of the FCA as a public health tool is that DOJ can only penalize harm after it occurs. The public health harms of pharmaceutical fraud might be better prevented through regulations that proactively safeguard patients from drug companies' misconduct, administered by officials with public health expertise. DOJ's enforcement of antifraud laws should not be considered a substitute for strong preventive public health regulation.

Antifraud statutes such as the False Claims Act are primarily a means of safeguarding taxpayer money, as DOJ's approach to pharmaceutical fraud enforcement reflects. DOJ's frequent use of settlements, financial penalties, and CIAs in pharmaceutical fraud actions generates billions of dollars in pledged recoveries every year for the federal government. DOJ's current antifraud system targets company behaviors that impermissibly waste taxpayer money, siphon funds away from worthy uses, diminish systemwide incentives to develop reliable evidence regarding useful drugs, and erode trust in the health care system. Bringing fraud actions against companies that engage in this behavior helps to minimize waste, protect health care systems, and deter future financial harms (Leder-Luis 2023).

The fact that pharmaceutical companies continue to engage in fraudulent behavior despite these measures indicates that the current antifraud system needs improvements to better deter fraud in the drug industry. Policy makers should reconsider whether methods such as bringing fraud actions to trial, imposing more severe financial penalties or nonfinancial sanctions, or other structural means of altering firms' behavior and incentives could better serve the public interest. For example, DOJ could reevaluate its longstanding use of CIAs. Even though DOJ has included CIAs in settlement agreements with pharmaceutical companies since at least the early 2000s, several companies have settled allegations that they committed fraud when they already had CIAs in place, and still more have settled fraud actions after earlier CIAs expired (Wolfe 2013).

## Conclusion

The federal government's recent enforcement of pharmaceutical fraud has focused on violations likely to result in lucrative settlements. Six firms (GSK, Purdue Pharma, Pfizer, Johnson & Johnson, Novartis, and Merck) accounted for more than half of federal recovery payments in these actions between 2006 and 2022. The most common types of drugs implicated in alleged fraud were nervous system products such as antipsychotics, cardiovascular system products such as antihypertensives, antineoplastic and immunomodulating

agents such as oncology treatments, and alimentary tract and metabolism drugs such as diabetes therapeutics. Improper promotion was the most prevalent type of alleged fraud for nervous system drugs, while kickbacks were the most common alleged violation among cardiovascular, anti-neoplastic and immunomodulating, and alimentary tract and metabolism drugs. Policy makers should ensure that DOJ's pharmaceutical fraud enforcement does not stand in for robust preventive regulation, and they should consider whether reliance on corporation-level financial penalties, rather than pursuing individual responsible corporate officers or other mechanisms, most effectively addresses fraud.

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**C. Joseph Ross Daval** is a postdoctoral fellow with the Program on Regulation, Therapeutics, and Law at Brigham and Women's Hospital. His work examines how public health policy is shaped by federal laws and regulations and covers topics such as FDA advisory committees, pharmaceutical fraud enforcement, and Medicare drug coverage authority.

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## References

- Almashat, Sammy, Ryan Lang, Sidney M. Wolfe, and Michael Carome. 2018. "Twenty-Seven Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 through 2017." Public Citizen, March 14. <https://www.citizen.org/wp-content/uploads/2408.pdf>.
- Arnold, Denis G., Oscar J. Stewart, and Tammy Beck. 2020. "Financial Penalties Imposed on Large Pharmaceutical Firms for Illegal Activities." *JAMA* 324, no. 19: 1995–97.
- Campbell, Eric G. 2007. "Doctors and Drug Companies—Scrutinizing Influential Relationships." *New England Journal of Medicine* 357, no. 18: 1796–97.
- Daval, Charles Joseph Ross, Jerry Avorn, and Aaron S. Kesselheim. 2022. "Holding Pharmaceutical and Medical Device Executives Accountable as Responsible Corporate Officers." *JAMA Internal Medicine* 182, no. 11: 1199–1205.
- DOJ (Department of Justice). 2007. "Bristol-Myers Squibb to Pay More than \$515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing." September 28. [https://www.justice.gov/archive/opa/pr/2007/September/07\\_civ\\_782.html](https://www.justice.gov/archive/opa/pr/2007/September/07_civ_782.html).
- DOJ (Department of Justice). 2008. "Otsuka to Pay More than \$4 Million to Resolve Off-Label Marketing Allegations Involving Abilify." March 27. [https://www.justice.gov/archive/opa/pr/2008/March/08\\_civ\\_244.html](https://www.justice.gov/archive/opa/pr/2008/March/08_civ_244.html).
- DOJ (Department of Justice). 2009. "Four Pharmaceutical Companies Pay \$124 Million for Submission of False Claims to Medicaid." October 19. <https://www.justice.gov/opa/pr/four-pharmaceutical-companies-pay-124-million-submission-false-claims-medicaid>.
- DOJ (Department of Justice). 2012. "GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data." July 2. <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report>.
- DOJ (Department of Justice). 2013. "Johnson and Johnson to Pay More than \$2.2 Billion to Resolve Criminal and Civil Investigations." November 4. <https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations>.
- DOJ (Department of Justice). 2015. "Daiichi Sankyo Inc. Agrees to Pay \$39 Million to Settle Kickback Allegations Under the False Claims Act." January 9. <https://www.justice.gov/opa/pr/daiichi-sankyo-inc-agrees-pay-39-million-settle-kickback-allegations-under-false-claims-act>.
- DOJ (Department of Justice). 2018. "Drug Maker Pfizer Agrees to Pay \$23.85 Million to Resolve False Claims Act Liability for Paying Kickbacks." May 24. <https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks>.
- DOJ (Department of Justice). 2022. "Justice Department's False Claims Act Settlements and Judgments Exceed \$5.6 Billion in Fiscal Year 2021." February 1. <https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year>.



- DOJ (Department of Justice). 2023. "Fraud Statistics—Overview." February 7. <https://www.justice.gov/opa/press-release/file/1567691/download>.
- Eliason, Paul J., Riley J. League, Jetson Leder-Luis, Ryan C. McDevitt, and James W. Roberts. 2021. "Ambulance Taxis: The Impact of Regulation and Litigation on Health Care Fraud." National Bureau of Economic Research, Working Paper No. 29491, November. <http://www.nber.org/papers/w29491>.
- Greenman, Cindy, and Zac Greenman. 2017. "Pharmaceutical Fraud: Off-Label Marketing of Drugs in the United States, 2009–2016." *Research in Economics and Management* 2, no. 5: 198–204.
- Gurwitz, Jerry H., Alice Bonner, and Donald M. Berwick. 2017. "Reducing Excessive Use of Antipsychotic Agents in Nursing Homes." *JAMA* 318, no. 2: 118–19.
- HHS and DOJ (Department of Health and Human Services and Department of Justice). 2022. "Annual Report of the Departments of Health and Human Services and Justice: Health Care Fraud and Abuse Control Program FY 2021." July. <https://oig.hhs.gov/publications/docs/hcfac/FY2021-hcfac.pdf>.
- HHS OIG (Department of Health and Human Services Office of Inspector General). 2023a. "Corporate Integrity Agreement Documents." May 4. <https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp>.
- HHS OIG (Department of Health and Human Services Office of Inspector General). 2023b. "Corporate Integrity Agreements." <https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp> (accessed November 14, 2023).
- Hoffman, Jan, and Katie Benner. 2020. "Purdue Pharma Pleads Guilty to Criminal Charges for Opioid Sales." *New York Times*, October 21. <https://www.nytimes.com/2020/10/21/health/purdue-opioids-criminal-charges.html>.
- Huybrechts, Krista F., Tobias Gerhard, Stephen Crystal, Mark Olfson, Jerry Avorn, Raisa Levin, Judith A. Lucas, and Sebastian Schneeweiss. 2012. "Differential Risk of Death in Older Residents in Nursing Homes Prescribed Specific Antipsychotic Drugs: Population Based Cohort Study." *BMJ* 344: article ID e977. <https://doi.org/10.1136/bmj.e977>.
- Kalb, Paul E. 1999. "Health Care Fraud and Abuse." *JAMA* 282, no. 12: 1163–68.
- Kesselheim, Aaron S., and David M. Studdert. 2008. "Whistleblower-Initiated Enforcement Actions against Health Care Fraud and Abuse in the United States, 1996 to 2005." *Annals of Internal Medicine* 149, no. 5: 342–49.
- Krause, Joan H. 2002. "'Promises to Keep': Health Care Providers and the Civil False Claims Act." *Cardozo Law Review* 23: 1363–1417.
- Krause, Joan H. 2016. "Truth, Falsity, and Fraud: Off-Label Drug Settlements and the Future of the Civil False Claims Act." *Food and Drug Law Journal* 71, no. 3: 401–40.
- Leder-Luis, Jetson. 2023. "Can Whistleblowers Root Out Public Expenditure Fraud? Evidence from Medicare." *Review of Economics and Statistics*, May 29. [https://doi.org/10.1162/rest\\_a\\_01339](https://doi.org/10.1162/rest_a_01339).
- Mitchell, Aaron, Ameet Sarpatwari, and Peter B. Bach. 2022. "Industry Payments to Physicians Are Kickbacks. How Should Stakeholders Respond?" *Journal of Health Politics, Policy and Law* 47, no. 6: 815–33.
- Osborn, John E. 2010. "Can I Tell You the Truth? A Comparative Perspective on Regulating Off-Label Scientific and Medical Information." *Yale Journal of Health Policy, Law, and Ethics* 10, no. 2: 299–356.

- Ray, Wayne A., Cecilia P. Chung, Katherine T. Murray, Kathi Hall, and C. Michael Stein. 2009. "Atypical Antipsychotic Drugs and the Risk of Sudden Cardiac Death." *New England Journal of Medicine* 360, no. 3: 225–35.
- Rodwin, Marc A. 2015. "Do We Need Stronger Sanctions to Ensure Legal Compliance by Pharmaceutical Firms?" *Food and Drug Law Journal* 70, no. 3: 435–52.
- Ross, Joseph S., and Aaron S. Kesselheim. 2013. "Prescription-Drug Coupons—No Such Thing as a Free Lunch." *New England Journal of Medicine* 369, no. 13: 1188–89.
- Sinnott, Sarah-Jo, Claire Buckley, David O’Riordan, Colin Bradley, and Helen Whelton. 2013. "The Effect of Copayments for Prescriptions on Adherence to Prescription Medicines in Publicly Insured Populations: A Systematic Review and Meta-Analysis." *PLoS One* 8, no. 5: article ID e64914.
- Shrank, William H., Teresa L. Rogstad, and Natasha Parekh. 2019. "Waste in the US Health Care System: Estimated Costs and Potential for Savings." *JAMA* 322, no. 15: 1501–9.
- Wang, Philip S., Sebastian Schneeweiss, Jerry Avorn, Michael A. Fischer, Helen Mogun, Daniel H. Solomon, and M. Alan Brookhart. 2005. "Risk of Death in Elderly Users of Conventional vs. Atypical Antipsychotic Medications." *New England Journal of Medicine* 353, no. 22: 2335–41.
- WHO (World Health Organization). 2023. "ATC/DDD Index 2023." January 23. [https://www.whooc.no/atc\\_ddd\\_index/](https://www.whooc.no/atc_ddd_index/).
- Wolfe, Sidney M. 2013. "Escalating Criminal and Civil Violations: Pharma Has Corporate Integrity? Not Really." *BMJ* 347: article ID f7507.

## Appendix

**Table A1** Sums of Recoveries Pledged by Pharmaceutical Manufacturers in Federal Fraud Settlements, 2006–2022

Parent company or company	Actions	Total recoveries pledged
GSK	2	\$3,432,379,245.33
Purdue	1	\$3,217,029,970.66
Pfizer	6	\$3,100,948,571.04
Johnson & Johnson	4	\$2,747,653,234.51
Novartis	6	\$1,838,103,051.45
Merck	3	\$1,808,176,455.91
Abbott*	3	\$1,266,182,510.33
Eli Lilly	1	\$1,133,525,620.08
Mylan	3	\$1,033,075,610.43
Biogen	2	\$932,430,524.40
Amgen	3	\$858,446,416.72
Bristol Myers Squibb	2	\$823,154,522.13
AstraZeneca	4	\$759,105,539.60
Sanofi	4	\$562,576,594.39
Cephalon	1	\$512,785,499.79
Boehringer Ingelheim	2	\$505,054,746.73
Daiichi Sankyo	2	\$499,427,280.16
Allergan	3	\$483,621,969.97
Invidior	1	\$346,393,877.29
Celgene	1	\$342,207,479.19
Mallinckrodt	2	\$288,493,719.87
United Therapeutics	1	\$254,846,181.30
Sun	2	\$254,489,459.06
Endo	1	\$245,548,230.05
Insys	1	\$227,756,175.26
Forest	1	\$204,284,107.28
Astellas*	2	\$126,282,125.24
Otsuka	2	\$125,618,417.38
Gilead	1	\$111,493,353.31
Novo Nordisk	2	\$89,497,565.28
Elan	1	\$81,203,332.32
Shire	1	\$71,012,200.09
Jazz	1	\$66,729,890.28
UCB	2	\$64,338,308.27
Lundbeck	1	\$61,578,811.03
Apotex	1	\$53,000,408.55

(continued)

**Table A1** Sums of Recoveries Pledged by Pharmaceutical Manufacturers in Federal Fraud Settlements, 2006–2022 (*continued*)

Parent company or company	Actions	Total recoveries pledged
CareFusion	1	\$51,286,431.88
Teva	2	\$40,334,653.84
Bayer	1	\$40,318,320.26
GE Healthcare	1	\$39,770,551.95
Aegerion	1	\$34,908,560.52
Par	1	\$28,917,980.18
KV	1	\$22,536,646.11
US WorldMeds	1	\$20,487,247.01
Braun	1	\$20,124,932.04
Bausch & Lomb	1	\$19,264,418.64
Alexion	1	\$15,219,097.78
Cell Therapeutics	1	\$15,197,314.95
Dava	1	\$14,455,005.86
Medicis	1	\$14,102,289.56
Incyte	1	\$14,003,016.40
Kaléo	1	\$13,669,675.62
The Gores Group	1	\$13,220,874.69
Shionogi	1	\$12,949,613.47
Galena	1	\$9,151,376.11
Eisai	1	\$8,656,220.02
Emcure	1	\$8,294,312.20
Akorn	1	\$7,962,868.25
Lehigh Valley Technologies	1	\$4,734,151.98
Cypress	1	\$3,651,722.82
Baxter	1	\$2,658,588.04
Rising	1	\$1,280,623.72
AbbVie	1	Not separately listed in press release
Roche	1	Not separately listed in press release
Astellas	1	Not separately listed in press release
Abbott	1	Not separately listed in press release
Healthpoint and DFB	1	Not separately listed in press release

Source: US Department of Justice press releases.

Notes: Recoveries are adjusted for inflation and reported in January 2023 US dollars.

\* Count of actions and recovery payout total exclude a press release in which DOJ did not report company-specific payouts.