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2025 OIG Year in Review: Part I Life Sciences

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The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG or HHS-OIG) serves as a central force behind health care fraud enforcement. Through investigations, audits, and evaluations—and in close partnership with the Department of Justice (DOJ) on criminal and civil health care fraud matters—HHS-OIG plays a decisive role in shaping health care enforcement landscape and compliance expectations.

This is the first of two articles summarizing HHS-OIG's key work and priorities in 2025. This article provides a high-level overview of significant developments within the agency, major initiatives, and enforcement activity affecting the life sciences industry. The second article will focus on OIG's efforts impacting health care providers. Together, these articles highlight enforcement trends that may inform proactive compliance strategies across the health care sector.

The past year marked a period of significant change at HHS-OIG. On January 24, 2025, President Trump removed 17 Inspectors General, including HHS-OIG Inspector General Christi A. Grimm.[1] As part of the administration-led workforce reductions, OIG's staff decreased by 185 employees—roughly 12% of its staff—within HHS' overall 18% staff reduction.[2] These departures included several senior leadership positions, such as the Chief Counsel to the Inspector General and Deputy Inspector General for Audit Services.

Thomas March Bell was sworn in as the HHS Inspector General on December 22, 2025, and now assumes responsibility for shaping the agency's future direction. Beyond filling key executive leadership positions, Inspector General Bell will influence the agency's oversight priorities. OIG's current Strategic Plan for Fiscal Years (FYs) 2025–2030 identifies oversight of HHS grants and contracts, managed care, and nursing homes as priority areas.[3] During 2025, OIG and HHS jointly announced new enforcement efforts related to information blocking.[4] Looking ahead, Inspector General Bell will determine how—and to what extent—OIG resources are deployed to oversee emerging HHS initiatives, including the administration's Make America Healthy Again agenda.[5]

DOJ and OIG Enforcement Priority Areas

Health care fraud enforcement remains a priority for the Trump administration. In spring 2025, Matthew Galeotti, Head of the DOJ's Criminal Division, announced the Criminal Division's White-Collar Enforcement Plan, stating that the Department was "turning a new page on white-collar and corporate enforcement."[6] Galeotti emphasized a renewed focus on "the most egregious white-collar crime," including fraud affecting federal programs, as well as violations of the Controlled Substances Act and the Federal Food, Drug, and Cosmetic Act.

That emphasis was reflected in DOJ's 2025 announcement of the largest national health care fraud takedown to date.[7] In that coordinated action, 324 criminal defendants were charged in schemes involving more than $14.6 billion in alleged fraud. The scale of the investigation—spanning more than 50 federal judicial districts and involving 12 state attorneys general—underscores both the level of interagency coordination and the government's capacity to deploy significant resources in health care fraud enforcement.

In July 2025, DOJ further reinforced this focus by announcing the formation of the DOJ–HHS False Claims Act (FCA) Working Group.[8] DOJ identified several priority enforcement areas for the group, including Medicare Advantage; drug, device, and biologic pricing and rebates; kickbacks, with particular emphasis on drugs, medical devices, and durable medical equipment; medical device safety; beneficiary access to care; and manipulation of electronic health records.

These enforcement efforts translated into record-setting recoveries.[9] For FY 2025, ending September 30, 2025, the government reported more than $6.8 billion in FCA settlements and judgments[10]—the highest annual total in the statute's history and more than double the $3.1 billion recovered in FY 2024. These results reflect sustained DOJ emphasis on FCA enforcement, particularly in the health care and life sciences sectors, as well as increased whistleblower activity, with relators filing a record number of qui tam actions.

Pharmaceutical Industry

For pharmaceutical and life sciences companies, these developments signal heightened enforcement risk across pricing, rebate structures, product safety, and government program interactions—making robust compliance controls, data governance, and early issue identification increasingly critical as DOJ and OIG continue to align their enforcement priorities. This section highlights FCA enforcement and OIG Advisory Opinions (AO) related to the pharmaceutical industry. As is common in FCA cases, most companies denied the allegations against them.

In 2025, FCA enforcement activity in the pharmaceutical sector focused heavily on allegations arising from speaker programs. As the enforcement actions discussed below demonstrate, payments and other transfers of value to prescribers remain a persistent risk area requiring heightened compliance oversight.

FCA Enforcement

In an FCA settlement, Pfizer paid $59.7 million, on behalf of its wholly owned subsidiary Biohaven Pharmaceutical Holding Company Ltd., to resolve allegations that, prior to Pfizer's acquisition of the company, Biohaven violated the Anti-Kickback Statute (AKS) and the FCA by paying kickbacks to health care providers to induce prescriptions of the migraine drug Nurtec® ODT.[11] DOJ alleged that from March 2020 to September 2022, Biohaven provided improper remuneration through speaker programs that DOJ believe included repeat events offering little or no educational value and attendance by individuals with no legitimate educational purpose. According to DOJ, this conduct resulted in false claims submitted to Medicare and other federal health care programs (FHCPs) and continued until Pfizer acquired Biohaven in October 2022 and terminated the speaker programs.

Gilead Sciences, Inc. paid $202 million to resolve allegations that it provided improper remuneration to health care providers to induce prescriptions of certain HIV medications.[12] DOJ alleged that, from 2011 through 2017, Gilead paid high-volume prescribers hundreds of thousands of dollars in honoraria, meals, and travel expenses through speaker programs. The government further alleged that providers were permitted to attend repeated dinner programs on the same topics that offered minimal educational value.

Finally, Assertio Therapeutics, Inc. agreed to pay $3.6 million to resolve allegations that it violated the FCA in connection with marketing its fentanyl nasal spray, Lazanda.[13] The drug was approved solely for the treatment of breakthrough cancer pain in opioid-tolerant patients. Between 2013 and 2017, Assertio allegedly targeted high-volume prescribers—including individuals flagged for diversion

concerns or were later indicted—through speaker bureau and advisory board arrangements. Assertio also allegedly operated a support program that facilitated insurance approvals, resulting in the submission of false claims for patients who did not have qualifying breakthrough cancer pain.

Taken together, these enforcement actions underscore DOJ's and HHS-OIG's continued scrutiny of pharmaceutical speaker programs, particularly where payments to prescribers correlate with prescribing volume, involve repeat engagements with limited educational value, or include luxury venues and meals. Companies should reassess speaker program design, monitoring, and documentation, with particular attention to fair market value, legitimate business need, audience selection, and post-event auditing, to mitigate AKS and FCA risk in an increasingly coordinated enforcement environment.

2025 AOs Related to the Pharmaceutical Industry

Through the advisory opinion process, health care stakeholders may request OIG's analysis of proposed arrangements to determine whether they present risk under the AKS or the Civil Monetary Penalty (CMP) Law. Although advisory opinions are binding only on the requestor, they provide valuable insight into OIG's fraud-and-abuse risk assessment, including the safeguards OIG views as mitigating enforcement risk. This section briefly summarizes OIG advisory opinions issued in 2025 that are particularly relevant to the pharmaceutical industry.

AO 25-01: Patient Assistance Program Providing Free Drug to Financially Eligible Patients

OIG issued AO 25-01,[14] a favorable opinion regarding a pharmaceutical manufacturer's patient assistance program that provides a Food and Drug Administration (FDA)-approved, intravenously infused drug at no cost to financially eligible patients, including FHCP beneficiaries. Under the program, patients and prescribers must certify that the free drug will not be billed to any payor or patient and that prescribing decisions are based on independent medical judgment. Providers may bill Medicare only for administration services.

Although the arrangement implicates the AKS, OIG concluded it presents low risk because the drug is never billed to FHCPs, prescribers lack a financial incentive to order the product, and the program does not steer patients or providers. The opinion underscores that patient assistance programs may present low AKS risk when they are need-based, non-billable to FHCPs, and supported by safeguards preserving independent prescribing.

AO 25-06: Travel and Lodging Assistance for Pediatric Gene Therapy Patients

OIG issued AO 25-06,[15] a favorable opinion regarding a pharmaceutical manufacturer's need-based program that provides travel, lodging, and related assistance to financially eligible pediatric patients and their caregivers to access a one-time, FDA-approved gene therapy available only at limited treatment centers. The program covers airfare, ground transportation, lodging, and certain incidental expenses for eligible families based on independently verified income and distance criteria, and excludes patients who receive assistance from insurers, treatment centers, or charities.

Although OIG concluded that the arrangement implicates the AKS by providing remuneration to patients and potentially to treatment centers, it determined that the program presents low risk because it removes financial and geographic barriers to medically necessary care, does not promote overutilization given the therapy's one-time administration, and includes safeguards such as income limits, duplication-of-benefits checks, receipt verification, and prohibitions on promotional use. OIG further concluded that the arrangement satisfies the "Promotes Access to Care" exception under the Beneficiary Inducements CMP.

AO 25-07: Manufacturer Coverage of Companion Diagnostic Testing

OIG issued AO 25-07,[16] a favorable opinion regarding a pharmaceutical manufacturer's program that covers the cost of an FDA-approved companion diagnostic test required to prescribe the manufacturer's oncology drug for certain indications. Under the program, the manufacturer pays the laboratory a fixed fee, the laboratory may not bill any other payor, and patients incur no cost-sharing. Eligibility is limited to on-label testing and requires provider attestations of clinical appropriateness, with safeguards including prohibition on third-party billing, non-branded communications, and restrictions on data access to aggregated, de-identified information.

OIG concluded that the arrangement presents low risk of fraud and abuse because it improves access to medically appropriate testing, does not promote overutilization or distort clinical decision making, and may result in patients receiving competing therapies if the manufacturer's drug is not indicated. OIG further concluded that the arrangement satisfies the "Promotes Access to Care" exception under the Beneficiary Inducements CMP.

AO 25-10: Manufacturer Support of Independent Nonprofit Grant Program for Pediatric Therapy

OIG issued AO 25-10,[17] a favorable opinion regarding a therapy company's financial support of an independent nonprofit foundation that provides need-based grants to families of children receiving a "family-powered" therapy. The company donates unrestricted funds, and the foundation independently administers tiered grants—based on prescribed therapy hours and adherence—to help families offset expenses related to supporting the child's care. Eligibility is based on objective financial-need criteria, is provider-neutral, and allows families to use non-company providers or switch providers without losing eligibility.

OIG concluded that the arrangement presents low risk of fraud and abuse because grants are available only after therapy has begun, are intended to offset ancillary expenses rather than induce therapy initiation or expansion, and are administered by an independent charity with no company involvement in eligibility or award decisions. OIG also found that the arrangement does not raise beneficiary inducement concerns and is unlikely to result in inappropriate steering or unfair competition.

AO 25-11: Vaccine Discount and Rebate Structures

OIG issued AO 25-11,[18] a favorable opinion regarding a biopharmaceutical manufacturer's discount and rebate arrangements for vaccines reimbursable under Medicare Parts B and D and other FHCPs. The arrangements include upfront discounts, volume- or market-share based discounts, and certain bundled discounts and rebates across multiple vaccines, including products reimbursed under different

payment methodologies. The manufacturer implemented safeguards such as written contract terms and reporting notices; detailed invoicing, training, and monitoring of personnel; and prohibitions on "marketing the spread," product swapping, and non-price inducements.

OIG concluded that straightforward upfront discounts and single-product purchase-requirement discounts satisfy the discount safe harbor when properly documented and reported. Although some bundled arrangements did not technically meet the safe harbor, OIG determined they present low fraud and abuse risk because discounts are transparent, clearly attributable to specific vaccines, and do not involve below-cost pricing to induce purchases of other products.

Medical Device Industry

FCA Enforcement

FCA enforcement in the medical device sector remained robust in 2025, with DOJ continuing to pursue cases involving alleged kickbacks, product safety and quality failures, and improper reimbursement claims tied to medical necessity. As noted above, most companies denied the government's allegations. These matters reflect sustained enforcement focus on manufacturers' obligations not only to ensure that devices meet FDA and safety requirements, but also to ensure that marketing practices, reimbursement representations, and financial relationships with clinicians do not result in the submission of false claims to FHCPs. The following cases highlight how DOJ and HHS-OIG continue to use the FCA to police the intersection of device safety, regulatory compliance, and reimbursement integrity.

Aesculap Implant Systems, LLC agreed to pay $38.5 million to resolve FCA allegations that, from 2010 through 2023, it sold the VEGA Knee System while allegedly knowing the implants were prone to premature loosening and failure at an unacceptably high rate.[19] DOJ alleged that the defects rendered the devices not "reasonable and necessary" for knee replacement surgeries, resulting in false claims to Medicare and Medicaid. According to DOJ, Aesculap learned shortly after launch that bone cement did not properly adhere to the implant, failed to disclose or remediate the issue, inadequately tracked and reported adverse events, and continued sales without corrective action. Aesculap stopped selling its knee replacement devices in the United States in April 2024. DOJ also alleged that Aesculap violated the AKS by providing consulting payments, international travel, and entertainment to a Georgia orthopedic surgeon to induce use of the VEGA system. Separately, Aesculap entered into a non-prosecution agreement related to distributing two additional devices without FDA clearance in 2017, stemming from an employee's failure to submit required documentation and alleged document forgery. That employee pleaded guilty and was sentenced to prison.

Semler Scientific, Inc. agreed to pay $29.75 million, and its former distributor Bard Peripheral Vascular, Inc. agreed to pay $7.2 million, to resolve FCA allegations that they caused false Medicare claims for photoplethysmography tests performed using the FloChec and QuantaFlo devices.[20] DOJ alleged that the devices do not perform an ankle-brachial index test, which is required for Medicare reimbursement under applicable CPT codes. According to DOJ, Semler nevertheless marketed the devices as Medicare-reimbursable, despite FDA guidance indicating otherwise, and continued doing so after receiving third-party warnings regarding reimbursement risk. Semler also entered into a five-year Corporate Integrity Agreement (CIA) with HHS-OIG.[21]

Exactech, Inc. agreed to pay $8 million to resolve FCA allegations that it knowingly sold defective knee replacement components that were not reasonable and necessary for surgeries reimbursed by Medicare, Medicaid, and the Department of Veterans Affairs.[22] DOJ alleged that, from 2008 through 2018, Exactech continued marketing and selling a finned tibial tray component despite knowing it failed prematurely at an unacceptably high rate. DOJ further alleged that, from 2019 through 2022, Exactech similarly marketed and sold Logic and Truliant knee systems with defective polyethylene components that also failed prematurely. The settlement was approved by the U.S. Bankruptcy Court for the District of Delaware as part of Exactech's Chapter 11 proceedings.

Diopsys Inc. agreed to pay up to $14.25 million to resolve FCA allegations related to vision testing services.[23] DOJ alleged that, from 2015 through 2021, Diopsys promoted use of its FDA-cleared NOVA device for electroretinography testing—an unapproved and medically unnecessary use—despite the device being cleared only for visual evoked potential testing. DOJ further alleged that Diopsys made substantial unsubmitted changes to the device that required additional FDA clearance.

2025 AOs Related to the Medical Device Industry

AO 25-04: Payment of Third-Party Compliance Screening Costs for Customers

OIG issued AO 25-04,[24] an unfavorable opinion regarding a medical device manufacturer's proposal to pay third-party compliance screening and monitoring fees on behalf of its hospital and health system customers. Under the proposal, the manufacturer would cover costs that customers would otherwise incur themselves for exclusion screening and related compliance services as a condition of doing business.

OIG concluded that the arrangement would constitute prohibited remuneration under the AKS because it relieves customers of routine operational expenses and could induce purchases of the manufacturer's federally reimbursable devices. OIG found that no safe harbor applied and expressed concern that the arrangement could promote inappropriate steering, unfair competition, and reliance on the screening vendor as a gatekeeper to continued business relationships.

AO 25-05: Reimbursement of Costs Associated with Needle Stick Injuries Under Device Warranty

OIG issued AO 25-05,[25] a favorable opinion regarding a medical device manufacturer's proposal to reimburse purchasers for certain documented costs arising from needle stick injuries caused by device failure. Although the arrangement implicates the AKS, OIG concluded that it satisfies the regulatory warranty safe harbor.

Under the proposal, the manufacturer would reimburse purchasers up to $2,500 for actual, documented costs attributable to device failure, but not user error, pursuant to a one-year product warranty. The warranty excludes services, medical expenses for FHCP beneficiaries, and any conditions tied to purchasing volume or exclusivity. OIG determined that these limitations place the arrangement squarely within the warranty safe harbor.

AO 25-08: Payment of Third-Party Portal Licensing Fees for Bill-Only Device Transactions

OIG issued AO 25-08,[26] an unfavorable opinion regarding a medical device manufacturer's proposal to pay third-party portal licensing fees so its field representatives could access a "bill-only" purchasing platform used by certain provider customers. Although the manufacturer does not require third-party software to process bill-only transactions, some customers required portal access as a condition of doing business, with licensing fees estimated at approximately $1.2 million annually.

OIG concluded that the arrangement would constitute prohibited remuneration under the AKS because it shifts costs that primarily benefit customers and is intended to retain or expand business where portal access functions as a de facto condition of purchasing. OIG found that no safe harbor applied, emphasized the lack of commercial necessity and safeguards, and cited risks of inappropriate steering and anticompetitive effects.

AO 25-09: Physician Ownership Interests in a Medical Device Company

OIG issued AO 25-09,[27] a favorable opinion regarding a medical device company's ownership structure that includes physician investors who may order, purchase, or recommend the company's stroke-treatment devices. Although the arrangement implicates the AKS, OIG concluded that it satisfies the small entity investment safe harbor.

The requestor certified that referral-capable investors hold no more than 40% of any class of investment interests, that physician investors receive interests on the same terms as other passive investors, and that investment opportunities and returns are not tied to referral volume or value. OIG concluded that, based on these safeguards and the absence of profit distributions unrelated to capital contributions, the arrangement does not involve prohibited remuneration.

Conclusion

In 2025, HHS-OIG continued to play a central role in shaping health care enforcement priorities, with a particular focus on life sciences companies operating at the intersection of pricing, marketing, patient access, and federal reimbursement. As this review highlights, DOJ and OIG maintained robust coordination across criminal, civil, and administrative enforcement, resulting in record FCA recoveries and sustained scrutiny of speaker programs, device safety, and reimbursement practices. At the same time, OIG's AOs provide important guidance on how drug and device companies can structure patient assistance, diagnostic support, grant funding, discount arrangements, and ownership interests to mitigate fraud and abuse risk—while also signaling clear boundaries where cost-shifting, inducements, or anticompetitive effects remain enforcement priorities.

Together, these developments underscore an enforcement environment that rewards careful program design, strong internal controls, and early identification of compliance risk, particularly as DOJ and OIG continue to align their priorities and deploy significant investigative resources. Next month, Part II of this Year in Review will turn to OIG's 2025 work affecting health care providers, examining enforcement actions with direct implications for hospitals, physicians, and other providers navigating medical necessity, reimbursement integrity, and evolving oversight expectations.

About the Authors

Lisa Re is a nationwide authority on health care fraud enforcement and compliance. She held key executive leadership roles during her twenty-year career at the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG), including Assistant Inspector General for Legal Affairs and Acting Chief Counsel. Her practice focuses on health care regulatory and enforcement matters, particularly involving OIG investigations, compliance, and government oversight.

Lisa served as HHS's representative for False Claims Act cases and spent years coordinating with the U.S. Department of Justice on these matters. She led OIG's administrative litigation and exclusion program, established enforcement priorities, and oversaw OIG's self-disclosure protocol. Lisa was also responsible for OIG's compliance policy and Corporate Integrity Agreement (CIA) enforcement, helping to strengthen the agency's oversight of the pharmaceutical, biotech, and medical technology industries.

Lisa has deep expertise advising on complex issues and laws, such as the Anti-Kickback Statute, Civil Monetary Penalties law, Emergency Medical Treatment and Labor Act, Information Blocking, and the Exclusions Statute. As a compliance authority, she signed, negotiated, monitored, and enforced OIG's CIAs. This sophisticated knowledge helps clients establish compliance programs and identify vulnerabilities to protect health care organizations from fraud liability.

Lori Wright counsels clients on a broad range of regulatory and transactional matters in the health care industry, primarily focusing on health care regulatory matters related to the expansion and acquisition of provider entities. She has experience advising health care organizations, health care professionals and private equity firms on a variety of regulatory issues, including licensure and certification of health care facilities, corporate practice restrictions, Medicare and Medicaid program participation requirements, telehealth and telemedicine, and federal and state health care fraud, abuse and self-referral laws.

Lily Cao focuses her practice on a range of life sciences and health care matters. She counsels clients on regulatory, compliance, transactional, and legislative issues. Lily graduated *cum laude* from the University of California College of the Law, San Francisco, where she served as a health law research assistant and a teaching assistant. During law school, Lily also served as an extern at AHLA, an intern at a major medical device company, and an extern at two global law firms. Prior to attending law school, she worked as a health care practitioner and later transitioned into business and operational management roles in the medical device industry.

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