

ENFORCEMENT TRENDS ACROSS THE HEALTHCARE INDUSTRY



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Enforcement Environment

- False Claims Act
- Civil Monetary Penalties
- Data Analytics
- Interagency Cooperation
- Parallel Investigations
- Individual Accountability
- Regulatory Enhancements
- Overpayment Liability
- Department of Justice
- Office of Inspector General
- Office for Civil Rights
- State Attorney General
- State Office of Inspector General
- Commercial Payors
- Competitors
- Whistleblowers

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The False Claims Act

- The False Claims Act continues to be a primary tool for enforcement in the healthcare industry.
- \$2.2 billion in FCA recoveries in 2022. The government and whistleblowers were party to 351 settlements and judgments—the second highest number in a single year.
- Majority of FCA claims involve healthcare providers and entities.
- 948 new FCA cases were filed in 2022 (a significant increase from prior years).
 - 652 new *qui tam* actions filed.
 - 296 non-*qui tam* actions filed (the highest since 1993).
- \$489 million awarded to whistleblowers.

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Physician Speaker Programs

- **Biogen Settles for \$900 Million to Resolve Kickback Allegations.**
 - According to the relator’s complaint, from Jan. 1, 2009, through March 18, 2014, Biogen offered and paid remuneration, including in the form of speaker honoraria, speaker training fees, consulting fees and meals, to health care professionals who spoke at or attended Biogen’s speaker programs, speaker training meetings or consultant programs to induce them to prescribe the certain drugs in violation of the Anti-Kickback Statute.
 - The suit alleged that Biogen hosted thousands of speaker programs, for which it paid speakers substantial fees and provided expensive meals and alcohol, typically at high-end restaurants and venues, including resorts, casinos, and country clubs.
 - The suit also alleged that nearly 200 providers who were treated to an all-expenses-paid weekend training event did not ultimately give a presentation on Biogen products.

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Physician Speaker Programs

- **Biogen Settles for \$900 Million to Resolve Kickback Allegations.**

- Many programs were allegedly held without using any slide deck on Biogen drugs, and when slide decks were utilized, the content was alleged to be repetitive of earlier trainings.
- Biogen allegedly inflated its poorly attended events by inviting individuals with no legitimate business need to attend or with repeat attendees.
- Biogen allegedly rejected a valuation advisors' fair market value (FMV) rate proposals and provided significant travel compensation to speakers even when events were held within walking distance of their offices.
- This was a declined case. The Relator received \$250 million.

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Physician Training Program

- **Biotronik Agrees to Pay \$12.95 Million to Settle Allegations of Improper Payments to Physicians.**

- Biotronik allegedly abused a new employee training program by paying physicians for an excessive number of training sessions and, in some cases, for training events that either never occurred or were of little or no value to trainees.
- Biotronik allegedly made these payments despite concerns raised by its own compliance department, which warned that: (1) salespeople had too much influence in selecting physicians to conduct new employee training and (2) "training payments" to physicians were being over-utilized.
- Biotronik also allegedly paid for lavish meals and other events for physicians, with a lack of controls and often no legitimate business discussions.

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