



# Compliance

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## Culturally appropriate compliance in rural Alaska

**an interview with Michael Cruz**  
Director of Quality, Compliance and Privacy  
Kenaitze Indian Tribe  
Dena'ina Wellness Center  
Kenai, Alaska

*See page 16*



**22**

**A new era of laboratory fraud, Part 1: Operation LabScam redux**

Douglas E. Roberts, Marc S. Raspanti, and Pamela C. Brecht

**29**

**Reporting quality data: Getting it right**

Lynn Asher

**35**

**Medical records access: Are you following the rules?**

Elizabeth A. Kastner and Jessica Hudson Bechtel

**43**

**Creating an ambassador program for continuing compliance training**

Maggie Perritt

by Douglas E. Roberts, Marc S. Raspanti, and Pamela C. Brecht

# A new era of laboratory fraud, Part 1: Operation LabScam redux

- » The Biodiagnostics cases have brought lab fraud back into the news.
- » Twenty years ago, Operation LabScam returned more than \$800 million to taxpayers.
- » HHS-OIG targeted questionable billing practices, upcoding, and kickbacks to physicians.
- » Large settlements and corporate integrity agreements were supposed to deter fraud.
- » Fines paid by labs are some of the largest settlements ever recovered under the False Claims Act.

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In the 1990s, a series of *qui tam* law suits, along with an enduring, multi-agency government investigation, returned more than \$800 million to the government coffers from clinical laboratories that had (1) billed Medicare and other government healthcare programs for medically unnecessary tests, upcoded tests, and tests that were never conducted; and (2) provided kickbacks to physicians who referred patients for the illegal testing. “Operation LabScam,” as the government called its investigation and the related suits, was supposed to reform the entire laboratory industry. But two decades later, a new rash of lab-based fraud and abuse has emerged. This article traces industry fraud from Operation LabScam to its current incarnation and discusses the enforcement responses that may be on the horizon.

## The Biodiagnostics cases

Laboratory fraud has returned to the public eye through one brazen scam, with its salacious

details and consequent criminal prosecutions. The government’s filing documents are a study in cinematic largess. A parking lot full of exotic vintage cars, some worth up to \$600,000; hundreds of thousands of dollars spent on chartered jets; a \$700,000 Manhattan apartment for a “female companion”; and personal seat licenses for the Philadelphia Eagles, Pittsburgh Steelers, and the New York Jets—three teams that typically play on the same day many miles apart from one another. These were the fruits of a massive scam orchestrated over a seven-year period, from 2006 to 2013, by David Nicoll and his Parsippany, New Jersey-based lab, Biodiagnostics Laboratory Services, Inc.

Biodiagnostics bribed doctors in three states to refer patients to the lab for medically unnecessary testing. The illegal kickbacks took many forms, including sham consulting fees, above-market payments for blood-processing services, and phony leases, pursuant to which Biodiagnostics



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placed its phlebotomists in physicians' offices and paid for far more space than the blood draw operations occupied. Government healthcare programs and private insurers funded the scam, paying Biodiagnostics in excess of \$100 million, according to the U.S. Attorney's Office for the District of New Jersey.

The Biodiagnostics scam resulted in a mass prosecution of laboratory executives and associates and, notably, physicians. Indeed, U.S. Attorney Paul Fishman called it "the largest number of medical professionals ever prosecuted in the same case."<sup>1</sup> Thirty-nine individuals involved in the Biodiagnostics scam have pleaded guilty to criminal charges, and at least one more is being prosecuted. Among those convicted are 26 doctors and one physician's assistant who profited from kickbacks. Many of those healthcare professionals were sentenced to prison time that can be measured in years, and not just months. The New Jersey physician who led the scheme in kickbacks received an admitted \$1.8 million and was slapped with a sentence of 63 months' (more than five years') imprisonment.<sup>2</sup>

Of course, Biodiagnostics and its principals profited most from the fraud. The \$1.8 million in kickbacks referenced above were a fraction of the \$6 million that Medicare, Medicaid, and private insurers paid for the medically unnecessary tests that the now-former physician referred to Biodiagnostics. Under the federal sentencing scheme, fraud sentences are driven by "loss amount," and specifically the amount of pecuniary harm that is reasonably foreseeable to the defendant. And in the Biodiagnostics case, the person in the position to foresee the greatest loss amount was the company's president, Nicoll. In June 2013, he pleaded guilty to one count of conspiracy to commit bribery, in violation of 18 U.S.C. § 371; and one count of money laundering, in violation of 18 U.S.C. § 1956(a)(1)(B)(1).<sup>3</sup> Nicoll also agreed to forfeit \$50 million in cash and

possessions, including the aforementioned luxury cars. Nicoll has yet to be sentenced, in part because his wife and "female companion" have fought to keep real property that the government claims is subject to forfeiture. But according to media reports, Nicoll's sentencing range under the advisory U.S. Sentencing Guidelines may be as high as 210 – 262 months' (17.5 – 21.8+ years') imprisonment.

Consistent with its usual practice in high-profile cases, the Department of Justice (DOJ) has deemed the criminal prosecution as evidence of its commitment to fighting the crime at issue. The Biodiagnostics case, per U.S. Attorney Fishman, "shows how pervasive [laboratory fraud] can be."<sup>4</sup> The scope of the prosecution, and the fact that doctors—and not just the lab or its executives—were prosecuted criminally "have made people in the profession sit up and take notice and made the deterrent message that much louder."

### Operation LabScam and its aftermath

Fifteen years ago, the government thought the "deterrent message" regarding laboratory fraud had been received. And it had good reason to believe that was the case. From 1992 through the end of the decade, so-called "Operation LabScam" resulted in a federal recovery of more than \$800 million from laboratories that charged government healthcare programs—Medicare, Medicaid, the Federal Employee Health Benefits Program, Tricare, and others—for millions of blood tests that were not medically necessary, not ordered by physicians, or not performed.

At its core, Operation LabScam was a series of four lawsuits and settlements under the federal False Claims Act (FCA),<sup>5</sup> that spanned from 1992 to 1997. Its impetus was a \$111 million settlement with National Health Laboratories (NHL)—then one of the nation's largest providers of clinical diagnostic testing. At the time, it was the largest settlement

ever reached between the government and a healthcare provider. In addition, NHL and its president, Robert Draper, pleaded guilty to two counts of submitting false claims to Medi-Cal and the U.S. Civilian Health and Medical Program. Draper was sentenced to five months' imprisonment, though he was eligible for home confinement at the end of three months.

According to court filings, NHL manipulated doctors into ordering medically unnecessary tests for iron and cholesterol, as part of a basic panel of bloodwork. Through a process called "unbundling," NHL then billed government healthcare programs and insurers for the tests separately from the bills for the basic panels. Prosecuting U.S. Attorney, William Braniff from the Southern District of California dubbed this practice a "primary reason" for escalating costs for insurance providers.<sup>6</sup> At the time of settlement, NHL claimed, through its counsel, that it had done nothing different from its competitors.

That contention proved to be accurate. Over the next few years, the three largest independent clinical laboratories in the nation paid large monetary civil settlements to resolve *qui tam* lawsuits. In 1996, Laboratory Corporation of America (LabCorp) and Damon Clinical Laboratories, Inc. (Damon) settled FCA claims arising from schemes—similar in substance to NHL's—to bill government healthcare programs for medically unnecessary tests and tests that were not performed. LabCorp paid \$187 million for the conduct at two laboratories it purchased, Roche Biomedical Laboratories and Allied Clinical Laboratories.<sup>78</sup> It also agreed to enter into pre-trial diversion to avoid criminal charges. Damon paid \$119 million, \$84 million to settle the FCA case and \$35 million in fines to resolve a criminal prosecution for the same conduct. Though no individuals were convicted, Damon pleaded guilty to one count of

conspiracy to defraud the federal government and was prohibited from participating in most government healthcare programs thereafter.<sup>9</sup>

The turn of the calendar to 1997 brought one of the largest civil FCA settlements ever, and the largest healthcare FCA settlement by an order of magnitude. In February, SmithKline Beecham Clinical Laboratories paid \$334 million, which included interest, to settle two whistleblower lawsuits that were consolidated in the U.S. District Court for the Eastern District of Pennsylvania.<sup>10,11,12</sup> The SmithKline Beecham fraud was larger in scope than, though similar in character to, the conduct undertaken by NHL, Damon, and LabCorp. SmithKline Beecham billed insurers and government healthcare programs for tests that were not performed, added tests to "automated chemistry" profiles and then billed separately for those tests, double-billed for tests, and paid illegal kickbacks to healthcare professionals who referred patients for testing.

The fraud came to light primarily due to the efforts of relator Robert J. Merena of Reading, Pennsylvania. Merena, a long-time senior billing systems analyst at SmithKline Beecham, filed the first FCA lawsuit against SmithKline Beecham. He provided detailed evidence, including reams of corporate billing records, to the government. In addition, he spent hundreds of hours over the course of a year helping FBI agents sort documents, interpreting evidence, and suggesting witnesses to be interviewed. Although the government fought to limit the relator share, the court awarded Merena and the relator from the second-filed *qui tam* case, Dr. Charles Robinson, \$52 million in total. At the time, it was the largest sum awarded to relators under the FCA.

In the afterglow of the SmithKline Beecham settlement, then-Secretary of the Department of Health and Human Services (HHS) Donna Shalala called Operation LabScam "a clear success story."<sup>13</sup> Beyond the

financial recoveries, the government claimed that substantial industry-wide reform would flow from the FCA settlements. The laboratories involved enter into what then-U.S. Attorney General Janet Reno dubbed, “extensive corporate integrity agreements that are designed to prevent the abuse from occurring again.” More broadly, the HHS Office of the Inspector General (HHS-OIG) rolled out compliance plans designed to educate labs and other healthcare providers about their obligations when billing programs like Medicare and Medicaid in order to protect those programs from fraud, abuse, and waste. In concert with promoting voluntary compliance efforts, Shalala asserted that the federal government would have a “zero tolerance policy” concerning laboratory fraud.

And whether due to education, reform, the deterrent effect of prosecution and litigation, or a combination of all those things, laboratory fraud appeared to recede significantly in the early 2000s. Annual reports from the Centers for Medicare and Medicaid Services (CMS), issued pursuant to the Clinical Laboratory Improvement Act,<sup>14</sup> showed relatively few laboratories that were convicted of fraud-related offenses under federal or state law or that had been excluded from Medicare or Medicaid for committing fraud and abuse.

HHS-OIG, the OJ, and FCA litigants shifted their enforcement efforts to other sectors, like Big Pharma. Pharmaceutical industry leaders like Pfizer, Abbott Laboratories, Johnson & Johnson, and the aforementioned SmithKline each paid settlements in the billions of dollars to resolve criminal charges and civil claims alleging kickbacks and off-label marketing. ©

Part 2 of this article will appear in the October issue of *Compliance Today*.

1. Peter J. Sampson: “N.J. Medical Bribery Scam Reached Grand Scale” *NorthJersey.com*, May 26, 2015. Available at <http://bit.ly/2aol4W>.
2. *United States v. Santangelo*, Case No. 2:13 CR 485-SRC (D.N.J.), Dkt. # 41 (Judgment).
3. *United States v. Nicoll*, Case No. 2:13 CR 385-SRC (D.N.J.), Dkt. # 37 (Transcript of Plea Hearing).
4. *Ibid*, Ref #1
5. Federal False Claims Act 31 U.S.C. § 3729 et seq.
6. Calvin Sims: “Company to Pay \$111 Million in Health-Claims Fraud Suit” *New York Times*, December 19, 1992. Available at <http://nyti.ms/2a2GY5t>
7. *United States ex rel. LaCorte v. Roche Biomedical Labs., Inc.*, Case No. 2:96-cv-417-NCT. Available at <http://bit.ly/2af4boB>
8. Department of Justice, press release: “DOJ and HHS Highlight Latest Efforts to Fight Fraud by Clinical Laboratories” February 24, 1997. Available at <http://bit.ly/2aeLUUL>
9. *United States v. Damon Clinical Labs.* Case No. 1:96-cr-10256-REK. Available at <http://bit.ly/2arFIC6>
10. *United States ex rel. Merena v. SmithKline Beecham Corp.*, Case No. 2:93-cv-5974-VA. Available at <http://bit.ly/2ajbNqI>
11. *United States ex rel. Grossenbacher v. SmithKline Beecham Corp.*, Case No. 2:95-cv-6953-VA (E.D. Pa.) See <http://bit.ly/2at0hKE>
12. False Claims Resource Center: “SmithKline Beecham Clinical Laboratories, Inc. Pays \$334 Million in a Historic Settlement” Available at <http://bit.ly/2af4DTu>
13. *Ibid*, Ref #8
14. Clinical Laboratory Improvement Amendments. See <http://bit.ly/2aeJUFr>

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