Health Care Innovators Under the Microscope: Important Takeaways Concerning Federal Research Grants and Contracts in the Face of Increased Law Enforcement Scrutiny

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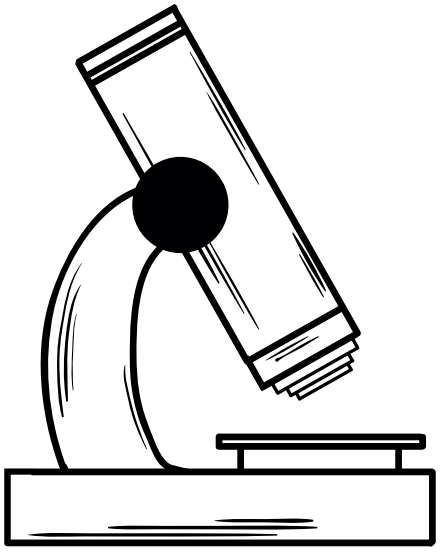
In January 2015, the U.S. Department of Justice made headlines when it brought criminal charges against a San Diego biotech company for alleged widespread accounting fraud arising from several grants and a $50 million contract awarded by the National Institutes of Health (NIH).[1] The company, Ansun Biopharma Inc. (Ansun), received federal grants and contracts from 2004 to 2011 to develop treatments to combat influenza, including an experimental antiviral treatment called Fludase.[2] According to settlement documents, top executives at the company: (1) "fabricated timesheets" for company employees to maximize billing on the NIH grants and contract; (2) billed employee project hours to the NIH contract, even if the project did not fall within the contract's scope; and (3) moved employee hours from nongovernment projects to the NIH-funded grants to recoup money from NIH for work not covered under the awards.[3] Ansun agreed to pay the federal government more than $2 million to resolve the allegations of accounting fraud.[4]

The *Ansun* settlement is noteworthy for two reasons. First, although the health care industry is no stranger to civil lawsuits based on claims of fraudulent accounting,[5] the *Ansun* case serves as a powerful reminder that improper accounting practices also can lead to criminal charges.[6] Second, the settlement comes at a time when the life sciences industry increasingly is under the microscope. The Affordable Care Act and recent Work Plans by the U.S. Department of Health and Human Services Office of Inspector General (OIG) have increased resources for government enforcement,[7] placed a renewed emphasis on accounting fraud,[8] and focused on new technology to identify red flags and outliers in a grantee's accounting records.[9] Moreover, Congress is poised to consider new legislation in 2015—dubbed the 21st Century Cures Initiative—designed to revise the regulatory process surrounding NIH research grants and contracts.[10]

Given the current enforcement environment, the stakes surrounding government-funded research are higher than ever. Recipients of federal grants and contracts therefore would be well-served to vigilantly maintain and enforce their compliance programs and to proactively monitor internal accounting controls.



Brief Reminder of OIG Compliance Guidance

Before addressing the risks associated with increased scrutiny of recipients of federal grants and contracts, it may be useful to provide a brief reminder of the applicable OIG guidance. In 2005, OIG issued recommended compliance guidance to companies seeking federal grants and contracts.[11] At a minimum, the OIG guidance indicates that academic medical centers, research institutions, and other recipients of public health funding awards should consider eight elements to minimize the risks—and potential damage—of improper conduct, like the accounting improprieties alleged in the *Ansun* case.[12] These internal controls and procedures include the following:

- **Written Policies and Procedures That Reflect the Institution's Commitment to Compliance.** Institutions receiving federal awards should develop written policies and procedures to promote compliance with federal grant and contract requirements;[13]
- **Designation of a Compliance Officer.** Every institution should designate a compliance officer with day-to-day responsibility for developing, operating, and monitoring the compliance program.[14] The compliance officer at a research institution should have visibility into, and oversight of, the specific policies and procedures relating to federal funding requirements (e.g., timekeeping policies for employees working on research funded by federal awards);
- **Regular Education and Training Programs.** Federal funding, by definition, comes with proverbial strings attached in the form of strict accounting and reporting requirements. At the outset of a newly funded grant or contract, research organizations should provide training sessions to educate employees about the time and effort reporting requirements, the importance of internal accounting controls, and the available mechanisms for reporting potential fraud and other possible unethical conduct.[15] Such training should be repeated on a periodic basis so that researchers are reminded of the federal

funding requirements throughout the duration of the award.[16] The compliance officer should keep a record of such trainings. If the government ever initiates an enforcement action, such records may assist the institution in defending the effectiveness of its compliance program to federal investigators;[17]

- **Effective Lines of Communication for Complaints and Questions.** For a compliance program to be effective, employees must be able to ask questions and report potential misconduct in a confidential manner.[18] An institution with an effective compliance program that fosters dialogue between its researchers and its managers has the potential to fix mistakes as they arise (and well before any government entity launches an investigation);
- **Clear Definition of Roles and Oversight Responsibilities.** It is critical for an organization to appoint personnel to monitor and enforce the key components of its compliance program, including the internal accounting controls needed to comply with federal awards.[19] The OIG guidance cites this element as the most important for research institutions;
- **Internal Monitoring and Auditing.** OIG recommends the regular use of internal audits and other risk evaluation techniques to monitor compliance and identify problem areas.[20] In the context of federal awards, compliance audits should include reviews of time and effort reporting, accurate submission of expenses, and precise recordkeeping relating to all labor and expenses incurred under the specific grant or contract;
- **Disciplinary Guidelines That Are Both Well-Publicized and Well-Enforced.** An effective compliance program should include specific disciplinary policies for employees or contractors who violate: (1) federal or state funding requirements in the applicable grant or contract; (2) the institution's code of conduct; or (3) the institution's policies and procedures; and[21]
- **Prompt Response and Corrective Action Plan When a Problem Is Detected.** Certain types of misconduct, including failure to comply with federal accounting requirements in grants and contracts, can harm an institution's reputation within the research community and threaten its ability to secure future federal funding for research.[22] As a result, when confronted with credible evidence of fraud or other misconduct, the institution should promptly initiate a privileged investigation to determine whether any misconduct occurred.[23] If the allegations are substantiated, the institution must take decisive action to rectify the problem, which may include disciplining the responsible parties.[24]

High-Risk Areas for Companies Receiving Federal Awards

In its guidance to recipients of federal grants and contracts, OIG specifically highlights three risk areas: (1) time and effort reporting; (2) proper allocation of charges to award projects; and (3) reporting financial support from other sources.[25] The *Ansun* case is a stark reminder of the serious consequences that may await a research institution if it does not take effective measures to protect against noncompliance in these three basic areas. As explained below, even where an institution does not experience misconduct like that alleged in the *Ansun* case, compliance in these high-risk areas is central to an institution's successful participation in public health funding programs.

Time and Effort Reporting

Compensation for the personal services of researchers, both direct salary and fringe benefits, typically is a major cost associated with an NIH grant or contract.[26] Because such a large portion of the federal award goes to labor costs, it is critical that a researcher's time for particular projects is properly recorded and reported, especially when researchers have multiple responsibilities, such as teaching, research, and clinical work.[27] Although it sometimes is difficult to discern the boundaries of a researcher's various activities, accurate time and effort reporting systems are essential to ensure that government funding sources are properly charged for the activities of the researchers.[28]

Step 1

Although basic, the first step in promoting compliance in time and effort reporting is to adopt a timekeeping policy governing the various covered and noncovered employee functions. A clear policy will provide employees with guidance about how to record their time and to which federal award (if any) they should attribute their time.

Step 2

Train employees on the nuances of the timekeeping policy and encourage employees to accurately record their time. For example, it would be improper for an employee at a university medical center to report that she spends 70% of her time on activities covered by an NIH research grant, when that employee dedicates 50% of her time to clinical responsibilities and patient care. Similarly, it would be improper for a researcher to separately report to three different awarding agencies that he intends to spend 50% of his time on each of the three awards. Finally, specific awards may require employees to attribute certain functions to overhead or general and administrative accounting categories. Research institutions can better position themselves to avoid lengthy internal and government investigations by instructing employees not only how to properly categorize their responsibilities, but also how to avoid potential pitfalls in this complicated area.

Step 3

Periodically audit the timekeeping system for both inadvertent errors and potential employee misconduct. A robust audit (either by the compliance officer or an independent auditing firm) before the initiation of an enforcement action or civil lawsuit can identify weaknesses in the system and afford a research institution the opportunity to address any areas of concern without the shadow of a parallel government investigation. Notably, Ansun had a timekeeping policy on paper that required employees to "accurately record the number of hours they devoted to [NIH-funded] projects."[29] In spite of this policy, settlement documents describe how senior executives at the company circumvented the timekeeping requirements and "corrupted the integrity of the time-keeping system by fabricating timesheets for certain employees, altering the number of hours entered on certain timesheets, and moving employee hours from labor category to another."[30]

Properly Allocating Charges to Award Projects

Research institutions commonly receive multiple awards for a single research area,[31] but given the scarcity of federal research funding, OIG guidance deems it "essential" for companies receiving federal awards to have accounting systems that properly separate the amount of funding from each funding source. The guidance also warns that a failure to account accurately for charges to various award projects can result in both civil and criminal investigations.[32] For example, according to the OIG guidance, it would be improper for an institution to make end-of-the-year transfers of direct costs on various federally funded research awards from overspent accounts to underspent accounts, with the purpose of maximizing federal reimbursement and avoiding the refund of unused grant proceeds.

It is important to recognize that, from an enforcement perspective, the "improper allocation of charges to various sources is not a mere 'accounting problem,' in the sense that it has no real impact on the conduct of science."[33] To the contrary, as shown most recently through the *Ansun* case, the failure to correctly allocate expenses can lead to criminal charges, even when there is no dispute about the soundness of the science.[34] According to settlement documents, Ansun personnel altered timesheets and allocated employee hours to various NIH awards without regard to the actual work performed to extend funding under the NIH grants and maximize reimbursement pursuant to the Fludase contract.[35]

Reporting Financial Support from Other Sources

In most cases, a research institution applying for federal funding from NIH must report other financial support as an element of the award application.[36] OIG requires such reporting for two main reasons. First, the awarding agency needs insight into a prospective grantee's funding sources so that it can make an informed decision about the need for public funding, and whether limited funds should be used on other worthy projects also in need of financial support.[37] NIH officials and research stakeholders have faced either flat or reduced budgets for several years, the impact of which has been a scarcity of public research funds.[38]

Second, accurate reporting of all funding sources is necessary to reduce the risk of duplicate funding for certain projects. For example, if an institution fails to report complete and accurate information about other sources of financial support, an NIH grant, Medicare, and a private, secondary health care insurer potentially could pay for the costs associated with a developmental drug in a clinical trial. Multiple funding of a project like this could result in a potential windfall to the research institution. Or, where an institution receives a mix of federal and private grant funding, incomplete reporting could result in the same costs on a project being charged to both funding sources.

This lack of transparency was reported as an issue in the recent *Ansun* settlement. According to court documents, Ansun recorded employee hours dedicated to nongovernment projects on the accounting ledger for NIH grants to receive reimbursement through the NIH grants.[39] Research institutions should implement internal accounting controls that allow researchers and employees to assign project costs to only one funding source, while affording auditors the ability to confirm that such costs are attributed to the proper source of funds.

Conclusion

The *Ansun* case is the most recent example of how health care innovators and research institutions increasingly are under the microscope when it comes to often scarce federal grants and contract awards. It should be noted, too, that while *Ansun* is an indication that the authorities are willing to pursue the most serious of sanctions against companies and research institutions, there also is evidence of a broader trend throughout the enforcement community toward more-expansive enforcement of accounting irregularities.

For example, in 2014, the U.S. Securities and Exchange Commission filed 99 accounting fraud enforcement actions, which marked a 46% increase from the previous year and the first year-over-year increase in accounting fraud actions since 2007.[40] Recent statements by enforcement officials suggest that companies should expect the upward trend of accounting fraud enforcement to continue, and that the overall increase in law enforcement scrutiny of accounting improprieties likely will extend to research institutions that compete for public health funding.[41] Law enforcement attention particularly is likely in light of the fact that NIH recently requested a $1 billion increase for its fiscal year 2016 budget.[42] As research institutions follow the money to expand their federal awards, they should expect that federal agents will not be far behind.

1 Press Release, United States Attorney's Office for the Southern District of California, "ANSUN BIOPHARMA to Pay More Than $2 Million for Overbilling the U.S." (Jan. 7, 2015), *available at* www.justice.gov/usao/cas/press/2015/cas15-0107-ansun.html.

2 *See* Ansun Biopharma, *Description of Fludase Treatment* (Feb. 27, 2015, 9:18 AM), *available at* www.ansunbiopharma.com/fludase-treatment/ (acknowledging receipt of more than $90 million in federal funding for Fludase treatment).

3 Deferred Prosecution Agreement, Ex. A ¶¶ 1-14, *United States v. Ansun Biopharma, Inc.*, No. 15-CR-0024-DMS (S.D. Cal. Jan. 7, 2015).

4 In total, Ansun agreed to pay $1,654,600 to resolve criminal allegations, as well as $495,000 to settle civil claims. *See* Press Release, United States Attorney's Office for the Southern District of California, *supra* note 1.

5 Most allegations of NIH grant and contract fraud arise in the context of civil litigation and qui tam lawsuits. *See, e.g., United States ex rel. Siebert v. Gene Security Network, Inc.*, No. CV-11-1987 (N.D. Cal. April 22, 2011) (clearing an in vitro fertilization testing company, Natera Inc., (formerly known as Gene Security Network) of civil liability following a federal jury trial after Natera's former chief operations officer alleged that the company submitted false claims to the federal government by certifying that it had employed required accounting standards on its grant when, in fact, it had not); *see also United States ex rel. Melissa Theis v. Northwestern Univ.*, No. CV-09-1943 (N.D. Ill. July 30, 2013) (settling civil claims stemming from allegations that a former researcher submitted false claims to NIH seeking reimbursement for personal expenses and purported "consulting" agreements; Northwestern agreed to pay $2.93 million to resolve); *United States ex rel. Resnick v. Weill Medical College of Cornell University*, No. CV-04-3088 (S.D.N.Y. Mar. 6, 2009) (settling allegations brought in a qui tam complaint that Cornell misapplied and fraudulently accounted for NIH grant funds, failed to fully disclose the amount of research funding received, and submitted the same projects for funding under multiple grants; Cornell agreed to pay approximately $2.61 million).

6 For publicly traded companies, accounting improprieties may lead to additional criminal sanctions (e.g., securities fraud) and parallel civil enforcement by the U.S. Securities and Exchange Commission (SEC).

7 The Affordable Care Act included an additional $350 million in program integrity resources over ten years, which can be used during Fiscal Year (FY) 2011 through FY 2020 to hire new OIG agents and enforcement officials. Pub. L. No. 111-148, 124 Stat. 119 (codified as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152 (2010)) (collectively referred to as the "Patient Protection and Affordable Care Act").

8 *See OIG, HHS-OIG Work Plan | FY 2015*, https://oig.hhs.gov/reports-and-publications/archives/workplan/2015/WP15-6%20Public%20Health.pdf (listing oversight of NIH grant and contract awards as top priority).

9 *See id.*; Jean Eagleshem & Michael Rapoport, "SEC Gets Busy With Accounting Investigations," *The Wall Street Journal*, Jan. 20, 2015, *available at* www.wsj.com/articles/sec-gets-busy-with-accounting-investigations-1421797895.

10 *See* H. Comm. on Energy and Commerce, *The 21st Century Cures Act [Discussion Draft] – April 29, 2015*, at 15-17 (2015), *available at* http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/20150429DiscussionDraft.pdf (proposing in Section 1023 to establish a "Biomedical Research Working Group" composed of NIH and stakeholders to provide recommendations on how to streamline the grant process for researchers).

11 Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards, 70 Fed. Reg. 71312, 71312-20 (Nov. 28, 2005) (notice).

12 *See id.* at 71316.

13 *Id.* at 71313, 71316-17.

14 *Id.*

15 *Id.* at 71318.

16 *Id.*

17 *Id.*

18 *Id.*

19 *See id.* at 71320.

20 *Id.* at 71319.

21 *Id.*

22 *Id.*

23 *See id.* at 17319-20.

24 *Id.* at 17320.

25 *Id.* at 71315-16.

26 *Id.* at 71315.

27 *Id.*

28 *Id.*

29 Deferred Prosecution Agreement, *supra* note 3, at Ex. A ¶ 9.

30 *Id.* at Ex. A ¶ 11.

31 *See, e.g., id.* at Ex. A ¶ 3.

32 Draft OIG Compliance Program Guidance, *supra* note 11, at 71315.

33 *Id.* at 71316.

34 Mike Trout, "Ansun Biopharma, Inc. Resolves Government Investigation, Continues Development of Late Phase Investigational Anti-Viral Therapies," Ansun Biopharma Blog Section (Jan. 8, 2015), *available at* www.ansunbiopharma.com/ansun-biopharma-inc-resolves-government-investigation-continues-development-of-late-phase-investigational-anti-viral-therapies/.

35 Deferred Prosecution Agreement, *supra* note 3, at Ex. A ¶ 14.

36 Draft OIG Compliance Program Guidance, *supra* note 11, at 71316.

37 *Id.*

38 Faced with the prospect of limited resources, NIH occasionally partners with private entities, including large pharmaceutical companies and private research funds, to fund time-sensitive research. For example, the National Institute of Allergy and Infectious Diseases, a subdivision within NIH, partnered with pharmaceutical giants GlaxoSmithKline (GSK) and Merck Corporation through the PREVAIL (Partnership for Research on Ebola Vaccines in Liberia) to develop a vaccine to fight the deadly Ebola virus. *See Questions and Answers: PREVAIL Phase 2/3 Clinical Trial of Investigational Ebola Vaccines* (Feb. 2, 2015), *available at* www.niaid.nih.gov/news/QA/Pages/EbolaVaxResultsQA.aspx. The first doses of the vaccine were shipped to Liberia in January 2015 for use in a Phase III clinical trial. *See* Press Release, "GlaxoSmithKline plc, Major Milestone for GSK/NIH Candidate Ebola Vaccine as First Doses Shipped to Liberia for Use in Phase III Clinical Trial" (Jan. 23, 2015), *available at* www.gsk.com/en-gb/media/press-releases/2015/major-milestone-for-gsknih-candidate-ebola-vaccine-as-first-doses-shipped-to-liberia-for-use-in-phase-iii-clinical-trial/.

39 Deferred Prosecution Agreement, *sup*ra note 3, at 6, 10, 13, 14.

40 *See* Eaglesham & Rapoport, *supra* note 9.

41 According to Chairwoman Mary Jo White, SEC "is working to identify areas susceptible to fraudulent financial reporting" through a variety of means, including increased review of restatements and revisions, analysis of industry performance trends, and the implementation of advanced investigative tools. *See* "Oversight of the SEC's Agenda, Operations and FY 2015 Budget Request Before The H. Comm. on Fin. Servs.," 113 Cong. 60-61 (2014) (testimony of Chair Mary Jo White). Similarly, Assistant Attorney General for the U.S. Department of Justice Criminal Division Leslie Caldwell recently described a renewed emphasis on using parallel civil-criminal proceedings to investigate allegations brought by whistleblowers in qui tam cases and described the use of "real time analysis of data" to step up financial and health care fraud prosecutions of corporate and institutional defendants. *See* Remarks by Assistant Attorney General for the Criminal Division Leslie R. Caldwell at the Taxpayers Against Fraud Education Fund Conference (Sept. 17, 2014), *available at* www.justice.gov/opa/speech/remarks-assistant-attorney-general-criminal-division-leslie-r-caldwell-taxpayers-against/.

42 *See* Stephanie Armour & Thomas M. Burton, "Obama Health Budget Calls for Authority to Negotiate Drug Prices," *The Wall Street Journal*, Feb. 2, 2015, *available at* www.wsj.com/articles/obama-health-budget-targets-efficiency-rooting-out-fraud-1422900670.