

DrinkerBiddle

Case Studies in Clinical Research Fraud Enforcement

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Case Study: Site Selection as Alleged Inducement

- > Dr. Gossman employed as interventional cardiologist at Lahey Clinic, teaching hospital affiliated with Tufts University
- > Dr. G alleges that Lahey fired him because he complained that he was pressured to use Medtronic stents and other devices so that Lahey could participate in a clinical trial for a new Medtronic heart valve.
- > Accuses Chair of Cardiology and Director of Interventional Cardiology of pressuring him (and of financial ties to Medtronic)

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Dr. Gossman's allegations:

- > 8/27/09: at a lecture, Dr. G asks:
"If a medical device company approaches a hospital offering access to a new investigational device, but predicates access to the device on increased utilization of other products sold by the company, what would be the position of the IRB regarding the arrangement?"
- > Within hours, Director of Interv. Card. speaks with HR about firing Dr. G
- > 9/9/09: Dr. G is fired, privileges stripped, escorted out by security

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Dr. Gossman's allegations

- > Chairman of cardiology told physicians that failure to increase use of Medtronic stents and other products would jeopardize access to new technologies.
- > Medtronic sales rep allegedly linked increased sales to site selection for clinical trial for heart valve

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Case Study: Site Selection as Inducement

- > Medtronic: The process for selection of research sites was “designed to be fair, objective, and independent of commercial interests.” “We’ve recently been made aware of allegations about that process and are looking into them.”
- > Lahey spokesman: Dr. Gossman’s allegations are “totally groundless,” and he was fired for “misconduct” occurring months earlier.
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Case Study: Site Selection as Inducement

- > Last month, Medtronic announced that the U.S. Attorney’s Office in Massachusetts has launched an investigation of Medtronic’s relationships with the Lahey Clinic cardiologists

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Case Study Review

- > Well-credentialed whistleblower
- > Inter-personal conflicts, other issues
- > Facially coherent allegations from someone in position to know

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Case Study: Relators Drive Enforcement

- > Tara Resnick – Administrative Assistant at Weill Medical College (Cornell Univ.) for eleven years.
- > Resigned in 8/02 and filed *qui tam* action in 4/04.
- > Alleges misconduct on part of her former boss, the Chair of Pharmacology Department (“Dr. G”) regarding multiple NIH and DOD grants for biochemistry/cancer research

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Ms. Resnick's Allegations

1. Dr. G failed to disclose other grants and support, over-committing her professional time.
2. Misrepresented which researchers were working on certain grants
3. Improper accounting of funds for certain grants
4. Falsified data from her research for certain grants
5. Submitted same projects to multiple grants (double-dipped)

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Settlement with U.S.

- > Sept 2007
 - Government intervenes and files complaint making over-commitment allegations as to 8 NIH grants and 1 DOD grant
 - Cornell and U.S. agree to \$2.6 million settlement
 - Settlement and complaint did not address 2 NIH grants and 1 DOD grant
- > Settlement approved by court in March 2009 over Resnick's objections and government's complaint is dismissed

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Case Study: Relators Drive Enforcement

- > Cornell: “All of the funded research in question was performed by Weill Cornell Medical College and resulted in numerous discoveries, publications and other contributions to the body of scientific and clinical knowledge. The government’s claims did not relate to the quality or scientific integrity of the research.”

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Post-Settlement

- > Cornell moved to dismiss Resnick’s complaint due to settlement
- > Court only partially dismissed
 - Siding with Cornell, dismisses all allegations as to grants identified in Government’s Complaint (not just as to over-commitment allegations) under *res judicata*
 - Siding with Resnick, no dismissal as to grants not included in Government’s Complaint

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Case Study Review

- > Interpersonal conflict between relator and head of Pharmacology Department?
- > Relator in a position to know
- > Fairly detailed allegations

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Lessons

- > What to do after an employee raises issues?
- > How can we encourage employees with compliance issues to raise them internally?
- > Please e-mail jesse.witten@dbr.com for an article on "Handling Potential Whistleblowers"

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