



Compliance with the Transparency Requirements: *Any benefit to early compliance?*

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Increasingly Intolerant Enforcement Environment

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- A shift in the balance of power in false claims act litigation in favor of whistleblowers
- An increase in foreign based “anti-kickback statute” investigations, commonly called the FCPA
- Continued aggressive federal enforcement
- A rise in state enforcement
- A changing agency attitude on violations
- A changing agency and prosecution attitude on exclusions
- A desire to use the misdemeanor prosecution authority to ban individuals from the industry



In this environment

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- Is there any incentive for a company to move early to comply?
- What should a company be doing to get ready to comply?
- What problems/issues can the industry expect?
- What additional liabilities may arise from the disclosures?



The Above the Fold impact on customers

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- “The Harvard Brand, unrivaled in education, is also prized by the pharmaceutical industry as a powerful tool for promoting drugs.” *Boston Globe “Prescription for Prestige”*, 10/19/2010, *Liz Kowalczyk*.
- “Doctors and researchers affiliated with Harvard Medical School collected 45% of the \$6.3 million given to Massachusetts doctors in 2009 and 2010 by seven pharmaceutical companies that disclosed their payments for parts of those years.” *Boston Globe “Prescription for Prestige”*, 10/19/2010, *Liz Kowalczyk*.
- “While some doctors … earned \$2,000 to \$3,000, more than two dozen … psychiatrists, endocrinologists and other specialists … brought in \$40,000 to \$100,000 … an allergy specialist, earned the most, \$219,775.” *Boston Globe “Prescription for Prestige”*, 10/19/2010, *Liz Kowalczyk*.

The impact?

- “Christopher Clark, who oversees compliance for Partners, said his staff searched drug company websites and identified 31 of its physicians who had been hired for speakers bureaus. All but two agreed to resign from the bureaus.” *Boston Globe “Prescription for Prestige”, 10/19/2010, Liz Kowalczyk*.
- “Harvard Medical School itself is also prohibiting participation in speaker’s bureaus, effective early next year.” *Boston Globe “Prescription for Prestige”, 10/19/2010, Liz Kowalczyk*.
- “One … physician … a cardiologist at Beth Israel Deaconess … earned the third most … \$126,500 … [He] declined to comment. Hospital spokesman .. acknowledged that the doctor “may have given talks that were not in compliance” but that he resigned from speakers bureaus in August.” *Boston Globe “Prescription for Prestige”, 10/19/2010, Liz Kowalczyk*.
- “… the other reported top earners in Massachusetts were …[the] director of the surgical intensive-care unit at Tufts Medical Center, who earned \$141,209; and … an endocrinologist in Fall River, who made \$109,658. *Boston Globe “Prescription for Prestige”, 10/19/2010, Liz Kowalczyk*.
- Dr. Richard Krugman, vice chancellor for health affairs, said he hoped members would soon consider a policy to clearly ban faculty from delivering talks for drug companies. <http://www.propublica.org/topic/dollars-for-doctors>

The existence of web based sources

- “Dollars for Docs” on www.propublica.org
 - Can see: payments by a doctor’s name, how much total from a company
 - Provides a comparison of reporting by a company to different authorities
- Massachusetts online and searchable database, posted 11/22/2010
 - “Dr. [G], a Boston cardiologist affiliated with Beth Israel Deaconess Medical Center, paid \$188,617 by six companies; Dr. [F], a general surgeon affiliated with Brigham and Women’s Hospital, paid \$187,443 by [L]; Dr. [D], a former Brigham allergist, paid \$153,385 by five companies; and Dr. [M], an orthopedic surgeon affiliated with New England Baptist Hospital and Beth Israel Deaconess, paid \$149,996 by [W]. More than 5,000 doctors received payments.” *Boston Globe Article*, http://www.boston.com/news/health/blog/2010/11/by_liz_kowalczy_2.html?p1=News_links.
 - Site includes prepared reports: Top 20 Manufacturers; Top 50 Physicians; Acute Care Hospitals; Top 100 Covered Recipients, Non-Hospital
 - Reporting breaks payments out by type of payment (charitable donation, compensation for services, training, grants, gifts, marketing studies, food
 - http://www.mass.gov/?pageID=eohhs2terminal&L=6&L0=Home&L1=Provider&L2=Certification%2c+Licensure%2c+and+Registration&L3=Programs&L4=Pharmaceutical+Code+of+Conduct&L5=Data+and+Reports&sid=Eeohhs2&b=terminalcontent&f=dph_quality_healthcare_p_ph_mdm_code_prepared&csid=Eeohhs2
- A different era for reports:
 - Minnesota required reporting in 1993, but “the drug company reports had been simply filed away. Only after researchers and others pressed to see them were they put on the website of the state’s pharmacy board in 2006.” <http://www.propublica.org/article/in-minnesota-drug-company-reports-of-payments-to-doctors-mistaken>

Any growing backlash?

- “Other physicians said they will not be deterred from what they consider a legitimate form of educating colleagues.” *Boston Globe “Prescription for Prestige”, 10/19/2010, Liz Kowalczyk*.
- “N[] gives talks, at least 50 a year, for [two companies] about medicines to treat drug resistant staph infections; Tufts new policy says doctors do not have to control the content of talks, they just have to agree with it. “This is not tobacco,” N[] said. “These are the guys who created penicillin.” *Boston Globe “Prescription for Prestige”, 10/19/2010, Liz Kowalczyk*.
- “We’ve gotten some pushback from doctors,” said Clark, the Partners compliance chief, “but most have said “We know the world has changed.” *Boston Globe “Prescription for Prestige”, 10/19/2010, Liz Kowalczyk*.
- “...doctors paid by pharmaceutical companies are “leaders in their fields,” and patients should want to see their physician among them. “If their doctor is not on the list” he said “maybe they should look for another doctor.”
<http://www.propublica.org/article/in-minnesota-drug-company-reports-of-payments-to-doctors-mistaken>
- [T]he St. Paul pain physician, said his patients aren’t concerned about his speaking fees. The media is lumping together educational speaking with the excesses of the past, he said, when drug companies showered physicians with gifts and free trips. “This is a mountain-molehill thing,” he said. “I know the problems of the past. I know what pharma has done to change those. People just can’t get over the past.”
<http://www.propublica.org/article/in-minnesota-drug-company-reports-of-payments-to-doctors-mistaken>



A concern for accuracy

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- “The Department of Public Health originally listed a University of Massachusetts Medical School psychologist as the health provider who had received the highest payment -- \$250,000. After inquiries by the Globe and a flat denial by the psychologist, the state acknowledged it was an error. The state this afternoon removed the psychologist's name from its database and Boston.com also has removed her name from its story.”

http://www.boston.com/news/health/blog/2010/11/by_liz_kowalczy_2.html?p1=News_links



Process Steps

- Evaluate existing “rules of engagement” (SOPs) for employees:
 - Have they been revised since the transparency rules have been implemented
 - Do they reflect current policy?
 - Will they help capture the data that must be reported?
 - Will they help assure that employees are seeking permission when they must ask for permission?
 - If there are computer forms that must be filled out, do they steer in any way the employee’s choices?
 - Are the various policies consistent with each other?
 - Are the policies covering conduct within the US followed by employees outside the US?
- Implement strategies to check accuracy of the mandated reporting
- Implement strategies to evaluate whether the transparency rules are causing a loss of or diminution in needed physician relationships
- Implement strategies to assure kickback concerns are absent



The Treadmill Impact

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- One resolution against a company sometimes begets many others. Companies on this list will be among those whose payment data is closely scrutinized
 - Aventis
 - 2009: \$95,500,000
 - 2007: \$190,000,000
 - 2001: \$33,100,000
 - Gambro Healthcare
 - 2005: \$37,500,000
 - 2004: \$350,500,000
 - 2003: \$3,000,000
 - 2000: \$53,100,000
 - GlaxoSmithKline
 - 2010: \$750,000,000
 - 2006: \$149,000,000
 - 2005: \$150,000,000
 - 2003: \$87,600,922
 - Novartis (various subsidiaries)
 - 2010: \$422,500,000
 - 2010: \$72,500,000
 - 2005: \$49,200,000
 - 1999: \$8,000,000
 - InterMune, Inc.
 - 2007: \$30,200,000
 - 2006: \$36,900,000
 - Omnicare, Inc.
 - 2009: \$112,000,000
 - 2006: \$49,500,000
 - 2005: \$5,750,000
 - Schering-Plough Corp.
 - 2006: \$435,000,000
 - 2004: \$345,469,482
 - 2004: \$27,000,000
 - 2002: \$500,000,000
 - Tenet Healthcare Corp.
 - 2006: \$900,000,000
 - 2006: \$21,000,000
 - 2004: \$22,500,000
 - 2003: \$54,000,000
 - 2003: \$4,300,000
 - 2002: \$17,000,000
 - 2002: \$29,000,000



Enforcement Realities

- Federal enforcement dollars, given the pressure to cut the federal budget, will not grow
- Potential impact:
 - Enormous sums paid to whistleblowers in 2010 will trigger a flood of new cases
 - Cases will remain under seal longer
 - Companies will be dealing with old matters
 - Settlement of an old matter will make it appear a company has a current problem; that will attract new W-B interest
 - More cases will be handled by whistleblower counsel
 - Government will choose not to intervene, leaving litigation to whistleblower counsel
 - There will be less consistent decision-making in the handling of cases

Your tax dollar

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	Total Recovery	Federal Civil Share	Whistleblower Payment	% share
	72,500,000	43,500,000	7,825,000	18
	81,510,000	50,688,483	9,000,000	17.8
	118,000,000	60,896,476	10,787,392	17.7
	313,000,000	88,000,000	14,000,000	17.5
	108,000,000	108,000,000	23,500,000	21.8
	422,500,000	149,241,306	25,000,000	16.8
	600,000,000	210,250,000	37,800,000	17.9
	302,000,000	262,000,000	45,000,000	17.1
	280,000,000	280,000,000	67,200,000	24
	421,200,000	421,200,000	88,400,000	21
	520,000,000	301,907,007	45,000,000	15
	750,000,000	436,440,000	96,016,800	22
	1,415,000,000	438,171,543	78,870,877	18
	2,300,000,000	668,514,830	102,000,000	15.2
Totals	7,703,710,000	3,518,809,645	650,400,069	18.4