



An Overview of the US Disclosure Laws and Implications for European Pharmaceutical Companies

Is it coming to a theater near you soon?

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Istanbul, Turkey

May 5, 2011

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Increasingly Intolerant Enforcement Environment

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- A shift in the balance of power in the United States in favor of whistleblowers
 - An increase in United States foreign based “anti-kickback statute” investigations, through the Foreign Corrupt Practices Act
 - A spread of the United States disclosure or “transparency” laws to other countries
 - A desire to use the misdemeanor prosecution authority to ban individuals from the industry
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United States Disclosure Requirements

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- “Applicable manufacturers” of a covered “drug, device, biological or medical supply” must report annually to the Secretary, commencing in March, 2013, certain payments in excess of \$10 (or annually in excess of \$100 in the aggregate) made to a “covered recipient.” These disclosures must be made annually by the end of March and cover only the prior year.
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Specifics that must be included:

- The amount of the payment, the date paid, and a description of the form of the payment (whether, e.g., in stock, cash, or in-kind services or items);
 - A description of the nature of the payment;
 - whether the payment was, for example, a consulting fee, an honoraria, a gift, or for education, research, or travel, or as compensation for speaking at a medical educational program
 - Whether the payment is “related to marketing, education or research specific to a covered drug, device, biological, or medical supply”, and if so, the name of the relevant item.
 - If a covered recipient asks a manufacturer to make a payment or transfer to another person or entity, that must also be reported in the same fashion.
 - E.g., the statute would require a manufacturer of a drug to report, for example, a grant given to a non-physician at the request of a physician, regardless whether the non-physician was thereafter expected to do something for the physician.
 - The Secretary is authorized by statute to designate additional required categories of information “regarding the payment or other transfer of value” as it deems appropriate.
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Publication

- The U.S. Secretary of Health and Human Services must establish procedures governing these disclosures by October 1, 2011, and must publish, with some limited exceptions, the information in a readily useable electronic format on a website no later than September 30, 2013, in the first instance, and by June 30 of each year thereafter.
 - The Secretary must also submit a report with the information to Congress in each year commencing with 2013, as well as to all states.
 - The Secretary’s disclosure must contain “a description of any enforcement actions taken” to obtain the filings, including any penalties assessed and “background information on industry-physician relationships.
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A spreading trend?

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- **Canadian Pharmaceutical Advertisement Advisory Board (PAAB) Commissioner, Ray Chepesiuk, from a discussion on March 29, 2011:**
 - *But the real problem of pharmaceutical industry gifts and payment to doctors is not secrecy, but influence. Doctors who take money or gifts from a pharmaceutical company are more likely to prescribe that company's drugs, write favorable journal articles about the drugs, give lectures recommending the drugs and suggest adding the drugs to a hospital formulary. That influence does not disappear when the payments are disclosed. To fix that problem, the payments must be eliminated."*
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U.S. Anti-kickback statute and the FCPA

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Whoever	It shall be unlawful ... for any issuer ... or for any officer, director, employee [of such issuer]
knowingly and willfully	corruptly
Offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind	In furtherance of an offer, payment, promise to pay ... or offer, gift, promise to give ... anything of value
To any person	To any foreign official
To induce such person	For purposes of influencing any act or decision ... inducing .. To do or omit to do any act in violation of the lawful duty of such official ... or inducing such foreign official to use his influence
To refer an individual ... for any item or service (paid for by FHCP) or ... To purchase, lease, order ... or recommend purchasing leasing, or ordering ... any item or service [paid for by a FHCP]	In order to assist such person in obtaining or retaining business for, or with or directing business to, any person

AKS and FCPA, continued

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- Spread abroad of U.S. enforcement for illegal payments to doctors through use of the Foreign Corrupt Practices Act
 - United States Justice Department and the U.S. Food and Drug Administration will look to find instances of FCPA violations abroad that involve payments to physicians and will thereafter evaluate whether those violations impacted any aspect of the United States drug or device approval process
 - If such a link is found, the FCPA violation will be used to support a Food Drug and Cosmetic Act prosecution in the United States
 - This will “extend” the FCPA reach into misdemeanor prosecutions in the United States
 - This will build pressure on foreign countries to adopt disclosure requirements
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In this environment

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- What is it realistic for European companies to expect and plan for?
 - What problems/issues can the industry expect?
 - What additional liabilities may arise from the disclosures?
 - In the April settlement with Johnson & Johnson regarding, in part, payments to physicians in Europe, the U.S. Department of Justice press release contained this statement:
 - “The Justice Department acknowledges and expresses its appreciation for the significant assistance provided by the authorities of the 8th Ordinary Interrogation Department of the Athens Court of First Instance and the Athens Economic Crime Squad in **Greece**; the 5th Investigation Department of the Regional Prosecutor’s Office in Radom, **Poland**; the Fraud Squad of the West Yorkshire Police Department in the **United Kingdom**; and the SEC’s Division of Enforcement, as well as the coordination and cooperation with the authorities of the United Kingdom’s Serious Fraud Office.”
 - <http://www.justice.gov/opa/pr/2011/April/11-crm-446.html>
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Media impact on customers

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- News articles will have a chilling impact on relationships with major educational institutions
 - From a U.S. media article:
 - “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.*
 - Precise payments will be emphasized:
 - “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.*
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Impact will chill relationships with physicians

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- Major institutional providers in the United States have stopped payments from drug companies:
 - “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 (Colorado institution), 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>
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Expect worldwide impact of web based sources

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- “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
 - U.S. State, 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&sid=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>
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Any growing backlash?

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- “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>
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Reporting mistakes will hurt relationships

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- “The [Massachusetts Web Site] 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 [news media] 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” for employees:
 - If you are publicly traded, is your stock sold on an American exchange?
 - Do you have U.S. operations?
 - Have you revised your rules on engagement since the transparency rules have been implemented?
 - Do you know what payments are being made to physicians in Europe? Are any of them “government employees”?
 - Are your policies covering conduct within the US followed by employees outside the US? Consistent with your policies in Europe?
 - Should you implement now a strategy to collect payment information, in anticipation of “mandated” reporting?
 - Should you implement now a strategy to evaluate whether mandatory reporting would cause a loss of or diminution in needed physician relationships?
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U.S. Payments to whistleblowers in 14 cases

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2009 and 2010	Total Recovery	Federal Civil Share	Whistleblower Payment	% share
1	72,500,000	43,500,000	\$7,825,000	18
2	81,510,000	50,688,483	\$9,000,000	17.8
3	118,000,000	60,896,476	\$10,787,392	17.7
4	313,000,000	88,000,000	\$14,000,000	17.5
5	108,000,000	108,000,000	\$23,500,000	21.8
6	422,500,000	149,241,306	\$25,000,000	16.8
7	600,000,000	210,250,000	\$37,800,000	17.9
8	302,000,000	262,000,000	\$45,000,000	17.1
9	280,000,000	280,000,000	\$67,200,000	24
10	421,200,000	421,200,000	\$88,400,000	21
11	520,000,000	301,907,007	\$45,000,000	15
12	750,000,000	436,440,000	\$96,016,800	22
13	1,415,000,000	438,171,543	\$78,870,877	18
14	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

Spill over from US Trends?

- The whistleblower payments from prior page involve only cases in United States where the U.S. government suffered a loss
 - U.S. law was expanded in 2010 to give whistleblowers in SEC matters 10% to 30% rewards for SEC recoveries
 - This will trigger a flood of FCPA whistle blower allegations involving payments to European (and Asian/African) doctors by companies whose stocks are traded on United States stock markets
 - As these cases grow in the United States, companies can expect pressure to mount for disclosure rules in Europe
 - Companies can expect increasing cooperation among U.S. and European law enforcement authorities
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