KING & SPALDING

National Disclosure Audioconference
February 10, 2009

The Disclosure Implications of Recent Settlements and CIAs

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Cautionary Notes

- All of the information discussed regarding the settlements is based on publicly available information
- None of the information we share today about identifiable companies reflects non-public or “inside” information
- Some of the information discussed today is based on settlement documents, complaints, DOJ statements and related materials
    - Caution is appropriate with respect to whether these documents provide a complete, accurate, and/or fair depiction of the conduct of any company or individual

Summary of Presentation

- Federal and State Settlements Impose Robust Disclosure Requirements
- Financial Disclosure
- Clinical/R&D Disclosure
- “Internal” Disclosure and Transparency Requirements

Disclosure Requirements in Recent Settlements

Selected Cases	External Disclosure			Internal Disclosure	
	HCP Payments	Promotional Activities	Clinical Data	Financial Arrangements	Medical Info
Bayer HC LLC	x			x	
Cephalon	x	x			x
GSK (State)		x	x		
Jazz		x			x
Lilly (State)	x	x	x		
Lilly (CIA)	x	x			x
Orthopedic Settlements	x			x	
Pfizer (State)	x	x	x		

I.

Physician/Provider Payment Disclosure

HHS OIG Views on Disclosure

OIG will continue to work with DOJ and other partners to investigate and pursue cases against device manufacturers and physicians who violate fraud and abuse laws. At the same time, we will continue our outreach to the medical device industry and physicians to increase awareness of the compliance risks and the resources available to assist them in managing those risks. OIG is also considering ways to promote increased transparency of financial relationships. Efforts by Congress, industry, physicians, and academia to promote awareness of the risks of conflicts of interest, increase the transparency of these financial relationships, and implement appropriate policies to manage these risks would go a long way to safeguard patients and health care programs.

HHS OIG Testimony on Physician-Industry Relationships
February 27, 2008

CIA Provisions -- HCP Payments

M. Reporting of Physician Payments.

1. Phase I Reporting

By January 31, 2010, Cephalon shall post in a prominent position on its website an easily accessible and readily searchable listing of all physicians who received any Phase I Payments (as defined below in Section III.M.3) directly or indirectly from Cephalon during Calendar Year 2009 and the aggregate value of such payments in the calendar year.

After the initial posting, 30 days after the end of each subsequent calendar quarter until March 2011, Cephalon shall also post on its website a listing of updated information about all Phase I Payments provided during the applicable calendar year during the preceding quarter(s). The quarterly listing shall be easily accessible and readily searchable.

Each listing shall include a complete list of all individual physicians to whom Cephalon directly or indirectly made Phase I Payments in the preceding calendar year. Each listing shall be arranged alphabetically according to the physicians' last name. The Payment amounts in the lists shall be reported in $10,000 increments (*e.g.*, $0 - $10,000; $10,001- $20,000; *etc.)* For each physician, the applicable listing shall include the following information: i) full name; ii) city and state of the physician's practice; and iii) the aggregate value of the payment(s) in the preceding quarter(s) or year (as applicable). The reporting described in this Section III.M.1 shall be referred to hereafter as "Phase I Reporting."

2. Phase II Reporting

No later than March 31, 2011 and during the remaining term of the CIA, Cephalon shall post in a prominent position on its website an easily accessible and readily searchable listing of physicians and Related Entities (as defined in Section III.M.3) who received any Payments directly or indirectly from Cephalon and the aggregate value of such Payments in the preceding Calendar Year. After the initial posting, 30 days after the end of each subsequent calendar quarter Cephalon shall also post on its website a listing of updated information about all Payments provided during the applicable calendar year during the preceding quarter(s). The quarterly listing shall be easily accessible and readily searchable.

Each listing shall include a complete list of all individual physicians and Related Entities to whom Cephalon directly or indirectly made Payments in the preceding calendar year. Each listing shall be arranged alphabetically according to the physicians' last name and the name of the Related Entity. The Payment amounts in the lists shall be reported in $10,000 increments (*e.g.*, $0 - $10,000; $10,001- $20,000; *etc.)* For each physician and Related Entity, the applicable listing shall include the following information: i) full name; ii) city and state of the physician's practice; iii) name, city, and state in which the Related Entity is located; and iv) aggregate value of the Payment(s) in the preceding quarter(s) or year (as applicable). The reporting described in this Section III.M.2 shall be referred to hereafter as "Phase II Reporting."

For purposes of this Section III.M, the term "Payments" is defined to include all payments or transfers of value (whether in cash or in kind) made to physicians and/or to Related Entities. The term Payments includes, for example, payments or compensation for services rendered, grants, fees, honoraria, and payments relating to research or education. The term Payments also includes food, entertainment, gifts, trips or travel, product(s)/item(s) provided for less than fair market value; or other economic benefit. The term Payments does not include: i) samples of drug products that meet the definition set forth in 21 C.F.R. § 203.3(i), or ii) discounts, rebates, or other pricing terms.

For purposes of this Section III.M, the term "Phase I Payments" is defined as those Payments made in connection with physicians serving as speakers, participating in speaker training, or serving as consultants (including for advisory boards, or preceptorships.)

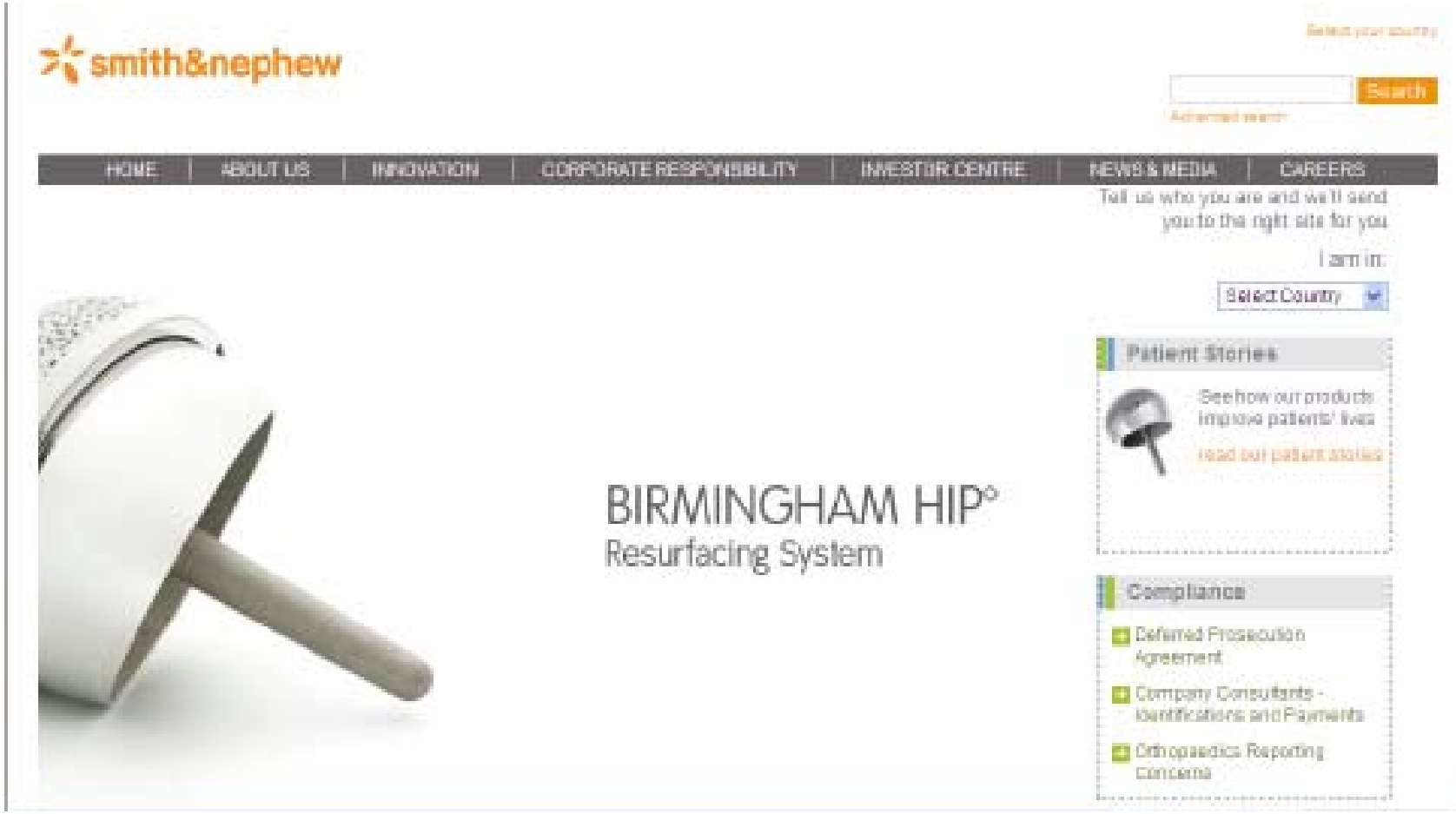
For purposes of this Section III.M, the term "Related Entity" is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

Orthopedic Settlements – HCP Payments

Disclosure

40. All new Consulting Agreements and renewals shall require Consultants to disclose their financial engagement with the Company to their patients, as well as affiliated hospitals.

41. Within thirty (30) calendar days of the Effective Date of this DPA, the Company shall prominently feature on its web site the name, city, and state of residence for each of the Company's Consultants who were retained at any time in 2007, who provided Consulting Services to the Company at any time in 2007, or who received any Payments from the Company in 2007. The Company shall also there disclose the Payments made to each Consultant to date in 2007 within $25,000 increments, and, within sixty (60) calendar days of the Effective Date, all other Payments made in other than dollar form. Within ten (10) calendar days after a new Consulting Agreement or renewal is executed, the Company shall post the name of the Consultant on its web site. If the Company has or does enter into a Consulting Agreement with an entity rather than an individual, the Company shall post both the name of the entity and the individual providing Services to the Company under the Consulting Agreement. Payment information shall be updated quarterly during the term of this DPA to reflect the total Payments made to each Consultant within $25,000 increments, and all other Payments made in other than dollar form. The Company must also disclose this information to the Consultant's affiliated hospitals.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NEWS & MEDIA
CAREERS
Tell us who you are and we'll send you to the right site for you
I am in:
Select Country
Patient Stories
See how our products improve patients' lives
Compliance
Deferred Prosecution Agreement
Company Consultants - Identifications and Payments
Orthopaedics Reporting Concerns
BIRMINGHAM HIP®
Resurfacing System

smith&nephew

The following disclosure of the Company's consultants and payments made to them is made pursuant to paragraph 41 of the Deferred Prosecution Agreement.

Name	Address	2007 YTD Payments	2008 YTD Payments	2007 In Kind Payments
David Abraham, MD	(Albany, NY)	$0	$0	$6.13 (meals)
Freddy Achecar Jr., MD	(Austell, GA)	$18,000	$0	$574.00 (public airfare) $33.44 (gifts) $807.37 (meals)
Advanced Technology, Inc.	(Houston, TX)	$75,001 - $100,000	$0	
Individual Providers				
Dr. Philip Noble				
Advocate Health Care - Chicago Trauma Symposium	(Oakbrook, IL)	$16,500	$0	
Alexandria Research Technologies LLC	(Alexandria, VA)	$150,001 - $175,000	$17,942	
Individual Providers				
Dr. Gerard Engh				$17,684.74 (public airfare) $1,230.50 (ground transportation) $1,749.31 (lodging) $394.38 (meals)
D. Gordon Allan, MD	(Springfield, IL)	$0	$0	$337.00 (public airfare) $341.00 (ground transportation) $703.00 (lodging)

State Settlements – HCP Payments

IV. Payments to Consultants and Speakers

A. The following subsections shall be effective for six years from the Effective Date of this Judgment.

B. This Section shall apply to U.S. based Consultants and Promotional Speakers to the Lilly Marketing organization.

C. Lilly shall provide to each Signatory Attorney General, in an electronic spreadsheet format, a list of HCP Promotional Speakers and Consultants who were paid by Lilly any taxable income in excess of $100 for Promotional speaking and/or Consulting performed for Lilly in the U.S., a list of all titles of Promotional presentations made, and the following additional information with respect to each individual Promotional Speaker and/or Consultant:

1. total compensation from Lilly for any Consulting or Promotional speaking fees;

2. total number of Promotional speaking events paid for by Lilly;

3. the state the Promotional Speaker/Consultant has provided to Lilly for contact purposes;

4. the state(s) in which the Promotional Speaker gave the Promotional presentations; and

5. any other compensation from Lilly as set forth in IRS Form 1099.

II.

Clinical/Medical Disclosure

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK by ELIOT SPITZER, Attorney General of the State of New York	:	
Plaintiff,	:	Civil Action No. 04-CV-5304 MGC Judge Cedarbaum
-against-	:	
GLAXOSMITHKLINE, PLC d/b/a GlaxoSmithKline,	:	
SMITHKLINE BEECHAM CORPORATION d/b/a GlaxoSmithKline,	:	
Defendant.	:	

Consent Order & Judgment

NY AG Settlement with GSK Requiring Clinical Trial Disclosure

August 26, 2004

Conduct, Funding of Clinical Trials

18.

Pfizer shall not compensate physicians for conducting individual, observational teaching sessions in their offices or in the hospital ("mentorships") in which sales

19.

Pfizer shall instruct investigators of Pfizer sponsored clinical trials regarding a Product to obtain a legally effective informed consent from all study subjects or from the subject's legally authorized representative. If Pfizer provides the investigator (or the investigator's Institutional Review Board) with a model informed consent, Pfizer shall not fail to include (a) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; (b) a description of any reasonably foreseeable risks or discomforts to the subject; and (c) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

Disclosure in CME Activities

13.

(a) Pfizer shall comply with the ACCME Standards for Commercial Support (a copy of the current version is attached hereto as Appendix 1).

(b) Any person who acts in a promotional capacity for Pfizer with respect to an FDA approved Pfizer Product shall be obligated under his or her contract with Pfizer, as a condition for any future promotional relationship with Pfizer, to disclose to Continuing Medical Education ("CME") participants orally and to the CME provider for inclusion in the written materials the existence, nature and purpose of his or her arrangement with Pfizer when a member of the faculty at a CME program if: (i) the Product the faculty member promoted for Pfizer is in the same therapeutic category as the subject of the CME program, and (ii) the CME program occurs within 12 months of the faculty member performing work for or receiving compensation from Pfizer. Such disclosure shall set forth the type of promotional work engaged in by the faculty member and the name of the therapeutic category with respect to such promotion.

Disclosure of Clinical Studies

23.

Pfizer shall not disseminate a Medical Information Letter, an unabridged reprint or copy of an article from a Peer Reviewed Journal or a Reference Publication, or written information through a Regional Medical Research Specialist ("RMRS") describing any Off-Label use of a Product in response to an unsolicited request by a prescriber or other health care professional unless (a) the information is about a clinical investigation with respect to the Product and experts qualified by scientific training or experience to evaluate the safety or effectiveness of the Product would consider the subject of the clinical investigation to be scientifically sound or the information is an unabridged reprint or copy of an article from a Peer Reviewed Journal or a Reference Publication; (b) the information is accompanied by a comprehensive bibliography of publications discussing adequate and well-controlled clinical studies published in a medical journal or medical or scientific text that have been previously published about the use of the Product covered by the information (unless the information is a Peer

Disclosure of Clinical Studies (cont'd)

Reviewed Journal or Reference Publication which already includes such a bibliography); and (c) in cases in which experts qualified by scientific training or experience to evaluate the safety or effectiveness of the Product would consider the conclusion of the information to have been specifically called into question by another article(s) or text(s) that experts qualified by scientific training or experience to evaluate the safety or effectiveness of the Product would consider to be scientifically sound, the information must be disseminated with a representative publication that reaches contrary or different conclusions regarding the Off-Label use.

III.

“Internal” Disclosure & Transparency

Internal Disclosure -- Financial Relationships

D. Compliance with the Anti-Kickback Statute.

1. *Arrangements Procedures*. Within 120 days after the Effective Date, the Company shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement, including Contractual Arrangements and Non-Contractual Arrangements, does not violate the Anti-Kickback Statute (taking into account the regulations, directives, and guidance related to this statute) (Arrangements Procedures). These procedures shall include the following:

a. creating and maintaining a database of all existing and new or renewed Arrangements, including Contractual Arrangements and Non-Contractual Arrangements, that shall contain the information specified in Appendix A (Arrangements Database);

b. tracking remuneration to and from all parties to Arrangements;

c. tracking service and activity logs to ensure that parties to an Arrangement are performing the services required under the applicable Arrangement;

d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the Arrangement (if applicable);

e. establishing and implementing a written review and prior approval process for all Contractual Arrangements, including but not limited to, a legal review by counsel with expertise in the Anti-Kickback Statute and appropriate documentation of all internal controls, the purpose of which is to ensure that all existing and new or renewed Contractual Arrangements do not violate the Anti-Kickback Statute;

f. establishing and implementing a written review and approval process for all Non-Contractual Arrangements, including but not limited to, an annual legal review by counsel with expertise in the Anti-Kickback Statute and appropriate documentation of all internal controls, the purpose of which is to ensure that all Non-Contractual Arrangements do not violate the Anti-Kickback Statute;

g. requiring the Compliance Officer to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis and to provide a report on the results of such review to the Compliance Committee; and

h. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events pursuant to Section III.I (Reporting).

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
JAZZ PHARMACEUTICALS, INC.

The Policies and Procedures shall include a requirement that Jazz develop one or more databases to track requests for information about Jazz' products that are made to Jazz' Medical Information department. Collectively these databases shall be referred to as the "Inquiries Database." The Inquiries Database shall includes the following items of information for each unique inquiry (Inquiry) received for information about Jazz's products: 1) date of Inquiry; 2) form of Inquiry (*e.g.*, fax, phone, etc.); 3) name of the requesting health care professional (HCP); 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about an off-label indication for the product; 6) nature/form of the response from Jazz (including a record of the materials provided to the HCP in response to the request); 7) the name of the Jazz representative who called on or interacted with the HCP; and 8) the status and findings of any follow-up review conducted by Jazz in situations in which it appears that the Inquiry may have related to improper off-label promotion;

Biography -- John T. Bentivoglio

John Bentivoglio is a partner in the firm's Washington, D.C., office and serves as Co-Chair of the FDA/Healthcare Group. His practice focuses on assisting pharmaceutical, medical device, and biotechnology manufacturers in three broad areas: FDA and healthcare regulatory counseling, compliance program development and implementation, and representation of companies in civil and criminal investigations by federal and state law enforcement agencies. On the regulatory side, he advises companies on federal and state anti-kickback laws, FDA advertising and promotional rules, drug pricing and reporting, and Medicare reimbursement issues. He has assisted numerous companies in developing, implementing and assessing corporate compliance programs in line with U.S. Sentencing Commission and HHS Office of Inspector General Guidelines, and with state compliance program laws and regulations. And he has represented pharmaceutical and medical device manufacturers in investigations by U.S. Attorney's Offices in Massachusetts, New York, Maryland, Philadelphia, and California.

From 1997-2000, he served as Associate Deputy Attorney General and Special Counsel for Healthcare Fraud at the U.S. Department of Justice. In these capacities, he advised the Attorney General and Deputy Attorney General on national enforcement initiatives, healthcare investigation and prosecution policies, interagency coordination, and related issues. Earlier in his career, Mr. Bentivoglio served as a professional staff member to the Chairman of the U.S. Senate Committee on the Judiciary, where he handled criminal law and procedure, white-collar crime issues (including healthcare and financial fraud), and international crime and terrorism legislation.

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