FRAUD ISSUES IN MARKETING AND STUDY OF MEDICAL DEVICES

Presentation to the Medical Device Regulatory, Reimbursement and Compliance Congress

November 10, 2009

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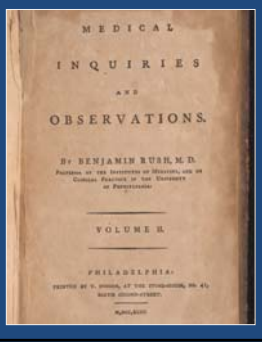
DISCLAIMER

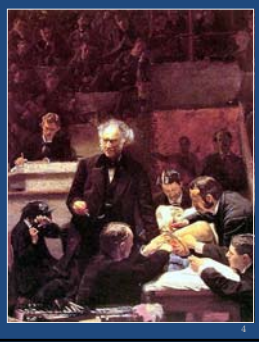
- Not U.S. Department of Justice policy
- In cases where there has not been a trial or guilty plea, government has duty to present evidence and carries burden of proof at trial, if defendants elect a trial
- Allegations of indictment or complaint are not evidence

WHO WE ARE

- U.S. Attorney's Office - Eastern District of PA.
  - Federal, not State
  - Part of U.S. Department of Justice
  - Jurisdiction over 9 Eastern Pennsylvania counties
    - *Main office in Philadelphia*
  - Civil Division and Criminal Division
    - Civil Division, e.g., brings actions on behalf of the U.S. to recover $$$ lost due to fraud upon U.S. gov't agencies such as HHS, DoD, SSA, VA

PHILADELPHIA A MEDICAL HUB SINCE ENLIGHTENMENT





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FEDERAL INVESTIGATION AND ENFORCEMENT

- Conduct-based Investigations
- Criminal, Civil, Administrative Exposure

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ENFORCEMENT TRENDS

- Felony Charges for Felony Conduct
- Accountability: Executives/Management
- Exclusion

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ENFORCEMENT THEMES

- ✓ **Defendants:**
  - ➢ *Judging/disregarding risks for others*
  - ➢ *Basing decisions on what think likely to be noticed/enforced*
  - ➢ *Disseminating false or misleading info.*
- ✓ **Gov't focusing on bad conduct, regardless of co. size and amt. of $$$**

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HOT ENFORCEMENT ISSUES: FRAUD ON THE FDA

- Subversion of FDA process
- How did the device get approved/cleared?
- How did the company treat approval/clearance?
- False statements/omissions about studies/A.E.'S
- Failure to report serious adverse events

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HOT ENFORCEMENT ISSUES: FRAUD ON PAYOR PROGRAMS/ PATIENTS/PROVIDERS

- Fraud by Commission
- Fraud by Omission

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THE RIGHT APPROACH

- Know/follow *letter* of laws
- Abide by *spirit* of laws
- Work w/agencies
- Take compliance program seriously
- Don't risk liability, reputational harm

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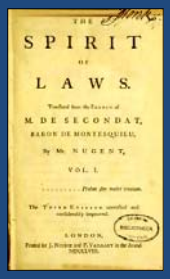

U.S. v. C.R. BARD, INC. (D. Mass. 1994)

"Bard deprived the FDA, doctors, and their patients of the benefit of crucial information. In doing so, Bard betrayed an important trust. . . . In the view of this court . . . the officers and directors . . . are morally responsible for a corporate culture which placed potential profit above the value of human life. "

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COLLATERAL CONSEQUENCES OF CRIMINAL CONDUCT

- Fed. Civ. False Claims Act suits (3x damages; per-claim penalties)
- Human Resources disputes, including *qui tams*
- State false claims suits/state consumer protection actions
- HHS-OIG mandatory exclusion (felony), permiss. excl. (misdem.)
- DoD debarment
- Civil money penalties
- Third-party payer actions
- Impact on mergers, other deals
- Securities fraud actions
- Product liability suits
- Shareholder derivative suits
- Insurance coverage litigation

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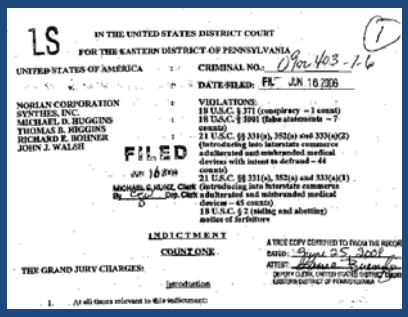
U.S. v. NORIAN / SYNTHES et al.



LS

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA : CRIMINAL NO.: 08cr403-16

v. : DATE FILED: JUN 16 2008

NORIAN CORPORATION
SYNTHES, INC.
MICHAEL D. HUGGINS
THOMAS B. HIGGINS
RICHARD E. BOHNER
JOHN J. WALSH

VIOLATIONS:
18 U.S.C. § 371 (conspiracy – 1 count)
18 U.S.C. § 1001 (false statements – 7 counts)
21 U.S.C. §§ 331(a), 352(a) and 333(a)(2) (Introducing into interstate commerce adulterated and misbranded medical devices with intent to defraud – 44 counts)
21 U.S.C. §§ 331(a), 352(a) and 333(a)(1) (Introducing into interstate commerce adulterated and misbranded medical devices – 45 counts)
18 U.S.C. § 2 (aiding and abetting)
notice of forfeiture

FILED
JUN 16 2008
MICHAEL E. KUNZ, Clerk
By Dep. Clerk

INDICTMENT

COUNT ONE

THE GRAND JURY CHARGES:

Introduction

1. At all times relevant to this indictment:

A TRUE COPY CERTIFIED TO FROM THE RECORD
DATED: June 25, 2008
ATTEST:
DEPUTY CLERK, UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

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NORIAN/SYNTHES, CONT.

The Defendants:

- Synthes, Inc.
- Norian Corp. (wholly owned Synthes sub.)
- President of Synthes North America
- President of Synthes Spine
- Synthes V.P. of Operations/Regulatory
- Director of Regulatory/Clin. Affairs, Spine

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EXCERPTS OF GOVERNMENT-CHARGED CONDUCT

May 2002:

- **FDA requests labeling specifying spinal load-bearing indications, e.g., vertebroplasty, not included in Norian XR indications**
  - ✓*Companies promise will not promote for these*

May to June 2002:

- **Univ. of Wash. researchers report to companies human blood/pig pilot study findings showing product's unique clot-forming properties**

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EXCERPTS OF CHARGES, CONT.

December 2002:

- **Synthes Professional Services advises: may not train on VCF use of XR because = illegal off-label promo. + unethical in light of pilot study-identified risks**

January 2003:

- **Pt. dies in SRS-R test market VCF surgery**

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EXCERPTS OF CHARGES, CONT.

July 2003:

- **Cos. convene "Safety Meeting" to address (1) three AE's in few surgeries, and (2) U. Wash. findings:**
  - ✓ 3 of individual defendants attend
  - ✓ Decision: proceed with XR test market to:
    - *assess acceptability of VCF use risk*
    - *generate published studies*

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EXCERPTS OF CHARGES, CONT.

August to Sept. 2003:

- **1st 2 company t.m. MD trg. sessions on VCF use of Norian XR -- no mention of WA findings/AEs**

Sept. 2003:

- **Second pt. dies -- in t.m. VCF surgery with XR**

Sept. 2003:

- **Mtg. attended by 3 of indivs. to review 2nd death:**
  - ✓ Decision not to stop t.m. but to proceed during review of why 2 deaths in few surgeries
  - ✓ Following review, t.m. continues

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EXCERPTS OF CHARGES, CONT.

January 2004:

- **3rd patient dies -- in t.m. VCF surgery with XR**

February 2004:

- **Dear Surgeon letters:**
  - ✓ Note VCF use of Norian XR = off-label
  - ✓ No mention: warning; t.m.; WA findings; 3 dths.

February 2004:

- **Decision not to recall/remove XR from market** (would have required disclosure to FDA of death details); no notice to FDA about safety risk

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ALLEGATIONS, CONT.

May to June 2004:

- **FDA unannounced inspection:**
  - ✓ 3 of indiv. defends. make false statements

June to July 2004:

- **Responses to FDA's 483 observations:**
  - ✓ 1 or more of 4 indivs. falsely state to FDA that:
    - *t.m. was for cleared indications*
    - *t.m. not designed to obtain safety/eff. info.*
    - *cos. had not trained MDs on VCF use of XR*

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NORIAN FELONY CONSPIRACY CHARGE

Norian Corp. allegedly conspired with others to defraud U.S. by impeding/ impairing/defeating FDA's lawful functions to protect public by ensuring (1) med. devices = safe/effective for intended uses, (2) labeling = true/ accurate info., and (3) FDA oversight of clinical invests. of signif. risk devices

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GUILTY PLEAS TO MISDEMEANOR CHARGES BY 4 INDIVIDUALS

Responsible Corp. Officer Misdemeanor Crim. Liability:

- Involvement in – awareness of – banned activity NOT NECESS.
- Liability risk if don't fulfill positive duty to (1) seek out/remedy violations when occur, and (2) implement corrective measures

Charges Against 4 Individual Synthes Defendants:

- Each of 4 charged with 1 count *strict liability* misdemeanor violation of 21 U.S.C. §§ 331(a), 352(a), and 333(a)(1)

Guilty Pleas (Summer 2009):

- **ALL 4 INDIVS. PLEADED GUILTY TO RCO MISDEMEANORS; SENTENCES PENDING**

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U.S. v. STRYKER BIOTECH, et al.: October 2009

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,
v.
(1) STRYKER BIOTECH, LLC,
(2) MARK PHILIP,
(3) WILLIAM HEPPNER,
(4) DAVID ARD and
(5) JEFFREY WHITAKER,
Defendants.

Criminal No.
Violations:
18 U.S.C. §2 (aiding and abetting)
18 U.S.C. §371 (conspiracy)
18 U.S.C. §1001 (false statements)
18 U.S.C. §1343 (wire fraud)
21 U.S.C. §§331(k), 333(a)(2) and 352 (misbranding)

INDICTMENT

The Grand Jury charges that:

General Allegations

At all times material to this Indictment, unless otherwise alleged:

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FOCUS ON INDIVIDUALS IN OTHER DEVICE CASES

McNULTY MEMORANDUM

- ***U.S. v. Caputo* (N.D. ILL.):**
  - **Conviction of both AbTox President & Chief Regulatory Off. for fraud on FDA; mail fraud; selling misbr./adult. devs.**
  - **Convictions affirmed, 2008**
  - **Pres. sentenced to 120 mos. jail; CRO sentenced to 72 mos.**
- ***U.S. v. Purdue Pharma LLP, et al.***
  - **COO/CEO, Chief Scientific Officer, and General Counsel: RCO misdem. pleas and 15-year exclusions**
- ***Human Growth Product Guilty Pleas (11/08 – 4/09)***

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INDIVIDUALS: CERTIFICATIONS

CIVIL: FALSE CLAIMS ACT/*QUI TAM* PROVISIONS

- *U.S. V. SULZBACH* (S.D. FLA.):
  - ✓ Pending USA-filed Sept. 2007 FCA action against hospital's associate general counsel/corporate integrity officer for alleged false certifs. of compliance with CIA requirements
- TREND: BOARD MEMBER/OFFICER CERTIF. REQ. IN CIAs

CRIMINAL: 18 U.S.C. § 1001

- CIA certifs.
- 510(k) truthful and accurate statements, etc.
- 510(k) Class III certifs. *("I am aware of the types of problems")*
- 510(k) declarations of conformity to design controls
  - ✓ Certifs. must be signed/dated by "responsible indiv."

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FRAUD ON FEDERAL PAYOR PROGRAMS, PHYSICIANS, PATIENTS

Scrutiny of arrangements -- device makers + providers

- *U.S. v. Gleason* (E.D.N.Y.): MD indicted (2006) vis-à-vis receipt of $700,000 to speak off-label; guilty plea (August 2008)

Fraud on payors:

- U.S. v. Kyphon (W.D.N.Y. 2008)
- U.S. v. Endoscopic Tech./Estech (S.D. Tex.: *Qui tam* settled, 7/09)
- U.S. v. Biomet, DePuy, Smith & Nephew, & Zimmer (D.N.J. 2007)
- U.S. v. Nichols Institute Diagnostics, Inc. (E.D.N.Y. April 2009)
- U.S. v. Endotec (11th Cir. March 2009)

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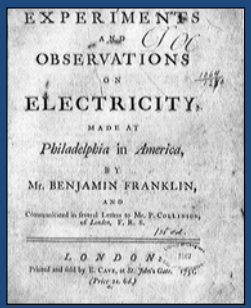
FRAUD ON PTS./PROVIDERS: STUDIES/RESEARCH


EXPERIMENTS
AND
OBSERVATIONS
ON
ELECTRICITY,
MADE AT
Philadelphia in *America*,
BY
Mr. BENJAMIN FRANKLIN,
AND
LONDON:

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FRAUD ON PTS./PROVIDERS: CLINICAL STUDIES

- Synthes Civil Settlement with New Jersey A.G. (2009)
- Patient Protections / IRBS
- Scrutiny of Industry Research Grants to Universities

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FRAUD ON PTS./PROVIDERS: MEDIA

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FRAUD ON PTS./PROVIDERS: ONLINE ADVERTISING

LIKELY TO RECEIVE SCRUTINY FROM FED. PROSECUTORS

- March/May 2009: FDA letters to pharma cos.
- May 2009: FDA draft "Guidance for Industry: Presenting Risk Info. in Prescription Drug and Medical Device Promotion"
- Oct. 2009: FDA's "Strategic Plan for Risk Communication"
- Nov. 12-13, 2009: FDA Pub. Hrg.: Internet/Soc. Media Promo.
- Best Practices

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FRAUD ON PTS./PROVIDERS: EDUC./CHARITABLE GRANTS

Comments of Lewis Morris to Senate Special Committee on Aging (7/29/09):

- "[T]he integrity of medical practice and the quality of patient care may be compromised if biased or inaccurate CME influences the [MD's] clinical practice, including . . . [device] prescription[s]."
- Risk of kickback, FDCA, FCA violations

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OUR WEBSITE

- http://www.usdoj.gov/usao/pae/press.html
  - (Includes press releases, indictments, settlement agreements, etc.)
  - For *U.S. v. Norian, Synthes, et al.* Press Release and Settlement Agreement, see "June Releases," entry for June 16, 2009

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  Gerald.Sullivan@usdoj.gov

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