



Fraud and Abuse Issues Involving Pharmaceutical Products and Medical Devices

Thomas S. Crane

**American Health Lawyers Association and
Health Care Compliance Association
Fraud and Compliance Forum 2004
September 27-28, 2004**

MINTZ LEVIN
MINTZ LEVIN COHN FERRIS GLOVSKY AND POPEO

© Copyright, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., 2004
non-exclusive license to American Health Lawyers Association

NOTE

The views expressed in these materials and in the seminar presentation are the personal views of the presenter and do not represent the formal position of Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C., any other individual attorneys at the firm, or any of its clients. The presenter expressly reserves the right to advocate freely other positions on behalf of clients.

OUTLINE

- **Applicable Laws And Available Guidance**
- Fraud and Abuse Enforcement Activity
- What the Industry Can Look For

Applicable Laws And Available Guidance

- Anti-Kickback Provisions
- OIG Pronouncements
- FDA Guidance
- Industry Guidance
 - AMA
 - PhRMA Code
 - AdvaMed Code
- Applicable State Law

Federal Anti-Kickback Statute

“Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing or **ARRANGING FOR** the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or in return for purchasing, leasing, ordering, or **ARRANGING FOR** or **RECOMMENDING** purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.” (Emphasis added)

Federal Anti-Kickback Statute (cont.)

“Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to refer an individual to a person for the furnishing or **ARRANGING FOR** the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or to purchase, lease, order, or **ARRANGE FOR** or **RECOMMEND** purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.”
(Emphasis added)

Breaking Down the Anti-Kickback Statute

- The Elements of the Statute (all of which must be present for a violation to occur):
 - Knowingly and willfully
 - Offer, solicit, pay or receive
 - Any remuneration
 - To induce or in return for (i) a referral or for recommending a referral, or (ii) purchasing, recommending, or arranging for the purchase
 - Of item of services
 - Paid for (in whole or in part) by any federally funded program.

What is Remuneration?

The transfer of anything of value, whether in cash or in kind and whether made indirectly or directly, covertly or overtly, including cash, free goods, services, discounts or otherwise below fair market value items constitutes “remuneration”.

Penalties

- **Criminal:** Fines of up to \$25,000 per offense, plus much higher fines based on application of the corporate sentencing guidelines, and/or five years imprisonment and, if convicted, automatic exclusion from the Medicare and Medicaid programs.
- **Administrative:**
 - Civil Monetary Penalties of up to \$50,000, plus damages of three times that amount.
 - Permissive exclusion (conviction not required)

Discount Exception

The anti-kickback statute shall not apply to –

“a discount or other reduction in price obtained by a provider of services or other entity. . . if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity. . .”

Managed Care Exception

The anti-kickback statute shall not apply to –

“any remuneration between a [qualifying HMO] and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the [HMO] and the individual or entity. . .”

OIG GUIDANCE

Available at www.oig.hhs.gov

➤ OIG Advisory Opinions

- Since 1997, the OIG has issued Advisory Opinions to provide information about how the OIG views certain conduct under the Anti-Kickback Statute. These opinions provide guidance about the OIG's views on remuneration, whether certain arrangements meet statutory exceptions or safe harbor requirements, and whether the OIG would likely seek to impose sanctions. The OIG's Advisory Opinions are only binding on the individual or entity requesting the opinion. **BUT**, the opinions provide insight into the OIG's thinking.

OIG GUIDANCE (cont.)

- Key Areas of OIG Concern When Considering Advisory Opinion Requests
 - Increased Risk of Overutilization
 - Escalated Program Costs
 - Impairment of Patient Freedom of Choice
 - Unfair Competition
 - Conflicts of Interest

OIG GUIDANCE (cont.)

Advisory Opinion Examples

- Advisory Opinion 02-13
 - Financial assistance provided by pharmaceutical manufacturers for renal failure drug held to create kickback issues
- Advisory Opinion 98-7
 - Funding for ambulance restocking and continuing education of EMS personnel by hospital could violate kickback provisions, but would not be subject to sanctions
- No Advisory Opinions Issued Under Recent OIG Pharma Guidance

OIG Guidance (cont.)

- **OIG Special Advisory Bulletins**
 - In 1999, the OIG began periodically issuing “Special Advisory Bulletins” which provide further guidance on ways to prevent fraud and abuse and promote high standards of ethical and lawful conduct. While Advisory Opinions are limited in their application to the requestor, the Special Advisory Bulletins offer broader insight. Bulletins that have been issued include:
 - Contractual Joint Ventures (2003)
 - Gifts and Other Inducements to Beneficiaries (2002)
 - Practices of Business Consultants (2001)

OIG Guidance (cont.)

OIG Special Fraud Alerts

- The OIG strongly believes that an important element in any compliance program is the development and enforcement of compliance policies that follow the OIG's Fraud Alerts. Fraud Alerts put the industry on notice of certain abusive practices that the government will investigate and prosecute.

OIG Guidance (cont.)

- The OIG has published 12 Special Fraud Alerts to date. They are an excellent source of guidance because they supply an extensive checklist of things NOT to do.
- Alerts issued include:
 - Provision of Services in Nursing Facilities (1996)
 - Prescription Drug Marketing Schemes (1994)

OIG Guidance (cont.)

Other Guidance

- The OIG periodically issues “other guidance” on important issues about which it believes clarification is needed
- Guidance issued include:
 - Education and Outreach Programs Regarding Drug Discount Cards (2004)
 - Upfront Rebates, Prebates and Signing Bonuses (2000)

OIG Compliance (cont.)

➤ Compliance Guidance

- The OIG has solicited comments on and has finalized a series of 11 compliance guidance documents each applicable to a different component of the health care delivery system. These guidance offer valuable assistance and provide the OIG's insight. Examples:
 - Pharmaceutical Manufacturers (2003)
 - Physicians (2000)
 - Hospitals (1998) – due to be reissued in updated form soon
- Compliance guidance being developed for researchers

OIG Guidance for Pharmaceutical Manufacturers

- In April 2003, the OIG issued its final Compliance Program Guidance for Pharmaceutical Manufacturers (the “Pharma Guidance”). While the Pharma Guidance is for pharmaceutical manufacturers, and is intended to assist them with their compliance activities, it provides valuable insight for any provider.
- Purchasers, benefit managers, formulary committee members, and GPOs (among others) are persons or entities in a position to generate Federal health care business.

OIG Guidance for Pharmaceutical Manufacturers (cont.)

- Data collection service agreements, as well as other agreements, between pharmaceutical manufacturers and purchasers should be structured, whenever possible, to fit within the personal services safe harbor; Pharma Guidance notes that any remuneration from a pharmaceutical manufacturer to a purchaser could implicate the kickback provisions and should be carefully reviewed.

OIG Guidance for Pharmaceutical Manufacturers (cont.)

- Rebates or payments that are based on, or otherwise related to, customers' purchases could implicate the kickback provisions.
- Pharmaceutical manufacturers may provide funding for communications with physicians and patients and notes that, while these communications indirectly benefit the manufacturer, "the primary economic beneficiary is typically the formulary sponsor."

OIG Guidance for Pharmaceutical Manufacturers (cont.)

- Educational grants and research funding could raise issues under the kickback provisions if they are conditioned in whole or in part on the “purchase of product” even if the purpose of the program is legitimate.
- “Grant making functions” should be separated from “sales and marketing functions.” To the extent the manufacturer has any influence over the substance of an educational program or a presenter, there is a risk it will be used for inappropriate marketing purposes.

FDA Guidance on Industry-Supported Scientific and Educational Activities

- Issued in 1997
- Programs performed by, or on behalf of, companies that market pharmaceuticals are subject to FDA's requirements on advertising and labeling
- FDA does not regulate independent and non-promotional industry-supported activities
- Determination of independence includes:
 - Control of content
 - Inclusion of promotional material
 - Single-product marketing vs treatment options
 - Source of invitation lists

PhRMA Code on Interactions with Healthcare Professionals

The Main Points of the Code are:

- **General Interaction**: Interaction should focus on informing the professional about scientific and educational information and supporting scientific medical research and education to maximize patient benefits.
- **Entertainment**: Interaction should not include entertainment. Interaction should occur at a venue conducive to providing scientific or educational information. Specifically, this means no “dine and dash,” no entertainment, and no recreational events (e.g., sporting events or spa visits).

PhRMA Code on Interactions with Healthcare Professionals (cont.)

- **Continuing Education**: Companies can provide support to the conference sponsor but should not fund individual participants. Sponsor may in turn provide grants to individuals to participate, or to reduce the overall registration fees for all attendees.

PhRMA Code on Interactions with Healthcare Professionals (cont.)

- **Consultants**: Legitimate consulting or advisory arrangements are appropriate if retention of professionals are based on their expertise and retention is made for no more than needed for the specific program. However, token consulting arrangements should not be used to justify payments to professionals.
- **Educational and Healthcare Practice-Related Items**: Educational and practice-related items may be provided to professionals, but should be for the health care benefit of patients and of less than substantial value (\$100 or less). Items for the personal benefit of the professional should not be offered or distributed.
- **The Code became effective on July 2002.**

AdvaMed Code of Ethics for Interactions with Health Care Professionals

Key points:

- **Defines “Health Care Professionals” as :**
 - ***“...individuals or entities that purchase, lease, recommend, use, arrange for purchase or lease of, or prescribe Members’ medical technology products in the United States ”***
- **Member-Sponsored Product Training and Education** – Must be held in settings conducive to education and training; moderate/low value meals and receptions; no other entertainment for HCP attendees; Reasonable travel and lodging for HCP attendees; Can not pay for guests of HCPs or others without *bona fide* professional interest in the meeting.

AdvaMed Code of Ethics for Interactions with Health Care Professionals (cont.)

- **Supporting Third Party Educational Conferences** – Members may provide funds to conference sponsor to reduce costs or allow HCPs-in-training to attend **if** meeting promotes scientific, educational or policy activities, **and** training institution or conference sponsors selects attendees. Such funds may be provided for modest meal and hospitality of HCP attendees, HCP *bona fide* faculty expenses, advertisements and booth space.
- **Sales and Promotional Meetings** – Meetings with HCPs on product features, contract negotiations, sales terms; occasional/infrequent meals and receptions for HCP attendees; reasonable travel costs for HCP attendees; not appropriate to pay for meals or other hospitality for guests of HCPs.

AdvaMed Code of Ethics for Interactions with Health Care Professionals (cont.)

- **Arrangements with Consultants** – Members may pay for reasonable compensation for services, and reasonable/actual expenses incurred;
 - *Bona fide* consulting arrangements are:
 - In writing, with services specified, and must be signed;
 - Compensation is consistent with fair market value;
 - Legitimate purpose and need for services identified in advance;
 - Selection based on consultant's qualifications and expertise;
 - Venues of meetings are modest;
 - Written protocol for research services

AdvaMed Code of Ethics for Interactions with Health Care Professionals (cont.)

- **Gifts** – Modest, occasional gifts allowed if gift benefits patients or serves genuine education function **and** gift has fair market value of less than \$100 (exceptions: text books and anatomical models). May occasionally provide branded promotional items of minimal value; No cash or cash equivalents; Legitimate practice of providing samples and product evaluations.
- **Grants and Charitable Donations** – Members may make donations for charitable purpose if made to charitable organization in support of : independent medical research, indigent care, patient education and public education, sponsorship of events where proceeds are charitable; all donations must be documented.
- AdvaMed Code became effective January 2004.

AMA Guidelines

- Ethical Opinion and Guidelines Related to CME
- AMA Cautions Physicians to:
 - Assess educational value of the program and attend program on that basis
 - Choose programs offered by accredited sponsors
 - Don't accept direct subsidies (vs. through sponsor) to attend program or for travel
- Became effective June 2002

State Law

- Many states have their own all-payor anti-kickback rules and self-referral prohibitions
- These laws may be of general application or specific to a particular payor (e.g., Medicaid)
- Could trigger enforcement actions
- Much less developed than federal law

OUTLINE

- Applicable Laws And Available Guidance
- **Fraud and Abuse Enforcement Activity**
- What the Industry Can Look For

Allegations Involving Pharmaceutical Manufacturers/Benefit Managers

- Price concessions, including volume discounts, prompt pay discounts, cash discounts, rebates, up-front payments, short-dated product discounts, and nominally priced or free products
- Educational, clinical, research or unrestricted grants or sponsorships
- Sponsorship of speaking engagements, honoraria, meetings, symposia, case study programs, exhibits and other similar events
- Paid consultancies, advisory boards or research panels

Allegations Involving Pharmaceutical Manufacturers/PBMs (cont.)

- Inducements structured to avoid new best price of drugs
- Free or low-cost continuing medical education programs or tuition payments
- Gifts, luxury trips, parties, and entertainment
- Free or low cost practice-support services, such as reimbursement guarantees, audit, accounting, third-party payor, billing assistance services
- Compensation for detailing, time and travel, marketing, switching, or converting from a competitor's product

Allegations Involving Pharmaceutical Manufacturers/PBMs (cont.)

- Items to gain access to physician's offices, such as meals and refreshments (often called "access tools") and preceptors
- Free medical and office equipment, including computers
- Charitable contributions
- Marketing of off-label uses
- Ghost-written papers
- Professional courtesies or debt forgiveness
- Equity in new enterprises or in new products

Allegations Involving Pharmaceutical Manufacturers/PBMs (cont.)

- Educational grants
- Free or heavily underwritten disease management programs
- Payment for switching
- Various forms of inducements related to formulary status

Government vs. Big Pharma

- U.S. *ex rel. Ven-A-Care v. Bayer* (2001)
 - Resolution: \$14 million to settle federal civil case and state claims
 - Whistleblower was an independent pharmacy
 - Bayer allegedly marketed the spread to physicians and home health agencies by giving them deep discounts and then concealed its best price

Government vs. Big Pharma (cont.)

- U.S. *ex rel.* Foster v. Pfizer (2002)
 - Resolution: \$49 million to settle federal civil case and state claims
 - Whistleblower was a former national accounts manager
 - Warner Lambert, acquired by Pfizer in 2000, allegedly concealed best price for Lipitor arising from provision of educational grants to an HMO in exchange for its promise to maintain Lipitor coverage

Government vs. Big Pharma (cont.)

- U.S. *ex rel.* Couto v. Bayer (2003)
 - Resolution: \$257 million to settle federal criminal and civil cases and state claims
 - Whistleblower was a Bayer marketing executive
 - Bayer allegedly enforced private labeling of Cipro to avoid Medicaid best price obligations arising from discount to Kaiser and violated FDCA

Government vs. Big Pharma (cont.)

- U.S. *ex rel.* Couto v. GlaxoSmithKline (2003)
 - Resolution: \$88 million to settle federal civil case and state claims
 - Whistleblower Couto also sued Bayer
 - GlaxoSmithKline allegedly privately labeled Paxil and Flonase to avoid Medicaid best price obligations arising from discounts to Kaiser

Government vs. Big Pharma (cont.)

- U.S. *ex rel. Ven-A-Care v. Dey Laboratories* (2003)
 - Resolution: \$18.5 million to settle state civil case
 - Whistleblower was an independent pharmacy
 - Dey Laboratories allegedly inflated AWP for asthma inhalants Albuterol Sulfate and Ipratropium Bromide and marketed the spread to pharmacists

Government vs. Big Pharma (cont.)

- U.S. ex rel. Franklin v. Pfizer, Parke-Davis, Division of Warner Lambert Company (2004)
 - Resolution: \$430 million to settle federal criminal and civil cases as well as state civil cases
 - Criminal plea by Warner Lambert for two counts of distribution for unapproved uses (off-label) & misbranding
 - \$150,000 criminal fine
 - \$190,000 (plus interest) civil fine to federal and state governments
 - Whistleblower was a Ph.D. microbiologist employed as Parke-Davis medical liaison -- \$24,640,000, plus attorneys fees.
 - Updated CIA (Original 2002)

Government vs. Big Pharma (cont.)

Parke-Davis/Pfizer (cont.) -- United States ex rel. Franklin v. Parke-Davis,

147 F.Supp.2d 39 (D.Mass 2001) – allegations:

- “Medical liaisons” employed by sales division of predecessor Warner Lambert
 - misrepresented credentials
 - made off-label claims related to indications and dosing
- Physicians coached to hide off-label nature of prescription
- Sham clinical studies with no scientific value
- Payments for consultants, preceptors, speakers bureau, access to patient records, gifts (Olympic tickets)

Government vs. Big Pharma (cont.)

Parke-Davis/Pfizer (cont.)

- Decision on 9(b) motion to dismiss by Parke-Davis for failure to plead fraud with particularity
- Neurontin– has many recognized off-label uses (pain, epilepsy) – 50% of sales
- Accupril – approved for hypertension
- Note: Amended Complaint subsequently filed, and unsealed in April 2002

Government vs. Big Pharma (cont.)

Parke-Davis/Pfizer (cont.)

Court found that scheme to promote off-label uses is actionable under the False Claims Act (“FCA”)

- Company concedes that off-label prescriptions are not reimbursable by Medicaid
- Complaint sufficiently alleges “a fraudulent marketing campaign in which kickbacks and unlawful and misleading marketing were allegedly used to encourage doctors to **increase their use** of Neurontin for unapproved purposes.” (Emphasis added)
- Material misrepresentation to obtain a benefit – false statements regarding these drugs and use of kickbacks

Government vs. Big Pharma (cont.)

Parke-Davis/Pfizer (cont.)

- Theory that kickback violation is actionable under FCA requires a showing that Parke-Davis caused or induced doctors and/or pharmacists to file a false or fraudulent certification regarding compliance with the Anti-Kickback Statute
- Court rejects allegation under FCA that Parke-Davis engaged physicians to perform clinical trials where drugs were charged in violation of § 312.7
 - Regulatory violation not actionable under the FCA
 - No allegation that Parke-Davis caused the submission of false claims

Government vs. Big Pharma (cont.)

Parke-Davis/Pfizer (cont.)

- Warner Lambert Sentencing Memorandum (June 2, 2004)
 - 53 pages
 - Inadequate directions for use
 - Distribution for unapproved use
 - Misbranding/false or misleading labeling or advertising
 - Encouraging off-label prescribing

Government vs. Big Pharma (*cont.*)

- U.S. *ex rel. Durand v. AstraZeneca* (2003)
 - Injectable prostate cancer drug, Zoladex
 - Resolution: \$355 million to settle civil federal and state claims
 - Corporate Integrity Agreement
- AstraZeneca allegedly “marketed the spread,” concealed best price of Zoladex, and violated the Prescription Drug Marketing Act by giving physicians samples so that they could bill Medicare for them

Government vs. Big Pharma (*cont.*)

- U.S. *ex rel.* Durand and Gerstein v. TAP (2001)
 - Injectable prostate cancer drug, Lupron
 - Whistleblowers were –
 - TAP vice president of sales
 - Tufts Health Plan Medical Director
 - Resolution: \$875 million to settle federal civil and criminal claims as well as state civil claims
 - Corporate Integrity Agreement
- As part of case, four physicians were charged and plead guilty

U.S. v. MacKenzie *et al.*

The Parties

- The day of the TAP settlement, the US Attorney's Office charges individual TAP senior managers and mid-level employees
- With superceding indictment in July 2002, 13 individuals indicted
- One is a physician whose case has been severed and is still awaiting trial

U.S. v. MacKenzie *et al.* (cont.)

The Charges

- Conspiracy to violate the anti-kickback statute – inducements:
 - Free samples and drugs
 - Gifts of money
 - Consulting services
 - Forgiveness of debt
 - Educational grants to physicians, hospitals and HMOs
 - Bundled discounts
 - Unreported discounts (“Return to Practice”)
- Conspiracy to violate FDA laws by knowingly causing the sale of free samples

U.S. v. MacKenzie *et al.* (cont.)

The Charges (cont.)

- Substantive kickback charges
 - Forgiveness of debt
 - Free samples
 - Discounts and educational grants to an HMO
- Aiding and abetting

U.S. v. MacKenzie *et al.* (cont.)

The Charges (cont.)

Summary

- Samples
 - Inducements
 - FDA violations
- Return to practice discounts
- Discounts
 - Bundled discounts
 - Other

U.S. v. MacKenzie *et al.* (cont.)

The Charges (cont.)

Summary (cont.)

- Managed care
 - Dr. Gerstein became whistleblower & cooperating witness (i.e., he wore a wire)
 - Tapes of TAP marketing presentations
 - At issue were
 - Bundled discounts
 - Unrestricted educational grants (\$20,000 X 3 years)
 - Extra \$5,000 grant for “conversion” of two urology practices with both Tufts and non-Tufts patients (pull through)
 - Whether the grants were a side deal, not in writing

U.S. v. MacKenzie *et al.* (cont.)

Motions to Dismiss

- Briefs filed in summer of 2003
- Samples
 - Defendants argued that PDMA sets out lawful use of samples as inducements – can't violate anti-kickback statute
 - If anti-kickback statute applies, defendants can't be found to have willfully violated the statute
 - Indictment fails to state a crime because Medicare billing is irrelevant to PDMA

U.S. v. MacKenzie *et al.* (cont.)

Motions to Dismiss (cont.)

➤ Return to Practice

- AWP issue cannot form the basis of a fraud crime
- The “spread” cannot constitute remuneration
- The discounted prices offered to physicians are protected discounts – no requirement for physicians to reduce their charges by the discounts received

U.S. v. MacKenzie *et al.* (cont.)

Motions to Dismiss (cont.)

- Other discounts – volume-based and bundled discounts are protected
 - Statutory exception
 - Uncertainty in the 1990s and the OIG’s 1999 “clarification” can’t form the basis for a conviction
- “Offer” of an agreement to Tufts was lawful under the managed care exception (“pursuant to a written agreement”)
- Several due process arguments

U.S. v. MacKenzie *et al.* (cont.)

Motions to Dismiss (cont.)

- Gov't reply brief re: discounts (at 10-11):

“The statutory [exceptions and regulatory] safe harbors are affirmative defenses. . . Affirmative defenses must be raised at trial and asserted by the defendant, and if not raised by the defendants at trial, will be deemed waived. . . If the defendants can adduce evidence at trial that they satisfy each and every element, . . . then they can *request* that the court instruct on the affirmative defense.” (Emphasis in original)

U.S. v. MacKenzie *et al.* (cont.)

Motions to Dismiss (cont.)

- Defendants sur reply re: discounts: conduct falling within a safe harbor shall –
 - “not be deemed illegal”
 - “not subject to prosecution”

U.S. v. MacKenzie *et al.* (cont.)

December 2003, one defendant (Chase) pleads guilty

U.S. v. MacKenzie *et al.* (cont.)

The cast of characters

- The Court: US District Court judge, Hon. Douglas P. Woodlock
- Prosecutors:
 - AUSA Michael K. Loukes
 - AUSA Susan G. Winkler
- Counsel to def. Janice Swirski: Tracy A. Miner (Mintz Levin)

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions Return to Practice / Discounts

- Government conceded that purchasers are allowed to profit for the amounts between list price and AWP

8 MR. LOUCKS:

11 The return to practice

12 evidence is essentially that there was a discount offered.

Source: June 29, 2004 Afternoon Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Return to Practice / Discounts

1 THE COURT:
3 appropriately reflected can simply be it is in
4 the invoices that we received. That's appropriately reflected.

8 THE COURT:
11 this is a safe harbor
12 that is in the nature of an interpretation of the statutory
13 safe harbor. So I'm reading it in conjunction with the
14 statutory safe harbor, and it tells me what it is that it
15 means to "appropriately report."

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Return to Practice / Discounts

7 THE COURT:

23 These are, as far as I'm concerned, affirmative

24 defenses inextricably intertwined with the obligation that

25 the statute itself makes.

* * *

7 THE COURT:

5 the government has to prove beyond a reasonable

6 doubt that defendants have not met the . . . safe

7 harbor.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Return to Practice / Discounts

20 THE COURT: But what is it that says this is

21 appropriate reflection and what isn't? There's nothing, right?

3 THE COURT: Where is the kind of freestanding

4 obligation to provide these charges to the secretary? You make

5 up your own list, you make up your own form? If you're a

6 buyer. Where is it that the secretary is giving you some or

7 someone has given you some -- something to fill out?

8 MR. LOUCKS: The HCFA 1500 form, your Honor, has

9 this spot for the charge.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Return to Practice / Discounts

22 THE COURT: You mean somewhere says that's where
23 you supposed to put it in the HCFA 1500 form? And really,
24 where is the advice do that? Ordinarily you've got a
25 government form and then you get 15 pages to explain what
1 you're supposed to do with the government form. Where is it
2 that you get that?
3 MR. LOUCKS: Well, your Honor, there isn't -- I
4 mean, the statute -- I can cite the Court to the legislative
5 history.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Return to Practice / Discounts

16 THE COURT: We keep talking about this legislative
17 history, and I have to tell you that I really think
18 statutory construction is, you know, a Talmudic undertaking.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Return to Practice / Discounts

The Court (continuing)

24 [But] if you have

25 to -- someone has to go through legislative history of things

1 that somebody couldn't get the votes to put into a statute,

2 then we've got a real problem.

3 So appropriately reflected, you've told me that

4 appropriately reflected means put it on the 1500 form, that

5 sounds, you know, plausible. Apart from you has anybody else

6 said that?

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Return to Practice / Discounts

9 THE COURT:

11 What we're talking

12 about is a statute with virtually no meaning.

18 THE COURT:

19 this thing is open

20 to a variety of different interpretations.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Return to Practice / Discounts

8 THE COURT: To appropriately reflect

* * *

18 THE COURT: How do we do that?

19 MR. LOUCKS: Send a letter, put it on a form.

20 THE COURT: Send a letter?

21 MR. LOUCKS: Put it on the form, give them a call.

22 Honestly, this is -- I mean, this is not hard.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Return to Practice / Discounts

2 MR. LOUCKS: Send in a letter to the carrier saying
3 my bills this year all had discounts in them, the charges that
4 I got -- and I'm reporting the discounts that I got this past
5 year on all the bills I sent in. That would be safe harbor.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Return to Practice / Discounts

5 MR. LOUCKS: If people

6 reported their discounts --

7 THE COURT: In the form of diaries, you say

8 letters, notes, scraps of paper.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Return to Practice / Discounts

6 THE COURT:

7 You know, the thing is the government has some

8 obligation, doesn't it, to square it's own corners, to get this

9 administrative structure in place?

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Return to Practice / Discounts

17 THE COURT: What we've done as a matter of policy
18 in our criminal law is said it has to be a fairly high standard
19 for the description of what the crime is. . . .
21 It's why we have due
22 process requirements and notice requirements and rules of
23 lenity and all that sort of thing.
24 And all I have here is kind of ragtag form of
25 regulatory regime in this area. Appropriately reflected. We
1 don't know what appropriately means. You tell me it's letters
2 and phone calls.

Source:
June 29, 2004
Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Return to Practice / Discounts

21 THE COURT:

22 What we have now, as I understand

23 it, is a circumstance in which the charge-based buyer has no

24 obligation to report the discounts in a clarifying amendment,

25 or that's where it's made clear. That it seems to me is

1 retroactive.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Return to Practice / Discounts

3 THE COURT: Yes. Disclosure in the sense of
4 providing to the purchasers the invoices that accurately
5 reflected the accurate cost.

* * *

19 MR. LOUCKS:
20 ... I don't -- the return to practice is a part of why
21 people did other things, but if your instruction is that these
22 discounts are protected as a matter of law, then the return to
23 practice volume discounts are protected from start to finish.

Source: June 29, 2004 Afternoon Transcript

U.S. v. MacKenzie *et al.* (cont.)
Rule 29 Motions and Decisions

Return to Practice / Discounts

IMPLICATIONS ON LEGALITY OF
BUNDLED DISCOUNTS PRIOR TO 1999
OIG “CLARIFICATION” SAFE HARBOR

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Managed Care

18 THE COURT: There's nothing in the statute that
19 says it has to be an integrate[d] written document.

16 MS. WINKLER: The -- I keep coming back to the
17 singularity of the arrangement, because if you separate --
18 THE COURT: Put that to one side because I don't
19 buy that part.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Managed Care

5 THE COURT: But the exception talks about
6 services. It doesn't talk about particular kinds of services.
7 You can make arrangements to do, I suppose, a variety of
8 things. For instance, pay them to put under Tufts sponsored by
9 TAP in a big sign. Would that be in violation of the -- it
10 would be tacky, but would it be in violation of the managed
11 care exception?

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Managed Care

15 THE COURT: Now we're talking about whether or not
16 it is illegal to have Gerstein engaged to encourage non-HMO
17 entities to do business with TAP.
18 MS. WINKLER: Yes.

* * *

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Managed Care

4 MS. WINKLER: No. It only applies to count three.

5 THE COURT: So count two goes. Right?

6 MS. WINKLER: Well, we don't agree with the
7 analysis, but under the analysis you're using --

8 THE COURT: The portion you don't agree with is the
9 multiple contracts.

10 MS. WINKLER: Right. The educational grants at the
11 20,000. And it would -- under your Honor's approach, I believe
12 the only thing left would be the \$5,000 payment, the additional
13 sweetener, not the \$20,000 educational grants.

14 THE COURT: Okay.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Managed Care

15 THE COURT: Okay. Let's say that they give them...
17 \$5,000 to provide to Phoenix Urology
18 as a way to compensate them for continuing to do business with
19 TAP.
20 MS. MINER: I think that's perfectly fine, your
21 Honor.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Managed Care

24 MS. WINKLER: Well, your Honor, as I understand
25 Cambridge Urology, it is a private practice and they have both
1 Tufts and non-Tufts patients... They
3 can switch the formulary. That switch is the decision for the
4 Tufts patients. But for the non-formulary patients, the
5 payment is \$5,000.

* * *

9 MS. WINKLER:
12 The activity expected on the tape was that Gerstein
13 was going to go use his political and persuasive power --

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Managed Care

3 But the extra \$5,000 sweetener, as I would call the
4 tapes...
5 They were asking him to go convince
6 this group because it was a special bur in the side of TAP --
7 THE COURT: Well, show me where we get ourselves
8 outside of the managed care safe harbor. What aspect of the
9 managed care safe harbor is offended by this?

* * *

16 Where is it that we have an offense to the managed
17 care exemption?

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Managed Care

14 MS. WINKLER: Because Dr. Gerstein's job was -- had
15 a certain set of elements to it, and this is a request for him
16 to do something outside his job as a Tufts person. It's to go
17 out and get private urology practice to switch its business,
18 including its non-Tufts patients. In essence, they're hiring
19 him outside the exception, and here, your Honor, the
20 language --
21 THE COURT: It says providing items or services.
22 Yes, he's providing a service, or more accurately, Tufts is for
23 him.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Managed Care

* * *

21 THE COURT: ... you get an exemption if you
22 pay any remuneration under these circumstances. Any
23 remuneration within the meaning of the anti-kickback statute.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Managed Care

22 MS. MINER:

25 ... all of the evidence is Cambridge Urology

1 was part of the IPA network, and what the \$5,000 was for was to

2 convince the Tufts HMO patients -- if you recall what

3 Dr. Gerstein was talking about, hey, I can't go to these two

4 practices because I went to them initially. I went to these

5 two practices and said go to Zoladex for me. Now I'm going to

6 have to go back and I'm going to look foolish because now I'm

7 going to go back and say the exact opposite.

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Managed Care

8 THE COURT:

9 I'm going to grant a judgment of acquittal with respect to

10 Swirski on the second substantive count, and I think that

11 means I'm going to grant a judgment of acquittal with respect

12 to the conspiracy count as to Ms. Swirski, because it seems

13 to me that there may be multiple agreements, but so long as

14 they're in writing, they are within the scope of what that

15 language means here...

Source: June 29, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Rule 29 Motions and Decisions

Other

- One defendant dismissed because of illness
- Another defendant – judgment of acquittal with consent of government because of the failure of evidence on inducement theory related to forgiveness of debt

U.S. v. MacKenzie *et al.* (cont.)

Jury Instructions

Managed Care Exception

8 You'll recall that there was a discussion and
9 evidence regarding the offers of discounts and educational
10 grants to Tufts, which is a managed care organization. I've
11 told you that I found as a matter of law that the offers
12 involving Ms. Swirski were lawful because they fell within the
13 managed care exemption to the anti-kickback statute

* * *

17 the evidence you heard regarding Tufts involved conduct that is
18 lawful under the anti-kickback statute

Source: July 9, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Jury Instructions (cont.)

Samples as remuneration

18 ... making samples available
19 as a means of introducing patients to the drug is not an
20 anti-kickback violation. Providing samples as a means of
21 getting free medication to poor people is not an anti-kickback
22 violation. But when samples are made a part of the valuable
23 exchange in a deal ... when samples are
24 tied as things of value into the purchase of drugs, then you
25 can have the use of a sample as remuneration under the
1 anti-kickback statute.

Source: July 9, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Jury Instructions (cont.)

Discount Exception

20 We had evidence, for example, of the offer of
21 discounts by TAP. I instruct you as a matter of law that
22 because TAP, as a seller, is conceded by the government to have
23 properly disclosed its discount within the meaning of the
24 discount safe harbor by providing the purchaser with an invoice
25 that reflected the actual price paid by the buyer, TAP's
1 discounts were brought within the discount safe harbor.
2 . . . [T]he physicians had no duty
3 to reduce their charges to the government as a result of those
4 discounts, and TAP had no duty to instruct them to do so.

Source: July 9, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Jury Instructions (cont.)

Inducement (One purpose)

17 . . . The efforts to gain influence over
18 the reason or judgment of the person making decisions regarding
19 the purchase of drug is what is at the heart of this element.

20 Even if a payment or offer of payment had other
21 purposes, if one purpose of the remuneration was to induce
22 purchases or arrangements for purchasing or recommending the
23 purchase of a drug, and that purpose was not what the law calls
24 "de minimis" or basically insignificant, the payment may be
25 found to meet the second element.

Source: July 9, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Jury Instructions (cont.)

Inducement (*Quid pro quo*)

1 . . . [T]o induce a
2 purchase, [means] to offer or pay remuneration for the explicit
3 purpose of causing a customer to purchase certain drugs in
4 return for the payment of remuneration. . .
5 [R]emuneration must be offered or paid as a
6 quid pro quo; a this for that.

Source: July 9, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

Jury Instructions (cont.)

11 It's not the purpose or within the scope of the
12 anti-kickback statute to prohibit transactions that reflect the
13 mere hope or expectation or belief that drug purchases
14 might ultimately ensue from the business relationship.
15 Likewise, simply providing a customer with an opportunity to
16 profit from a large number of purchases does not in and of
17 itself constitute an inducement. And mere oral encouragement
18 to convince someone to purchase a drug does not itself violate
19 the law. Rather, the statutory requirement of improper
20 inducement is satisfied only if remuneration, as I have defined
21 it, is offered or paid as a quid pro quo for the specific
22 purchase of the drug.

23 Cultivating a business relationship is not
24 improper.

Source:
July 9, 2004
Transcript

U.S. v. MacKenzie *et al.* (cont.)

Jury Instructions (cont.)

Willful

9 To demonstrate that a defendant acted willfully,

* * *

1 [t]he government has to prove beyond a reasonable
2 doubt that the defendant was aware of the legal duties imposed
3 by the anti-kickback statute, even if the defendant did not
4 know the specific statute involved, that the defendant knew the
5 conduct was prohibited, and despite that awareness, the
6 defendant nevertheless engaged in conduct with the specific
7 intent to disobey or disregard the known legal duties.

Source: July 9, 2004 Transcript

U.S. v. MacKenzie *et al.* (cont.)

- Result: All remaining defendants found innocent on July 14
- July 15 – Judge Woodlock *sue sponte*: “During the three-month trial. . . I found that the legal and factual bases upon which I accepted the plea of the defendant, Kimberlee Chase on December 19, 2003 were subject to substantial refinement. That refinement was so significant that I have come to question whether I would have accepted Ms. Chase's plea if I had known then what I know now. Accordingly, the parties are directed to show cause. . . why Ms. Chase's plea of guilty in this case should not be vacated.

U.S. v. MacKenzie *et al.* (cont.)

- Gov't objected on grounds that the guilty plea was “wholly unrelated to the Tufts transaction.”
- September 14, 2004, Judge Woodlock vacates guilty plea “in view of the evidence presented at the trial of the co-defendants”

U.S. v. MacKenzie *et al.* (cont.)

- Factors in Result?
 - Relators Durand and Gerstein
 - Complicated single conspiracy
 - 12 defendants
 - TAP guilty plea was not admitted
 - Judgment of acquittal on managed care issue
- Implications on future health care fraud cases?

Government vs. Big Pharma (cont.)

Schering-Plough July 28, 2004 Settlement

- Total civil and criminal fines: \$345.5 million
- Criminal
 - Schering Sales Corp. plead guilty to a one count violation of the Anti-Kickback Statute
 - Criminal fine of \$52,500,000
- Civil
 - Schering-Plough Corporation agreed to pay \$292,969,482
 - Three former employee-whistleblowers receive \$31,662,173
 - Corporate Integrity Agreement

Government vs. Big Pharma (cont.)

Schering-Plough (cont.) – Sales Corp. Statement of Facts in Support of Plea

- During 1997, Schering and HMO enter into agreements to govern the price of Schering drugs, most notably Claritin
- HMO's enrollees utilized more than \$100 million worth of Schering drugs included on the HMO health plan formularies
- In 1998, HMO complained Claritin price was substantially higher than price it was paying for Allegra
- HMO asked Schering to decrease the effective Claritin price by increasing Claritin discounts and rebates

Government vs. Big Pharma (cont.)

Schering Sales Corp. Statement of Facts (cont.)

- September 1998 – HMO’s Pharmacy and Therapeutics (“P&T”) Committee voted to remove Claritin from the HMO’s formulary
- Schering was aware that providing the HMO with a lower Claritin price would have required Schering to report lower Claritin Best Prices to the government
- To avoid lowering the Claritin price, Schering ultimately provided the HMO with a \$10 million package of other types of payments and services that was specifically tailored to lower the HMO’s effective price for Claritin
- Schering made annual cash payments of ~ \$2.5 million that were described as a “data fee.”

Government vs. Big Pharma (cont.)

Schering Sales Corp. Statement of Facts (cont.)

- HMO provided Schering with annual reports containing detailed, regional utilization data
- HMO was already required and had been providing Schering with the same detailed, regional data quarterly in order to calculate Schering's rebate payments to the HMO
- Annual report was merely a cumulation of the quarterly reports – no practical value to Schering
- The primary purpose of the data fee payment to the HMO was to keep Claritin on the HMO's formulary

Government vs. Big Pharma (cont.)

Schering Sales Corp. (cont.)

- Protected by Managed Care exception?
- Compare result in MacKenzie et al. Rule 29 judgment of acquittal related to educational grants, etc. made to Tufts Health Plan
- Other theories related to best price?
- Query: Is there a lawful way to structure an incentive package that avoids best price?

Other Pending Investigations

- Schering-Plough – *Qui Tam* case in Texas alleging sale of drugs to U.S. that were not manufactured in conformance with requirements for good manufacturing practices
- Merck – *Qui Tam* case in Louisiana alleging failure to charge Medicaid best price for Pepcid, switching, FDCA violations and kickbacks
- Abbott – California attorney general sued Abbott for inflating drug prices and falsely reporting pricing data to Med-i-Cal

State AWP Cases

- Texas Attorney General sued Abbott, Baxter and B. Braun Medical
- Pennsylvania Attorney General sued 13 manufacturers including TAP, AstraZeneca, Bayer, GlaxoSmithKline, Pfizer, Amgen, Schering-Plough, BMS, Johnson & Johnson, Baxter, Aventis, Boehringer Ingelheim and Dey
- Ohio Attorney General has sued Dey, Abbott, Pharmacia, Warrick, Schering-Plough and Schering
- Arkansas Attorney General has sued Dey, Abbott, Pharmacia, Warrick, Schering-Plough and Schering
- Massachusetts Attorney General has sued Mylan, Barr, Duramed, Ethex, Par, Ivax, Warrick, Teva, Watson, Schein, Purepac and Roxane

Additional Reported Investigations

- Biovail: Marketing of Cardizem, alleged payments of \$1000 to doctors to prescribe and \$150 to office managers for assisting
- BMS: Investigation of sales, marketing and best price reporting practices
- Eli Lilly: Investigation of its marketing and promotional practices related to Byprexa, Prozac and Evista and off-label usage of Evista

Additional Reported Investigations (cont.)

- GlaxoSmithKline: Investigation of sales and promotional practices
- Johnson & Johnson: Investigation of subsidiary Ortho-McNeil's off-label promotion of Topamax; Investigation of subsidiary Centocor's sales and marketing of Remicade
- King: Investigation of sales, marketing and other business practices of Altace, Levoxyl and Aplisol
- Merck: Investigation of sales and marketing practices

Additional Reported Investigations (cont.)

- Pfizer: Investigation of practices related to Genotropin and Bextra
- Watson: Kickback investigation involving Ferrlecit (doctors reportedly received \$500 and dinner as “consulting fee”)

OUTLINE

- Applicable Laws And Available Guidance
- Fraud and Abuse Enforcement Activity
- **What the Industry Can Look For**

What the Industry Can Look For

- Compliance
 - Already having an impact in changing the industry
 - Infancy
- Enforcement
 - No real end in sight
 - Both sides are learning
- Pharma in the middle of a storm
- Device manufacturers at the start of a storm



Presented By:

Thomas S. Crane, Esq.

Mintz Levin Cohn Ferris Glovsky and Popeo, P.C.

**Boston Office:
One Financial Center
Boston, MA 02111
Phone: 617-348-1676
Fax: 617-542-2241**

**Washington, D.C. Office:
701 Pennsylvania Ave. N.W.
Washington, D.C. 20004
Phone: (202) 661-8787
Fax: 202-434-7400**

TCrane@mintz.com