PRESCRIPTION DRUG ENFORCEMENT AND COMPLIANCE ISSUES EFFECTS OF THE NEW MEDICARE DRUG PROGRAM

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DISCLAIMER

- My opinions, not official DOJ policy
- An indictment or a complaint is an accusation, and every defendant has a right to trial on the accusation, and a right to put the Government to its proof

INVITATION

- If your organization is engaging in what you believe is improper conduct, tell them directly or through a compliance process
- If they don't give an appropriate explanation or take appropriate action, tell us.
- Jim.Sheehan@USDOJ.gov or 215 861-8301

THINGS YOU MAY WANT

- Astra-Zeneca corporate integrity agreement-6/20/03 (HHS WEBSITE)
- USA ex rel Franklin 2003 WL 22048255 (D. Mass. 8/22/03)
- USA ex rel. Hunt v. Medco Health, government amended complaint filed 12/9/03 (www.usao-edpa.com)

HOW THE WORLD WILL CHANGE

- CMS Estimate 2004 - $207 billion
- CMS Estimate – annual drug spend $519 billion in 2013
- 15.5 % of total health expenditures in 2013
- Federal Share equal to all defense procurement

Medicare Part D

- Card program summer 2003 (Federal share for indigent seniors up to $600)
- Full program January, 2006 ($50 billion plus per year)
- $35/month premium (95% coverage over $3,600)

MEDICARE PART D

- Medicare Medicaid Anti-Kickback Act applies to transactions under Part D
- Public Contracts Anti-Kickback Act, 41 U.S.C. 52 applies to transactions under Part D
- State Anti-Kickback and pharmacy practice anti-referral statutes apply to transactions under Part D to the extent they involve licensed entities within a state

MEDICARE PART D

- Applies to broad spectrum of oral medications not currently covered by Medicare
- Introduces Federal health plan regulatory structure to full range of detailing, marketing, and CME activities (previously enforcement focused on Medicare covered drugs and Federal employee benefit programs

FIRST AMENDMENT

- CORE ISSUE-PRIOR RESTRAINT-WHEN CAN FDA FORBID COMMUNICATIONS BETWEEN REPS AND PHYSICIANS?

- COURT LINE UNCLEAR-DISSEMINATION OF TRUTHFUL INFORMATION YES, MARKETING NO?

- DRAWING THE REGULATORY/PROSECUTORIAL LINE-TRUTHFUL, ACCURATE COMMUNICATION VS. MISLEADING, INCOMPLETE, OR FALSE INFORMATION

Why do physicians select a particular drug?

- Best drug for patient, considering efficacy, side effect profile,cost
- Familiarity/ease of use
- Formulary restrictions
- Free samples
- Relationship w/rep. and company
- Economic benefit to physician-kickbacks,product sales

Bad Influences

- False or misleading information
- Paying agents to make formulary recommendations to principals (Medco allegations)
- Samples for sale (TAP guilty plea)
- Gifts, payments, and “unrestricted educational grants”(TAP allegations and civil release)

Pharmaceutical Fraud Cases-Present

- TAP-free samples, gifts
- Astra-Zeneca-free samples, gifts
- Bayer-spread marketing
- Kickback cases-role of third party vendors in spreading the wealth, measuring its effects

Pharmaceutical Cases-Present

- Albuterol pricing litigation-Texas
- Massachusetts AG lawsuit vs. generic drug manufacturers-10/8/03-alleges inflated drug pricing to Medicaid
- Does inflated spread constitute kickback to referring physicians (oncology, AIDS drugs paid by Medicare)

Pharmaceutical fraud cases-present

- Kickbacks to hospitals and nursing homes Providing free tubes and pumps to induce purchases of parenteral and enteral nutrition products-Abbott Labs settlement-$622 million (New York Times June 27, 2003)
- Promotion of off-label use of approved drug through false information to physicians, payments to consultants (USA ex rel. Franklin 96-11651) opinion cited

Prosecution

U.S. v. Genentech, Inc. (N.D.Ca. 1999). Guilty plea to Introduction of Misbranded Drug in Interstate Commerce. 21 U.S.C. 331(a), 352.
Fine $30 million
Restitution to Medicaid and CHAMPUS $20 million

USA v. Genentech, Inc.

- Protropin approved and labeled "only for long-term treatment of children who have growth failure from lack of adequate endogenous growth hormone secretion."
- Genentech promoted for short stature for which drug not approved under Section 355.
- Genentech introduced Protropin into interstate commerce intending it to be used for medical conditions for which it had not been approved and not been shown to be safe and effective.

Pharmaceutical Fraud Cases Present

- Payments to institutional providers for exclusive access to patients for prescription drugs Us ex rel. Van Thiel v. HCMF
- Inflation of AWP in order to increase federal and state reimbursement

Pharmaceutical fraud cases-future

- USA ex rel. Hunt and Gauger v. Medco Health
- Government alleges false claims because of drug-switching, improper cancellation of prescriptions, failure of Medco pharmacists to perform professional duties
- USA Amended Complaint filed December 9, 2003

MEDCO AMENDED COMPLAINT

1. Failure to comply with state pharmacy law in dispensing prescriptions (DUR, Doctor Calls)
2. Kickbacks from pharmaceutical manufacturers, payments to health plans
3. Improper switching of patient prescriptions
4. Lack of effective compliance program as reckless disregard

Pharmaceutical fraud cases-future

- The biggest expansion of federal entitlements in history-$50 billion per year-beginning 1/1/2006
- 40 million Medicare beneficiaries, heaviest users of prescription drugs.
- New program, huge new opportunities for fraud

Quality of Care cases-pharmaceuticals and devices

- Models from the device industry
  - Bard (1989-2001) broken catheter tips
  - Guidant-problematic abdominal aortic aneurysm device
  - Failure to report adverse events
  - How many adverse events occur in drugs which are not reported
  - 7 major recalls of FDA approved products since 1997

Pharmaceutical fraud cases

- Drug marketing and promotion meet the Anti-Kickback Act-oral medications receive major new scrutiny-TAP, Parke-Davis qui tam cases expanded to all oral medications

- What about quality, safety, efficacy, adverse events (especially in elderly) ?

Quality of Care cases-pharmaceuticals

- Future
  - Drugs don't work for 50% of patients for whom they are prescribed
  - Adverse events not reported-black box or withdrawal from market
  - Promotion for off-label uses – doesn't work, false reports of research
  - Putting patients at risk-costs

Quality of Care cases-Pharmaceuticals

- Future
  - Medication errors/bad events/failure to report to state or family
  - Failure to integrate drug dosage,lab results,patient reports, medical records
  - Switches-Can't Switch Back
  - Drugs which can't work
    -Epogen without iron
    - Calcium for hospice patients

Quality of Care-pharmaceuticals

- Trust relationship of patient to physician/pharmacist
- Risk of Harm to patients
- Patient Information
- Patient choice

CONCLUSION

- LARGEST NEW BENEFIT PROGRAM IN HISTORY OF THE UNITED STATES+
- LIMITED PROGRAM ENFORCEMENT AGENCY EXPERIENCE WITH ORAL DRUGS+
- LIMITED REGULATORY CONTROLS+
- =SIGNIFICANT INCREASE IN FRAUD REFERRALS AND PROSECUTIONS
- BE CAREFUL OF EXISTING BUSINESS RELATIONSHIPS-THEY NEED A CLOSE REVIEW