

McKenna & Cuneo, LLP

**BEHOLD THE FUTURE:
THE PAST WAS ROCKY ENOUGH
Protecting The Public Sector Business**

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The Future Is The Past

Public Sector Legal Problems

- **Statutory Discounts - Audits/Investigations**
- **Formulary Competition**
- **Ethics/Gifts**

The Future Is The Past

STATUTORY DISCOUNTS

- **Medicaid (15% AMP)**
- **PHS Hospitals, AIDs CLINICS**
(Section 602 discount)
- **VA, DOD, State VA Homes**
(24% NON-FAMP)
(nominal price issue)

The Future Is The Past

- **VA FSS - Bureau of Prisons - VA FSS
(most favored customer)**
- **State local governments?**
- **Medicare?**

The Future Is The Past

AUDITS AND INVESTIGATIONS

- **VA Inspector General (\$150 million)**
- **Medicare/Medicaid AWP/WAC (doctors and pharmacists) - Marketing The Spread**
- **PBMs paid to switch drugs**

The Future Is The Past

AUDITS AND INVESTIGATIONS

- **Repackaging/Relabeling to Avoid Best Price**
- **Price Certifications**
- **Gifts to P&T members, PBMs, Plan Sponsor Personnel**
- **Voluntary Disclosure Program**

The Future Is The Past (cont.)

CLOSED FORMULARIES

- **Determinations of Therapeutic Equivalency**
- **Branded vs Branded; Generic vs Generic**
- **Low Price vs Efficacy, Outcome and Safety**

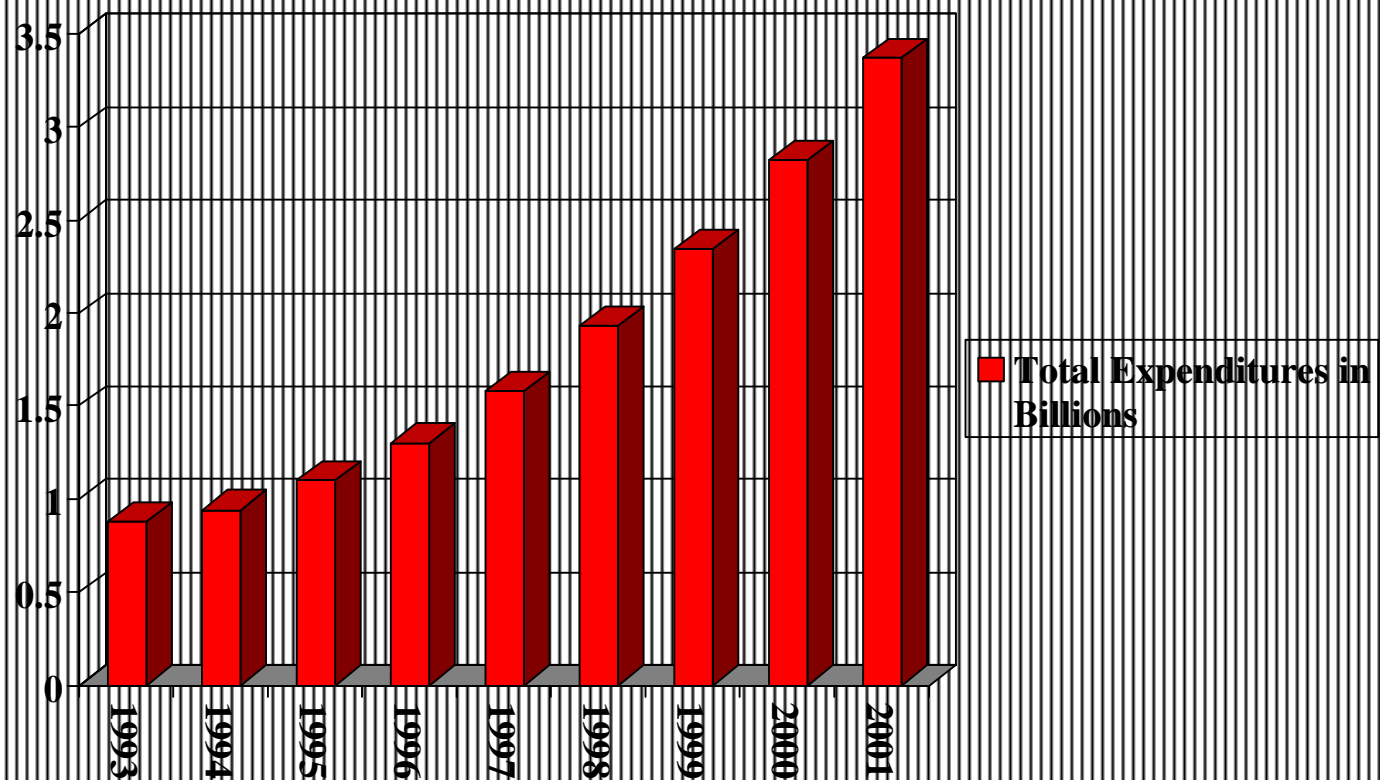
Federal Government Offices that Purchase Pharmaceuticals Through VA Contracts

- **Department of Veterans Affairs**
- **22 VISNS**
- **Department of Defense**
- **Public Health Service**
- **Indian Health Service**

Federal Government Offices that Purchase Pharmaceuticals Through VA Contracts (cont.)

- **Bureau of Prisons**
- **Tribal Contractors**
- **State Veterans Home**
- **Cooperative Purchasing?**

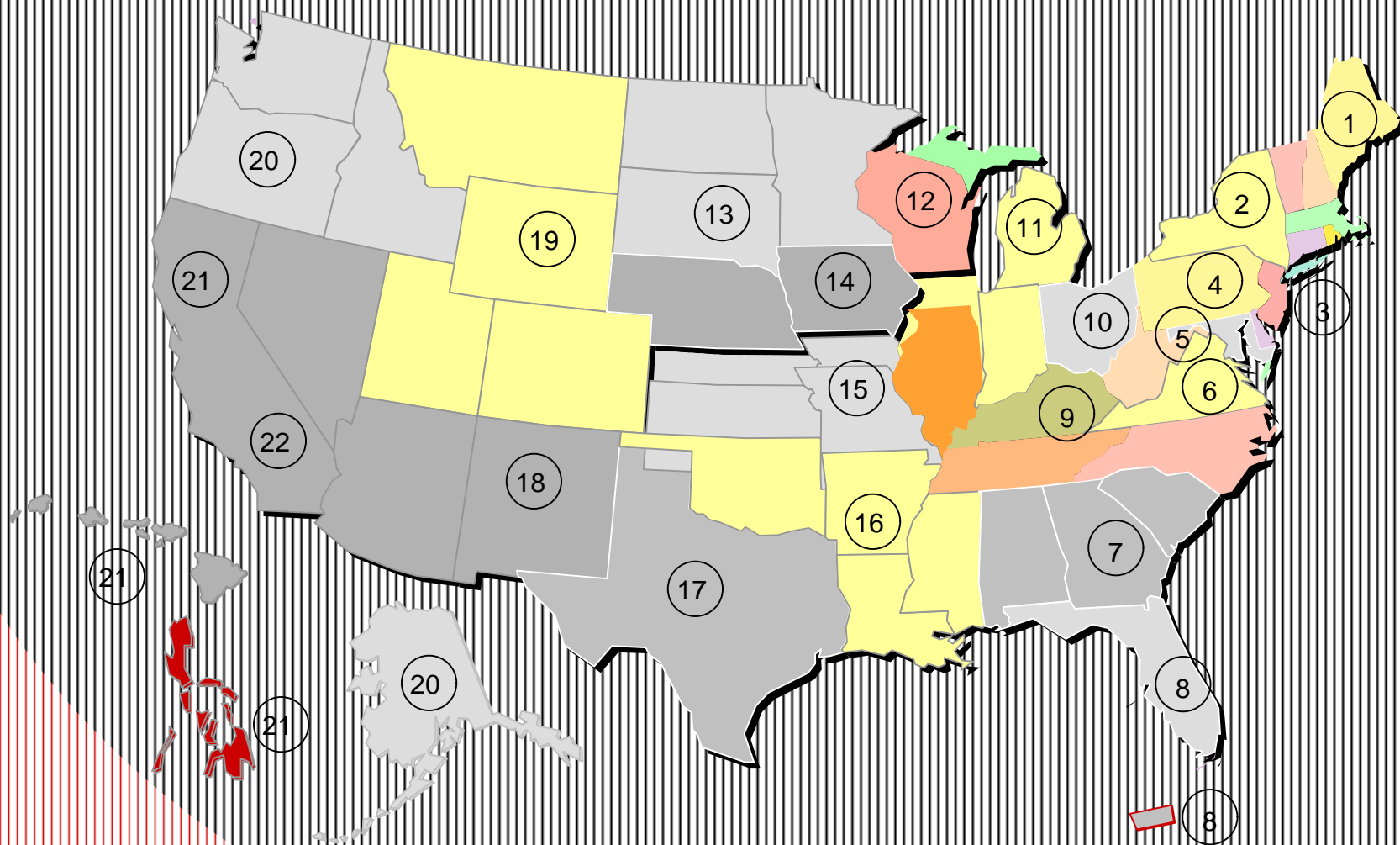
VA Pharmacy Expenditures



Medicaid & PHS

- **State Medicaid**
- **PHS Entities (Section 602)**
- **Disproportionate Share
Hospitals (Section 602)**

22 Veterans Integrated Service Networks



• Most Favored Customer Pricing Goal

“The Government will seek to obtain the offeror’s best price (the best price given to the most favored customer). However, the Government recognizes that the terms and conditions of commercial sales vary and that there may be legitimate reasons why the best price is not achieved.”

GSAR 538.270

CSP Sheets

- **Bidder Must Disclose Sales and Discount Information on the CSP so that the VA can Evaluate the Offer Based upon Discounts, Terms, Conditions and Concessions Offered to Commercial Customers for Similar Purchases**

CSP Sheets

- **Failure to Disclose Current, Accurate, and Complete Information on CSP can Result in Liability**
 - **Information Must be Current, Accurate, and Complete as of 14 days Before Submission**

Discounts

- **Rebates, Quantity Discounts, Purchase Option Credits, and any Other Terms or Conditions (other than concessions) which Reduce the Amount of Money a Customer Ultimately Pays for Goods or Services Ordered or Received**

Disclosure Obligations - What to Disclose?

- **Regular Discounts**
- **Rebates**
- **Bundling**
- **Free Goods**
- **Nominal Prices**
- **Administrative Fees**
- **Ad Hoc Discounting Policies**

Remember: Update Discount Policies After Initial Submission & Before Close of Negotiations

Post-Award Audits Can Be Conducted

- **Three Years After Final Payment for**
 - **Overbillings**
 - **Billing Errors**
 - **Compliance with Price Reduction Clause**
 - **Compliance with IFF**

Basic Contract and Each Option Treated as Separate Contract

GSAR 552.215-71

Price Reduction Clause

- Contractor Must Make Same Offer to the Government

Veterans Health Care Act

Master Agreement and PPA

Covered Drugs Include:

- **Single Source Drugs**
- **Innovator Multiple Source Drugs**
 - **Drugs Marketed Under an Original NDA**
- **Biological Products**
- **Insulin**

Master Agreement and PPA

- **The Price During One-Year Term of PPA May not exceed 76% of the Non-FAMP Less and Additional Discount**
- **Non-FAMP is the Weighted Average Price Paid by Wholesalers, less any Cash Discounts, Chargebacks, or Similar Price Reductions**

“National Formulary?”

National Formulary

- **VA's Recent Initiative to Standardize Pharmaceuticals and Medical/Surgical Items**
- **“The VA seeks to accomplish its greater goals of quality care, access, customer service and cost efficiency by creating national formularies for various drugs.”**

National Formulary

- **Additional Savings for the Government Achieved Through National Buys**
 - **IV Solutions and Sets - \$65 Million**
 - **Dietary Supplement - \$20.7 Million**
 - **Pharmacy Standardization - \$178 Million**

National Formulary

- **Pharmacy Benefits Management (“PBM”)**
 - **Staffed by Doctors of Pharmacy**
- **Medical Advisory Panel (“MAP”)**
 - **Consists of Nine VA Doctors**
- **Pharmoeconomic Center (“PEC”)**

VISNs

- **22 Geographical Areas**
- **Authority to Enter into a BPA with Contractors Based upon their MAS Contracts**
- **National Formulary Contracts Override any Contract Entered into by a VISN**

Refining The Solicitation Process

- **Therapeutic Equivalency**
- **Oral Presentations of Clinical Data**
- **Comments on Draft Solicitations**
- **Award Primary and Secondary Drugs on a Single Contract**

Clinical Drug Class Reviews

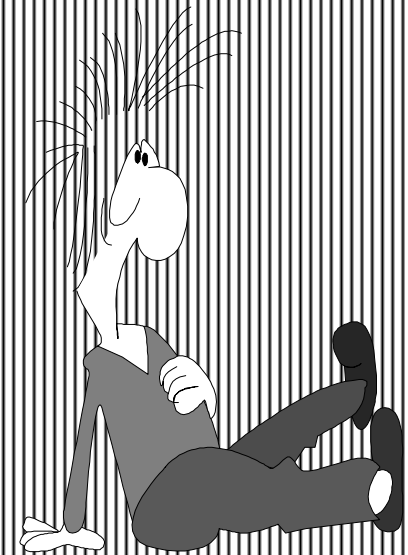
- **Specific to VA Patient Needs**
- **Evidence Based**
 - **Pharmacology**
 - **Indications**
 - **Pharmacokinetics**
 - **Safety and Administration**
 - **Clinical Trials and Outcomes**
 - **Conclusions**
 - **Recommendations for Formulary Addition**

Evaluation Criteria I

H2 Receptor Antagonists



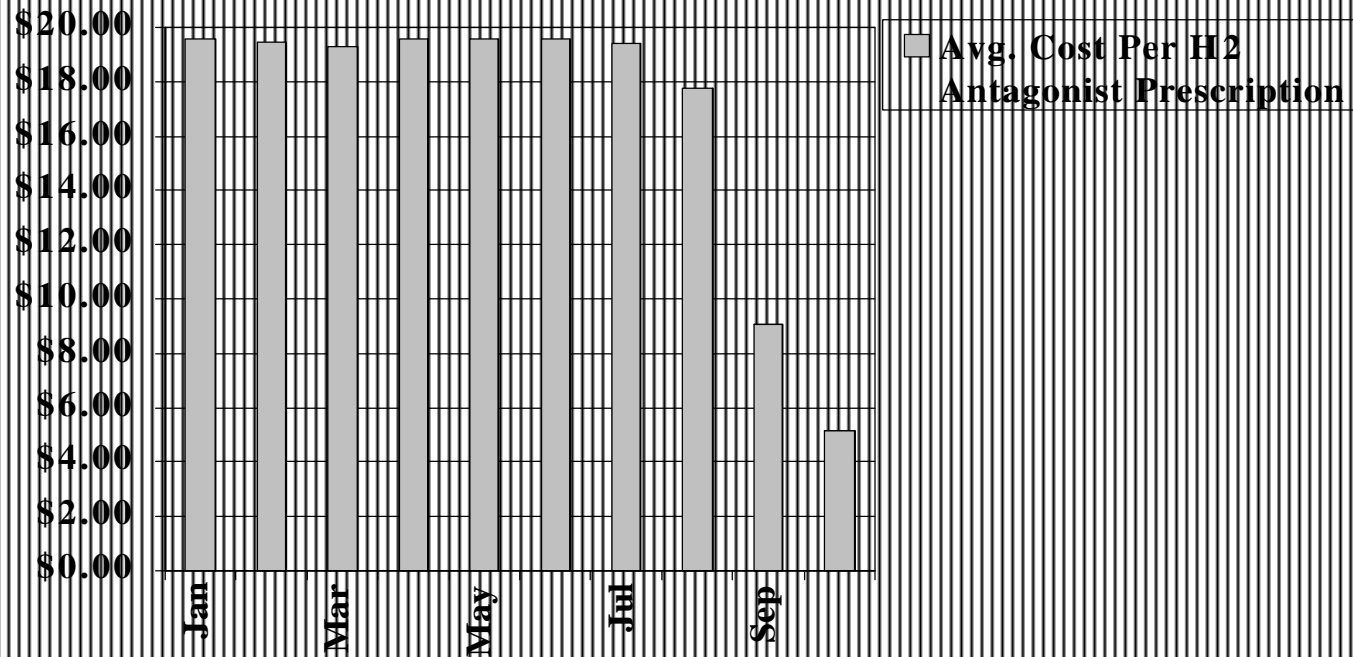
- **Award Solely on Price**
- **Prespecified Dose and Package Sizes**
- **Award Based on Weighted Average price Per Dose**



Evaluation Criteria I

- **Total Est. Annual Usage = 42 Million Average Daily Doses**
- **Contract Period - 1 yr. + 1 yr. Option Period**
- **Offerors Shall Indicate Unique NDC Number**

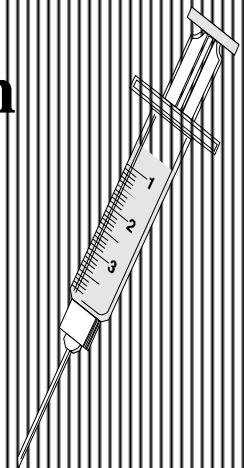
Formulary Award's Effect on Cost



Evaluation Criteria II

LHRH Agonist (Prostate Cancer)

- **Gov't Will Award Contract Most Advantageous, Price Alone Considered**
- **Pricing Evaluation Based on Lowest Overall Cost Per Month Per Patient**
- **Contract Period - 1 yr. + (4) 1 yr. Option Periods**



Evaluation Criteria II

1	Goserelin Acetate Implant	
1a	3.6 mg., 1 Implant Syringe	30%
1b	10.8 mg., 1 Implant Syringe	70%
	Total Weight	100%
2	Leuprolide Acetate for Depot Suspension	
2a	7.5 mg., 1 vial	15%
2b	7.5 mg., 6 vials	15%
2c	22.5 mg., 1 vial	70%
	Total Weight	100%



Evaluation Criteria III

Multi-Source Prescription Drugs

- **Best Value Procurement**
 - **Price More Important than Past Performance**
 - **No Award if Poor Performance Record**
- **Past Performance**
 - **Evaluated to Assess Offeror's:**
 - **Reputation, Good Workmanship, Cooperative Behavior, Commitment to Cust. Sat., Business Concern for Interest of Customer**
 - **Gov't Will Evaluate Depth, Breadth, Relevancy and Currency of Work Experience**

Evaluation Criteria IV

Cimetidine Tablets

- **Best Value Procurement**
- **Prespecified Dose and package Sizes**
- **Technical Evaluation Factors**
 - **Product Availability/Continuity of Supply**
 - **Quality Assurance Plan**
 - **Innovative and Flexible Packaging**
- **Past Performance:**
 - **3 Most Recently Completed Contracts**
 - **2 Current Contracts**

Evaluation Criteria V

HMG-CoA Reductase Inhibitors

- **Best Value Procurement**
- **Two Awards**
 - **Primary: 60% - 80% of 80,000 Patients**
 - **Secondary : 20% - 40%**
- **Oral Presentation**
- **Cost less Important Than Technical Factors**
- **Technical Proposal - Limited to 30 Pages Including Index**

Evaluation Criteria V

HMG-CoA Reductase Inhibitors

- **Technical Factors (of Unequal Weight)**
 - **Safety**
 - **Efficacy**
 - **Outcome - Reduction in Cardiovascular Event**
 - **Rate of Mortality**
 - **Responsiveness To Special Need of VA Patients**
 - **Best Combined Value of Outcome, Safety and Efficacy**
 - **Pharmacy Factors - Ability To Supply CMOP In Set Dose Amount**

Outcome

- **Reduction of the Condition that the Drug Treats**
 - **Reduction in Cardiovascular Event Rate or Mortality**
 - **Reduction in Mortality due to Congestive Heart Failure or Post Myocardial Infarction**
 - **Based Upon FDA Approvals and Published Studies**

Compliance

- **Evaluation of the Method of Administration of the Drug**
 - **Compliance Drops as the Frequency of Drug Intake per Day Increases**

Efficacy

- **The Effectiveness of the Drug as Evidenced in Clinically Relevant Studies**

Safety

- **Drugs Are Evaluated for Adverse Reactions and the Government Ranks the Offered Drugs on the Basis of Severity of Adverse Drug Reactions**

VA Population

- **The Government Seeks to Award a Contract to the Drug that Can Be Administered to the Most VA Patients with the Best Combined Outcome, Safety, and Efficacy.**

Pharmacy Factors

- **The Offeror's Ability to Provide the Specific Packages of Drugs Within an Identified Time Frame**

Bristol Myers Squibb Protest

- **Solicitation Cost Evaluation Model Is Irrational**
 - **Fails to Produce Proper Cost Comparison**
 - **Model Uses Wrong Ratio Between Simvastatin and Pravastatin**
 - **BMS Says 2:1 not 3:1**
 - **VA Methodology Skews Costs by \$23 Million**
 - **VA Methodology Allegedly Overstates Cost of Pravachol by \$8.5 Million**

Bristol-Myers Squibb Protest

- **Technical Criteria Are Flawed**

BMS contends that by ranking Efficacy ahead of Outcome, the VA is in effect, putting the lesser goal of reduced cholesterol ahead of the greater goal of reduction in cardiovascular event rate. BMS contends that this inversion prejudices pravastatin, because pravastatin produces greater outcome benefits through means other than reduction in LDL-C levels.

Bristol-Myers Squibb Protest

GAO Decision

“The agency explains that the MAP believes as a matter of medical policy that the safety associated with the use of the particular statins and their relative efficacy in reducing LDL cholesterol levels are more important in the treatment of hypercholesterolemia than the statins’ abilities to produce certain other desired outcomes. The agency’s determination here is a reflection of its medical policies and judgments, which we will not consider under our bid protest function.”

ACE Inhibitors - Solicitation No. M5-Q4-97

- **VA Awarded Lisinopril National Formulary Status**
 - **Lisinopril Tablets Comprise 41% of Tablets Annually Dispensed by VA**
- **Award Based on “Lowest Overall Cost” to Government**

ACE Inhibitors

- **Two Procurements**
 - **Lisinopril (Sol. No. M5-Q4-97)**
 - **Zeneca v. Merck**
 - **Lowest Overall Cost**
 - **Another ACE Inhibitor (Sol. No. M5-Q3-97)**
 - **BMS v. Novartis**
 - **Best Value Procurement**

Bristol-Myers Squibb Protest - Solicitation No. M5-Q4-97

- **Bifurcated ACE Inhibitor Procurement is on a “Brand Name” or Directed-Source Basis**
 - **VA Cannot Justify Limiting Competition to the two Manufacturers of Lisinopril**
 - **VA Improperly Conducted two Procurements Because Lisinopril has 41% of Market**
- **BMS Withdrew this Protest and Contract was Awarded to Merck**

ACE Inhibitors - Solicitation No. M5-Q3-97

- **Technical Factors (cost less important)**
 - **Outcome**
 - **Compliance - Method of Drug Administration**
 - **Efficacy**
 - **Safety**
 - **Responsiveness to Needs of VA Population**
 - **Pharmacy Factors**
- **Oral Presentation**
- **Final Proposal Limited to 30 Pages**
- **Pricing Evaluation**
 - **Offered Unit Prices Evaluated on Weighted Average**

Novartis Pharmaceuticals Protest - Solicitation No. M5-Q3-97

- **Contract Awarded to BMS**
- **VA Conducted Defective Technical Evaluation**
 - **VA Did Not Evaluate Specific Technical Subfactors in RFP**
 - **VA Did Not Follow Evaluation Criteria in RFP**
 - **Novartis Argues a Careful Technical Evaluation Did Not Occur**
 - **VA Did Not Consider/Credit Documented Technical Advantages in Novartis' Offer**

Alpha Blockers (Pfizer v. Abbott)

- **Best Value Procurement**
- **One Award**
- **Priced Based on Proposed Aggregate Price for All Line Items**
 - **Prices Not Part of Evaluations**
 - **Additional Strengths**
 - **Packaging Sizes**
 - **Optional Line Items**
 - **Additional Consideration for Scored Tablets Will be Integrated**
- **Awardee to Provide Standard Starter Kits at No Additional Cost**

Pfizer, Inc. Protest

- **Solicitation Fails to Consider Differences Between Competing Drugs**
 - **Pfizer Argues Longer “Half-Life” than Competitor’s**
 - **Pfizer Drug Can be Administered in A.M. and P.M.**
 - **Higher Switching Costs if Competitor’s Product Selected**
 - **Starter Packs**
 - **Pfizer - Five-Week Supply**
 - **Competitor’s - Three-Week Supply**

Pfizer, Inc. Protest

GAO Decision

“While the drug formulations solicited are not identical, the record makes clear that, after a detailed examination of product and test reports, the VA reasonably determined that the drugs are essentially equal for treatment of HTN and BPA. Under these circumstances, the agency determination that price should be the determinative factor is unobjectionable, and this determination obviated the need for inclusion of any technical factors in the evaluation scheme.”

Nifedipine Procurement (Bayer v. Pfizer)

- **Price Only Procurement**
- **One Award**
 - **Two Formulations of Long-Acting Nifedipine**
- **Prices Evaluated According to a Weighted Average Formula**
 - **The Weighted Average Does Not Incorporate Additional Strengths Offered**

Pfizer, Inc. Protest

- **The Two Formulations of Nifedipine Should Not Compete**
 - **The MAP Should Defer to FDA's Judgement**
 - **Bayer's Formulation is Only Approved for Hypertension**
 - **Pfizer's Formulation is Approved for Hypertension and Angina**
 - **Other Differences Between the Two Drugs**
 - **Dosing Range**
 - **Condition of Administration**
 - **Rate of Delivery and Resulting Plasma Drug Level**

Pfizer, Inc. Protest

- **Other Factors, Even if the Two Drugs are in Competition**
 - **Potential Adverse Effects From Switching**
 - **Increase in Overall Costs By Using Bayer's Product**
- **Comptroller General Denied Protest**
 - **VA Within Discretion**

Hoechst Marion Roussel Protest

- **RFP Issued for Diltiazem**
 - **Award of Single Requirements - Type Contract for a Base Year and Four One-Year Options**

RFP

- **Price and Past Performance**
 - **Price More Important**
- **Some, but Not All, of Commercially Available Dosage Strengths Evaluated**
- **Any Additional Strength May be Added After Award by Mutual Agreement**

HMR

- **RFP Does Not Accurately Reflect Agency's Needs**
- **Any Post-Award Modification is Improper Sole-Source Award**
- **Payment of Cost of Recalibrating Machines is Prohibited Remuneration Under the Anti-Kickback Act**

Comptroller General

- **The VA's Failure to Permit Offerors to Propose Larger Doses is Improper**
 - **RFP Does Not Adequately Reflect Agency's Needs**
- **VA May Not Award a Contract with the Intention of Materially Modifying it after Award**

Comptroller General

- **Sustained VA's Evaluation Scheme Concerning Efficacy**
- **Declined to Rule Upon Allegations Concerning the Anti-Kickback Act**

Summary of Evaluation Criteria

- **Lowest Evaluated Price**
- **Lowest Evaluated Price and Past Performance**
- **Best Value**
 - **Balance of technical merit, management capability and cost factors providing “best value” to Government**
- **Demonstrate Productivity Benefit Yielding Greater Cost Savings**

Expanded Listing of Drug Categories for National Standardization and Contracting

- **Exchange Resins**
- **Hypoglycemic Agents**
- **Orally Inhaled Corticosteroids**
- **Topical Corticosteroids**
- **Acyclovir/Fancyclovir/Valacyclovir**
- **Potassium Chloride Supplements**
- **Theophylline Products**
- **Ophthalmic Beta Blockers**
- **Long-acting Morphine Products**

Expanded Listing of Drug Categories for National Standardization and Contracting

- **Tubex/Carpujet Product Lines**
- **OTC Multisource Products**
- **Quinolones**
- **Controlled Substances**
- **Tricyclic Antidepressants (dosage review)**
- **Diagnostic Test Strips (to be referred to radiology service lab medicine)**
- **Radiologic Contrast Media (to be referred to radiology/cardiology services)**

Expanded Listing of Drug Categories for National Standardization and Contracting

- **Proton Pump Inhibitors**
- **Selective Serotonin Reuptake Inhibitors**
- **Glucose Test Strips**
- **Beta Agonist Inhalers**
- **Nasal Inhaled Steroids**

Disease Management Protocols Completed

- **Chronic Obstructive Pulmonary Disease**
- **Hypertension**
- **Diabetes - non-insulin dependent**
- **Hyperlipidemia**
- **HIV/AIDS - antiretroviral therapy**

www.dppm.med.va.gov

Upcoming Procurements

Generic 2000 Group

Acyclovir

Azothioprene

Etodolac

Furosemide

Glipizide

Hydroxyurea

Rentoxiphylline

Rifampin

Sedegilene

Sucralfate

Upcoming Procurements

Generic 2000 B Group

Albuterol tablet

Amitriopyline

Bupropion

Buspirone

Carbidopa/Levidopa

Carisopridol

Capsaisin

Dillofenal

HCTZ

Imipramine

Isoorbide

Ketoconazole cream

Meclizine

Clonidine

Disease Management Protocols in Development

- **Congestive Heart Failure**
- **Depression**
- **Coronary Artery Disease: Pharmacologic Management Post MI**
- **Chronic Stable Angina**
- **BPH/Advanced Prostate Cancer**
- **Glaucoma**
- **Peptic Ulcer Disease**
- **Degenerative Joint Disease**

BID Protests

- **Baxter Health Care Corporation B-230580.5 (4/26/90)**
- **Baxter Health Care Corporation B-238306 (5/14/90)**
- **SmithKline Beecham Pharmaceuticals B-252226.2(8/4/93)**
- **Merck & Co., Inc. GAO Bid Protest B-248655 (5/19/92)**
- **SmithKline Protest to PEC in Texas against Eli Lilly over Placement on DOD Formulary**
- **Bristol Myers Protest vs. Merck (HMG)**
- **TAP Protest vs. Zenaca (LDHG)**

BID Protests cont'd

- **Pfizer Protest (Alpha-Blockers)**
- **Bristol Myers Protest (ACE)**
- **Novartis Protest (ACE)**
- **Bayer Pfizer (Nifedipine)**
- **HMR (Diltiazem)**

BID Protests

- **Time For Filing A Bid Protest**
 - **Defects or Ambiguities in the Solicitation Before Proposals are Due**
 - **Pre-award - 10 days**
 - **Post-award - 10 days**
 - **Automatic Stay**
 - **Request Debriefing Within 3 Days of Notification (Negotiated Procurements Only)**
 - **10 Days After Debriefing**
 - **5 Days After Debriefing**

THE FUTURE UNDER MEDICARE

- **Pharmacists and PBMs have a fiduciary responsibility to Act in the Best Interests of patients and not to accept gifts or payments to influence those acts**
- **PBMs Under Medicare as Government Contractors**

THE FUTURE UNDER MEDICARE (Cont.)

- **Every beneficiary in geographic region would have some PBM**
- **Different formularies for different regions**
- **Closed vs open formularies**
- **Federal funding and Federal oversight**

THE FUTURE UNDER MEDICARE (Cont.)

- **QUI TAM actions by insiders involving common practice of drug manufacturers, insurers, and PBMs, and physicians**
- **Close scrutiny from media, Congress and interest groups, and access to previously confidential information**

THE FUTURE UNDER MEDICARE (Cont.)

- **Formulary control programs involving secret payments will not survive media or Congressional scrutization**