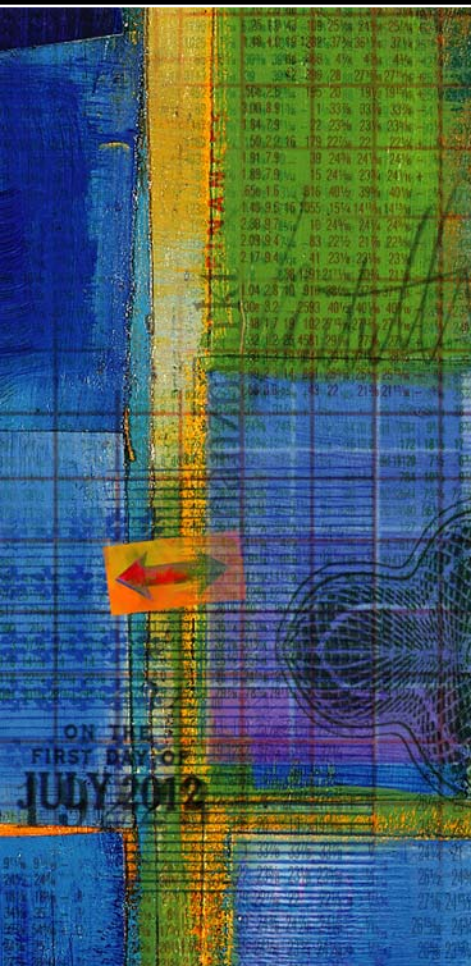


**STANDARD
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Setting the Standard



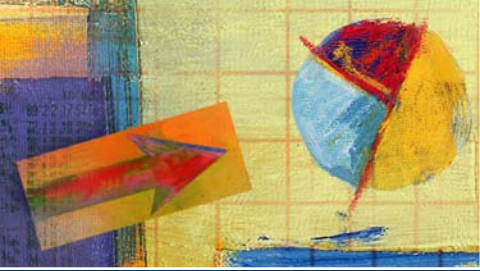
Mitigating Anti-Kickback Risk: Fair Market Value Analyses

*Pharmaceutical Regulatory and Compliance Conference
and Best Practice Forum*

November 15, 2002

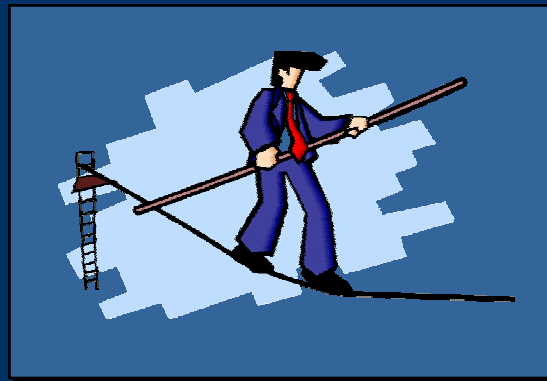
Gary Brewster

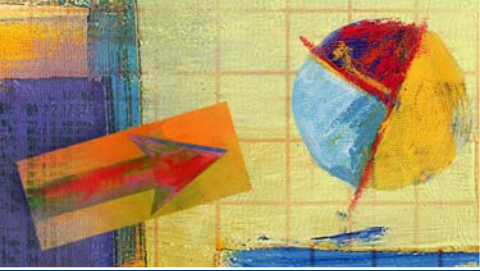
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Summary

- *Fair Market Value (FMV)* has become a critical concern to the industry as part of an effective compliance program
- To withstand regulatory scrutiny, it is important to ensure that FMV issues are dealt with consistently and appropriately
- In addition, through improved understanding of FMV, pharmaceutical companies can refine their customer engagement strategies early in the process



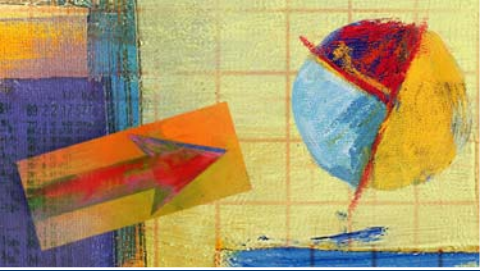


The Pharmaceutical Industry Faces Heightened Scrutiny

Several agencies have stepped up investigations of the industry:

- Office of the Inspector General (OIG)
- Department of Health and Human Services (HHS)
- Department of Justice; U.S. Attorneys (Sheehan, Sullivan, Loucks)
- The Center for Medicare and Medicaid Fraud Control Units
- State Medicaid Fraud Control Units
- Food and Drug Administration (FDA)
- Drug Enforcement Administration (DEA)
- Federal Trade Commission (FTC)
- Securities and Exchange Commission (SEC)
- Occupational and Safety Health Administration (OSHA)
- Consumer Products Safety Commission (CPSC)

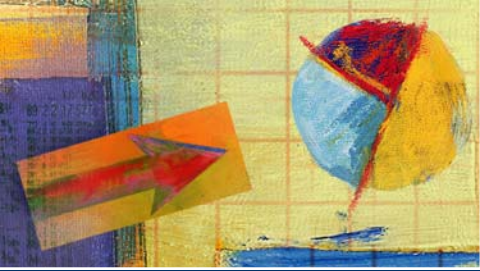




Many State and Federal Laws Apply

- Federal Healthcare Anti-Kickback Statutes
 - Recent interpretation is that a pharmaceutical company cannot provide anything of value to a healthcare provider if the single purpose is to influence treatment
 - Some “safe harbors” were written into the statutes (e.g., properly reported discounts; paying a fixed amount, consistent with fair market value, for a personal service -- the price cannot be tied to the volume or value of business generated by the service)
- Various Fraud & Abuse Guidelines
 - Engaging in deceptive trade practices
 - Providing misleading or incomplete information
- FDA Regulations
- Medicare/Medicaid and other Federal Guidelines
 - Best price (i.e., lowest price)
- Health Insurance Portability and Accountability Act (HIPAA)
 - Proposed changes may restrict how pharmaceutical companies interact with members





Significant Scrutiny Is Having a Direct Effect on Companies' Performance

- TAP Pharmaceuticals (2001) -- \$875 million judgment



- Alleged to have provided “free samples” to physicians and then helping them get Medicare and Medicaid to pay for them

- Bayer Corporation (2001) -- \$14 million judgment



- Alleged to have been “marketing the spread” – selling product to physicians and hospitals for a lower price and then helping them get Medicare and Medicaid reimbursements at AWP

- Schering-Plough



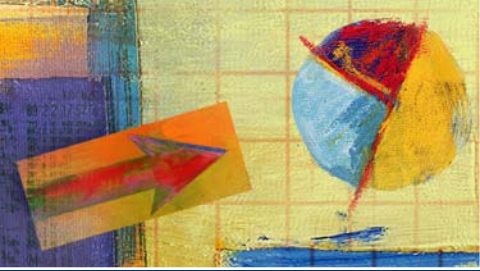
- U.S. Attorney issued grand jury subpoenas in March 2001.
- Focus on transactions with MCOs to which the company offered deeply discounted products in exchange for preferred formulary status.

- Pfizer (Warner-Lambert)



- U.S. Attorney's office in Boston is conducting criminal and civil investigations into Warner-Lambert's marketing of Neurontin, alleging payment to physicians to inappropriately push off-label use.

- In 2002, U.S. Attorneys in Philadelphia and Boston sent subpoenas to several insurers, PBMs and pharmaceutical manufacturers for information on discounts, educational grants and other incentives to determine their effect on drug prices.

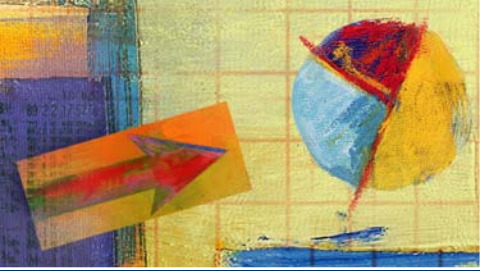


What Is “Fair Market Value”?

The “*Fair Market Value*” of a product is defined as:

The price at which the product would be exchanged between a willing buyer and a willing seller

- **Assuming:**
 - An “arm’s length” agreement between buyer and seller
 - Neither buyer nor seller is under any obligation or compulsion to enter into agreement
 - Both buyer and seller have reasonable knowledge of relevant facts and circumstances
- One measure of Fair Market Value is the expense the buyer would have to incur if the seller did not offer the product (i.e., the price of the “next best” alternative)
- FMV is also informed by the benefit to the parties



Fair Market Value Depends on the Product or Service

A key driver of FMV is whether the product is a commodity.

Fair Market Value

Commodity

Unique Provider



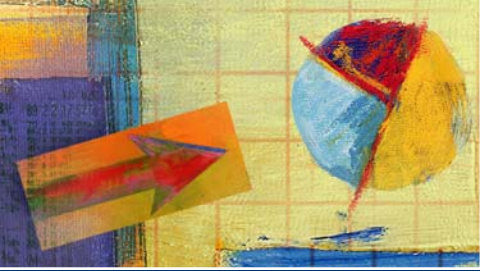
“Cost-based”
Low

- Multiple providers
- Competitive market
- Established prices
- Low profit margins



“Value-based”
High

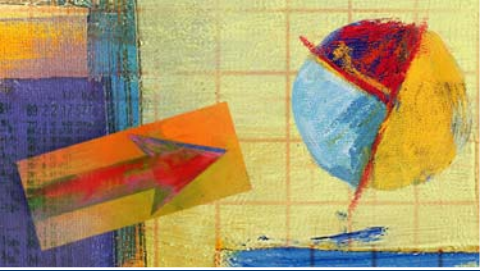
- Few providers
- Monopolistic market
- Negotiated prices
- High profit margins



FMV Applies to the OIG Guidance on Kickbacks and Other Remuneration That Inappropriately Influence Purchase or Referrals

Situations that could invite scrutiny as distortions of drug-pricing information or inappropriate inducements to refer business include a pharmaceutical company that:

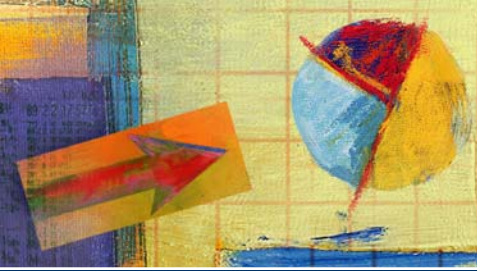
- Provides free or below-FMV products or services to a purchaser or potential referral source (including a physician or a PBM) in connection with the sale of their drug
- Obtains free or below-FMV services from a buyer of its drug, such as PBM- or MCO-provided patient or physician education or prescription intercept programs
- Purchases these same services at higher than FMV
- Compensates physicians or other health providers to act as consultants, researchers, or advisors at higher than FMV for the services rendered
- Provides gifts or other benefits to physicians or other health providers that exceed FMV of any legitimate service rendered to the pharmaceutical company



S&P Utilizes the Following FMV Approaches

- Analysis of *actual costs incurred* by providers of service (used for elements of a service for which reliable information on alternative market comparables is not readily available)
- *Cost-based analysis* where price is “built-up” from information on widely available alternatives (used for elements of a service that are essentially commoditized)
- *Market comparables* of full service (used for services for which reliable information on similar alternatives is readily available)
- *Adjustments for performance* relative to the comparable or cost-based services (used for elements of the service that go beyond commoditized alternatives)





S&P's Analysis Reflects Cost and Relative Performance

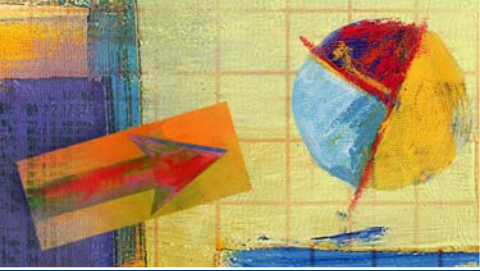
Cost

- Actual cost
- Cost build-up
- Comparable product

Performance

- Response rate
- Time with MD
- Meet customer need
- Etc.

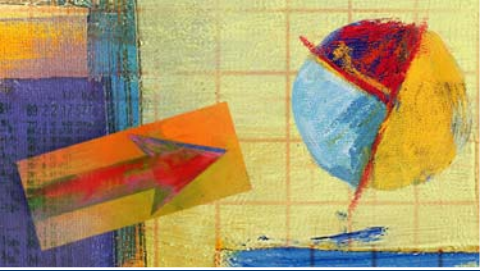
*Fair
Market
Value*



Illustrative Examples

- You bought your house 10 years ago for \$200,000.
- Two years ago you remodeled at a cost of \$100,000.
- A similar house to yours sold last month for \$500,000.
- What is the **Fair Market Value** of your house?

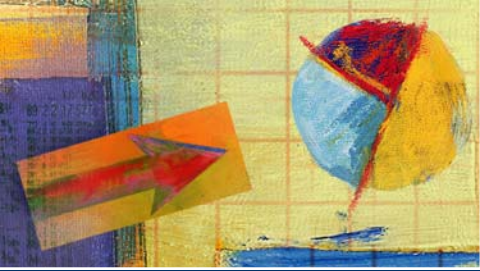




Illustrative Examples

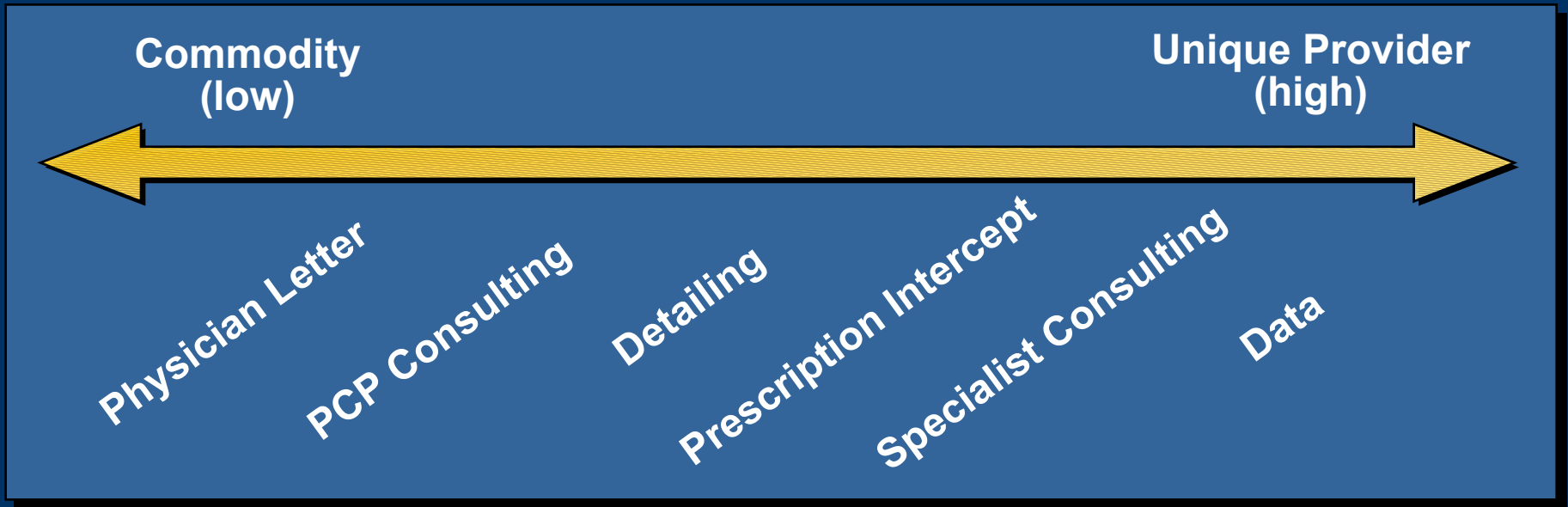
- In the middle of the workday, you find yourself very hungry for a candy bar.
- The person in the cubicle next to you has a Snickers Bar they are willing to sell you.
- You are so hungry that you'd be willing to pay up to \$5 for a Snickers Bar.
- Your colleague would be willing to sell their Snickers Bar for \$2 or more.
- What is the **Fair Market Value** of the Snickers Bar?
- What is the **Fair Market Value** if your office cafeteria sells Snickers Bars for \$1?

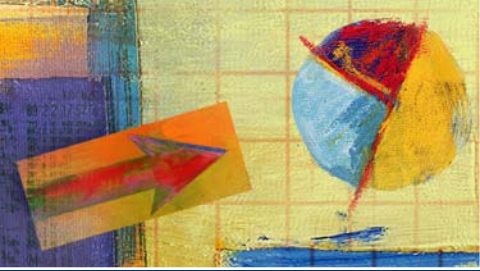




Customer Engagement Strategies Vary on the Fair Market Value Spectrum

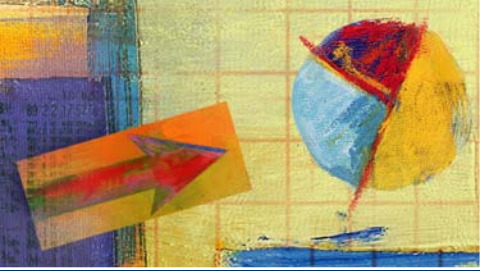
Fair Market Value





The Fair Market Value Analyses Issues

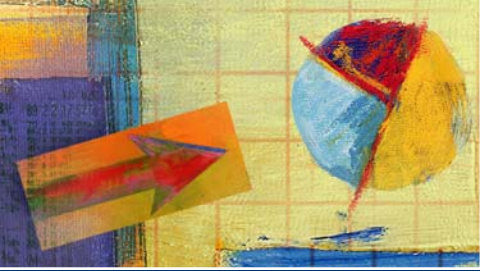
- Fair Market Value is not necessarily the price one should charge a customer. The price one actually charges can depend upon strategic factors as well as the specific relationship with the customer
- Fair Market Value is typically a range, not a single number
- A price within the Fair Market Value range should withstand regulatory scrutiny
- An independent, objective assessment of Fair Market Value, and a process for ensuring compliance, will also help withstand regulatory scrutiny and assist the customer engagement process
- A cross-industry survey of existing arrangements may not be sufficient, as it may not pass an arm's length test



Valuing a Consulting Arrangement

- What is the business rationale? (e.g., unmet needs)
- What alternative way can this be achieved? (e.g., patient research, blinded physician research, consulting with advocacy groups)
- How much would an alternative cost?
- Is there a performance difference between consulting arrangement and alternative?



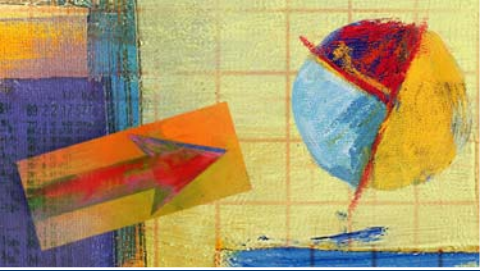


Practical Considerations

- “Bucketing” segments of consultants

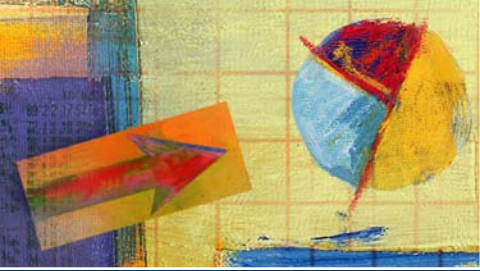


- Too many “buckets” is expensive to evaluate and monitor
- Too few “buckets” can be counter-productive to marketing
- Again, surveys of other Pharma company consultant remuneration is not sufficient



Valuing Data Services: Customer Needs Drive the FMV Analysis

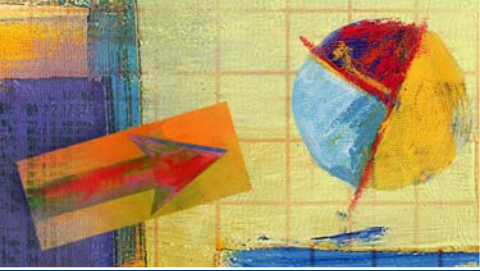
- There are few direct competitors for many data offerings, and pricing data are not public
- Need to gather as much comparable pricing data as possible, recognizing the limitations
- A short survey can measure potential buyers' needs for Rx data:
 - Market research and marketing department heads
 - Both pharmaceutical and biotech firms
 - A mix of large, medium, and small companies
- The FMV price for data offerings should reflect prices of comparable products and measures of buyers' needs for these products
 - Analogy: Valuing a 2-year old Ford Mustang when we know the price of a 2-year old Honda Civic and of a 1-year old Ford Mustang



Value Based Approaches

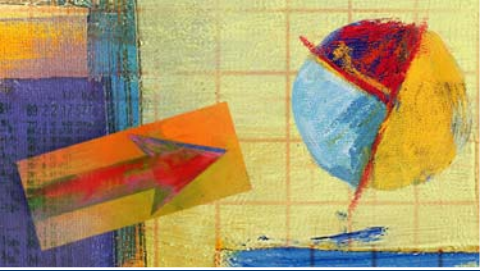
- Although valid from a pure “FMV” standpoint, may not be appropriate in the pharmaceutical marketing context
 - Which has a higher FMV, mailing for a compliance program for Avonex (priced at \$8,000/year), or for Xalatan (priced at \$600/year)?
- Yet, value may be relevant as a “cap”
 - Can use cost and comparables to FMV a single consultant / advisory board
 - However, how do we know that the sum total of payments to all advisory boards is fair?





Summary

- *Fair Market Value (FMV)* has become a critical concern to the industry as part of an effective compliance program
- To withstand regulatory scrutiny, it is important to ensure that FMV issues are dealt with consistently and appropriately
 - Approach based primarily on value add vs. commodity
 - Cross-industry surveys are insufficient
 - FMV is a “range”; it is not the “price”
- In addition, through improved understanding of FMV, pharmaceutical companies can refine their customer engagement strategies early in the process
 - FMV analysis consistent with a quantification of business rationale
 - Similarly, Pharmaceutical Benefits Managers (PBMs) can add value to their pharmaceutical customers and to their sales process by understanding the FMV of their services



Standard & Poor's Corporate Value Consulting

- Standard and Poor's was established in 1860 to provide independent insight, analysis and information to help investors determine value in the marketplace
- Corporate Value Consulting (CVC) has advised clients on valuation and corporate finance issues for over 30 years.
 - Largest valuation consulting practice globally, with over 365 professionals
 - Provides strategic investment and valuation advice to senior management using state-of-the-art analytical methods and organizational processes
 - Analysis and valuation advice supports merger & acquisition decisions, product development and marketing strategy, technology investment, capital allocation, financial planning and financial and regulatory reporting

