Rx Drug Pricing BOOT CAMP

A Manufacturer's Guide to Critical Drug Pricing and Reimbursement Considerations for New Products (May 5, 2023)

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A C5 Group Company

Agenda

- Drug Pricing Law Fundamentals
- Pre-Launch Product Value Proposition Development
- Impact of Drug Pricing on Business Relationships
- Corporate Counsel Perspective
- Reputational Considerations
- Legislative and Regulatory Initiatives Targeting Drug Costs
- Q&A

Drug Pricing Law Fundamentals

Drug Pricing Law Fundamentals

AKS

- The Anti-Kickback Statute attaches criminal liability to knowingly and willfully offering anything of value in exchange for the referral or recommending of Federal healthcare program business. (1128B(b) of the Social Security Act)
- The Department of Health and Human Services Office of Inspector General ("OIG") has created certain safe harbors for:
  - Qualifying discounts
  - Certain personal services
  - Fees to GPOs

Drug Pricing Law Fundamentals

AKS – What is acceptable to the government?

- Volume Based Discounts **YES**
- Market Share Rebates **Generally NO**
- Patient Assistance Program **Generally YES**
- Starter Programs **Generally YES**
- Free transport and lodging for patients **Possibly YES**
- Copay Cards to Medicare beneficiaries **NO**
- GPO WAC-Based Admin Fees **YES**
- PBM WAC-Based Admin Fees **??**

Drug Pricing Law Fundamentals

AKS – What is acceptable to the government? *(cont.)*

- Reimbursement Support Services **YES**
- Reimbursement Guarantees **Generally NO**
- Replacement Product **YES**
- Warranties **YES**
- Value adds **Generally, NO**
- FMV Payments for bona fide services **YES**

Drug Pricing Law Fundamentals

Robinson Patman

- Prohibits charging different prices to different purchasers of a product of like grade or quality where the price discrimination may substantially lessen competition
- Exceptions include:
  - Meeting the competition
  - Differences in cost, such as volume discount efficiencies
- Private right of action
- Results in manufacturers creating different classes of trade

Drug Pricing Law Fundamentals

Robinson Patman *(cont.)*

- To minimize risk, consider:
  - Offering standard t's&c's to all members of a COT, including returned goods policy
  - Having narrow bands of discounting for members within the same COT
  - Making sure special deals are available to all members of the COT
  - If excluding any customers, make sure that is based on objective quality issues

Drug Pricing Law Fundamentals

Price Calculation and Reporting Requirements – Federal

Medicaid Drug Rebate Program & 340B Drug Pricing Program	Medicaid Average Manufacturer Price ("AMP")	• Average price to Retail Community Pharmacies (RCP AMP) for per NDC-9 • If product not typically dispensed through RCPs, then AMP is the average price to all commercial customers per NDC-9 (5i AMP) • Used to determine Medicaid rebate liability • Used to set the 340B Ceiling Price
	Medicaid Best Price	• Lowest single price paid by a commercial customer for an NDC-9, net of discounts
	Medicaid Unit Rebate Amount ("URA")	• Greater of AMP – BP or AMP * 23.1% (or applicable alternative percentage), plus Inflation Penalty (if AMP increases more than CPI-U) • Used to determine Medicaid rebate liability
	340B Ceiling Price	• Equals AMP – URA • Set quarterly (*e.g.*, Q3 340B Ceiling Price based on Q1 AMP and URA) • Price paid by 340B Covered Entities • If URA = AMP, penny pricing

Drug Pricing Law Fundamentals

Price Calculation and Reporting Requirements – Federal

Medicare Part B Program	Average Sales Price ("ASP")	• Per NDC-11, average price to all commercial customers for physician-administered products • Used to set Part B provider reimbursement • Two quarter lag (*e.g.*, Q1 ASP sets Q3 reimbursement)

Drug Pricing Law Fundamentals

Price Calculation and Reporting Requirements – Federal

Medicare Part B & Part D Inflation Rebates	Part B: based on amount Part B payment rate exceeds "Inflation-Adjusted Payment Amount" Part D: based on amount volume-weighted AMP exceeds "Inflation-Adjusted Payment Amount" (calculated for each dosage form/strength)	• Benchmark based on pre-Inflation Reduction Act enactment prices, so no impact to benchmark price used to calculate rebate for existing products • Prospectively, manufacturers can consider inflation rebate implications in pricing actions and contracting decisions that affect future ASP and AMP calculations for existing products and when launching new products • Rebates calculated on Medicare units only, but potential spillover impact in commercial market

Drug Pricing Law Fundamentals

Price Calculation and Reporting Requirements – Federal

VA FSS Program & TRICARE Retail Refund Program	Non-Federal Average Manufacturer Price ("NFAMP")	• Average price to wholesalers for sales distributed to non-federal customers per NDC-11 • Based on sales and discounts through wholesalers (*e.g.*, IMA fees, chargebacks) • Used to set Annual FCP and FSS price
	Federal Ceiling Price ("FCP")	• Equals NFAMP – 24% – Inflation Penalty (if NFAMP increases more than CPI-U) • Set annually • FSS price = FCP, unless lower price negotiated by manufacturer and VA
	TRICARE Rebate	• Equals Annual NFAMP – FCP • Set annually • Represents the per-unit rebate amount paid for TRICARE Retail Network drug utilization • TRICARE Retail Network includes long term care facilities, specialty pharmacies, and pharmacies inside physician offices or hospitals

Drug Pricing Law Fundamentals

Price Calculation and Reporting Requirements – State

New Mexico	Reporting Prescription Drug Information Act (HB 666) N.M. Stat. Ann. § 27-2E-1	• For each prescription drug it sells in NM, a manufacturer must report, on an annual basis: AMP; price that each wholesaler / PBM doing business in NM pays the manufacturer for the drug; and the price paid to the manufacturer by any entity in an arrangement or contract that sells or provides prescription drugs in NM without the services of a wholesaler • Reporting period is July 1 – September 30; reports due by January 15 of the year following the reporting period
Texas	1 Tex. Admin. Code § 354.1921	• Texas Drug Code Index Certification of Information forms to add new drug or new formulation of existing drug to Texas Drug Code Index • Manufacturer must submit pricing data changes within 10 calendar days of receipt of a request from the Texas Health and Human Services Commission
Per State Supplemental Rebate Agreements	Varies	• For example, manufacturers that have entered into an AMP-based Supplemental Drug Rebate Agreement with California Medi-Cal are required to submit AMP data to the state on a quarterly basis

Polling Question 1

Florida's "Prescription Drug Reform Act" (SB 1550):

A. Was signed into law by Governor DeSantis on May 3, 2023;

B. Takes effect July 1, 2023;

C. Requires prescription drug manufacturers to report any increase of 15% to a product's WAC during the preceding 12-month period, or any cumulative increase of 30% or more of the product's WAC during the preceding 3 calendar years; or

D. All of the above.

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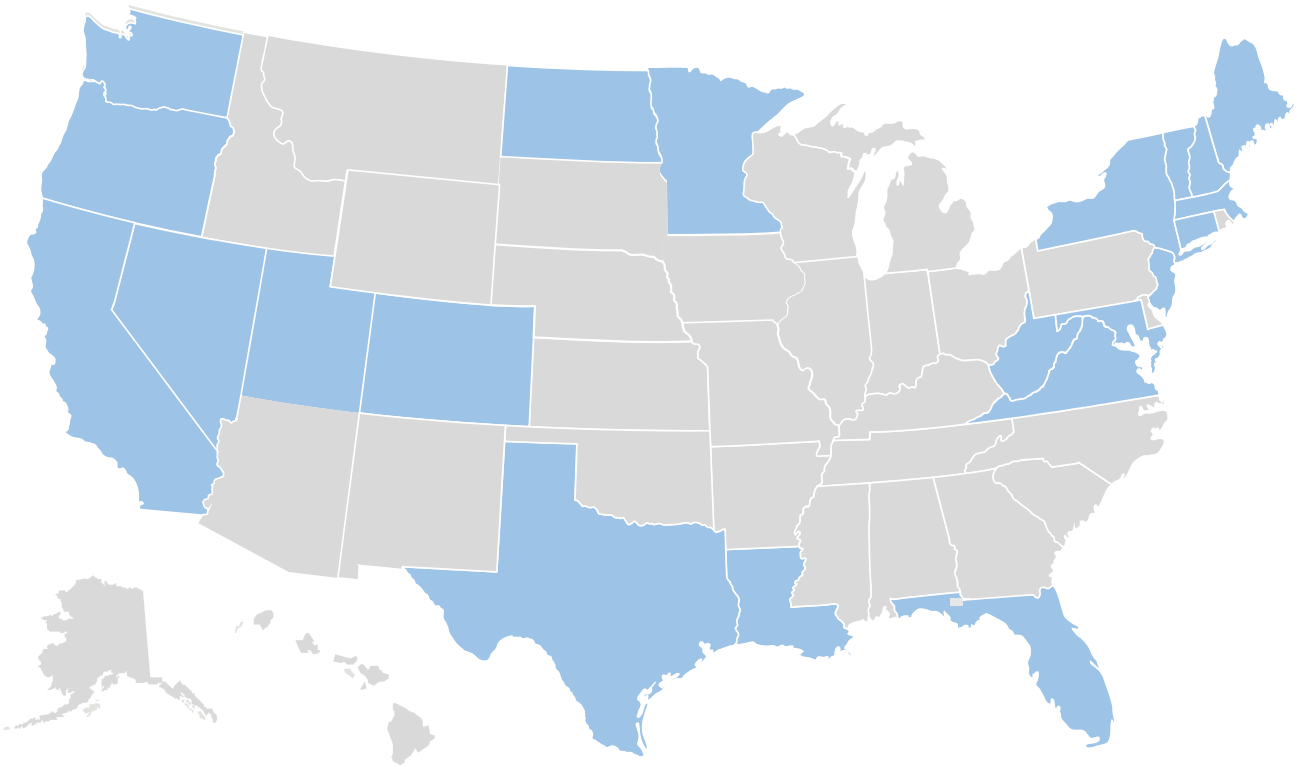
Drug Pricing Law Fundamentals

State Price Transparency Reporting Obligations



1. California
2. Colorado
3. Connecticut
4. Florida
5. Louisiana
6. Maine
7. Maryland
8. Massachusetts
9. Minnesota
10. Nevada
11. New Hampshire
12. New Jersey
13. New York
14. North Dakota
15. Oregon
16. Texas
17. Utah
18. Vermont
19. Virginia
20. Washington
21. West Virginia

Drug Pricing Law Fundamentals

Common Types of State Price Transparency Reporting Obligations

Drug Pricing Law Fundamentals

State Price Transparency Reporting Obligations

- Variability in obligations across jurisdictions
- Complexity of applicable requirements with limited program guidance
- Resources needed to monitor changes, gather and analyze data, prepare submissions, etc.
- Ensuring confidentiality and trade secret protections are properly asserted and maintained
- Increased outreach and enforcement activity from states
- New laws and expanding obligations

Pre-Launch Product Value Proposition Development

Setting the Price of a New Drug in the U.S.

- "List Price"
- New drug v. new formulation of existing drug
- Development costs
- Patient population
- Competition
- Commercial strategy
- Coverage and reimbursement
- Value proposition

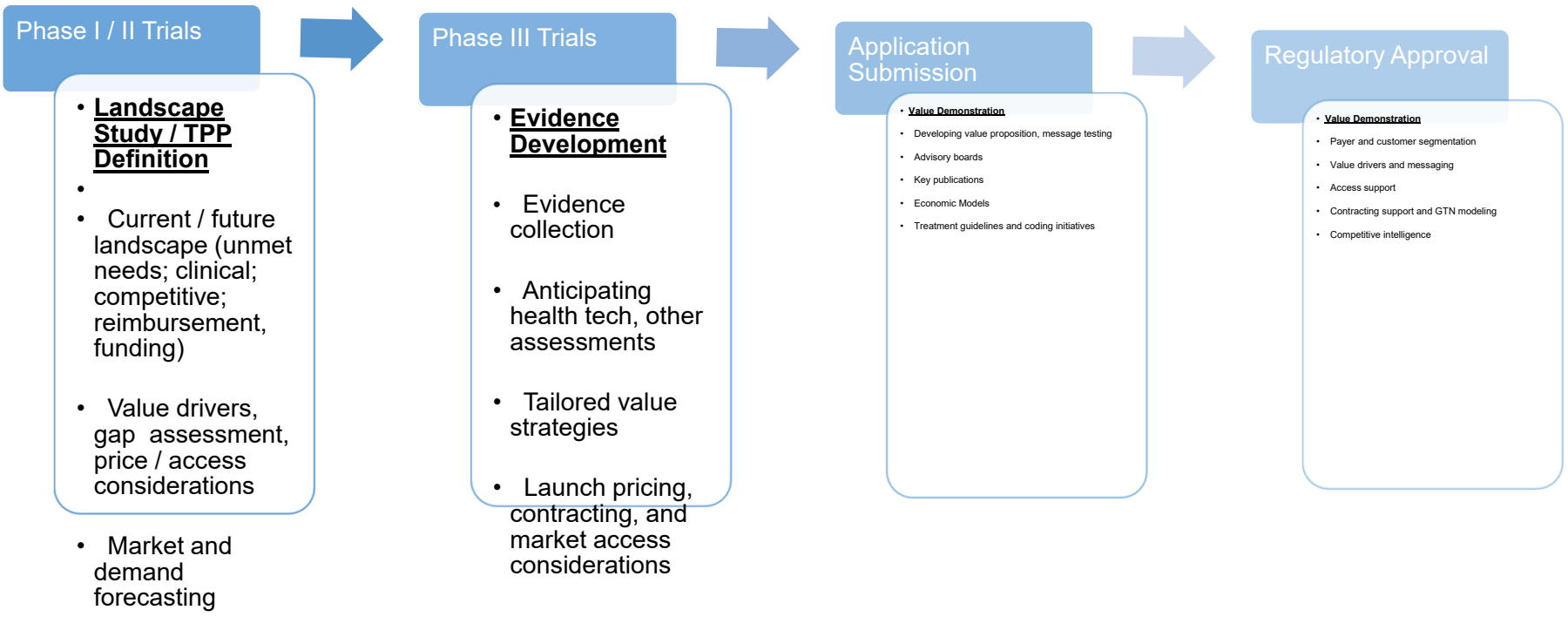
Pre-Launch Value Proposition Development

- Increasingly important component of successful product launch
  - Early engagement with customers to co-develop value proposition
  - Alignment of R&D, medical, and commercial functions
  - Focus on pricing, contracting, and market access strategies
  - Collection of supporting data
- But pre-approval regulatory constraints
  - FDAMA 114 exception to the FDCA's misbranding provisions for certain communications with payors, formulary committees, or other similar entities about unapproved or investigational uses of drugs
  - "Health Care Economic Information" ("HCEI")

"Health Care Economic Information" Defined

- "Any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes of the use of a drug. Such an analysis may be comparative to the use of another drug, to another health care intervention or to no intervention"
  - Can include, for example, evidence dossier; peer-reviewed reprints; software packages comprising a model, with user guide; BIMs; slides; brochures
- "Competent and Reliable Scientific Evidence" ("CARSE")

Considerations for the Pre-Launch Period



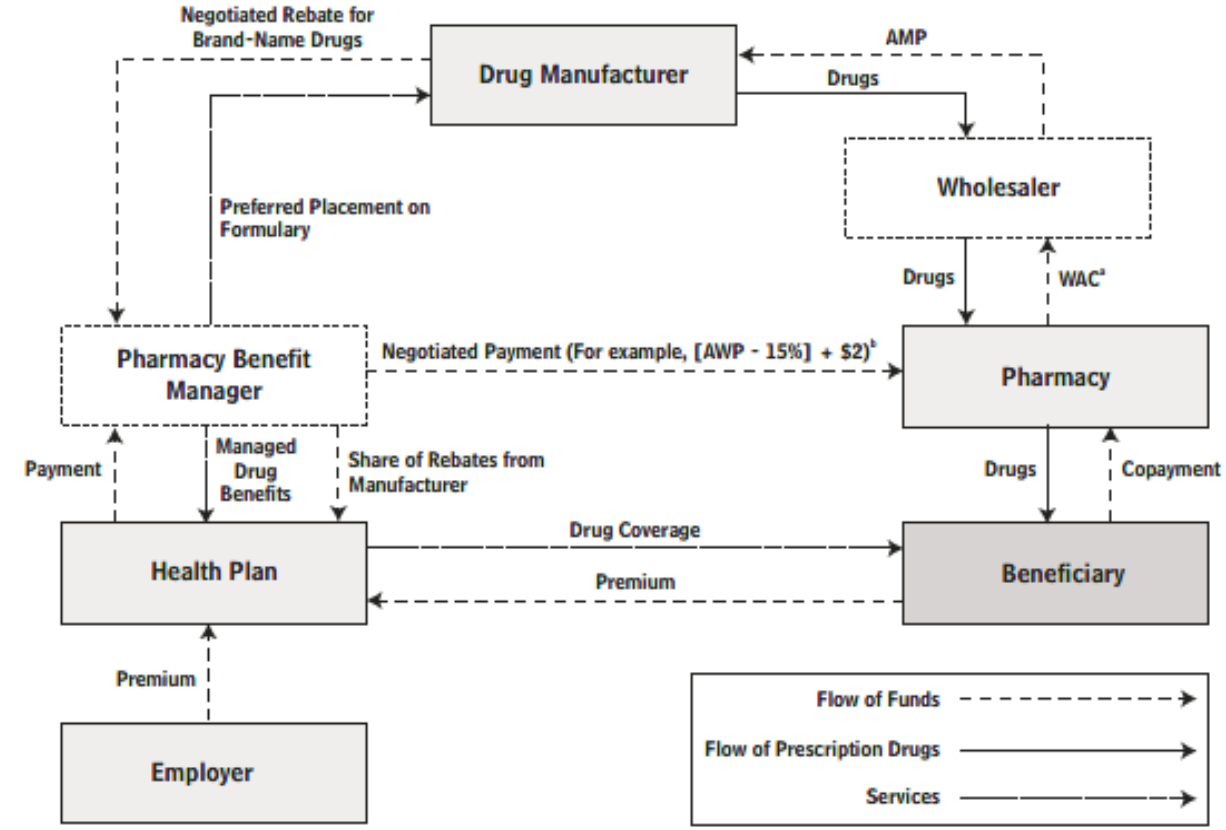
Source: Certera, "Preparing for High Stakes Meetings; How to Best Convey a New Drug's Value to Payers" (June 2021)

Impact of Drug Pricing on Business Relationships

Impact of Drug Pricing on Business Relationships

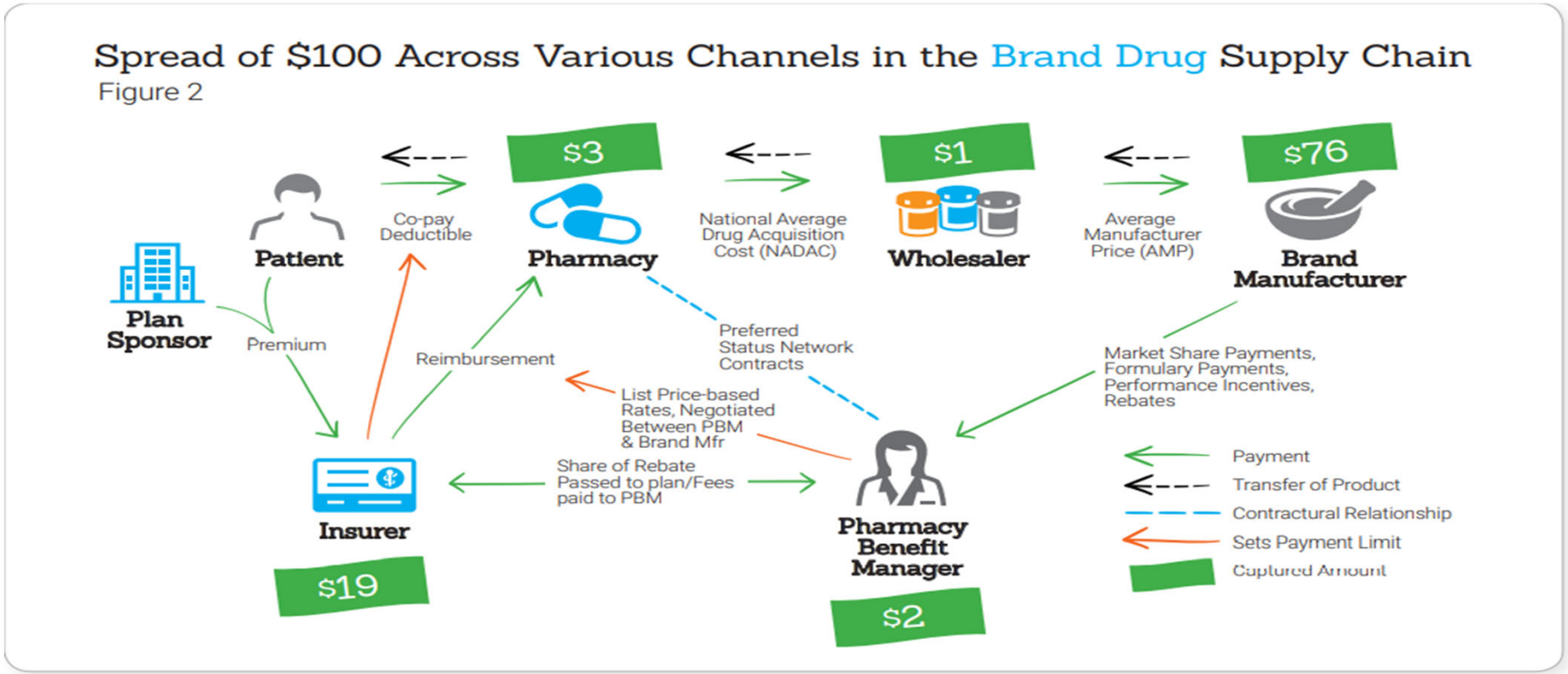
- Stakeholders include:
  - Distributors/Wholesalers
  - Pharmacies
  - PBMs
  - GPOs

Impact of Drug Pricing on Business Relationships



Source: Congressional Budget Office.

Impact of Drug Pricing on Business Relationships



Impact of Drug Pricing on Business Relationships

- Important to distinguish between discounts and *bona fide* service fees
- Related question of whether a service is a “core” or “expanded” service
- FMV analyses can be valuable
- Fees do not have to be the same, or even for the same bundle of services, to still be *bona fide*

Polling Question 2

How often does your company conduct FMV analyses of service fees paid to channel partners?

A. Annually

B. Whenever a change is made to approved contracting terms

C. Some other time period or triggering requirement

D. We do not conduct FMV analyses of service fees

Impact of Drug Pricing on Business Relationships

- ***United States ex rel. Borzilleri v. Abbvie, Inc., et al.***
  - Dismissed case where relator claimed that fees to PBMs were above FMV and were not for *bona fide* services [used quotes from a CBI conference to prove his case]
- ***Streck* cases**
  - Disconnect between language in contract and price reporting practices pertaining to "price appreciation" fees paid to wholesalers, regarding whether they are *bona fide* service fees or discounts, led to FCA liability

Corporate Counsel Perspective

Corporate Counsel Perspective – Initial Considerations

- Industry standard for companies to conduct a market assessment to determine whether development of a new product or indication is financially attractive
- Market assessment inherently involves establishing a price – or price range - and demand forecast
  - Gross revenue = price x volume
- Market assessments vary in sophistication based on company infrastructure and groups involved

Corporate Counsel Perspective – Initial Considerations

- Even though established early, market assessments tends to be extremely “sticky”
  - Fundamental assumption with respect to virtually all subsequent business decisions
  - Can be particularly challenging for smaller public companies where the market assessment is material from a capital markets perspective

Corporate Counsel Perspective – Initial Considerations

- Market assessment considerations for corporate counsel
  - Price/Price range
    - Does the price/price range seem reasonable in light of competitive landscape and the target product profile?
  - Demand forecast
    - Has the addressable market been appropriately sized?
    - Are market share assumptions reasonable in light of competitive landscape and the target product profile?

Corporate Counsel Perspective – Refining Assumptions

- As launch approaches, efforts to refine price/price range and market forecast begin
- Typically implemented through market research
- Helpful for corporate counsel to remain close to the process
  - Review of market research stimuli
  - Continue to check assumptions regarding price/price range and demand forecast
- Likely to be a very dynamic process
  - Assumptions regarding competitive market impacted by changes in clinical development timelines and success or failure of regulatory milestones

Corporate Counsel Perspective – Pricing Governance as Launch Approaches

- Complexities associated product pricing – including establishing launch price and the subsequent pricing strategy - warrant disciplined governance
  - Centralizing discussions within a group of subject matter experts reduces risk of uninformed communications within the organization
  - Especially important in US companies that are subsidiaries of ex-US parents

Corporate Counsel Perspective – Pricing Governance as Launch Approaches

- A “Pricing Committee” or similar governing body is common
- This infrastructure likely exists in larger, established organizations
- If a Pricing Committee does not exist, when is it appropriate to establish one?
  - Consider internal dynamics and the amount of internal “noise” being generated around pricing
  - Establishing a Pricing Committee before there are concrete decisions to be made has the benefit of setting the tone within the company that pricing-related matters are subject to a disciplined process and are not to be discussed casually

Corporate Counsel Perspective – Pricing Committee Considerations

- Memorializing the composition, scope of responsibilities, and decision-making authority of the Pricing Committee in a written charter is best practice
- Composition of the Pricing Committee will be driven, in part, by size and structure of the organization

Corporate Counsel Perspective – Pricing Committee Considerations

- Common functions/capabilities represented on the Pricing Committee include:
  - **Senior Market Access representative (typically the Chair)**
  - **Senior Finance representative (*e.g.*, Division Controller or CFO in a smaller company)**
  - Government Pricing representative (if this function exists independently of Market Access or Finance)
  - Trade/distribution representative (if this function exists independently of Market Access)
  - **Senior business leader (*e.g.*, Division GM or Chief Commercial Officer in a smaller company)**
  - Corporate Counsel (consider whether this should be a voting or non-voting role)
  - Senior Sales representative (consider whether this should be a voting or non-voting role)
  - Corporate Communications representative (consider whether this should be a voting or non-voting role)

Corporate Counsel Perspective – Pricing Committee Considerations

- Establishing or revising pricing becomes more complicated in global organizations
  - Need to balance complexities of US pricing mechanics with expectations of ex-US stakeholders
- Maintaining US Pricing Committee's final decision-making authority over US pricing actions is advantageous
  - Keeps decisions with subject matter experts
  - May limit potential exposure of ex-US stakeholders from inquiries with respect to which they are not best positioned to address
- May require education of ex-US stakeholders regarding complexities of US pricing considerations
  - Having ex-US stakeholders establish price range may be an effective approach

Corporate Counsel Perspective – Pricing Committee Operations

- Memorializing the decisions taken at a Pricing Committee in meeting minutes is best practice
  - It is not practical or necessary to have meeting minutes be a transcript
  - Including high level of detail on some topics and not others could leave a reader with an inaccurate understanding of the meeting
  - Consider circulating minutes in draft form to voting members and corporate counsel
- In order to enhance efficiency after the launch price is set, it is typical for a Pricing Committee to establish a "sandbox" or set of business terms which the Market Access may offer customers without approval of the Pricing Committee
  - Typically defined by class of trade of customer
  - "Sandbox" terms are ones that have been determined in advance to ones that will not have unintended pricing consequences (*e.g.*, set a new Best Price)

Reputational Considerations

Reputational Considerations

- Mylan EpiPen – Price increase of over 500% over 7 years; resulted in Congressional hearings, and class action and DOJ settlements relating to Antitrust and Medicaid Drug Rebate reporting violations
- Valeant/Philidor – Two dermatology drugs increased in price by over 1700% over 6 years; used a pharmacy with purportedly dubious tactics to obtain health insurance; resulted in criminal prosecutions of certain execs
- Martin Shkreli/Turing – Increased a drug used to treat AIDS patients by 2000%; investigated for Antitrust and Securities laws violations; “banned for life” from pharma

Reputational Considerations – Corporate Counsel Perspective

- In addition to the traditional reputational risks, key opinion leaders represent an important stakeholder for pricing decisions and mismanagement of their expectations can result in negative attention
- Key opinion leaders involved in the registration study as well as those who are not each warrant consideration
- Considerations associated with key opinion leaders involved in the registration study include:
  - These physicians know the clinical data as well as anyone
  - They are also likely to be keenly aware of clinical data for other approved and investigational products as well as the pricing of such products
  - They are likely to be in frequent contact with senior company representatives, perhaps in connection with publication of the study or in preparation for an FDA Advisory Committee meeting
  - These combination of factors put such physicians in a unique position to have – and express – an informed opinion regarding a product's potential price

Reputational Considerations – Corporate Counsel Perspective

- Considerations associated with key opinion leaders *not* involved in the registration study include:
  - In many therapeutic areas there is often a vocal group of physicians who are active on social media, particularly Twitter
  - These physicians will likely be less informed regarding the clinical data
  - They may be less likely to be motivated by a desire to engage in a meaningful dialogue regarding a product's value proposition and more likely to be motivated by desire to generate a headline
  - Those with negative opinions are often more vocal than those with a more balanced or even positive perspective

Legislative and Regulatory Initiatives Targeting Drug Costs

Legislative and Regulatory Initiatives Targeting Drug Costs

- Transparency laws
- Prescription drug affordability boards ("PDABs")
- Payment reform and benefit design laws
- Executive Orders and other administrative actions
- Center for Medicare & Medicaid Innovation models
- Congressional inquiries
- Enforcement actions

HAVE A QUESTION?