

US Pricing Basics and What to Expect from Healthcare Reform

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Research Forum, UCSD Skaggs School of Pharmacy

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Agenda

- ▶ General pricing basics / pricing value
- ▶ US health care reform and pricing

MME Basics

- ▶ MME was established in 2001 and has offices in Oxford, MS; Montclair, NJ; and Oxford, UK
 - Client base includes large and emerging bio/pharmaceutical firms
 - Areas of expertise include biotech, oncology, hospital, and managed care
- ▶ We specialize in developing value-based marketing strategies for health care goods and services with the ultimate goal being:

To help our clients make the most informed and profitable decisions possible for their products

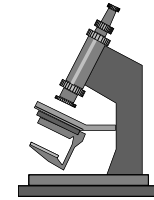
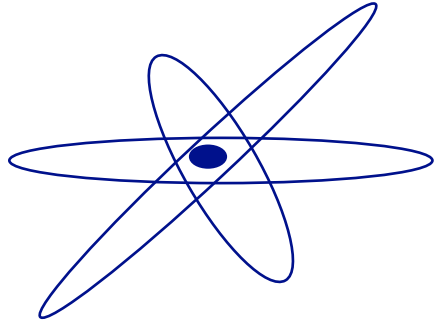
- ▶ We make available to our clients:
 - A unique combination of manufacturer and customer economic and clinical perspectives combined with solid academic theory
 - Strategy development and tactical execution to support informed decision making
 - Assessment and planning of opportunities and competitive situations at every stage of the product life cycle
 - Breadth and depth of experience, with the completion of > 125 price strategies in the US and EU in the last 5 years

Our clients learn from our experience & profit from our thinking

MIME

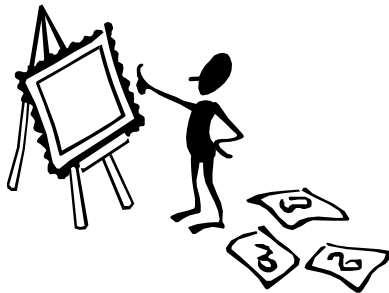
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General Pricing Basics



Is pricing a science?

Or an Art?



Pricing Art: Three Basic Choices

▶ Premium

- Class-(re)defining – far higher than current competitors, connoting a unique and superior value proposition
- Premium – within reach of current competition, but sufficiently higher to be noticeable

▶ Parity

- Similar to the current competition but slightly higher or lower (usually a tactical difference)

▶ Penetration

- Discount – within reach of current competition, but sufficiently lower to be noticeable
- Low-ball – far lower than current competitors, implying a value shift (generic)

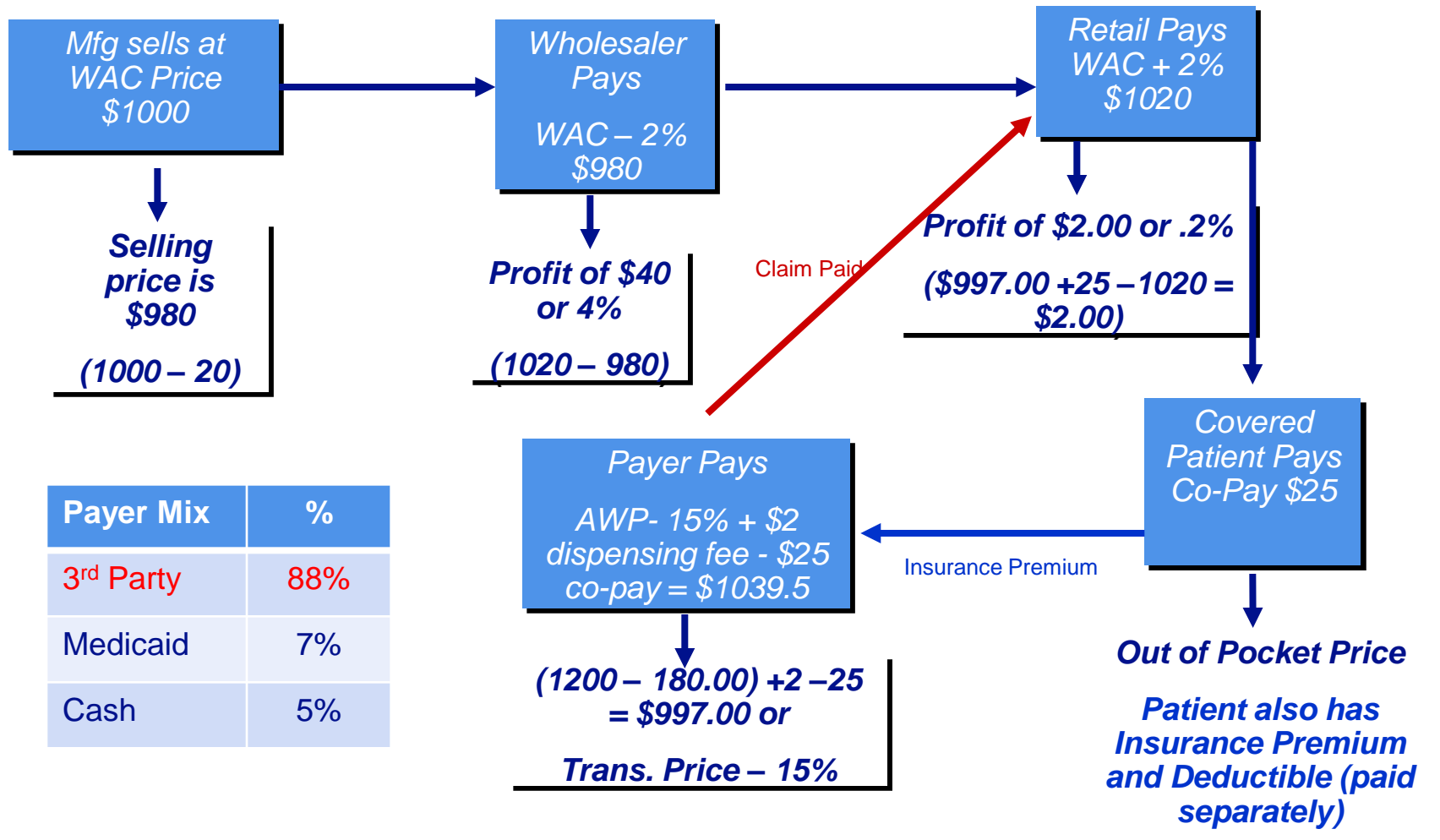
Informed and Profitable Decisions Are Based Upon:

- ▶ Not only ...
 - Past experience
 - Common knowledge or preconceptions
- ▶ But also ...
 - Knowing what is important and to whom
 - Whose opinions matter and why
 - Asking basic questions in a practical structure and...
 - Putting input and feedback in proper context
 - Data collection, review, and analysis
 - Building a present market understanding and designing the future
 - Applying “open-minded discipline” throughout

US Drug Prices Definitions

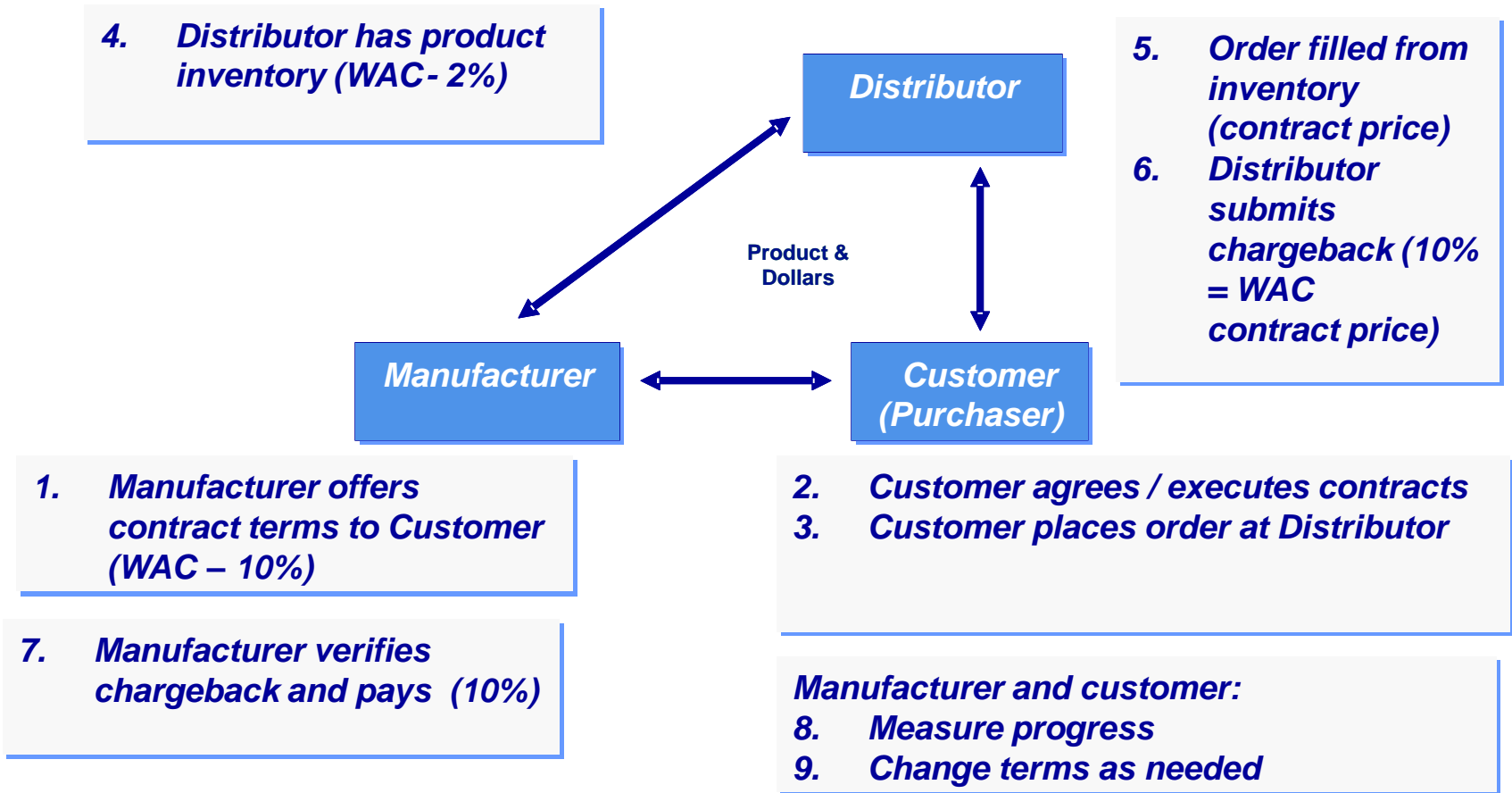
- ▶ **Public Price** = Estimated price charged by retail pharmacies to cash payers and/or reimbursed by third party payers (minus co-pays and/or discounts)
 - **AWP or Average Wholesale Price** = average price at which wholesalers sell drugs to physicians, pharmacies, and other customers
 - Perceived as “sticker price” of drug and “Ain’t What’s Paid”
 - Scheduled to disappear or at least get a new name
- ▶ **Wholesale acquisition cost (WAC)** = Price normally charged by manufacturers to wholesalers
 - Discounts and rebates reduce prices below WAC
- ▶ **Net Price** = price paid to manufacturer after all discounts and rebates
 - **Average Manufacturer Price (AMP)** = price paid to manufacturer by wholesale for drug distributed to the retail pharmacy class of trade
 - **Average Selling Price (ASP)** = Base price for the reimbursement of drugs administered under Medicare Part B
 - Both are calculated quarterly as roughly total net sales divided by units sold (exclusions from calculation differ e.g. Federal / Medicaid sales, chargebacks, etc.)

Pharmacy Benefit: Pricing Flow (3rd party)



Illustrative but differences can exist for chain, retail, acute, chronic and mail order.

Purchase Based Contracts – Chargeback flow



Pricing Value

The Elements of Pharmaceutical Pricing



- ▶ Several factors must be considered in setting or managing pharmaceutical pricing
 - 6 external
 - 2 internal
- ▶ Each individual factor is not always important – failing to consider each can lead to problems
- ▶ Main drivers in determining price and price changes
 - Value
 - Competitive situation
 - Company needs and abilities

Pharma Pricing = Value Judgment

- ▶ Context is provided by ...
 - Clinical data
 - Recognition of need
 - Alternatives and competitors
 - Reimbursement
 - Marketing activities
- ▶ Different players view these same things differently

Value at the Core

- ▶ Recognizing, framing, delivering and capturing value is the core of marketing
- ▶ Manufacturers and customers both judge the value of a product or offering and then make decisions
 - Value can be inherent in the molecule and readily perceived ...
 - However, the value of innovation is often more difficult to recognize and communicate.
 - Value can be judged in terms of substitutes or competitors
 - Value judgments evolve and change, especially with experience
- ▶ Value is always “in the eye of the beholder”

Value Comparisons

- ▶ We should be most interested is the **incremental value** that a new product brings to market
- ▶ Determinants of Incremental Value
 - Level of Unmet Needs
 - Criticality of Condition
 - Incremental Benefit Provided

These factors interact

The Core of Pricing Strategy

- ▶ Having a clear understanding about the positioning, differentiation and potential of your product
- ▶ Making informed decisions about the issues at hand
- ▶ Acting in order to optimize marketing in the dynamic healthcare environment
 - Building a Value Frame™ for the market
 - Understand the customer's perspective and not just your own
- ▶ All within the context of both today and tomorrow
 - Factors and questions to consider
 - Challenges and opportunities
 - Activities and actions
 - Evaluate and change

Pharmacoeconomics Today

▶ Current uses include:

- Retrospective price justification
- Quest for a “hook”
- CV fodder

▶ Current results include:

- Studies that don't affect product use
- Marketing and pricing decisions are often made without the benefit of pharmacoeconomic information
- The **undervaluing** of pharmacoeconomics by:
 - Corporate management
 - Marketers
 - Medical Practitioners
 - Payers

The Promise of Pharmacoeconomics

At its best, pharmacoeconomics should:

- Drive clinical research protocols
- Describe important aspects of the market to the marketer
- Inform and guide pricing and marketing decisions
- Help customers to both:
 - Comprehend value and
 - Use products efficiently and effectively

Role of Health Economics in the US

- ▶ No formal economic submissions are mandated in the US nor are they a major factor in most P&T reviews
- ▶ AMCP (Academy of Managed Care Pharmacy) has issued a “format for formulary submissions”¹
 - A standardized “dossier” for drug companies’ submissions of new and existing detailed information, not only on the drug's safety and efficacy, but also on its overall clinical and economic value relative to alternative therapies
 - There are two important goals:
 - Improve the quality, timeliness, scope and relevance of the data and information made available for P&T Committees
 - Facilitate and streamline the acquisition of data and information and the review process for managed care organizations' pharmacists
 - While these submissions are often necessary they are rarely sufficient to achieve formulary status
- ▶ Healthcare reform emphasis on comparative effectiveness may change this landscape significantly

1. <http://www.amcp.org/amcp.ark?p=0F6E1295>



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Patient Protection and Affordable Care Act (“PPACA”) US Healthcare Reform

US Healthcare Reform Background

▶ Current system

- 58.3% Employer based coverage for the bulk of the population through private insurers
- 26.4% Government coverage for elderly / disabled (Medicare & Medicaid), indigent (Medicaid), other groups (VA/DoD, IHS, etc.)
- 15.3% No coverage for those who can't afford it or choose to go without
 - Medicare Part D = drug coverage for many previously uncovered

▶ Employer based coverage grew out of historical wage controls and non-taxability of benefits provided

▶ Reform efforts were targeted at:

- Security and stability for those with existing health insurance
- Insurance for those without coverage
- Slow growing healthcare cost

Source: Kaiser Family Foundation and whitehouse.gov (Presidential Address September 9, 2009)

US Health Care Reform

- ▶ Passage of US Health Care Reform touches several parts of the pharmaceutical market:
 - Medicaid: New mandatory rebate levels and expanded coverage
 - Medicare Part D: Filling in the donut hole
 - 340B pricing extended to more institutions
 - Decisions on Biosimilars
 - Private Insurers: Coverage of pre-existing conditions and new caps on total out of pocket requirements
 - Comparative Effectiveness Research and Patient Centered Outcomes
 - Early Industry Response
- ▶ This presentation provides our initial assessment of how these initiatives change our clients' business thru:
 - Direct impact
 - Trends to watch

US Health Reform Implications: Private Insurers

- ▶ Coverage of uninsured will expand customer base
 - An estimated 32 million newly insured
- ▶ Elimination of lifetime caps
 - For many expensive drugs the lifetime caps have been a worry, that worry is removed for both patients and manufacturers
- ▶ Capping of annual out-of-pocket (OOP) costs
 - Annual caps on OOP (proposed to be about \$5,000)
 - Cap would apply to ALL costs (deductible, co-pays, etc.)
 - Would mean that a 20% co-insurance could be less problematic for patients in private plans because the cap is on all OOP expenses
- ▶ Elimination of exclusion / denial for pre-existing conditions

US Health Reform Implications: Medicaid Rebates

- ▶ Eligibility for Medicaid program will be expanded
- ▶ Medicaid basic rebate moving from 15.1% to 23.1% effective 1/1/10
 - Clotting factors and pediatrics at 17.1%
 - Managed Medicaid now eligible for rebates effective 03/23/2010
 - Generic base rebate increased from 11% to 13%
 - Medicaid rebate capped at 100% of AMP
 - Payers are likely to ask for more rebates and discounts because companies have used the 15.1% as a cap that payers could understand
 - For heavy Medicaid use drugs, such as atypicals and HIV meds, the net price will be substantially lower
- ▶ New calculations and definition of AMP – a higher AMP means higher rebates and the need to be very careful in computations
 - New definition effective 10/1/10
 - See following slides for details
- ▶ Medicaid AMP for line extensions will be tied to base AMP of original formulation
 - Potential problem for “life cycle management”

US Health Reform Implications: Medicaid / 340B Expansion

- ▶ More entities are eligible for the program and therefore additional product volume will be subject to mandatory discounts:
 - Children’s hospitals, free standing cancer hospitals, critical access hospitals, rural referral centers, sole community hospitals
 - Limits to out-patient pharmacy and exclusion of drugs purchased through GPOs still apply
 - “New” pricing effective 3Q10 based on new 1/1/10 Medicaid rebates
- ▶ Orphan drugs are excluded from the expanded 340B program
- ▶ Onerous dispute resolution process to ensure covered entities receive 340B ceiling prices
 - Refunding of overpayments in instances of retroactive pricing adjustments and other circumstances of erroneous overcharges
- ▶ Institutions are still pushing for both expanded eligibility and special pricing on inpatient drugs

Medicaid Rebate Change Chart

NDC Code: 12345-1234-XX	4Q09	4Q10	
WAC	\$100.00	\$102.00	Annual 2% Price Increase
Step 1: Calculate AMP	\$95.00	\$102.00	New "Definition of AMP, closer to WAC"
Step 2: Calculate Basic Rebate:			
a) AMP x Rebate %	\$14.345	\$23.562	15.1% of AMP
b) AMP – Best Price	<u>\$5.000</u>	<u>\$5.000</u>	Changed from 15.1% to 23.1%
Greater of a) or b) above	\$14.345	\$23.562	
Step 3: Additional URA	<u>\$0</u>	<u>\$1.230</u>	Increasing Price faster than inflation
Medicaid Rebate:	\$14.3450	\$24.7924	
340B Price	\$80.66	\$77.21	

- ▶ In step 1, new definition of AMP is higher since less exclusions apply
- ▶ In step 2, Base Rebate increases to 23.1%
- ▶ In step 3, calculate and apply CPIU impact for additional rebate
 - Also impacts 340B price

Assumes Base AMP gets re-stated, discount levels remain constant (BP = \$93)

Medicaid Rebate Change Chart: Line Extensions

- ▶ Original formulation launched at WAC = \$100 and has annual 2% price increase
- ▶ 2015 same manufacturer launches a new “one a day” formulation 2x/day existing price

NDC Code: 12345-9999-XX	1Q015
WAC	\$112.62
Step 1: Calculate AMP	\$112.62
Step 2: Calculate Basic Rebate:	
a) AMP x Rebate %	\$26.014
b) AMP – Best Price	<u>\$20.000</u>
Greater of a) or b) above	\$26.014
Step 3: Additional URA	<u>\$10.750</u>
Medicaid Rebate:	\$36.7641
340B Price:	\$75.85

Annual 2% Price Increase

23.1% of AMP

Use Base AMP of Original Formulation = \$100 (not \$112.62)

Steps:

1. Base AMP/Base Index = Base factor
2. Base factor x Current Index = Inflation Index
3. Current AMP - Inflation Index = Inflation

- ▶ Base AMP is linked to the baseline of the original formulation – launched in 4Q2009

Assumes Base AMP gets re-stated, discount levels remain constant (BP=\$93)

US Health Reform Implications: Medicare

- ▶ Elimination of employer's tax deduction for a portion of the cost of retiree drug plans could add 6 million patients to Part D
 - Part D plans may become even more important and influential as they grow
 - An estimated 6 million retirees will move from private plans to Part D
- ▶ Potential for increased commercial rebating requests due to Medicaid rebate floor change and additional Part D rebates pressure
- ▶ Part D: Donut Hole Rebate
 - Starting January 1, 2011 brand manufacturers will pay 50% rebate of the cost of drug in the donut hole
 - Discount amount will count towards patients' TrOOP
 - Starting in 2013, insurers will fill part of this gap, escalating to 25% by 2020
 - Starting in 2011 generic manufacturers pay 7% rebate that escalates to 75% by 2020
- ▶ Part B: Provisions allow assignment of same J-Codes for drugs identified as "biosimilar" products
 - Placing all into the same J-code will essentially allow CMS to "MAC" biologicals
 - Similar to old US Least Costly Alternative ("LCA") designation or the Festbtrage system in Germany
 - LCA was ruled illegal by US courts, so CMS may need to be creative
 - If brands cut prices and the "generics" respond, prices will spiral down

US Health Reform Implications: Biosimilars

- ▶ Legislation provides a path for approval for “highly similar” biologic products after 12 years of exclusivity
 - The exclusivity period is determined 12 years from “the date on which the reference product was first **licensed**” under the PHS Act
- ▶ Approval will be through a newly-created abbreviated biologic product application (aBPA) process
 - “Biosimiliars” defined as “highly similar” to referent product
 - Requires “no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency of the product.”
 - Applications for an aBPA can be filed 4 years after reference drug **approved**
 - First biosimilar approved will be allowed 12 months exclusivity
- ▶ New definitions imply that the FDA could request extensive clinical testing to demonstrate non-inferiority
 - FDA is not required to approve an application when the science and experience does not allow approval
 - Will require clinical testing for evidence that the aBLA product safety (including immunogenicity), purity and potency
 - Study requirements may be waived at the Secretary’s discretion
 - Must have the same mechanism of action; an indication for which the referent drug is already approved; and same route of administration, dosage, strength and quality

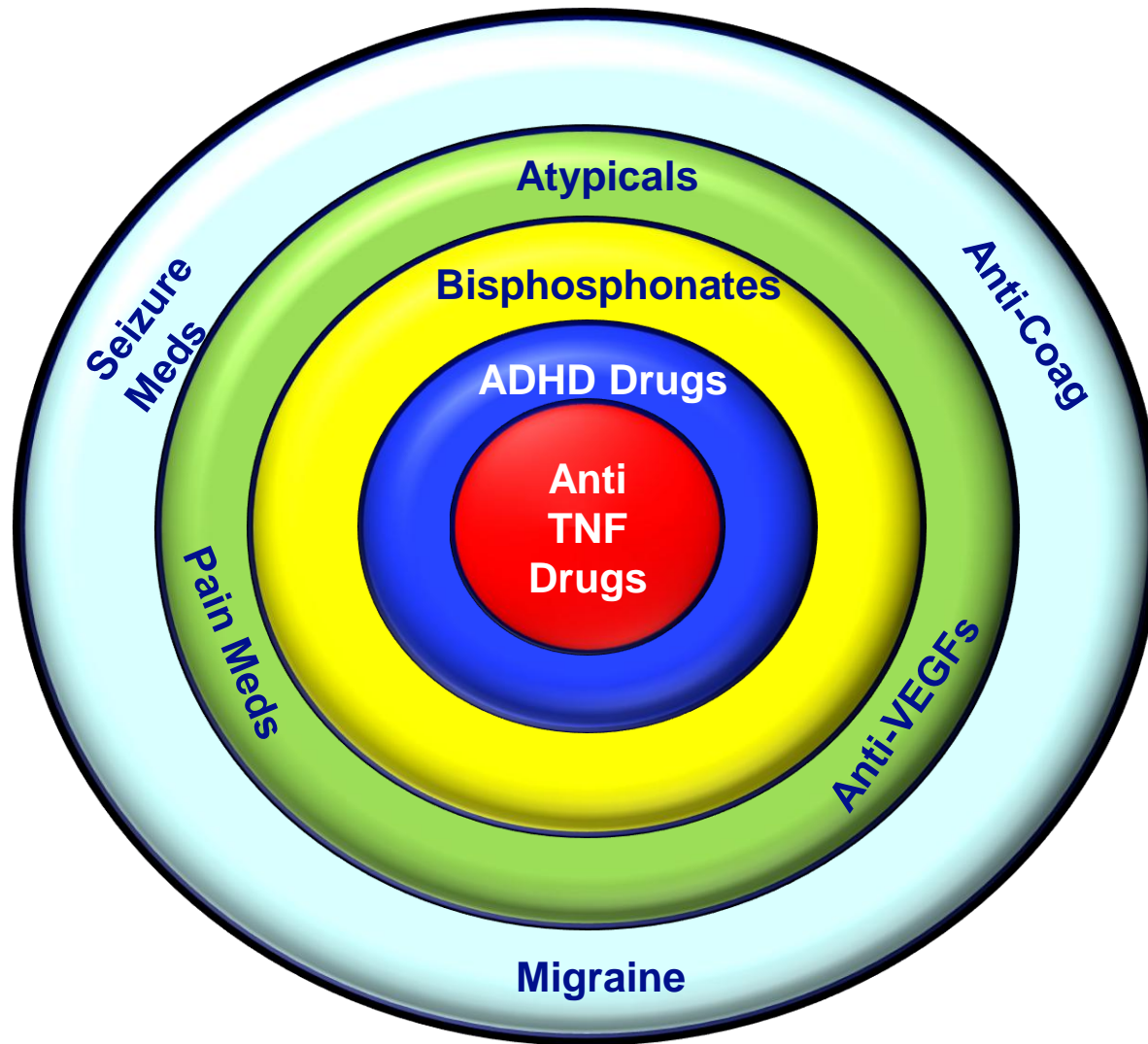
US Health Reform Implications: Biologic Interchangeability

- ▶ Any aBLA product may be classified as either “biosimilar” to, or “interchangeable” with, the referent product
- ▶ An “interchangeable product is defined as a “biosimilar” product that is “expected to produce the same clinical result”
 - Must be minimal risk in terms of safety and efficacy if substituted for referent product
 - Currently, there is no guidance provided beyond these requirements
- ▶ Substitution of “interchangeable” product would be allowed “without the intervention of the health care provider who prescribed the reference product”
 - Likely to be controlled by state laws and regulations
 - States currently regulate pharmacy practice of pharmaceutical substitutions
 - Process likely to be similar to regulation of generic aNDA product substitution
 - States highly motivated to allow substitution if a product meets the high standard of “interchangeability”
- ▶ Secretary has substantial discretion in this entire process

CER and Patient Centered Outcomes Research

- ▶ New private, nonprofit organization, the Patient-Centered Outcomes Research Institute
 - AHRQ is the key agency for innovative dissemination initiatives
 - Terminates Federal Coordinating Council for Comparative Effectiveness Research
- ▶ Will “set a national agenda for identifying priorities in patient-centered outcomes research” that will help healthcare providers and payers make informed decisions about how to treat patients effectively without wasteful overspending
 - Aimed at determining the best clinical choices using studies that are designed for the “real world”
 - Funding of “counter-detailing” initiatives will begin to show how this might take effect
- ▶ Establishes limitations around the use of the Institute’s research findings which include:
 1. Requiring the Secretary use an iterative and transparent process when using the research in making coverage determinations;
 2. Allows stakeholders to provide information to inform the determination, review draft proposals and submit public comments on draft proposals;
 3. Prohibits Secretary from using the Institute’s research as sole evidence in making a determination.

MME Assessment of the most affected Rx areas for CER



- ▶ < 10 products or categories that may be affected
- ▶ Anti-TNFs are squarely being targeted for evaluation, followed by ADHD drugs
- ▶ Drugs in other categories are less likely to be scrutinized
- ▶ Several areas of study will benefit pharmaceutical companies, especially those that seek to improve compliance and chronic disease outcomes

To Judge Price from Multiple Perspectives Ask:

1. How do you want to serve patients?
2. What problem(s) does this product solve?
3. Who owns those problem(s)? Who else?
4. Who can act on it? Who else?

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Questions?



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Thank You

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