Adapting Pharmaceutical Reimbursement Policies to Manage Spending on High-Cost Drugs

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What are specialty drugs?

So-called specialty drugs are *high-cost* drugs

- high prices (US Medicare threshold is $USD600 or more monthly cost, although many drugs exceed the threshold)
- *may* require special handling or administering, shipping, or storage (such as an injectable)
- *may* have a Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS) in place specifying that there is required training, certifications, or other requirements that must be met in order for the drug to be administered

Specialty drugs (cont'd)

- Specialty drugs accounted for 1% of drugs prescribed in the USA in 2014, but 32% of drug spending
- Diagnoses treated include cancer, multiple sclerosis, rheumatoid arthritis, kidney disease, cardiovascular disease, growth hormone deficiency, hepatitis C, hemophilia, and immune disorders.
- Typically no or limited competition
  - No generic versions
  - In the USA, (until last month) no biosimilars
- In USA, with a reimbursement system based on leveraging competition, this is a big problem!

Recent headlines put high-cost drugs in the spotlight

How an obscure drug's 4,000% price increase might finally spur action on soaring health-care costs (*Washington Post* Wonkblog, 21 September 2015)

Lack of regulation, little competition, research costs boost US prescription drug prices (Associated Press, 25 September 2015)

Exclusive: Americans overpaying hugely for cancer drugs – study (Reuters, 22 September 2015)

Cancer drugs aren't as cost-effective as they used to be (*Forbes*, 30 September 2015)

Valeant's drug price strategy enriches it, but infuriates patients and lawmakers (*New York Times*, 4 October 2015)

Recent headlines (cont'd)
Value? Affordability? Fairness?

- New drugs launched with very high prices raise questions about affordability (total cost), value for money
- Dramatic price increases for existing drugs raises questions about the basis of price decision-making
- High U.S. versus international prices for specialty drugs in the news again
- Questioning fairness of US taxpayers subsidizing R&D through funding for basic science as well as profits for industry

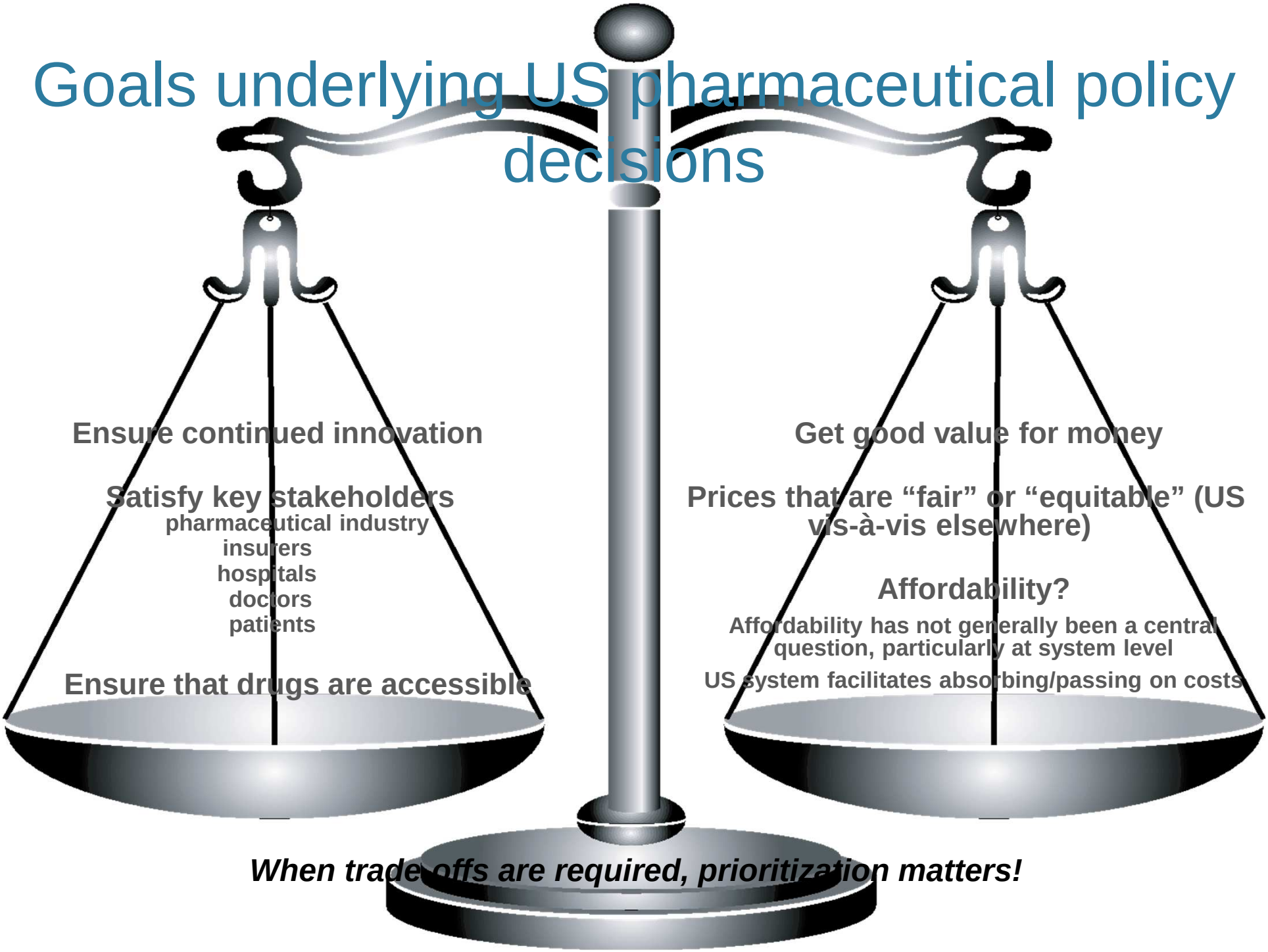
Recent headlines (cont'd)

- Rising drug costs in the US are the current driver of health spending increases
- Out of pocket spending increases for insured patients raise affordability concerns

A window of opportunity for policy change

- Main issues of “Obamacare” (coverage) have been settled; attention shifting to health care cost control
- Congressional investigation launched into “exorbitant” drug prices.
- 2016 Presidential election debates are under way
  - Candidates for Democrat party nominee have put forward proposals to address drug costs

Goals underlying US pharmaceutical policy decisions



When trade offs are required, prioritization matters!

Specialty drug coverage in the USA

- In the USA, specialty drugs are reimbursed as part of pharmacy benefit or medical benefit (specialty drug split is 50/50)
  - **Pharmacy benefit**: Typically covers self-administered oral, injectable and inhaled drugs
  - **Medical benefit:** Typically covers drugs that are injected or infused by a health care professional in the doctor's office, hospital out-patient center, free-standing infusion center/clinic or by a mobile infusion therapy provider at home
- Different reimbursement schemes apply

High-cost drugs: The US reimbursement model

- Manufacturers set prices in a “free” market, albeit one replete with market failures (e.g., monopoly, agency decision-making, moral hazard)
- For specialty drugs reimbursed through the medical benefit
  - Insurers pay hospitals based on price charged, subject to negotiated discounts. Physician offices paid by formula based on average sales price.
- For specialty drugs reimbursed through the pharmacy benefit
  - Insurers define formularies based on medical necessity; Most insurers have no effective ability to decline reimbursement on cost basis. Relative cost-effectiveness (or just price) may come into play when there are alternative therapies.
  - Pharmaceutical benefits managers negotiate discounts or rebates on behalf of insurers, where possible. Savings not always passed on to insurers, consumers.
  - Insurers often restrict usage through, e.g., step therapy, prior authorization requirements

Tiered formularies

- High-cost drugs often listed in fourth or fifth tier of a tiered formulary, in which higher tiers have higher cost sharing.
- Fourth or fifth tier drugs often have co-insurance, rather than co-payment rates.
- Manufacturers may offer patient incentives to defray cost-sharing, limiting impact of tier status on utilization.

Example of a four-tier formulary structure

Drug Tier	Type of Drugs Included	Patient Cost
Tier 1	Most generic drugs	Lowest copay
Tier 2	Most common brand name drugs Preferred brand name drugs Some high-cost generic drugs	Medium copay
Tier 3	Non-preferred brand name drugs	Highest copay
Tier 4: Specialty Tier	Unique or very high-cost drugs	Percentage of total drug cost, called “coinsurance”

How well is this model working?

The US sees big price variation compared to other countries, across insurers and sites of service.

- According to the International Federation of Health Plans, Americans pay anywhere from two to six times more than the rest of the world for brand-name prescription drugs.
- Very large variation in prices paid by U.S. insurers
  - In 2013, the average U.S. insurer paid USD$2225 for Enbrel, prescibed to treat autoimmune diseases. A quarter of insurers paid less than $1950, while 5% paid more than $4000.
  - In 2013, the average U.S. insurer paid $USD6214 for Gleevec, a cancer drug. A quarter of insurers paid less than $5500, while 5% paid more than $11000.
- Commercial insurers pay hospital outpatient clinics two to three times as much as physician offices for the same specialty drug (Fein, 2015).

On the table: Ideas for specialty drug reimbursement policy change

The U.S. Medicare program provides coverage for elderly and disabled, often leads in implementing new payment models.

Policies focused on selected high-cost drugs could have a big impact. In 2014, the top 10 specialty drugs accounted for 44.4% of per-member-per-year spend for all specialty drugs reimbursed by Medicare.

What could Medicare do, given legislative authority?

- International price referencing for select high-cost drugs
- Therapeutic reference pricing (to replace tiered formularies)
- Price negotiations/risk sharing agreements for select high-cost drugs

International price referencing for certain high-cost drugs

- Technically challenging due to problem of non-transparent prices
- As USA often an early or first-launch country, retrospective/retroactive adjustment of payment levels may be needed
- Would likely mean lower U.S. prices and inflated prices internationally
- Potential contribution to loss of dynamic efficiency and innovation in the pharmaceutical sector

Therapeutic reference pricing

- International experience demonstrates potential to achieve very significant savings where there are therapeutic alternatives
  - May be attractive option with increased availability of biosimilars
- Savings could help to meet costs of true breakthrough drugs (high cost, acceptable value)
- Strengthen out-of-pocket spending caps to protect patients
- Concerns about incentives to invest in second-in-class drug development, which yield savings through competition, whether or not they offer comparative advantages in effectiveness

Price negotiations/ risk-sharing agreements

- Adaptable to unique considerations of products under consideration
  - e.g., performance-based agreements in case of uncertain benefits or high potential prescription beyond approved indications
- Value-based pricing models could assist in promoting “appropriate” price differentials that are consistent with U.S. social values and policy priorities
  - May not help with cost/affordability problem in the case of drugs offering very valuable benefits
- Lack of acceptance in USA in bringing affordability (total cost) and cost-effectiveness into coverage and reimbursement decisions is a factor in prospective terms of negotiation

Is reimbursement policy change the best solution?

- With policy changes in the UK and Germany, the US is now alone among developed countries in choosing not to regulate (directly or indirectly) drug prices
- Many believe there is a fundamental problem in granting monopoly power over life-extending treatments to firms that have a fiduciary responsibility to their shareholders to extract maximum profits
- Ultimately, may need to look for solutions outside the reimbursement “toolbox”
  - New R&D models
  - Importation from markets in which prices are lower
  - Compulsory licensing
  - Exercising so-called march-in rights
  - Paying for cure/amortize
  - Regulating direct-to-consumer advertisting to temper demand

Conclusions

- No one-size-fits-all solution. Different payers and different drugs may benefit from different approaches.
- Keeping all options on the table and under discussion may help bring stakeholders together to find an agreeable solution
- These problems require solutions urgently. About 40 percent of drugs under development (about 650) in 2012 were considered specialty drugs (close to half of these are expected to be used to treat cancer) (Milliman, 2012).

Recap

- US reimbursement policies are not well-equipped to manage costs in the era of specialty drugs
- Confluence of public attention to problems, appetite for change, timing of political transition has created a “window of opportunity” for policy change
- US solutions may be influenced by international experience, adapted to fit US policy priorities and the circumstances of the US health system