Pharmaceutical Pricing Policy Options: We Are Only Hostage to Our Own Devices

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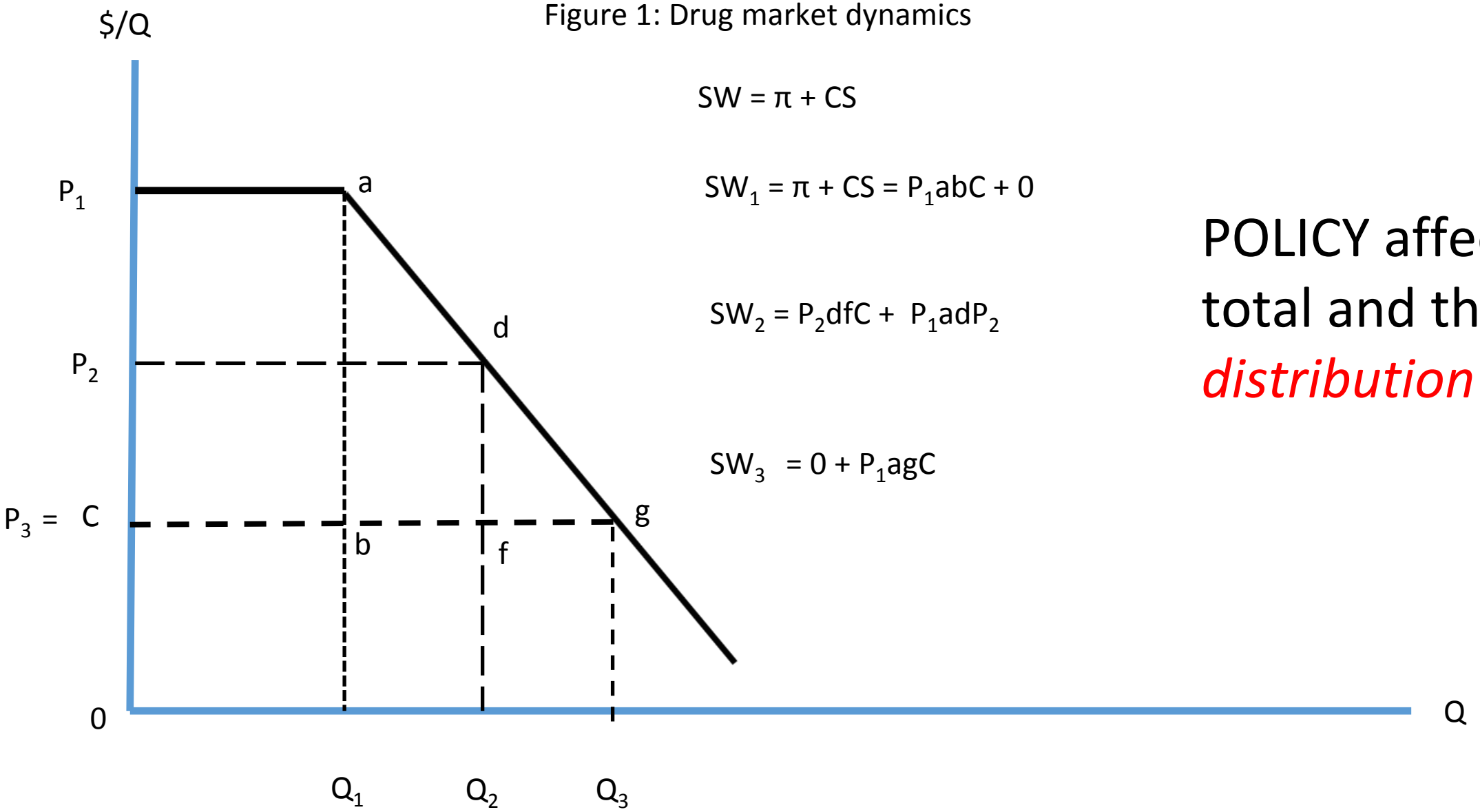
The Bargain We Have Struck

- In the Beginning, … (1928-1940) penicillin was not patented
- Modernity => incentives are necessary
- SO, we grant “fixed term” monopolies to spur innovation
  - Patents = 20 years (formerly 17)
  - Exclusivities, Data and Marketing, range from 180 days to 12 years
- And THEN we HOPE competition ensues to drive price down and increase access, eventually

Figure 1: Drug market dynamics



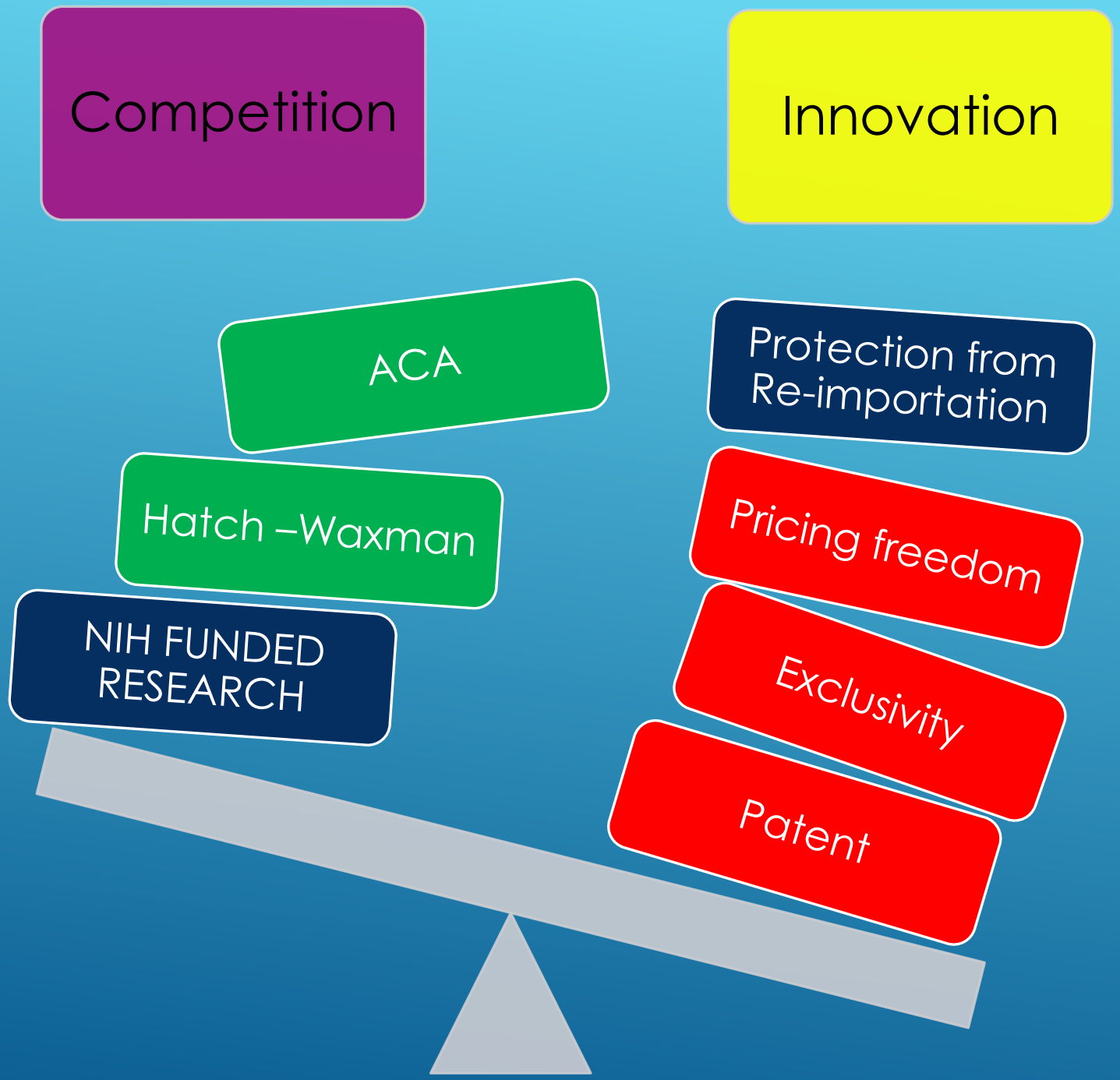
$SW = \pi + CS$

$SW_1 = \pi + CS = P_1abC + 0$

$SW_2 = P_2dfC + P_1adP_2$

$SW_3 = 0 + P_1agC$

POLICY affects the total and the *distribution* of SW


Competition
Innovation
ACA
Hatch –Waxman
NIH FUNDED RESEARCH
Protection from Re-importation
Pricing freedom
Exclusivity
Patent

T. Valoir and L. Paradiso,

"Patent Strategy for Medical Products,"

Intellectual Property and Technology Law Journal

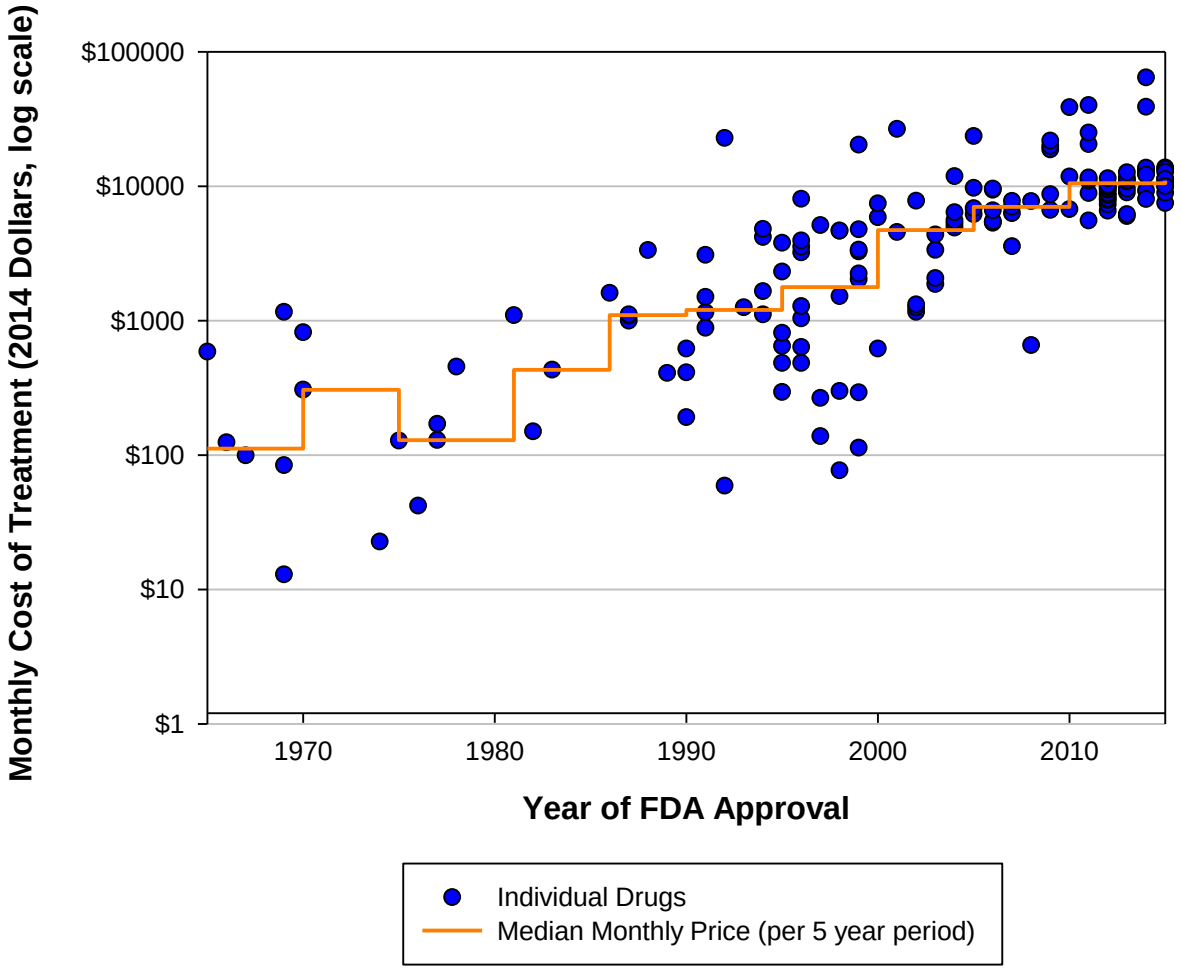
v. 23 n. 9, Sept 2011.

Table 1: Summary of FDA exclusivity periods

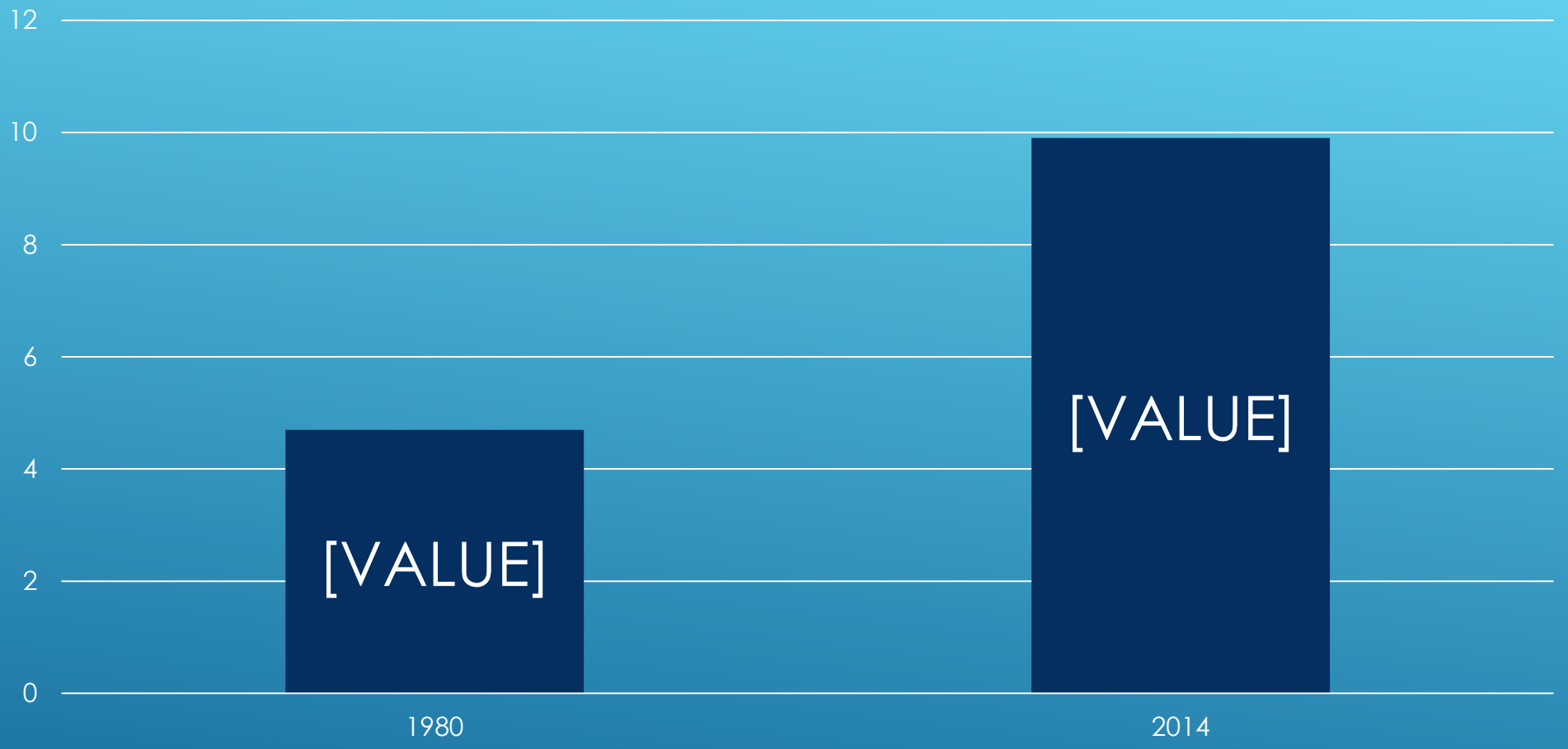
Type	Requirements	Period	Cumulative
New Chemical Entity	Chemical entities never previously approved by FDA either alone or in combination with other drugs. Bars 505(b)(2)[11] and ANDA applications for five years where applicant has not provided its own data or authorized data.[12] Can be reduced to four years if ANDA application contains a ¶ IV certification. 12 years data exclusivity and four year submission exclusivity for biologics.[13]	Five years 12 years for biologics	No
New or Modified Indication	Changes in an approved drug product that affect its active ingredient(s), strength, dosage form, route of administration, or conditions of use may be granted exclusivity if clinical investigations were essential to approval of the application containing those changes. Bars 505(b)(2) or ANDA applications where applicant has not provided own data or authorized data.[14] Not available for biologics.	Three years	No
Pediatric	FDA must request pediatric data, can be two pediatric term extensions, scope of protection same as that to which the six months is appended.[15]	Six months	Yes
Orphan Drug	For a rare disease affecting fewer than 200,000, bars any other FDA applications for that same active pharmaceutical ingredient (API) for treatment of the same disease for seven years, unless the holder cannot manufacture sufficient quantities to meet the needs or the holder gives consent.[16]	Seven years	No
First ANDA	First to file ANDA for generic drug with ¶ IV certification challenging a patent. Bars subsequent ANDA applications until six months after first marketing or favorable patent decision.[17] If patentee files infringement suit, first ANDA is stayed for 30 months.	Six months for ANDA applicant 30 months for patentee	No
Animal Product	Includes both new animal drugs and new uses.[18] Can be reduced to four years if ANDA application contains a ¶ IV certification.[19]	Five years for new animal drug; three years for new use	No

Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval

1965-2015



Source: Peter B. Bach, MD, Memorial Sloan-Kettering Cancer Center



DRUG SPEND / TOTAL HEALTH SPEND

SOME POLICY OPTIONS

- Transparency
  - Require set percent of R&D spend and specific ratio of R&D/marketing (HC)
  - Require disclosure of transaction prices and profits earned overseas (BS)
  - Explain how prices are set, R&D costs, and US tax credits received (BS)
  - Outlaw "pay for delay" deals (BS, and FTC)
- Mandate Cost-shifting
  - Cap OOP Costs (HC)
- Price Controls/ "Pure" Regulation
  - Impose price or inflation controls; require bigger "discounts" (HC and CA)
  - Allow importation from Canada (HC and BS)
- Market-oriented regulatory changes
  - Use reference pricing and relative efficacy determination before sales (Europe)
  - Binding arbitration for truly unique drugs in Medicare
  - Enable Medicare to negotiate (BS: part D; HC: B and D; and TRUMP!)
  - Reduce biologic exclusivity period from 12 to 7 years (HC and TPP)
  - Replace private capital with public capital OR grant prizes
  - Use fast access and diagnostics for better matches (HC, all Rs shorten FDA time)
  - Just say NO to low-value drugs; use indication specific pricing (Peter Bach, ICER)
  - Tie Exclusivity grant to launch price level

PCSK9 Inhibitors for Treatment of High Cholesterol: Effectiveness, Value, and Value-Based Price Benchmarks

Draft Report

A Technology Assessment

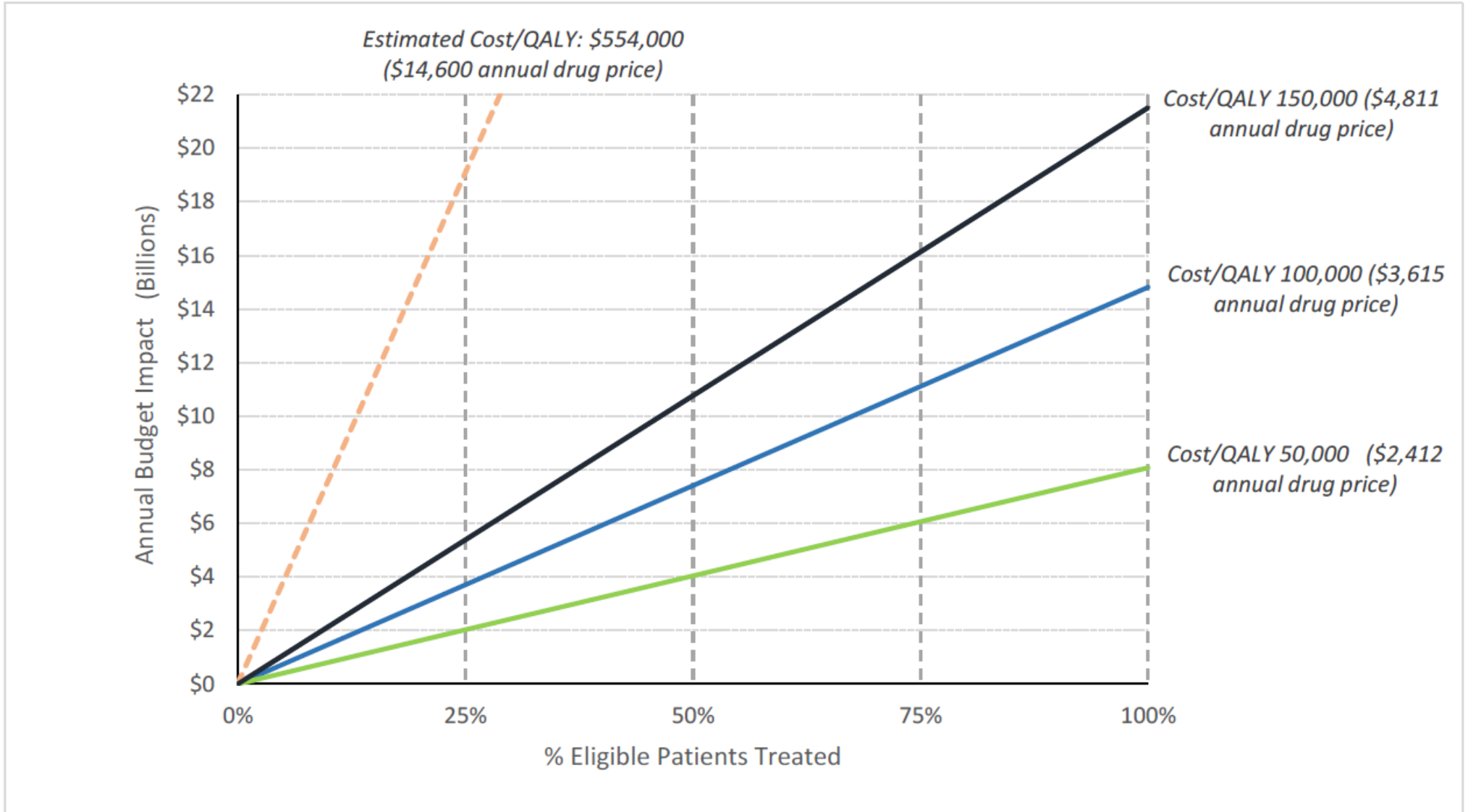
Draft Report

September 8, 2015

Completed by:

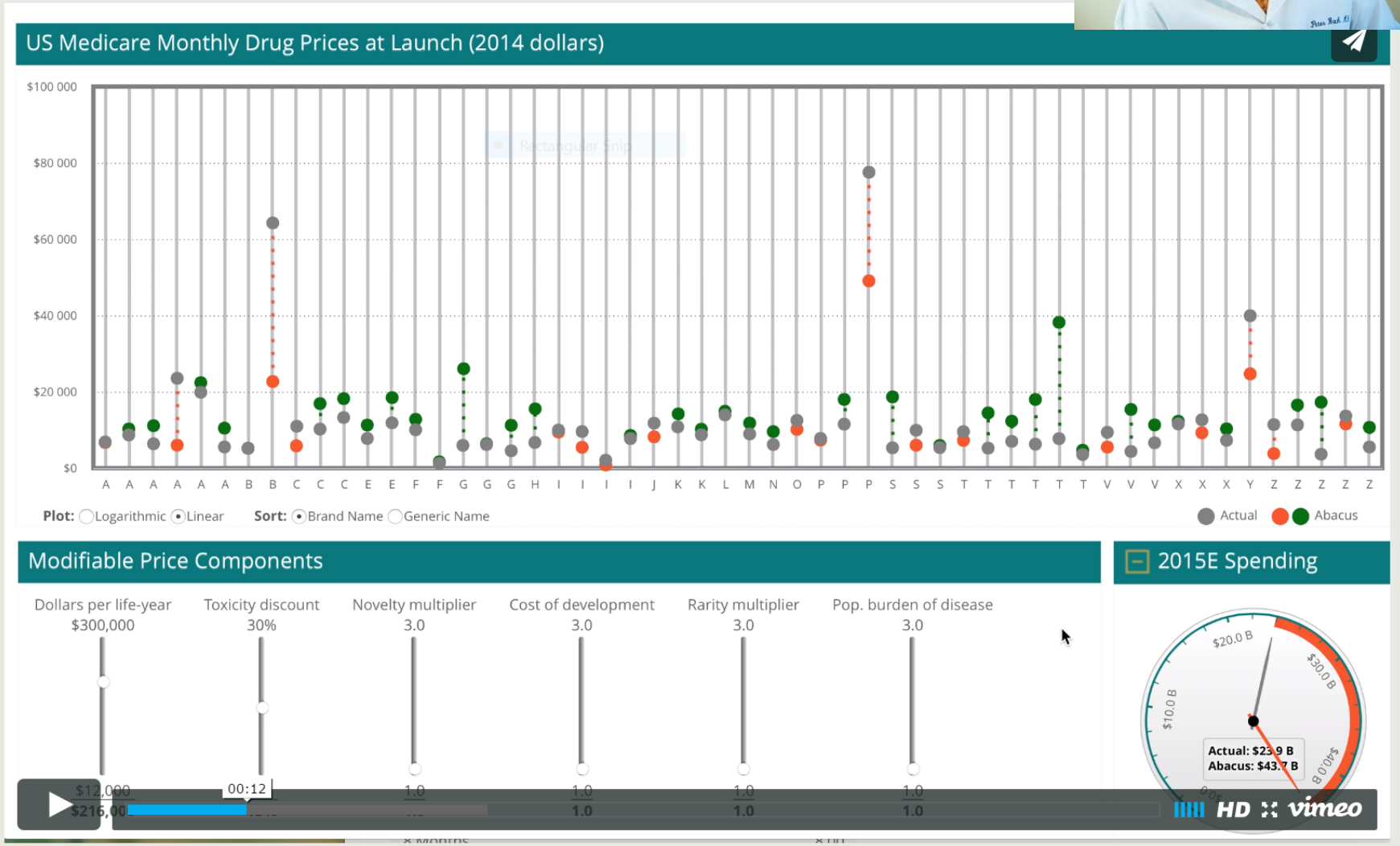
Institute for Clinical and Economic Review

Figure ES1. ICER combined cost-effectiveness and potential budget impact graph. Colored lines represent the impact on annualized budget impact of different uptake patterns (eligible patients treated) at the actual list price of the drug (dashed line), and at drug prices needed to achieve common incremental cost-effectiveness ratios.



http://drugabacus.org/drug-abacus-tool

The DrugAbacus in action



Conclusions

- We are not *helpless*

- But we must be ***Bold***