NASEM "AFFORDABLE MEDICINES" REPORT: AN ECONOMIST'S PERSPECTIVE

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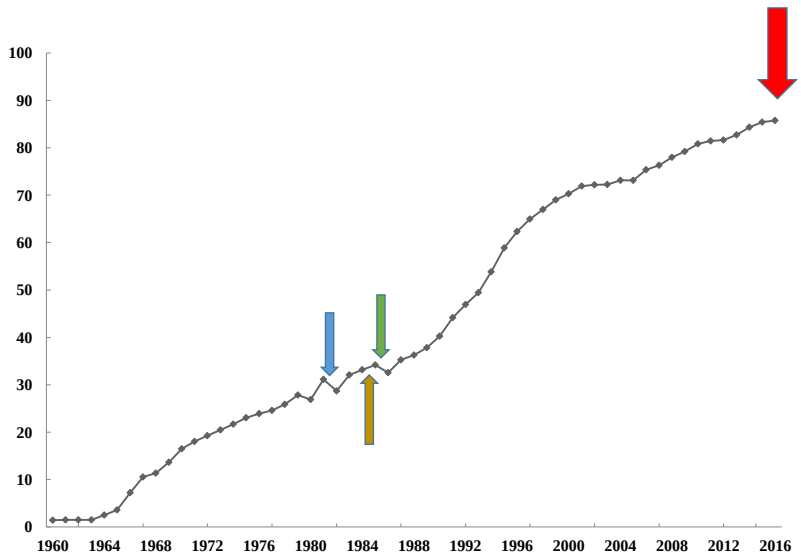
CONTEXT

- INNOVATION vs. AFFORDABILITY
- THE KEY BALANCING ACT FOR PUBLIC POLICY

LANDMARK LEGISLATION IN 1980s

- Bayh-Dole (1980)
  - Transferred ownership of patents from federally funded research to inventor
  - "Tech transfer" offices became ubiquitous in higher education
  - Major expansion of biomedical research and commercialization
- Orphan Drug Act (1983)
  - Multiple incentives to develop treatments for "rare" diseases
    - 200,000 or fewer target population
  - About 400 new drugs with "orphan" status
  - "Salami slicing" – some "blockbuster" drugs get multiple benefits
- Hatch-Waxman (1985)
  - Extended exclusivity for pharmaceuticals from 20 to 25 years
  - Increased incentives for generic competition when exclusivity ends

INSURANCE COVERAGE FOR RETAIL DRUGS (CMS)



NOW: 86%

Bayh-Dole: 27%
Orphan Drug: 33%
Hatch-Waxman: 34%

UNPRECEDENTED COLLISION OF MARKET EXCLUSIVITY (MONOPOLY) AND INSURANCE COVERAGE

- Insurance increases utilization AND reduces price sensitivity
- Danzon: "optimal markup is the inverse of coinsurance rate"
  - Average coinsurance is 14% now ➔ 7X markup
  - Average coinsurance in 1980s was 33% ➔ 3X markup
  - "Regulation best thought of as a response to insurance"
- Garber, Jones and Romer (2006)

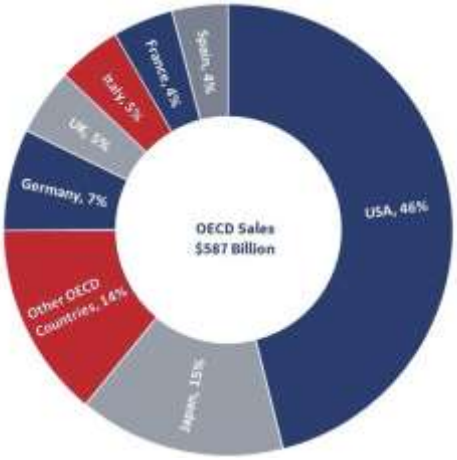
  "The subsidy to demand inherent in the low copayment leads to excess profits…. The resulting dynamic inefficiency raises the possibility that finite patent lives could be welfare improving by reducing excessive innovation. **…. [Further]… an upper bound on the price received by the manufacturer may in some cases be required to ensure that revenues are not too large in relation to the benefits consumers receive**."

"Insurance and Incentives for Medical Innovation" *Forum for Health Economics and Policy* 2006, 9(2), Alan M Garber, Charles I. Jones, Paul Romer

WHAT WORKED IN 1985 IS NO LONGER APPROPRIATE

- NASEM Report recommends that CMS negotiate directly prices
- US is only industrialized country in the world that has extensive insurance AND no price negotiation or control
- Hence we provide a large fraction of pharmaceutical industry profits

COUNCIL OF ECONOMIC ADVISORS ESTIMATES



PROFIT BY NATION

78% OF OECD-NATION PROFITS FROM US

34% OF OECD PER CAPITA INCOME IS US

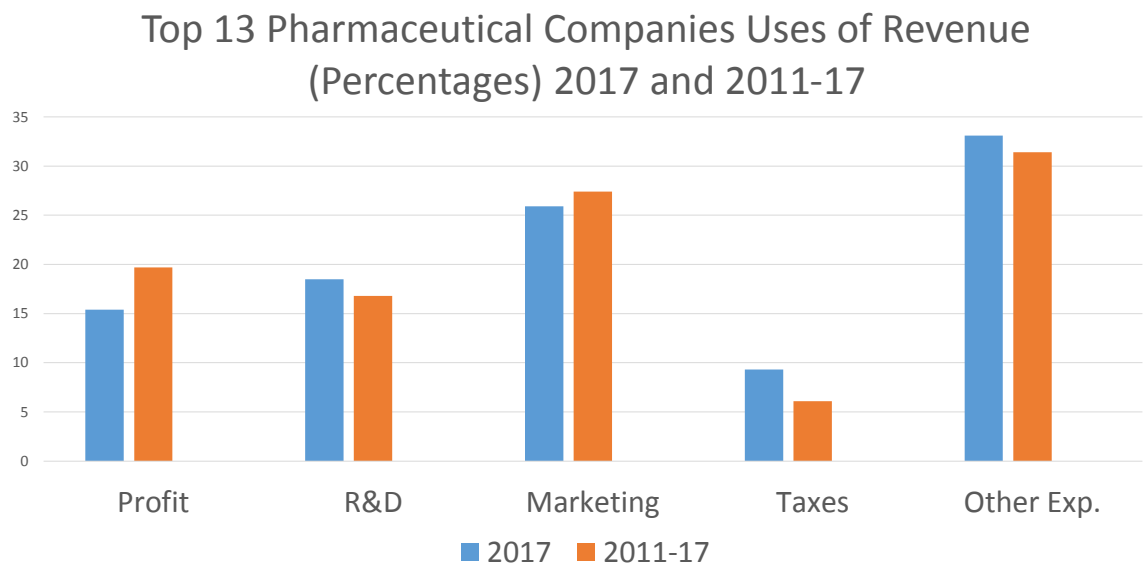
THUS MARKUP IS MORE THAN 2X IN US THAN IN REST OF OECD NATIONS

FOUR ASSESSMENTS OF INDUSTRY PROFITABILITY (PAGE 63 ff from NASEM)

- University of Southern California -- profit margins
  - Branded pharma and generic pharma highest margins of any industry
  - Only tobacco and alcoholic beverages are in same vicinity
- Forbes profit margin study
  - Generic highest, branded drugs 4th,
- Bond ratings
  - Morningstar bond ratings for Pharma A- or higher,
    - J&J gets AAA rating, only other is Microsoft
- Deloitte Report: declining ROI in recent years
  - Only cautionary note in otherwise robust evaluation of industry

INDUSTRY HAS MANY USES FOR PROFITS

- R&D
- Advertising
- Share purchases to raise price
- Executive and Board compensation
- Philanthropy
  - Some patient advocacy groups "captured" by sponsors
- QUERY: If profits fall, what happens to each of these?



WITHOUT MAJOR CHANGE……

- Total spending on biopharmaceuticals continues to rise
- Value/cost tradeoff worsens
- Balance between affordability and availability becomes increasingly skewed away from affordability
- US continues to shoulder excessive portion of industry profits to finance R&D and other uses of industry profits

THANK YOU FOR YOUR ATTENTION