Pharmaceutical Pricing and Innovation

Merrill Goozner
Director
Integrity in Science Project
Center for Science in the Public Interest
The $800 Million Pill

The Truth Behind the Cost of New Drugs
Spending on Prescription Drugs in the United States – 1990-2013 (projected)

SOURCE: IMS HEALTH
The Rx Cost Gap

- 2003 -- $184 billion
- 2013 -- $510 billion
- Senior citizens buys 60 percent of all drugs
- Government projected annual spending under last year’s Medicare bill -- $60-100 billion
- Senior out-of-pocket expenditures by 2013 will double – even with Medicare benefit
Why do Americans pay the highest prices in the world for drugs?
The Industry Story:

- The U.S. foots the bill for global pharmaceutical innovation
- Industry is the primary source of new drugs
- It now costs over $1 billion to develop a new drug – Tufts
- R&D costs and expenditures are rising rapidly
- Without high prices, Rx innovation will dry up
The alternative (common sense) story:

- Innovation depends on understanding the biological causes of disease.
- Even then, developing successful therapeutic interventions is a long, difficult process that requires the single-minded focus of dedicated scientists who often don’t succeed.
- The most creative steps of the innovation process – the steps on which innovation depends – take place early in the process.
- As a result, significant medical breakthroughs are rare and are almost always the product of research funded by the public sector.
Where does the Consumer drug dollar go?

The Rx Industry Dollar -- Where It Goes

- **Cost of Goods Sold**: 20.7%
- **Marketing & Administration**: 31.7%
- **R&D**: 15.6%
- **Other**: 9%
- **Taxes**: 5.5%
- **Profit**: 18.3%
Wasteful expenditures

- 90,000 detailers
- Direct-to-consumer advertising
- Seeding trials
- Building physician loyalty
  - Continuing Medical Education
  - Speakers bureaus
  - Consultancies
The R&D story
Trends in Biomedical Research Spending

SOURCE: “Innovation or Stagnation?” Food and Drug Administration
Trends in New Drug and Biological Product Submissions to FDA

SOURCE: “Innovation or Stagnation?” Food and Drug Administration
Biohype I – Amgen and Epogen

- Eugene Goldwasser – the longest search
- Applied Molecular Genetics v. Genetics Institute at the dawn of the biotech era
- Selling the cancer market to fund clinical trials
- ESRD and Epo – biomedical industrial policy
- The fat gene and other dead ends
- The next blockbuster – Aranesp
Biohype II – Genzyme and Rare Disease

- Roscoe Brady, lipid disorders and the birth of Genzyme
- Ceredase -- the most expensive drug in the world despite government R&D
- Cerezyme – no change despite falling costs
- Robert Desnick and the Fabry gene – delaying the cure
- TKT and the failed promise of biotechnology competition
The endless promise of biotech

- One protein, one disease, one cure – the low-hanging fruit for biotechnology
- Cancer, dementia, arthritis, sepsis, auto-immune diseases result from a cascade of biochemical events
- Targets galore, but validated targets a rarity
Directed Research – the government role

- HIV/AIDS and the triple cocktail – the most significant medical advance of the last quarter of the 20th century
- Government spending 1985-1996 -- $10 billion
- Industry spending 1985-1996 -- $3 billion
- Annual AIDS medication market today: $7 billion
- From drug development through clinical trials – the government role was key
- Abbott and Norvir
$35 billion a year in Rx industry research – where does it go?

- The Prontosil affair
- Sen. Estes Kefauver and the antibiotic cartel
- Nexium, Aranesp, Celebrex, et al – *plus ça change, plus c’est la même chose*
- At least 50 percent of corporate R&D is devoted to me-too drugs – the NIHCM study

Source: National Institute for Health Care Management
Accounting for the $800 Million

- Over half is for time-value of money
- R&D is an expense, not an investment
  - The economist’s view: Investment or Internal Tool for decision-making?
  - The accountant’s view: Cost or Investment
- Current revenue pays for current R&D
- Over half is for me-too drugs
- The Global Alliance study
Prescription for Reform

- Focus industrial R&D on innovation by:
  - Comparative clinical trials like ALLHAT
  - Require comparative arm for FDA approval
  - Remove unnecessary R&D cost drivers like protein, SNPs and gene patents
- Targeted Research for government R&D
- Patience and humility