FTC Health Care Workshop Panel on Branded and Generic Pharmaceuticals

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Outline

- Focus on the economics of branded and generic pharmaceutical markets
  - Market Overview and Drivers of Growth
  - Economic Impact of Hatch-Waxman Act and Other Market Dynamics
  - Dynamics and Variety of Competition
  - Findings from Key Academic and Government Sources
  - Johnson & Johnson's position on Hatch-Waxman Reform

Market Overview and Drivers of Growth

- How has the overall cost of health care changed over time, and what has driven Rx drugs' growth the most?

- Components of health care costs
  - Prescription drugs have accounted for a modest share of total U.S. health expenditures over the period 1960-2000
  - 2000 share for Rx drugs (9.7%) comparable to or below 1960 level
  - Hospital care has been the single largest component of health care expenditures, ranging from 33 to 44 percent.
  - Physician Services have ranged from 20 to 23 percent.

- From 1994 to 2000, price growth has accounted for 1/5 of total expenditure growth with the remaining 4/5 reflecting volume/mix changes in utilization rates for incumbent drugs, as well as spending on new drugs.

Source: *Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price*, Ernst R. Berndt, MIT and NBER

Market Overview and Drivers of Growth

- The growth in the use of pharmaceuticals is attributable to their dramatic impact on improving health care, as well as their cost-effectiveness.
  - There is a growing body of evidence in the clinical and economic literature that pharmaceuticals are cost-effective, often reducing total costs associated with an illness, by replacing less effective and more expensive treatments.
  - The President's 2002 Economic Report alludes to this fact as well (page 182).
- The growth of pharmaceuticals is further explained by the dramatic increase in third-party insurance and Medicaid vs. out-of-pocket payments (about 70% now vs. 18% in1970).

Economic Impact of Hatch-Waxman Act*

- Overall, the existing Hatch-Waxman Act provides an appropriate set of incentives for innovation by research-based companies and for market entry by generic manufacturers.

- Generic drugs now account for approximately 47% of all pharmaceutical prescriptions, up from about 13% in 1980 and 19% in 1984.

- Market penetration by generics has become increasingly rapid.
  - Within two months of patent expiration, generic Vasotec received 75% of prescriptions.
  - Merck-Medco achieved an 80% substitution rate within one week of the launch of Prozac's generic version.

*The above market dynamics have resulted from both the Hatch-Waxman Act, as well as demand side factors.

Economic Impact of Hatch-Waxman Act*

- CBO has estimated annual savings of $8-10 billion dollars from generic substitution in the mid-1990s.
- CBO has also concluded that the expected returns from marketing a new drug have declined about 12% because of the 1984 Act.

*The above market dynamics have resulted from both the Hatch-Waxman Act, as well as demand side factors.

Source: CBO study – *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998

There is More than just Price Competition

- There are various forms of intense competition confronting the pharmaceutical industry
  - Price competition from generic manufacturers
  - Therapeutic competition
  - Dynamic or Schumpeterian competition

Future Generic Competition

- Many commercially important products will face generic competition within the next five years.
- Products with aggregate sales of over $20 billion in 2000 have patent expirations between now and 2005.

Source: Henry Grabowski, Duke University

There is More than just Price Competition: Examples

- Therapeutic Competition -- Shifts in market dominance even among patented products
  - Later entrants often supersede the first product in a category.
    - (e.g. Zantac, Lipitor, Celebrex)
  - No fixed first-mover advantage
- Product differentiation among brands and their attributes
  - Patient tolerance and efficacy are not uniform and are well-served by increased variety.
- Dynamic or Schumpeterian Competition
  - Paradigm shifts and obsolescence prior to patent expiration
  - (e.g. PPIs vs. H2s cited in the 2002 Economic Report of the President; statins vs. channel blockers)

Cost of Drug Innovation versus Imitation

- Innovator Drug Development
  - Long and intensive drug development process - 12 to 14 years
  - Highly risky - only 20 in 5,000 compounds that are screened enter pre-clinical testing, and then only 1 in 5 drugs in clinical trials receive FDA approval
  - High R&D costs - on average about $800 million per NCE
  - High cost of failures or delays - enormous impact on market value
- Imitation Process
  - Short gestation process - 1 to 2 years
  - Low R&D costs - about $2 million to demonstrate bioequivalence*

*Source: Henry Grabowski, Duke University (2001)

Importance of Pharmaceutical Patents to Risky Innovation

- Many economic studies have found that patent protection is a critical factor for pharmaceutical innovation.
- The length of the market exclusivity period is more important in pharmaceuticals than in other high-tech industries.
  - The basic reason is that the costs of innovation are high in pharmaceuticals, while the costs of imitation are low (transition point).
- Contrary to popular misconception, on average, most marketed pioneer drugs do not recover their R&D costs.*

* Source: H. Grabowski and J. Vernon, 1984, 1994 and 1998)

Importance of Pharmaceutical Patents to Risky Innovation

- There are many diseases such as stroke, cancer and CHF for which there are no good treatments – this necessitates innovative new therapies, which can only come about given appropriate incentives.
- In today's competitive environment, "patents play an essential role in encouraging firms to spend the huge resources needed to develop ideas and products that competitors could easily copy in the absence of legal protection."
- "Companies will be motivated to develop drugs only if successful drugs can achieve high profits and capture a leading market share in a relatively short time before new innovations emerge. In the drug industry, substantial market share can easily be lost in just a few years."

Source: Economic Report of the President, 2002

J&J's Position on Hatch-Waxman Reform: Certain Current Proposals Are Inappropriate

- Laws should not deprive NDA holders of patent enforcement rights that are available to all other patentees.
  - No forfeiture provisions for failing to bring suit within 45 days - normal statutes of limitations should apply
  - No forfeiture of right to trial by jury - S.812 now effectively deprives patentees of right to have juries hear validity and infringement issues in ANDA cases, as they do for all other patentees
- No private action for de-listing from the Orange Book should be created.

J&J's Position on Hatch-Waxman: Summary

- Existing laws are generally adequate to address abuses, which are infrequent.
- It is our view that the Federal Trade Commission Study on the issue at hand is a balanced analysis which confirms that no major reforms of the Hatch-Waxman Act are warranted.