


# ***Biogenerics***

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Outline for today's discussion

- I. Background
  - A. The advent of modern-day biological medicines
  - B. Differences between biologics and chemical drugs
- II. Biologic Market
  - A. Sales
  - B. Product costs
  - C. Market trends
- III. The Need for Biogeneric Competition
  - A. Savings for patients and payers
  - B. Impact on new drug innovation
- IV. Workable Biogeneric Approval Process
  - A. Flexible, science-based regulations
  - B. Process for timely resolution of patent disputes
  - C. Reasonable brand exclusivity periods
- V. Status of Current Legislation



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### Significant events shaping biologic industry

- 1901 St. Louis tragedy
- 1902 Biological Control Act
- 1944 Public Health Service Act
- 1972 Center for Biologics Evaluation & Research
- 1984 Hatch-Waxman Act
  - Did not envision generic biologics
  - Did not include abbreviated approval process for biogenerics
  - However, patent term extension provisions apply to biologics

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### FDA defines a biologic product as...

*Federal Regulations (21 CFR 600.3(h))*: "Biologic product means any virus, therapeutic serum, toxin, anti-toxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries"

In general, biologics are drugs derived from living sources such as humans, animals and micro-organisms. FDA says that "biologic products are a subset of drug products" distinguished by their manufacturing processes (biological process vs. chemical process).

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### General characteristics of chemical and biologic drugs

<b>chemical drugs</b>	<b>biologic products</b>
➢ chemically synthesized	➢ derived from living systems
➢ molecular structure	➢ mixtures of proteins
➢ small molecules	➢ large molecules
➢ New Drug Application (NDA)	➢ Biologic License Application (BLA) or sometimes NDA

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## Biologics and the Hatch-Waxman Act

- In 1984, Hatch-Waxman did not envision generic biologics marketplace
- Abbreviated biologics approval process not included in specifically addressed
- However, patent term extension provisions of Hatch-Waxman apply to biologics

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## U.S. biologics marketplace

- FDA has approved more than 150 biologics, now used in treatments of more than 325 million patients
- There are approximately 300 biologic products currently in clinical trials targeting some 200 diseases
- Spending on biologics increased 127% from 2001-2005
- In 2008, biologics accounted for \$60 billion in U.S. sales
- Last year, spending on biologics increased nearly 20%, compared to a sales growth of 6% for chemical drugs
- 28 Molecules make up 87.2% of value of biologics

Sources: DataMonitor, IMS Health

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### Biologic market trends

- By 2011, 12 of the current U.S. top 20 biologic products will be off patent; \$18 billion in current market value
- Spending on biologics is growing 20% annually and will eclipse \$100 billion by 2012, totaling 26% of US drug spend.
- By 2011, about half of all new FDA approvals will be for biologic medicines

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### Major benefits of competition

- Competition from biogeneric will lower costs for patients and payers
- Competition from biogeneric will spur the innovation of new medicines
- U.S. is one of only a few remaining industrial nations with no biogenics

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**We have seen competition at work in the small molecule space**

- 69% of all prescriptions filled in 2008 were dispensed using generic drugs
- Generics saved the U.S. healthcare system \$734 billion over past decade; \$121 billion in 2008 alone
- \$85 average difference in retail price between a brand prescription and a generic prescription
- Generic competition has spurred unprecedented innovation and new drug development since 1984
- 475 new generics approved by FDA in 2007

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**Savings are needed now**

- Shapiro (Clinton Under Sec. of Commerce) study: generic versions of top 12 biologic categories with patents expiring would save \$67bn-\$108bn over 10 yrs.; \$378bn over 20 yrs.
- Pharmaceutical Care Management Association: generic versions of 32 leading biologics would save Medicare Part B \$14 billion over first 10 years.
- Citizens Against Government Waste: total savings for all payers would be \$43 billion in the 2011-2020 period

*“Opponents have attempted to attack biogenerics by arguing competition will only lower prices by a small amount. Well, even a small amount could bring in billions of dollars of savings.”* **Rep. Henry Waxman**

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**Biogeneric competition will promote innovation**

“Legislation to expose today’s biologics to easier competition, after legitimate patents have expired, is going to accelerate development of improved products, not just lower-cost.”

*Former FDA Dep. Commission for Medical Policy  
Dr. Scott Gottlieb*

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**BIO acknowledges competition will work**

“[W]e will have competition from the generic companies... and it will reduce prices and it will take some of this political pressure, frankly, away.”

*BIO President/CEO James Greenwood*

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**Generic launches in other countries include:**

- Sandoz Omnitrope approved and marketed in Australia and EU
- Shire launched Dynepo across Europe, Stada and Hospira received approval to market EPO
- Several companies already widely marketing “first wave” products HGH, EPO, Interferons and Insulin in China, India, Asia, Eastern Europe, and South America
- Indian companies pioneering development of “second wave” products: DRL launched first generic MAb (rituximab); Ranbaxy in advanced development
- EMEA provided guidance for approval path, allows for case-by-case review; separate guidelines for most common biologics such as human insulin and HGH

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***When a Drug Costs \$300,000***  
*[The New York Times Editorial, March 23, 2008]*

**“For the future, it would be wise to foster generic competition for biological drugs...”**

“Genzyme, a Massachusetts-based biotechnology company, has long charged more than \$300,000 a year for typical patients on Cerezyme...The company is essentially exploiting a monopoly position to charge what the market will bear to treat desperate patients with no other option.”

“This is hard to take, given that the federal government did much of the scientific work that led to development of the drug and provided contract money that got the company started.”

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**What is a workable biogeneric process**

- A workable process will provide patients access to safe, effective and less-costly FDA-approved biogeneric and biosimilar medicines.
- A workable process will be void of needless and unwarranted barriers intended only to delay competition and prolong brand market monopolies.

***An unworkable bill is a pathway to nowhere.***



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**To be workable, legislation must contain:**

- Flexible, science-based biogeneric approval processes, which allow for interchangeability as determined by FDA
- A process that enables the timely resolution of patent disputes
- Reasonable brand product exclusivity that balances innovation and access to less-costly biogeneric medicines



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### Science-based regulatory approval system

- Flexible regulatory approach not rigid checklist
- FDA determines need for any clinical studies
- Let science guide the process
- FDA should make approval decisions on a case-by-case basis to ensure safety and efficacy

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### FDA determines interchangeability

- Empower FDA to approve safe and effective biologics
  - While using expertise on a case-by- case basis to determine the interchangeability rating for these biologics
- Interchangeability is important to achieve maximum savings

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### Timely resolution of patent disputes

- Biologics have numerous patents
- Workable legislation must contain a mechanism that allows a generic company to resolve patent disputes without the litigation impacting FDA approval process
- Workable bill would discourages frivolous suits that delay competition

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### Reasonable exclusivity period

- 12 to 14 years base exclusivity is too long
  - FTC Report
- Rest of the world is less 10 years or less
  - Even with price controls in several countries
- Evergreening adds even more monopoly
- Unwarranted exclusivity will extend monopolies and keep biologics from patients



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### Current biogeneric language in Health Care Reform legislation

- Senate HELP Committee language
- House Tri-Committee language
- Next action



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Those opposed to biologics use same arguments as in 1984

- 1984 Hatch-Waxman debate:
  - Generic companies do not have science to prove equivalency
  - Generics will take money brands need for R&D of new drugs
  - Generic companies do not have adequate manufacturing facilities to make equivalent versions
  - Generic versions will not provide the same level of patient safety and efficacy
- 2007 biologics debate:
  - Generic companies do not have science to prove equivalency
  - Generics will take money brands need for R&D of new drugs
  - Generics do not have adequate manufacturing facilities
  - Generic versions will not provide the same level of safety



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In closing...

- The debate is no longer “if” but “when”
- Generic companies have made investments and are ready to roll
- Congress holds the key to opening the door for meaningful savings

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**Thank you!**

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