The Future of Generic Pharmaceuticals

David R. Gaugh, R.Ph.
Senior Vice President,
Sciences and Regulatory Affairs
Generic Pharmaceutical Association
A Look Ahead…
Aging Demographics

- Elderly as % of Total US Population
- Total Elderly Population (MM)
A Look Ahead…
Life Expectance is Rising
U.S. Total Health-Care Spending

- U.S. 2014 TOTAL healthcare spend = $2.9 TRILLION
- $1 of every $5 spent in U.S. in 2015 will be on health care.*
- Projected spending $3.3 TRILLION
- Per capita spending: $9,255
- Percent of GDP: 17.4%

* Office of the Actuary; Centers for Medicare and Medicaid Services; July 2015

Source: CDC National Center for Healthcare Statistics & IMS (Rx Spend based on 12 months ending July 2015)
Loss of Exclusivity 2015 - 2018
Valued at $78.4 Billion

Source: IMS Health, December 2014
Generic Dollar Sales and Growth

Source: IMS Health, National Sales Perspectives, Branded generics disaggregated, November 2014
Total Prescriptions and Growth

Source: IMS Health, National Sales Perspectives, Branded generics disaggregated, November 2014
Generic Cost Savings

Generic drug use saved the U.S. healthcare system $1.68 TRILLION over the decade (2005 - 2014)

In 2014, generic drug use saved the U.S. healthcare system $254 BILLION

3.8 BILLION Prescriptions in 2014

88% of Prescriptions but only 28% of drug costs
Generic Drug Price Increases

• Much of the discussion around generic drug price increases has been motivated by the false assumption that Daraprim is a generic
  – While the product is off-patent, Turing acquired the original license to market the product and it did not have any generic competition

• On the whole, generics continue to create significant savings and provide significant value over brand drugs

• One analysis found that between December 2012 and 2013, generic drug prices decreased by 15.9%
  – This trend is distinct from the brand market, where over the same period prices increased 13.9%
Price Trends

According to one analysis conducted by Express Scripts between December 2012 and 2013 generic prices decreased in price by 15.9% as a market basket.

This trend is markedly different from what has been seen on the brand side, particularly for specialty drugs. In the same timeframe in the Express Scripts analysis brand prices increased by 13.9%.
Industry Consolidation

- Wholesalers
- Manufacturers
- Insurers/Payers
- Retail
USA Industry Dynamics

- **2001**: AmeriSource + Bergen wholesaler consolidation
- **2004**: Econdisc is formed & Express Scripts acquired Medco MS 15%
- **2005**: CVS & Cardinal merge purchasing $10.5B purchasing power MS 25%
- **2007**: Cardinal Purchases Harvard/Major RAD acquires Envision RX $2B Cigna/Anthem Merge
- **2001**: CVS Leases Target & Purchases Omnicare AHold & Hannaford Bros. Merger Aetna & Humana Merger
- **2004**: CVS acquires Caremark
- **2005**: RAD & McKesson merge MS 15%
- **2007**: WBAD formed between WAGS, Alliance Boots & ABC $12B purchasing power MS20%
- **2012**: Red Oak Sourcing CVS & Cardinal merge purchasing $10.5B purchasing power MS 25%
- **2015**: Rumors of Increased Consolidation Global Agreements
- **FUTURE**: AmeriSource + Bergen wholesaler consolidation
- **2014**: Cardinal Purchases Harvard/Major RAD acquires Envision RX $2B Cigna/Anthem Merge
- **2015**: CVS Leases Target & Purchases Omnicare AHold & Hannaford Bros. Merger Aetna & Humana Merger
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In the creation of GDUFA I, the industry aimed to address a growing backlog of ANDAs, decrease time to approval, improve the growing lack of transparency and predictability in FDA actions and address different inspection standards between manufacturers operating in the U.S. and those abroad causing an unleveled playing field and delays in application approvals.

• **Safety** – Ensure that industry participants are held to consistent high quality standards and inspected biennially, using a risk-based approach, with foreign and domestic parity

• **Access** – Expedite the availability of low-cost, high-quality generic drugs, increasing predictability and timeliness to approvals

• **Transparency** – Improve FDA’s communications and feedback with industry in order to expedite product access as well as enhance FDA’s ability to protect Americans in the complex global supply environment by requiring the identification of facilities involved in the manufacture of generic drugs and associated APIs
Some good foundations have been made but execution is still lacking.

To date approximately $1 billion has been invested into the program which resulted in decreased transparency, decreased certainty for industry and decreased access for patients.

FDA met GDUFA goals to hire new staff, bringing on more than 1000 hires as a result of the GDUFA program.

Industry has experienced unforeseen “pain” during the foundation building period for the new OGD and GDUFA program and patients have experienced delays in accessibility of products at the first available date.

“GDUFA is aimed at putting FDA’s generic drugs program on a firm financial footing …to ensure timely access to safe, high-quality, affordable generic drugs.”

-Janet Woodcock, MD, FDA
House Subcommittee on Health,
February 9, 2012
Since passage of GDUFA, OGD’s median review time to approval has continued to rise. When the program was negotiated in FY2011, median review time to generic approval was at 30 months. Since then, median review times increased to 31 months in FY2012, 36 months in FY2013, an estimated 42 months in FY2014 and around 48 months in FY2015.

Overall approval numbers (including both tentative and final) are down as well, with 619 approvals in FY2012, declining to 535 in FY2013, dropping to 500 approvals for FY2014. FY2015 ended around 612.

First generics continue to miss approval on earliest legally eligible date, counter to Hatch-Waxman’s purpose.

Overall filing compared to approval data shows a continually increasing gap: 3200 submissions, 1400 approvals (2013 - present).
• In the last year and a half, it is estimated that the U.S. health care system lost hundreds of millions if not over a billion in savings due to first generic approval delays. Collectively these first generic applications have experienced median approval times estimated at 50 months.

• Increasing health care costs impacts access to pharmaceuticals for key patient populations.

• Timeliness and number of generic drug approvals have a direct impact on generic drug price competition as provided in the aptly named Patent Term Restoration and Generic Price Competition Act (aka Hatch-Waxman) which has historically provided the framework to allow more than a trillion dollars in savings to the U.S. healthcare system.
In working toward our objective of accelerating approvals, the industry will take our learnings from GDUFA I and aim to build upon the initial goals to deliver, in GDUFA II, enhanced safety, access, transparency and improved competition for generic drugs through more timely approval of generic drugs.

**GDUFA II Negotiations**

- Improved Access → Key Performance Metrics
- Improved Transparency → Fed-Ex Like Tracking System
- Improved Safety/Quality → GMP Certificate
- Fee Amount/Structure → Zero-Sum Budgeting
Biosimilar Opportunities

- Biosimilars and interchangeable biological products hold great promise, not just for consumers and the pharmaceutical industry, but for sustaining a healthcare system with finite resources.
- Express Scripts estimates potential savings of $250 billion in the next decade with the approval of just 11 biosimilar products.
- Biosimilars have been on the market in Europe and other parts of the world since 2006.
- Key challenges and policy decisions remain unresolved and in the hands of FDA: such as naming, labeling, extrapolation and interchangeability.
- The first biosimilar filings were received by the FDA in 2014 and we saw the first approval in Q2 of 2015.
Where Things Stand in Implementing BsUFA I

According to FY2013 and FY2014 BsUFA Performance Metrics:

• FDA has expended a considerable effort in drafting guidances, some of which are now final. The Agency has met with multiple sponsors, and an estimated 50 products are under development in the U.S.

• To date, eight (8) BLAs have been announced as submitted to FDA. We only know the review outcome and timing for two (2). FDA has completed review within the 10-month goal for approval of Sandoz’ Filgrastim and a complete response letter for Pfizer’s Epoetin alfa

• Overall, there are fewer biosimilars approved at this point in time than FDA had predicted
Outstanding Biosimilar Policy Issues

• To date FDA has issued approximately four (4) final and eight (8) draft biosimilar guidances, plus a proposed rule on nonproprietary naming.

• It is critical that FDA continue to provide guidance to industry and proceed with the outstanding guidances the agency said would be introduced this year (including interchangability, labeling, statistical considerations for demonstrating analytical similarity).
FDA Proposed Labeling Rule

- Would require ANDA applicants to submit CBE-0 supplements and immediately revise product labeling.

- FDA has consistently interpreted the Hatch-Waxman Act to prohibit generic drug manufacturers from distributing labels that are different than the brand equivalent.

- The proposal will not enhance public health but will decrease patient access to affordable medicine and create ill-advised confusion for healthcare practitioners and patients.

- GPhA opposes the rule in its current form but continues to advocate for a multi-stakeholder collaboration to find a workable solution that does not undermine patient safety or access.
Expedited Agency Review (EAR)

• Unlike individual applicant holders, FDA possesses all the significant clinical trial data on a pharmaceutical product and all the adverse event and periodic reports from all manufacturers.

• EAR would require FDA to provide NDA and ANDA holders with prompt notice of approval of a required label change, and specify the timeframes for response.
**EAR Process**

**Step 1.** NDA or ANDA holder requests EAR or FDA initiates EAR on its own.

**Step 2.** FDA begins review of all available safety data and engages NDA and ANDA holders in discussion of potential label change.

**Step 3.** If FDA determines through a review of all available safety data that a labeling change is required, FDA informs the NDA and ANDA holders of the content of the final labeling language immediately (within 15 days) and instructs the NDA and ANDA holders to update their labeling within 30 days via e-labeling.

**Step 4.** All application holders update labeling via e-labeling within 30 days.
Summary

- RX utilization drivers favor continued strong demand for generics
- Rapid impact on brand market share upon approval of generics
- Cost savings provided by generics are dramatic
- Regulatory uncertainties are always a challenge for the pharmaceutical industry