

## I Love You, I Love You Not Reflections on the Past, Present and Future Relationship Between Pharmacy and the Pharmaceutical Industry

Presented by  
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## Objectives of this Presentation

1. Describe the evolution of the pharmaceutical industry and its relationship with health care professionals (emphasis on pharmacists and pharmacy technicians) and patients
2. Explain the pharmaceutical industry's paradigm shift from patient-centered to profit-centered and the reasons for it
3. Identify current issues related to the industry-pharmacy-patient triad, including drug pricing, direct to consumer advertising, drug shortages, etc.
4. Discuss the differences in the relationship between pharmacists and the pharmaceutical industry in the 1970s and the present

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## Acknowledgement

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## No Conflicts of Interest

Perspectives based on 45 years  
of engagement and observation

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## History of Pharmacy/Pharmaceutical Companies

- Beginning of time thru 1600s to 1700s
  - First Pharmacy thought to be found in Baghdad in about 792
- Empiric Era – 1600 / 1700 to 1940s
- Modern Pharmaceutical Era - 1870's to the 1930s
- Golden Era of Pharmaceutical Companies – 1930s to 1960s
- Patient Care and Clinical Pharmacy Era – 1960s to 1990s
- Industry Consolidation – 1990s to the present

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## Evolution of Big Pharma:

Many of the first Pharmaceutical Companies started as Apothecary Shops

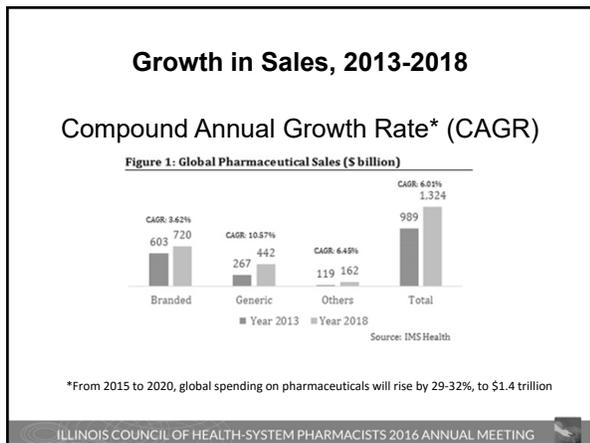
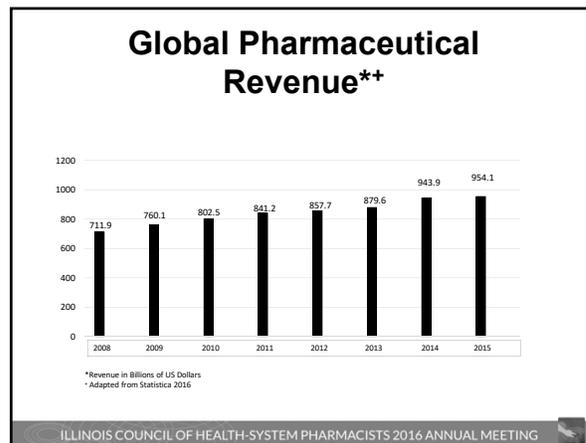
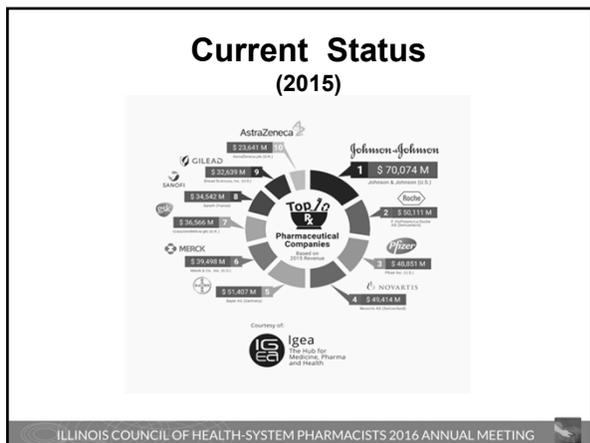
### Europe

- Merck
- Schering
- Hoffmann-La Roche
- Burroughs Wellcome
- Etienne Poulenc

### United States

- Abbott
- SmithKline
- Parke-Davis
- Eli Lilly
- Squibb
- Upjohn

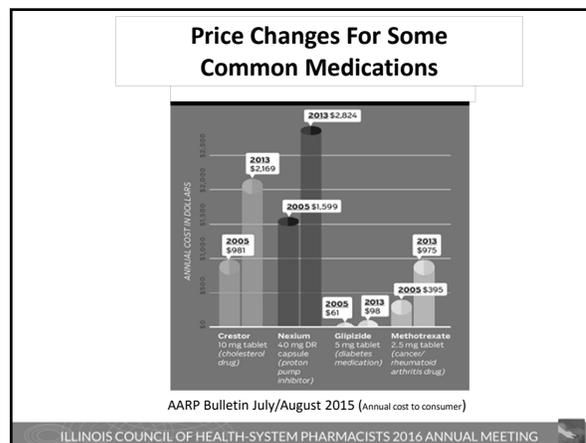
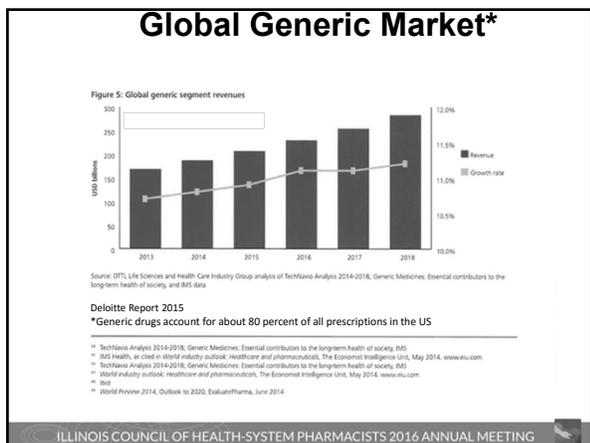
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### Worldwide Pharmaceutical Market by Sectors (\$ Billions)

	2000	2001	2002	2003	2008
Ethical	317.1	363.4	401.0	437.6	677.8
Generics	24.0	27.0	30.5	37.0	64.0
OTC	70.5	73.8	78.5	82.0	101.0
Biopharmaceuticals	22.1	26.3	31.0	36.5	58.6
<b>Total World Market</b>	<b>433.7</b>	<b>490.5</b>	<b>541.0</b>	<b>593.1</b>	<b>901.4</b>

Source: BCC Research, Inc., IMS Health



## Generic Price Increases\*

- Recent data reveal 222 drug categories increased in price by 100% or more (between 2013 and 2014)
- Some extreme cases (17 drug categories) price increases of more than 1000% were seen
- One product tetracycline, between 2013 and 2014 its per tablet price increased from \$0.0345 to \$2.36
  - A 67-fold increase in one year

\*Reported by Elsevier

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## High Cost of Drugs

- Eli Lilly charges roughly \$13,000 a month for Cyramza
  - The newest drug to treat stomach cancer
- Novartis's Zykadia, costs almost \$14,000 a month
  - The latest medicine for lung cancer
- Amgen's Blincyto, will cost \$64,000 a month
  - For leukemia

New York Times, Jan 14, 2015

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## High Cost of Drugs

- In Europe prescription drugs cost 50 percent less than what we pay in the US
  - Gleevec costs \$4,500 per month in Germany
  - Gleevec costs \$3,300 per month in France
    - This price is less than what Americans paid in 2001
  - Gleevec costs \$8,488 per month in the US

McKinsey study from 2008

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## Drug Pricing “the Ideal”

- Sellers sell for as much as they can
- Buyers buy for as little as they can
- Ideally, through the process of competition, prices are determined based on benefits to buyers and sellers
- This process of competition is protected by law to prevent anticompetitive conduct

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## Drug Pricing “the Reality”

- The law provides monopoly protection for sellers
- Public and private third party payment is the norm, and the physicians (the product selectors) are generally price insensitive
- For decades, public and private third party payers (buyers) have had their bargaining power systematically undermined

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## Drug Pricing “the Reality”

- Prices are increasing at an unsustainable rate
- Pharmaceutical market competitiveness has been systematically undermined for decades
- Americans pay the most for drugs and face significant obstacles to access

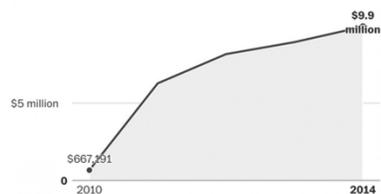
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## Increased Pricing (Profiteering?? Gouging??)

- **Turing Pharmaceuticals** increased the price of Daraprim, overnight, in September 2015, from \$13.50 to \$750 a tablet, after acquiring Daraprim
- **Valeant Pharmaceuticals** increased prices of Isuprel, Nitropress, Cuprimine, and Syprine
  - Cuprimine's price for 100 capsules ↑ to \$26,189 from \$800
- **Rodelis Therapeutics** increased the price for Cycloserine 2,600 percent, from \$500 for 30 capsules to \$10,800
- **Ovation Pharmaceuticals** purchased Indomethacin from Merck, and raised the price from \$10 to \$36 per vial, but after buying the competing drug (NeoProfen) in 2006, it raised the price of both to nearly \$500 per vial

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Revenues from sales of Daraprim

Source: IMS Health  
THE WASHINGTON POST

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## Image Issues and Pharmaceutical Companies

- Pharmaceutical companies depend on illness to succeed
- Pharmaceutical companies have been accused of withholding potentially valuable information from patients
- Companies have been accused of “profiteering” at the expense of patients
- Patients have become far less trusting of the industry
- Industry seen as market traders with sole focus on stockholders not patient wellbeing

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## Loss of Confidence in Big Pharma

### Recent Lawsuits

- Glaxo paid out \$3 billion in fines for issues related to Paxil
  - illegally persuading doctors to prescribe the drug to children and teenagers despite internal evidence that it's ineffective and can trigger suicidal thoughts in adolescents
- Takeda paid out \$2.34 billion in settlements for Actos
  - failed to inform consumers and medical professionals about the risk of bladder cancer associated with use
- Johnson & Johnson and Bayer Corp. being sued for \$10 Million based on allegations that they deliberately concealed Xarelto's potential fatal side effect of internal bleeding

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## Drug Shortages: Fact and Fiction

- Quality/manufacturing issues
- Companies have experienced delays receiving raw materials and components from suppliers
  - limitations with raw material
- Discontinuations of older products in favor of newer (more expensive products)
- Fewer companies making drug products (mergers/acquisitions)
- Increased demand from a growing world market

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## Big Pharma: How Did we Get Here

- Historically, pharmaceutical companies led the way in medical research
- Knowledge generated by internal basic research programs or licensed from academic institutions to develop products
- This position was supported by the substantial capital and infrastructure investments, this drug development process created significant barriers to entry for companies
- Academic institutions and smaller companies lack the expertise, infrastructure, and financial resources to engage in drug discovery and development

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## Big Pharma: The New Model

- Recently big Pharma has been disappointed by the performance of their in-house labs
- To address slowing productivity companies initially sought a quicker path to accessing new technologies and novel drug candidates
- As a result they have increasingly looked for small firms with promising ideas leading to a wave of industry mergers
- Interestingly some companies got more than 70% of their revenues from products that were not developed in-house
- Valeant, a Canadian drugs company, has grown fast by buying other companies and cutting R&D spending

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## Big Pharma: The New Model

- These mergers failed to ignite productivity, even as sales and R&D spending dollars have increased
- Moreover, the number of new molecular entities (NMEs) being approved has been declining
- Only 19 new drugs or vaccines were approved in 2007, the lowest numbers since 1983.
- 2012: 39 NMEs approved
- 2014: 41 NMEs approved

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## Big Pharma: Future

- A confluence of internal and external factors is now transforming the landscape for discovering, developing, commercializing, and marketing pharmaceuticals
- Industry Issues:
  - pressure to increase sales
  - pressure to decrease development time and cost
  - competition from smaller companies
  - looming patent expirations
  - increased regulatory scrutiny

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## Big Pharma: Future

- Recent trends indicate a handful of companies controls 2/3 of NMEs
  - growth in the number of NMEs controlled by marketing organizations that have little or no internal drug discovery or development activities
- Instead of developing new drugs easier to take existing therapies and make them more effective
- Companies also working on different delivery methods, or combining different drugs in new ways

Kinch, Haynesworth, Kinch and Hoyer, 2014

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## Pharmaceutical Industry Growth Drivers

- Demographic changes
  - Number of Americans over 65yo expected to double over next 50 years
    - health care expenditures 4 times higher for those over 65yo than those under 65yo
- Innovative medicines targeting life-style diseases
  - Cardiovascular agents, CNS products
  - Gastrointestinal/metabolism products
- New Drug Approval Outlook
  - Biotech drugs of increasing importance
  - Major Biotech companies raised more than \$32 billion in financing last year\*

\*EY Life Sciences 2016

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## Pharmaceutical Industry Growth Drivers

### Pharmacogenomics

- Predicts whether a patient will have a severe, negative reaction to a prescribed medication
- May aid in selection of better medications for patient
- Still in development
- Major Role for Pharmacy??

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## Pharmaceutical Industry Growth Drivers

- Emerging Markets seen as growth engine for healthcare demand worldwide (India, China, Brazil)
- The growth of the Chinese pharmaceutical market in 2012 was 22 percent. In 2013, the increase was 14%
- Medicare Drug Benefit Plan should boost profits
- Increased access to medicines through the Affordable Care Act provisions and expansion of Medicaid

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## Pharmacy – Pharmaceutical Representative Collaboration

- 1930s to 1970s: Collaborative Relationship
  - Open access to Pharmacist
- 1970s to 2000s: Competitive/Adversarial/legal
  - Restricted access Pharmacist
- 2000s – future: ???

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## Direct To Consumer Advertising

- Up thru 1980's the consumer garnered information through a friend or healthcare provider
- Prohibited by FDA until industry won a 'free speech' lawsuit against prohibition
- The first DTC advertisement
  - 1983-1985: FDA voluntary moratorium
  - 1985: new regulations provide "provides protections for consumers"
- 1990's: print advertisements begin to proliferate
- By mid 1990's, broadcast advertisements enters mix

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## Specialty Pharmacy & Drugs

- Pharmaceuticals called "specialty drugs" – *including biologics*
- These drugs can change the course of a disease instead of just treating the symptoms
- Specialty drugs have increased between 15 – 20% over the past several years
- Created new models of distribution with limited number of distribution points
- These agents are only used by a small percentage of the population (1 to 5%)
- These agents expected to account for over 40 – 50% of U.S. drug spending in the future
- Annual drug cost ranges from \$20,000 - \$250,000+ per patient

Source: PREDMA.org 2013 Report

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## Pharmacy-Pharma Collaboration

- Can we move to shared values and collaboration between the industry and the profession of pharmacy?
- Focus on the patient
- Accessibility to medicines: fiscal, physical and sustainability
- Rational pricing
- Clear scientific and clinical evidence of outcomes, safety and utility
- Quality products and packaging that meet regulatory requirements

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## Thank You!

Questions/Discussion

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