Retirement Funds Spent on Medications or Vacations?

Addressing the escalating costs of prescription drugs

SACRS May 2015

Peggy Wedgworth
Why do we care?

• Health care costs are one of the most rapidly increasing segments of most municipal budgets
• Pharmaceutical costs have historically been one of the most rapidly increasing segments of health care costs
• A 1998 Congressional Budget Office study concluded that generics saved consumers $8 to $10 billion annually
### TOP 20 GENERICS DELAYED BY PAY-FOR-DELAY DEALS

<table>
<thead>
<tr>
<th>Prescription Drug (and Drug Maker)</th>
<th>Condition the Drug is Commonly Prescribed to Treat</th>
<th>Annual Sales Before Generic ($ millions)</th>
<th>Year of Pay-for-Delay Deal</th>
<th>Length of Delay</th>
<th>Price of Brand-name Drug vs Price of Generic Drug ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adderall XR (Shire)</td>
<td>Attention deficit hyperactivity disorder (ADHD)</td>
<td>1,500 M</td>
<td>2006</td>
<td>3.0 years</td>
<td>238 vs 102</td>
</tr>
<tr>
<td>Aggrenox (Boehringer Ingelheim)</td>
<td>Stroke risk, blood clots</td>
<td>331 M²</td>
<td>2008</td>
<td>6.8 years</td>
<td>294 vs 73¹</td>
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<tr>
<td>Altace (Sanofi)</td>
<td>High blood pressure, heart failure</td>
<td>700 M³</td>
<td>2006</td>
<td>3.0 years</td>
<td>115 vs 12</td>
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<tr>
<td>AndroGel (Solvay Pharmaceuticals/Abbott Laboratories)</td>
<td>Low testosterone in patients with AIDS, cancer and other conditions</td>
<td>1,332 M¹¹</td>
<td>2006</td>
<td>8.7 years</td>
<td>379 vs 96¹</td>
</tr>
<tr>
<td>BuSpar (Bristol-Myers Squibb)</td>
<td>Anxiety</td>
<td>600 M¹³</td>
<td>1994</td>
<td>6.25 years</td>
<td>not available¹⁵ vs 12</td>
</tr>
<tr>
<td>Caduet (Pfizer)</td>
<td>High cholesterol and coronary artery disease</td>
<td>266 M</td>
<td>2008</td>
<td>1.7 years</td>
<td>266 vs 113</td>
</tr>
<tr>
<td>Cipro (Bayer)</td>
<td>Bacterial infection, anthrax exposure</td>
<td>1,300 M¹⁷</td>
<td>1997</td>
<td>7.0 years</td>
<td>346 vs 23</td>
</tr>
<tr>
<td>Effexor XR (Wyeth/Pfizer)</td>
<td>Major depressive disorder, anxiety and panic disorder</td>
<td>2,400 M</td>
<td>2005</td>
<td>4.7 years</td>
<td>194 vs 17</td>
</tr>
<tr>
<td>Drug</td>
<td>Indication</td>
<td>Approval Date</td>
<td>Time to Failure</td>
<td>M (in millions)</td>
<td>Market Share</td>
</tr>
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<tr>
<td>K-Dur (Schering-Plough/Merck)</td>
<td>Low blood levels of potassium (hypokalemia)</td>
<td>1997</td>
<td>4.0 years$^{17}$</td>
<td>250 M$^{20}$</td>
<td>not available$^{22}$</td>
</tr>
<tr>
<td>Lamictal (GlaxoSmithKline)</td>
<td>Epilepsy, bipolar disorder, Lennox-Gastaut Syndrome</td>
<td>2005</td>
<td>3.0 years$^{23}$</td>
<td>1,500 M</td>
<td>465</td>
</tr>
<tr>
<td>Lipitor (Pfizer)</td>
<td>High cholesterol, coronary artery disease</td>
<td>2008</td>
<td>1.7 years$^{24}$</td>
<td>7,400 M</td>
<td>205</td>
</tr>
<tr>
<td>Nexium (AstraZeneca)</td>
<td>Gastroesophageal reflux disease (GERD), other digestive disorders</td>
<td>2008</td>
<td>6.1 years$^{26}$</td>
<td>5,638 M$^{25}$</td>
<td>222</td>
</tr>
<tr>
<td>Niaspan (Abbott Laboratories)</td>
<td>High cholesterol, coronary artery disease</td>
<td>2005</td>
<td>8.3 years$^{28}$</td>
<td>1,037 M$^{27}$</td>
<td>122</td>
</tr>
<tr>
<td>Nuviq (Cephalon/Teva)</td>
<td>Narcolepsy, obstructive sleep apnea and hypnnea syndrome</td>
<td>2012</td>
<td>4.0 years$^{29}$</td>
<td>331 M$^{29}$</td>
<td>450</td>
</tr>
<tr>
<td>Nolvadex/Tamoxifen (AstraZeneca)</td>
<td>Breast cancer</td>
<td>1993</td>
<td>9.0 years$^{32}$</td>
<td>400 M$^{31}$</td>
<td>99$^{33}$</td>
</tr>
<tr>
<td>Propecia (Merck)</td>
<td>Enlarged prostate, male pattern baldness</td>
<td>2006</td>
<td>7.0 years$^{33}$</td>
<td>142 M$^{34}$</td>
<td>89</td>
</tr>
<tr>
<td>Provigil (Cephalon/Teva)</td>
<td>Narcolepsy, multiple sclerosis-related fatigue</td>
<td>2005</td>
<td>6.25 years$^{37}$</td>
<td>1,100 M$^{26}$</td>
<td>1,213</td>
</tr>
<tr>
<td>Sinemet CR (Bristol-Myers Squibb)</td>
<td>Parkinson’s disease</td>
<td>1995</td>
<td>11.0 years$^{39}$</td>
<td>150 M$^{38}$</td>
<td>39</td>
</tr>
<tr>
<td>Wellbutrin XL - 150 mg (Biovail)</td>
<td>Major depressive disorder, seasonal affective disorder</td>
<td>2006</td>
<td>1.0 years$^{44}$</td>
<td>835 M$^{40}$</td>
<td>250</td>
</tr>
</tbody>
</table>
Effective cost containment for health care means:

• Less budgetary pressure elsewhere
• Greater sustainability of existing benefit levels
• Assuring that illegal conduct is unprofitable
Gaming the Drug Patent System

With high drug prices becoming an acrimonious part of the health care debate, attention has justifiably focused on the devious tactics used by some pharmaceutical companies to extend the patents of their best-selling drugs, forestalling competition from cheaper generics. These underhanded tactics must be stopped.
Exclusive Licensing Arrangements
A recent Generic Pharmaceutical Association study found that generic medicines saved $1 trillion from 2002 to 2011 and $193 billion in 2011 alone.
Lorazepam (generic) and Clorazepate (brand name) Antitrust Litigation

(marketed under brand names Ativan and Tranxene)
Mylan Laboratories

Pharmaceutical Ingredient Supplier

Exclusive license agreement for active pharmaceutical ingredient
Lorazepam Wholesale Prices

Before exclusive deal

After exclusive deal

500 count bottle of 2 mg Lorazepam
Clorazepate Wholesale Prices

500 count bottle of 7.5 mg Clorazepate
Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony...

15 U.S.C. Section 2
Mylan Laboratories Settlement

$100 Million in restitution to consumers and state agencies
Games Drug Companies Play
Act II

Generic Delay

Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions: A Federal Trade Commission Staff Study
January 2010
Economics of Generic Competition
Price of Medication

Pre-generic entry 180 days

Generic medication
Branded medication
Effect on Branded Firm Revenues When Generics Enter the Market

<table>
<thead>
<tr>
<th>Time</th>
<th>Revenues (in $)</th>
</tr>
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<tbody>
<tr>
<td>Pre-generic entry</td>
<td>1,200,000,000</td>
</tr>
<tr>
<td>180 days</td>
<td>800,000,000</td>
</tr>
<tr>
<td>One Year</td>
<td>600,000,000</td>
</tr>
</tbody>
</table>
To protect competition in the marketplace, antitrust law prohibits agreements that create or perpetuate monopolies. Patent law, in contrast, grants temporary monopolies to inventors to encourage the development of useful innovations. We consider here a crucial question at the intersection of these two bodies of law: what limits, if any, does antitrust law place on the ability of a patent holder to make agreements restricting competition during the life of its patent? In particular, when another entity tries to invalidate a patent and enter the marketplace, can the patentee pay the would-be competitor to withdraw its challenge and refrain from competing until at or near the natural expiration of the potentially invalid patent’s life?
DISPOSITION

We reverse the Court of Appeal’s judgment and remand for further proceedings consistent with this opinion.

WERDEGAR, J.

WE CONCUR:

CANTIL-SAKUYE, C. J.
CHIN, J.
CORRIGAN, J.
LIU, J.
CUÉLLAR, J.
KRUGER, J.
California Cartwright Act

• At its heart is a prohibition against agreements that prevent the growth of healthy, competitive markets for goods and services and the establishment of prices through market forces.

• The act generally outlaws any combinations or agreements which restrain trade or competition or which fix or control prices, and declares that, with certain exceptions, every trust is unlawful, against public policy and void.‘ || (Pacific Gas & Electric Co. v. County of Stanislaus (1997) 16 Cal.4th 1143, 1147.)
Pay to Delay/Reverse Settlement

Cipro

• 1987 – Patent to Bayer which will expire in 2003
• 1987-2003 Cipro gross sales of $6 billion
• 1991 – Barr asked FDA to market generic Cipro – Bayer sues Barr for patent infringement.
• 1997 – Bayer pays Barr $398 million to settle and keep generic off market through 2003
• 1997 – Consumers file antitrust lawsuits
• 1997-2003 - Bayer’s Cipro profits over $1 billion
The California Supreme Court on Thursday revived a class-action lawsuit that accuses German pharmaceutical giant Bayer of paying another drug company to delay introducing a generic version of a Bayer antibiotic.

The practice is known as “pay to delay” and can violate antitrust law, according to a 2013 U.S. Supreme Court decision.

The unanimous ruling by the state’s highest court was aimed at a settlement reached by Bayer, the holder of a patent on Cipro, and Barr Laboratories Inc., which wanted to introduce a generic version of the popular antibiotic and challenged Bayer’s patent.
Games Drug Companies Play
Act III

Product Hopping

The Washington Post
June 5, 2002
p. A22
Yanking Namenda IR Would Cost Medicare $6B, 2nd Circ. Told

Law360, New York (May 11, 2015, 8:39 PM ET) -- As the Second Circuit weighs whether to uphold an injunction barring Actavis PLC from pulling an older, immediate-release version of Namenda from the market, the federal government has estimated without the order Medicare will spend an extra $6 billion on the drug over the next decade.

The New York Attorney General's Office on Friday pointed the court to the report the U.S. Department of Health and Human Services released Thursday estimating how much Medicare will save on the dementia treatment once a generic version of the immediate-release formulation of the drug enters the market.
• The federal government has estimated without the order Medicare will spend an extra $6 billion on the drug over the next decade.
Namenda Product Jump
(the moving target) Actavis/Forrest Labs

Namenda IR
Immediate Release
Twice daily

Namenda ER
Extended Release
#2
Once Daily
Some Observations Related to the Generic Drug Market

May 6, 2015

drives prices down "close to marginal cost." It is not unusual for successful new drugs to have annual sales of a billion dollars or more during the exclusive sales period, so delaying the availability of an inexpensive generic alternative even for a short time can preserve enormous profit for the original manufacturer.

Department of Health and Human Services
Office of the Assistant Secretary for Planning and Evaluation

http://aspe.hhs.gov

Another common approach to extend exclusivity in sales is to develop a new product formulation of an existing brand-name drug facing impending generic competition. For example, a new formulation, or “line extension,” would have the same active ingredient and general clinical effect as its predecessor but might have a different timing of release.
When a manufacturer develops a new formulation of an existing brand-name drug, it typically seeks through marketing efforts to shift patients to the newer version that would be protected by its own statutory exclusivity.
UNIVERSAL STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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THE PEOPLE OF THE STATE OF NEW YORK,

Plaintiff,

-against-

ACTAVIS, PLC, and
FOREST LABORATORIES, LLC,

Defendants.

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APPEARANCES:

Attorneys for Plaintiff
NEW YORK STATE OFFICE OF THE ATTORNEY GENERAL
Sweet, D.J.

The plaintiff, the People of the State of New York (the “State” or the “Plaintiff”), has moved pursuant to Rule 65 of the Federal Rules of Civil Procedure to preliminarily enjoin the defendants, Actavis, PLC (“Actavis”) and Forest Laboratories, LLC (“Forest”) (collectively, the “Defendants”), from engaging in antitrust violations by discontinuing the current sales of the Forest drug Namenda IR, used in the treatment of Alzheimer’s disease, currently scheduled to take effect on January 1, 2015. Based on the findings of fact and
The injunction requires Actavis and its Forest Laboratories LLC unit to keep an immediate-release version of the dementia drug on the market until generic competition can launch in July.
The state maintains that the drugmakers violated federal antitrust law by trying to force patients to switch to the extended-release formulation, which will continue to benefit from patent protection, a process known as product hopping. The company has argued, among other things, that it has no obligation to keep making an older drug to help its competitors under the patent laws.
Actavis manufactures Namenda and Namenda XR, drugs used to treat moderate-to-severe dementia from Alzheimer’s disease. The drugs come in two dosage forms: Namenda, a twice-daily formulation (“Namenda IR”), and the more recently-developed Namenda XR, a once-daily formulation.
Actavis seeks to remove its older product from the market and force patients to switch to its line extension product. “We believe such actions come at a substantial cost to consumers and taxpayers.”
• Issued a preliminary injunction enjoining Actavis from implementing its plan to remove Namenda IR from the market while the court considers a challenge to the legality of Actavis’ planned course of action. The court found that “[o]nce patients have switched to Namenda XR, it is very unlikely that most of them will switch to generic Namenda IR.....”
U.S. Supreme Court held that settlements can amount to payment in return for staying out of the market and permit monopoly premiums still to be charged and simply divided up between the patent holder and patent challenger; the patentee and the challenger gain; the consumer loses.
• BREYER, J., delivered the opinion of the Court, in which KENNEDY, GINSBURG, SOTOMAYOR, and KAGAN, JJ., joined. ROBERTS, C. J., filed a dissenting opinion, in which SCALIA and THOMAS, JJ., joined. ALITO, J., took no part in the consideration or decision of the case.
The U.S. Supreme Court in *Actavis* makes clear that for antitrust purposes patents are no longer to be treated as presumptively ironclad.
Antitrust law condemns a patentee’s payment—to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market. And, as we have said, that consequence constitutes the relevant anticompetitive harm.

*Actavis*, 570 US 756
• Cipro: Bayer pays Barr $398,000,000 to stay off market for six years
• Provigil: Cephalon pays over $200,000,000 to four generic companies
Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Overview of Agreements Filed in FY 2013
A Report by the Bureau of Competition

During fiscal year 2013 (October 1, 2012 to September 30, 2013), pharmaceutical companies filed 145 agreements constituting final resolutions of patent disputes between brand and generic pharmaceutical manufacturers. This preliminary assessment summarizes the types of final settlements received in FY 2013 and describes how the FY 2013 results compare to filings in other recent years.

Overview of Final Settlements

- 29 final settlements potentially involve pay for delay because they contain both compensation from a brand manufacturer to a generic manufacturer and a restriction on the generic manufacturer’s ability to market its product in competition with the branded product.

  - These 29 potential pay-for-delay settlements involve 21 different branded pharmaceutical products with combined annual U.S. sales of approximately $4.3 billion.
Thank You

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