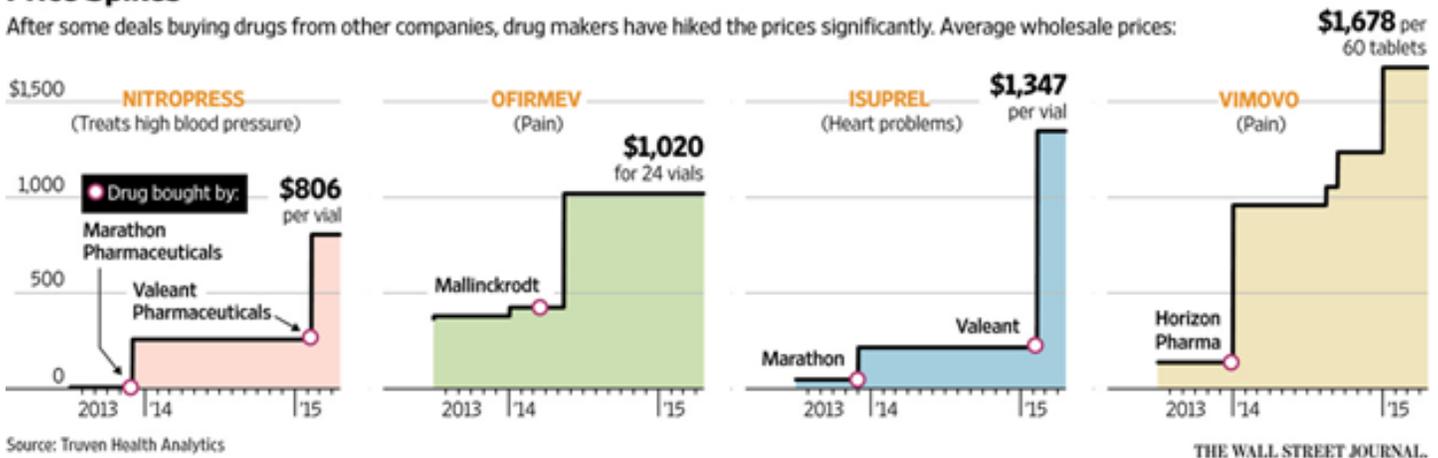


# Can Employers Control Big Pharma Greed?

The pharmaceutical industry has become a cesspool of abuse and greed. Profit, shareholder returns and risk minimization are the primary goals for most stakeholders. Half of specialty drug spending is for cancer, rheumatoid arthritis, and multiple sclerosis.<sup>1</sup> Saved lives and cured diseases are products of these primary objectives, but as a multi-trillion dollar money trail evolves, capitalism prevails. Predatory pricing is a major business strategy for many. Besides the well-publicized saga of Martin Shkreli and Turing Pharmaceuticals, other examples of recent post-acquisition hikes are:

## Price Spikes

After some deals buying drugs from other companies, drug makers have hiked the prices significantly. Average wholesale prices:



Although sensational, predatory pricing is just one component of the overall prescription drug cost explosion. The proliferation and utilization of specialty drugs is the major cost and profit driver. Specialty drugs are medications derived from biotechnology processes or a small molecule that treat rare or chronic diseases. There is no common definition, but generally these medications may require special storage or handling, treat a chronic condition, cost in excess of \$6,000 per year, or require close supervision when administered. They treat complex conditions such as cancer, HIV, hepatitis C, multiple sclerosis, and inflammatory diseases, and fulfill the promise of modern medicine by enriching, extending or saving lives.

A subset of the specialty drug sector is biologics, which are manufactured in living systems such as microorganisms, plant or animal cells. Most of these drugs are very large, complex molecules or a mixture of molecules. Development of biologic drugs is extremely elaborate and expensive as many of these drugs are produced using genetic DNA technology.

One class of biologic specialty drugs is PCSK9 inhibitors. PCSK9 is an abbreviation for an enzyme known as protein convertase subtilisin/kexin type 9. These drugs lower LDL-C ("bad") cholesterol by increasing the ability of the liver to remove cholesterol from the body. Approximately 33% of U.S. adults have high LDL-C levels, of which half are currently being treated. PCSK9 inhibitors will be prescribed for:

- those with statin intolerance
- those with familial hypercholesterolemia
- those who cannot achieve adequate results with current therapies

This third category of patients tends to be the largest. For the majority of people, diet and exercise continues to be the most effective way to reduce LDL-C, but proper diet and exercise as effective therapies are often the most difficult,

therefore the pill or injectable will continue to prevail. By 2018, global sales for cholesterol medications will reach \$21-\$24 billion. Two PCSK9 inhibitors were approved last summer: Alirocumab (PRALUENT), manufactured by Sanofi/Regeneron and Evolocumab (REPATHA), manufactured by Amgen.

PCSK9 inhibitors have been shown to lower LDL-C cholesterol by up to 70% when added to statin therapy. These drugs will be covered under the pharmacy benefit and sales are expected to reach \$3.4 billion by 2020. This is just one class of specialty drugs contributing to the projected 40% of total prescription spend in 2020.

The specialty pharma market will be measured in trillions. Personalized medicine, patent expirations, aging population, lack of competition, and higher cost treatment sites are just some of the contributing factors leading to the double and triple digit trends. The future for specialty pharmaceuticals looks like this:

- Overall drugs in the development pipeline: Traditional = 31%, Specialty = 69%<sup>2</sup>
- Specialty drugs in the market: 1990 = 10, 2015 = 300 with 700 in development<sup>3</sup>
- Specialty drug compounded annual growth rate: 20%<sup>4</sup>
- Specialty drug annual cost per person: 2012 = \$290, 2018 = \$845<sup>5</sup>
- Specialty drug trend of 3 large Pharmacy Benefit Management (PBM) companies = 20%-32% in 2014<sup>6</sup>

The forecast looks alarming, bleak, or encouraging, depending on your view. Hepatitis C is almost 100% curable, hyperlipidemia as a cause of coronary artery disease is on the same path, and many cancer mortality rates are steadily decreasing. These are certainly amazing advances in medicine, offering hope and cure to all affected however, the specialty drug gold rush carries a massive burden. Two guarantees are built in:

1. The massive (trillions) revenue stream for the pharmaceutical companies
2. The financial burden will continue to fall on:
  - Employers: premiums or claims
  - Employees: cost share, coinsurance, co-pays
  - Government: Medicare, Medicaid
  - Tax payers: FICA

What can employers do? A reactive approach will assure employers of double or triple digit increases. Smaller, fully insured companies will have very little control other than the traditional protections offered by pooled underwriting. This pooling of risk will smooth the impact of isolated large claim risk, but will also impact overall trend at double and triple digit rates. Public outcries, sensational reporting, and pleas for government intervention will have little financial impact. For small or fully insured employers, the tsunami is coming and they might be stuck on the beach.

For larger or self-funded employers, levers do exist. The focus will be on incentives, site of care, appropriate use, cost share, and provider negotiations. However, this system is complex by design. The first-pass obvious levers will impact trends and significant further impact can be realized in the analysis and redrafting of the carrier or PBM contract. This requires an extremely sophisticated partner. Visibility Rx incorporates the best of first- tier levers with the contract analysis and subsequent redrafting in favor of the employer to ensure the best possible outcomes for employees, and the highest financial impact for the employer.

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