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# Specialty Drug Hyperinflation: The Risk to Patients and the Health Care System

**Specialty drugs<sup>1</sup> offer important hope for many patients with complex, hard-to-treat illnesses. While the price of specialty drugs at launch has received a great deal of attention – particularly with the recent controversy over the pricing of Hepatitis C drug Sovaldi<sup>2</sup> – annual price increases have largely slipped under the radar screen. However, annual price increases are equally – if not more – troubling given the tendency for manufacturers to raise prices of specialty drugs far in excess of inflation. At a time of limited wage growth and when private and public purchasers are trying to hold the line on health care costs, these pricing trends are unsustainable.**

## ***Overview***

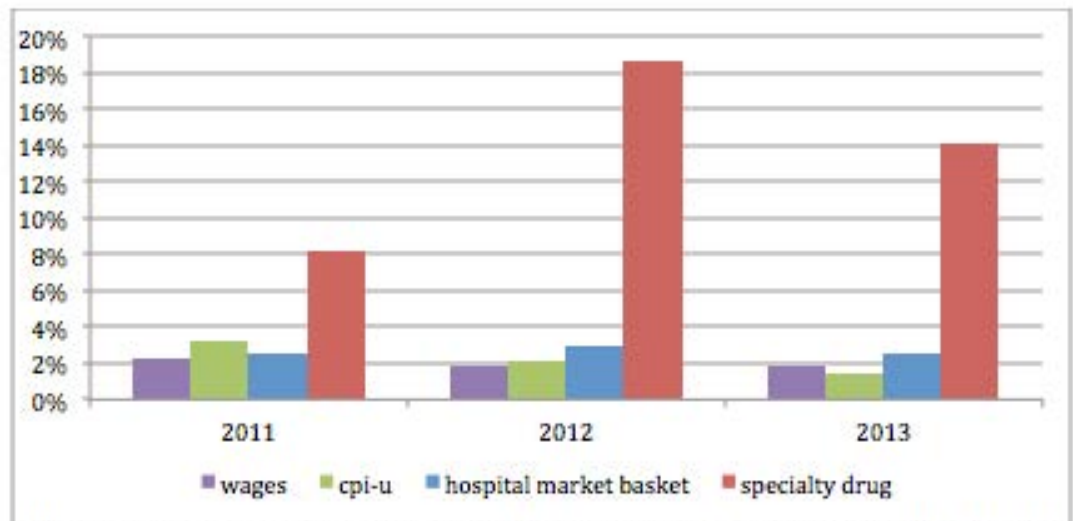
In 2013, the U.S. health care system spent more than \$80 billion on specialty drugs, which cost on average 37 times as much as traditional drugs.<sup>3</sup> Specialty drugs currently represent only 1 percent of all U.S. prescriptions<sup>4</sup> but make up more than 31 percent of drug spending, and are expected to increase to 44 percent of overall drug spending by 2017.<sup>5</sup> Key drivers of this anticipated increase in spending on specialty drugs include the introduction of many more new products to market, increased specialty drug utilization (of current and new products), and the much higher rate of inflation for these products.<sup>6</sup>



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## Specialty Drug Hyperinflation: Escalating Costs for the Healthcare System

Between 2011 and 2013, specialty drug price increases far outstripped wage growth, increases in the consumer price index and the “hospital market basket”<sup>7</sup> of health care goods over the same period.



\*Comparison of percentage price increases for specialty drugs vs. wage growth, consumer price index and hospital market basket between 2011 and 2013

**Hyperinflation of specialty drug prices impacts consumers, businesses and plans.** In 2012, specialty drugs accounted for 17 percent of the average employer’s overall pharmacy costs,<sup>8</sup> but they are projected to make up 40 percent of an employer’s total pharmacy spend by 2020.<sup>9</sup> Specialty drug spending per member per year is anticipated to increase from \$290 in 2012 up to \$845 by 2018.<sup>10</sup>

**Specialty drug price inflation affects taxpayers.** The Medicare and Medicaid programs witnessed 45.9 percent and 35.8 percent increases in specialty drug spending respectively in 2014.<sup>11</sup>

Many recent examples of manufacturers raising specialty drug prices far in excess of inflation exist. Enbrel, a specialty drug used for inflammatory conditions such as rheumatoid arthritis, increased in price 17 percent in 2014.<sup>12</sup> Similarly Humira, a competitor, increased 17.6 percent in 2014.<sup>13</sup> These increases were on top of a 15 percent price increase for specialty drugs treating inflammatory conditions the year before that.<sup>14</sup>



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During that same period, consumer prices rose 1.5 percent.<sup>15</sup> A month's supply of one of these therapies averages \$3,000, so a 15 percent increase would add \$450 a month, or \$5,400 a year, to a patient's prescription costs.

Specialty Therapy Class	Unit Price Increase (2012-2013)	CPI (2012- 2013)
<b>Inflammatory Conditions</b>	15.0%	1.5%
<b>Multiple Sclerosis</b>	14.7%	
<b>Cancer</b>	13.6%	
<b>HIV</b>	10.9%	
<b>Growth Deficiency</b>	9.9%	
<b>Total</b>	11.6%	

\*Unit price increases vs. CPI in 2012-2013 for top 5 key Specialty therapy classes<sup>16</sup>

Because Enbrel and Humira are not cures, but rather treatments, patients taking these drugs have and will continue to absorb – either through higher premiums or greater burdens on employers –dramatic cost increases for every year they take the products. Such hyperinflationary increases financially burden patients, family members, businesses and tax payers, and over time potentially threaten access to medically necessary prescription drugs.

### **Access to Important Medications in Jeopardy**

Large, compounded price increases in already expensive specialty products yield cost increases that greatly exceed those of any other prescription drug product on the market. This creates a situation in which products that were priced virtually out-of-reach at the time of their launch become increasingly inaccessible and unaffordable over time due to inflation. The result is reduced patient access to important medications and excessive premium and out-of-pocket costs. Over the last three years, businesses and consumers have experienced an increase of approximately \$300 per year in their premiums due to the cost of specialty drugs (which average \$3000).<sup>17</sup> On the other hand, traditional medications, averaging \$58, have added less than one dollar per year to premiums over the same time period.<sup>18</sup>



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This situation is particularly devastating for the large population of people with chronic conditions, such as multiple sclerosis, HIV and cancer, since they rely on specialty drugs that are life-long maintenance treatments.

### **The Case of Acthar:**

#### *Pricing a Critical Treatment Out of Reach for Babies and Their Families; Marketing a Specialty Product with Questionable Efficacy to the Chronically Ill*

Acthar, a hormone-based drug originally indicated for use in treating infantile spasms, has been on the market since 1952. The product was not widely known until Questcor Pharmaceuticals bought it in 2001 for \$100,000. At that time, the price of Acthar was \$40 per vial. However, Questcor swiftly raised Acthar's price, which reached \$23,000 per vial by 2007. Since then, the company has aggressively marketed Acthar as a specialty drug for the treatment of more common chronic conditions, including multiple sclerosis and lupus.<sup>19</sup>

Scant clinical evidence exists to demonstrate Acthar is more effective than much cheaper alternatives to treat these chronic conditions. However, Acthar received FDA approval for use in the treatment of multiple sclerosis, lupus and other diseases decades ago, prior to the FDA requiring manufacturers to conduct new clinical trials before marketing a drug for additional indications.<sup>20</sup>

Given the limited data, high price, and cheaper alternatives, Acthar is not often prescribed by doctors for conditions other than infant spasms.<sup>21</sup> Physicians who do commonly prescribe Acthar for the treatment of conditions such as multiple sclerosis or lupus often have financial ties to Questcor. These physicians typically receive research grants, payments for delivering speeches on behalf of the company or compensation for serving on advisory boards.<sup>22</sup>



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## Summary

Recent controversies in pharmaceutical pricing have brought attention to the launch price of new specialty medicines. Equally troubling, however, are the unsustainable price increases for these medicines after they are brought to market. These price increases are disturbing because they often appear completely arbitrary and independent of overall cost inflation.

The status quo is unsustainable – our health care system cannot afford the unrelenting specialty drug price increases and devastating cost burden. A drug's efficacy is only as good as its affordability. We hope this report helps spark a national discussion about potential solutions to the general crisis of affordability, and the specific, outrageous price increases in specialty medicines.





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<sup>1</sup>Specialty drugs are generally defined as having one or more of the following characteristics: complex to manufacture, requiring special handling and administration; injectable or oral, self-administered or administered by a health care provider; costly, both in total and on a per-patient basis; taken by a relatively small share of the population who have complex medical conditions, and; difficult for patients to take without ongoing clinical support as well as challenging for providers to manage.

<sup>2</sup>Gilead Sciences Inc., manufacturer of Solvadi, has been accused of "price-gouging" on the sale of its \$1000-per-pill, coming to \$84,000 per patient for a standard course of treatment; Sovaldi costs \$130 to manufacture.

<sup>3</sup>The Growth of Specialty Pharmacy: Current Trends and Future Opportunities. Issue brief no. April 2014. United Health Center for Health Reform & Modernization, Apr. 2014. Web. 25 Mar. 2015. <<http://www.unitedhealthgroup.com/~media/UHG/PDF/2014/UNH-The-Growth-Of-Specialty-Pharmacy.ashx>>.

<sup>4</sup>The 2014 Drug Trend Report. Issue brief. The 2014 Drug Trend Report Highlights. The Express Scripts Lab, Mar. 2015. Web. 25 Mar. 2015. <[http://lab.express-scripts.com/~media/PDFs/Drug%20Trend%20Report/ExpressScripts\\_DrugTrendReport\\_Highlights.ashx](http://lab.express-scripts.com/~media/PDFs/Drug%20Trend%20Report/ExpressScripts_DrugTrendReport_Highlights.ashx)>

<sup>5</sup>The 2014 Drug Trend Report. The 2014 Drug Trend Report. The Express Scripts Lab, Mar. 2015. Web. 25 Mar. 2015. <<http://lab.express-scripts.com/drug-trend-report>>.

<sup>6</sup>*Id.*

<sup>7</sup>A market basket is a measure of all the goods and services needed that a specific organization must purchase to provide care. The hospital market basket measures a fixed set of goods and services for the hospital, and compares it with how much those same items would cost at a later, or earlier time.

<sup>8</sup>URAC, *The Patient-Centered Outgrowth of Specialty Pharmacy: Why Patient Management Strategies Are Critical to 21st Century Providers* (Washington, D.C.: URAC, 2011), available at [https://www.urac.org/Whitepaper/PQM-Specialty\\_Pharmacy.pdf](https://www.urac.org/Whitepaper/PQM-Specialty_Pharmacy.pdf)

<sup>9</sup>Medco Health Solutions - Drug Trend Report 2011. Rep. N.p.: n.p., n.d. Drug Trend Report 2011: Fast Forward to the Future. Medco Health, 2012. Web. 25 Mar. 2015. <<http://digital.drugtrendreport.com/i/31288-drug-trend-report-2011/39>>.

<sup>10</sup>"NBCH Action Brief." (n.d.): n. pag. Dec. 2013. Web. 25 Mar. 2015. <[https://www.nbch.org/nbch/files/ccLibraryFiles/Filename/000000003258/NBCH\\_AB\\_SP%20Pharmacy%20original.pdf](https://www.nbch.org/nbch/files/ccLibraryFiles/Filename/000000003258/NBCH_AB_SP%20Pharmacy%20original.pdf)>.

<sup>11</sup>The 2014 Drug Trend Report. The 2014 Drug Trend Report. The Express Scripts Lab, Mar. 2015. Web. 25 Mar. 2015. <<http://lab.express-scripts.com/drug-trend-report>>.

<sup>12</sup>*Id.*

<sup>13</sup>*Id.*

<sup>14</sup>"REPORT: Specialty Drug Spending at Lowest Rate Since 2007." REPORT: Specialty Drug Spending at Lowest Rate Since 2007. Express Scripts Lab, n.d. Web. 26 Mar. 2015. <<http://lab.express-scripts.com/insights/industry-updates/report-specialty-drug-spending-at-lowest-rate-since-2007>>.

<sup>15</sup>CPI-U from the Bureau of Labor Statistics.

<sup>16</sup>The 2014 Drug Trend Report. <<http://lab.express-scripts.com/~media/pdfs/drug%20trend%20report/express%20scripts%202013%20drug%20trend%20report.ashx>>

<sup>17</sup>*Looking Back Moving Forward: 2014 Report on Prescription Drug Costs*. Rep. N.p.: n.p., n.d. Prime Therapeutics, Feb. 2014. Web. 25 Mar. 2015. <[http://cdn2.content.compendiumblog.com/uploads/user/220a4eb2-dd7f-4520-ab96-7cfb9e87326b/8e648f20-2a6c-4610-9b15-849b37ce4f51/File/8ea45ca5f37f3c8048bd8e82779c650/5476\\_k\\_reportrxdrugcosts\\_2014.pdf](http://cdn2.content.compendiumblog.com/uploads/user/220a4eb2-dd7f-4520-ab96-7cfb9e87326b/8e648f20-2a6c-4610-9b15-849b37ce4f51/File/8ea45ca5f37f3c8048bd8e82779c650/5476_k_reportrxdrugcosts_2014.pdf)>.

<sup>18</sup>*Id.*

<sup>19</sup>Weintraub, Ariene. "Is Medicare Wasting \$220M a Year on Questcor's Controversial Acthar?" FiercePharma. N.p., 5 Aug. 2014. Web. 26 Mar. 2015. <<http://www.fiercepharma.com/story/medicare-wasting-220m-year-questcors-controversial-acthar/2014-08-05>>.

<sup>20</sup>Pollack, Andrew. "Questcor Finds Profits, at \$28,000 a Vial." *The New York Times*. The New York Times, 29 Dec. 2012. Web. 26 Mar. 2015. <[http://www.nytimes.com/2012/12/30/business/questcor-finds-profit-for-acthar-drug-at-28000-a-vial.html?\\_r=0](http://www.nytimes.com/2012/12/30/business/questcor-finds-profit-for-acthar-drug-at-28000-a-vial.html?_r=0)>.

<sup>21</sup>Oral prednisone, which might be used for some rheumatological diseases, can cost \$10 a month. Intravenous steroids, used to treat multiple sclerosis flares, cost several hundred dollars.

<sup>22</sup>Ornstein, Charles. "The Obscure Drug With a Growing Medicare Tab." Top Stories RSS. N.p., 04 Aug. 2014. Web. 26 Mar. 2015. <<http://www.propublica.org/article/the-obscure-drug-with-a-growing-medicare-tab>>.