

<b>Date:</b> February 4, 2016	<b>POLICY BRIEF/ANALYSIS</b> PREPARED FOR THE BOARD OF DIRECTORS	 OF NORTHERN LARIMER COUNTY
<b>Staff:</b> Dan Sapienza Carol Plock		

## HB16-1102 – DRUG PRODUCTION COSTS TRANSPARENCY REQUIREMENTS

Concerning a requirement that drug manufacturers report production costs for certain high-cost prescription drugs

### Details

---

**Bill Sponsors:** House – Ginal (D) and 6 others  
Senate – Newell (D) and Roberts (R) and Sens. Aguilar and Kefalas

**Committee:** House Health Insurance and Environment

**Bill History:** 01/19/2016 Introduced In House - Assigned to Health, Insurance, & Environment

**Next Action:** Hearing – House Health Insurance and Environment – Thursday, Feb. 18

### Bill Summary

---

For prescription drugs made available in Colorado with a wholesale acquisition cost of \$50,000 or more per year, HB16-1102 requires a drug manufacturer to submit a report to the Colorado Commission on Affordable Health Care detailing the production costs for the drug. The report must include research costs, clinical trial and regulatory costs, material and manufacturing costs, marketing costs, a history of prices, and total profit attributable to the prescription drug.

### Background

---

High pharmaceutical prices have been an issue of significant concern for many years, but the proliferation of therapies costing in the tens or hundreds of thousands of dollars has thrust the issue into the spotlight. Sovaldi, produced by manufacturer Gilead, is a new cure for Hepatitis C costing as much as \$84,000 per person per treatment.<sup>1</sup> Daraprim, a drug primarily used to treat toxoplasmosis in patients with HIV and pregnant women, had its price raised from \$13.50 per pill to \$750 per pill, costing patients tens of thousands for treatment.<sup>2</sup> One analysis by Express Scripts recently found that about 600,000 people in the United States have annual medication costs that exceed \$50,000.<sup>3</sup>

The United States is a global outlier in terms of pharmaceutical prices. Compared to the United Kingdom, the prices of some of the highest selling drugs in the United States are three times higher in the US.<sup>4</sup> Comparing U.S. drug prices to those of other developed nations shows an ever wider divide. Even after significant discounts (as much as 60%) provided by manufacturers to U.S. patients, a Bloomberg News analysis of prices showed U.S. prices were significantly higher.<sup>5</sup> Drugs like Daraprim, which is widely available on the generic drug market as pyrimethamine (its patent expired decades ago), can see an even wider price divide. In India, where pyrimethamine is widely used to treat both toxoplasmosis infection and malaria, pyrimethamine can

<sup>1</sup> Wall Street Journal. April 8, 2015. Gilead's \$1,000 Pill Is Hard for States to Swallow. Accessed February 3 at <http://www.wsj.com/articles/gileads-1-000-hep-c-pill-is-hard-for-states-to-swallow-1428525426>

<sup>2</sup> Chicago Tribune. December 4, 2015. After 5,000% Daraprim hike, pharma CEO 'would have raised prices higher'. Accessed February 2, 2016 at: <http://www.chicagotribune.com/business/ct-turing-doubles-down-1205-biz-20151204-story.html>

<sup>3</sup> Forbes. May 13, 2015. Drug Costs Top \$50K A Year For Half Million Americans. Accessed February 4, 2016 at: <http://www.forbes.com/sites/brucejapsen/2015/05/13/drug-costs-top-50k-a-year-for-half-million-americans/#4e11bd905532>

<sup>4</sup> Reuters. October 12, 2015. Transatlantic divide: how U.S. pays three times more for drugs. Accessed February 4, 2016 at: <http://www.reuters.com/article/us-pharmaceuticals-usa-comparison-idUSKCN0S61KU20151012>

<sup>5</sup> Bloomberg Business. December 18, 2015. The U.S. Pays a Lot More for Top Drugs Than Other Countries. Access February 4, 2016 at: <http://www.bloomberg.com/graphics/2015-drug-prices/>

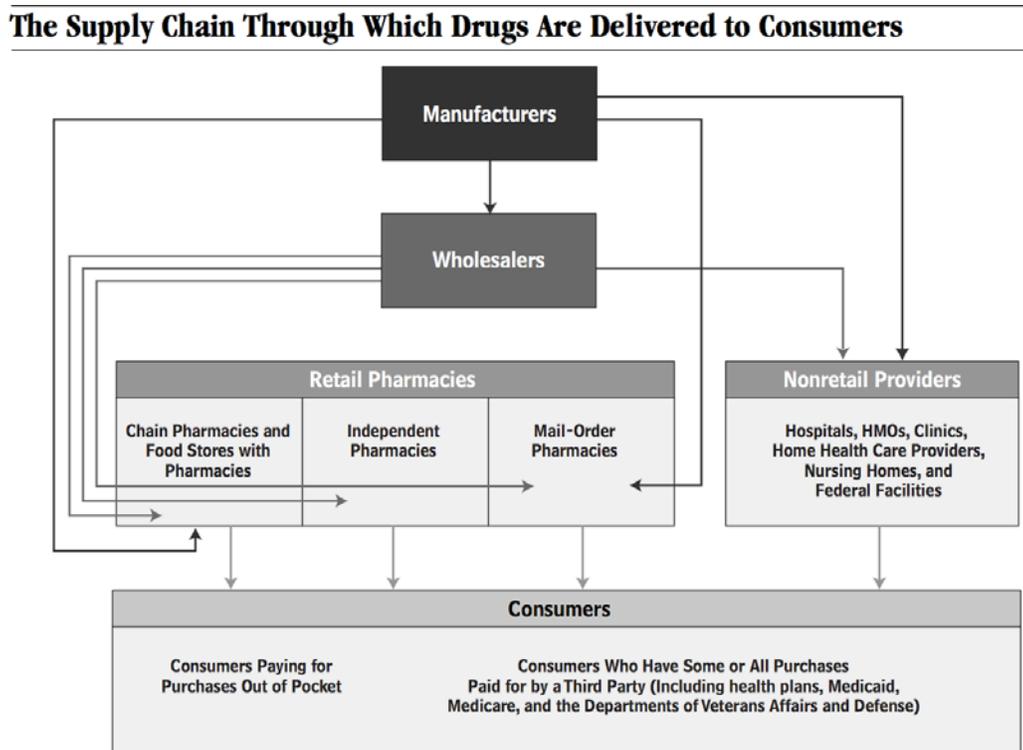
be obtained for as little as \$0.05 per pill, compared to current price of \$750 per pill in the United States.<sup>6</sup> There are a multitude of reasons for the global price disparities, but the differences frequently lead to questions about how pharmaceutical prices are set in the United States.

---

*Complexities in the U.S. Pharmaceutical Market*

Sales of pharmaceuticals in the United States are made through a complicated mix of sellers, buyers, payers, suppliers, and the end customers – the patient. In 2007, the Congressional Budget Office (CBO) drafted a report titled “Prescription Drug Pricing in the Private Sector” that detailed the complex markets for these drugs.<sup>7</sup> See Figure 1 for a diagram of the regular flow of pharmaceuticals from manufacturers to patients and Figure 2 for a diagram of the flow of funds for “single-source drugs,” those with no generic substitute,

“As prescription drugs move from manufacturers to consumers, a complex set of market transactions involving prices, discounts, and rebates occurs along the supply chain. Although the drugs themselves move in a relatively straightforward way from manufacturers to wholesalers to retail pharmacies or nonretail providers (such as hospitals and clinics) to final consumers, the flow of payments that occurs is more complicated.”



Source: Congressional Budget Office.

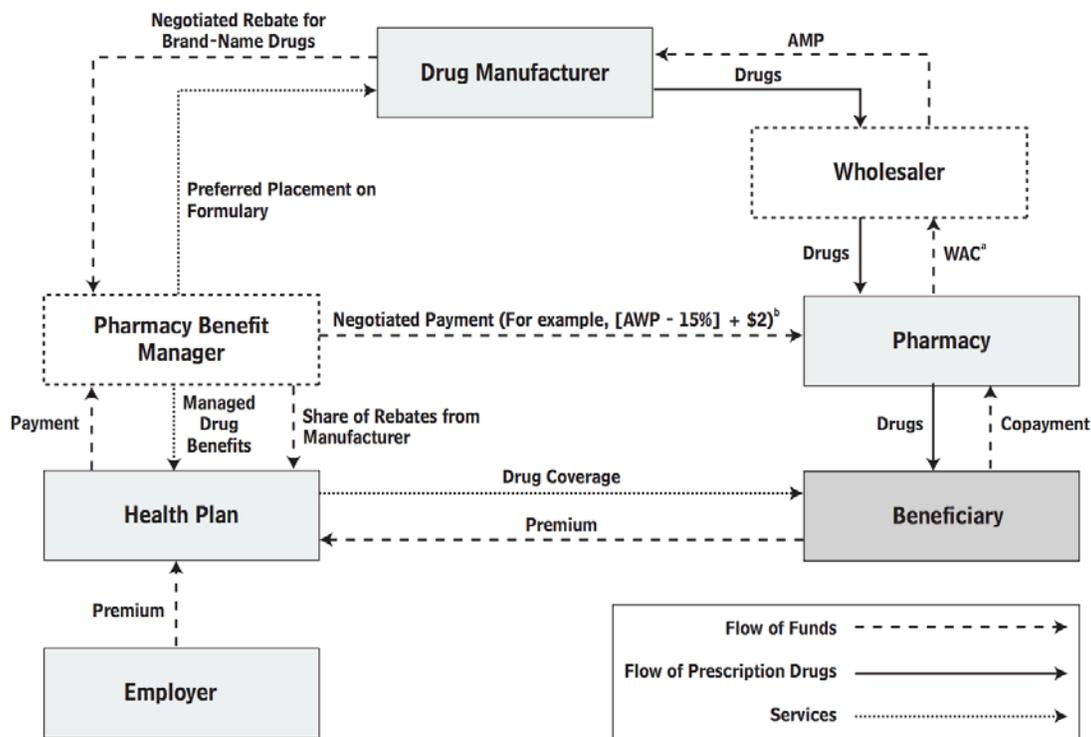
Figure 1

---

<sup>6</sup> International Business Times. September 25, 2015. Daraprim: Generic version of drug costs less than £0.07 in India. Accessed February 4, 2016 at: <http://www.ibtimes.co.uk/daraprim-like-drug-costs-less-0-07-india-1521144>

<sup>7</sup> Congressional Budget Office. January 2007. Prescription Drug Pricing in the Private Sector. Accessed February 4, 2016 at: <http://www.dol.gov/ebsa/pdf/cbo010711.pdf>

## Flow of Funds for Single-Source Brand-Name Drugs Purchased at a Retail Pharmacy and Managed by a Pharmacy Benefit Manager for an Employer's Health Plan



Source: Congressional Budget Office.

Note: AMP = average manufacturer price; WAC = wholesale acquisition cost; AWP = average wholesale price.

a. The WAC is a list price that approximates what conventional pharmacies pay wholesalers for single-source brand-name drugs.

b. Based on Novartis Pharmaceuticals Corporation, *Pharmacy Benefit Report: Facts & Figures* (2004), p. 16.

Figure 2

These complicated market structures highlight the many layers between the end customer (the patient) and the drug manufacturers. An insured patient frequently sees only the cost-sharing for their prescriptions at the pharmacy (copays, coinsurance, etc.). Especially with high-priced specialty drugs, this cost-sharing makes up just a small percent of the actual transaction. What the patient doesn't see are payments from the insurer to the pharmacy benefit manager (PBM), the payment from the PBM to the pharmacy (discounted by certain amounts), the payments from the pharmacy to the wholesaler for the drug itself, or the payments from the manufacturers to the PBM (rebates).

Pharmacy Benefit Managers are positioned in these transactions as a middle-man, facilitating payments for patients' drugs to pharmacies and managing drug formularies for insurers to reduce their costs. To determine which drugs the PBM will cover and how much the patient will have to contribute (copayments and coinsurance based on the drug's tier placement), the PBMs will work directly with the drug manufacturers. Manufacturers want favorable placement on the PBM's formulary, meaning a tier with lower cost-sharing that encourages patients to seek the drug as opposed to an alternative therapy. To receive this placement, PBMs negotiate for rebates paid directly from the maker to the PBM for each dispensed prescription. In addition to managing formularies, PBMs pay pharmacies per script filled. To reduce these costs, many PBMs operate their own mail-order pharmacies. Through these pharmacies, the PBM does not

have to pay another vendor (the local pharmacy) for dispensing scripts and can more actively be involved with encouraging patients to switch to pharmaceuticals that pay the PBM higher rebates.

With the actual prices and costs of pharmaceuticals hidden within the layers of actors in the market, often customers are shielded from high prices, but they are also shielded from information that would allow them to better understand the price of their care. As an example of the impact this shielding can have on the setting of prices, executives at Turing Pharmaceuticals behind the large increase in Daraprim prices used this as justification for the increase:

On September 14, 2015, Dr. Eliseo Salinas, Turing’s President of Research and Development, gave an interview in which he stated: “No patient, no patient, uh, should bear the burden of the cost of the medication. Uh, in this country as in many other countries, medications are covered by either private insurance programs or public insurance programs; we make sure the patient, patients don’t have to incur a, any additional cost for this medication. Uh, including those patients that might have no coverage at all—we are making sure those patients receive the medication at not—no cost for the patient.”<sup>8</sup>

Uninsured patients, however, are not shielded from pricing, which has led to the proliferation of prescription assistance programs. The Partnership for Prescription Assistance is a PhRMA-sponsored (Pharmaceutical Research and Manufacturers of America) organization that helps connect patients with manufacturer assistance programs.<sup>9</sup> The programs offered by manufacturers will provide high cost pharmaceuticals to patients who otherwise would not be able to receive the treatment.<sup>10</sup> These programs have been criticized as a means for serving as another means for shielding patients from the costs of their care, leading to patients not using other treatments (such as generic drugs) that might offer the same benefits at lower cost.<sup>11</sup>

Traditionally in the pharmaceutical market, the introduction of generic versions of drugs has led to significant decreases in prices for patients. These drugs are possible after the expiration of patents and other periods of exclusivity for the original “innovator” drugs. With multiple sellers of the medication, the dynamics of the marketplace shift significantly. Payers and customers downstream have more power to decide which supplier they will buy from and prices usually drop precipitously. One U.S. Food and Drug Administration study estimates that the first generic on the market will lower prices by only about 6%, while the second entrant into the market leads to the price being just over half of the original price, on average.<sup>12</sup> See Figure 3.

---

<sup>8</sup> U.S. House of Representatives Committee on Oversight and Government Reform. February 2, 2016. Memorandum re: Documents Obtained by Committee from Turing Pharmaceuticals. Accessed February 3, 2016 at:

<http://democrats.oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%20Turing%20Documents.pdf>

<sup>9</sup> Partnership for Prescription Assistance. See: <https://www.pparx.org/>

<sup>10</sup> Consumer Reports. 2007. Shoppers Guide to Prescription Drugs – Number 5: Assistance Program. Accessed February 4, 2016 at:

<https://www.consumerreports.org/health/resources/pdf/best-buy-drugs/money-saving-guides/english/AssistancePrograms-FINAL-April2007.pdf>

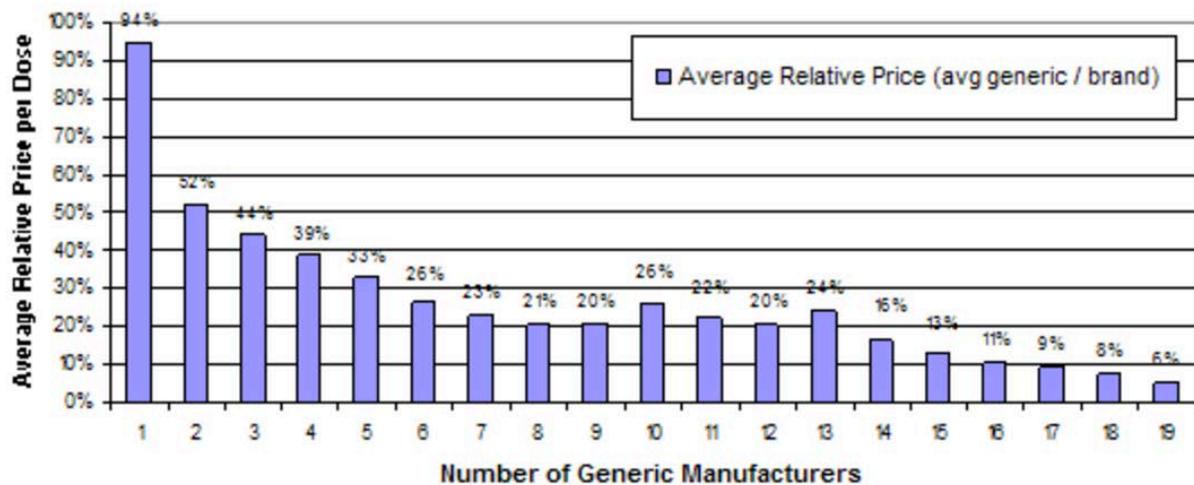
<sup>11</sup> Consumer Reports. 2007. Shoppers Guide to Prescription Drugs – Number 5: Assistance Program. Accessed February 4, 2016 at:

<https://www.consumerreports.org/health/resources/pdf/best-buy-drugs/money-saving-guides/english/AssistancePrograms-FINAL-April2007.pdf>

<sup>12</sup> Food and Drug Administration. May 13, 2015. Generic Competition and Drug Prices. Accessed February 4, 2016 at:

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>

## Generic Competition and Drug Prices



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

Figure 3

For many years, the pharmaceutical market has been extremely complex, but generally followed this pattern: innovator drugs with patent protection or other regulatory exclusivity have been offered at relatively high prices, but with the entry of multiple generic competitors, the price of those drugs are reduced significantly. These lower prices then incentivized manufacturers to create new innovative products that could be offered at the higher prices possible with patent or other exclusivity.

---

### *Biologics, Specialty Pharmaceutical and Pharmacies, and Other Complicating Factors*

Further complicating the pharmaceutical market are two relatively new issues that have broken the “traditional” cycle of high-priced-innovator-drug followed by low-cost-generic drugs. First, many new treatments are biological therapies that are not easy to create generic versions of, unlike “small-molecule” treatments. Second, the storage and use requirements of many of these biologics has created a new class of specialty drugs and specialty pharmacies that can have very high prices and can restrict distribution significantly. Combined these two have led to some high-cost and very visible changes within the pharmaceutical market.

The increase in development of biologic therapies has been a major development in treating many diseases and conditions. This increase has been spurred by major advancements in genetics and scientific understanding of cell and disease processes.<sup>13</sup> While the production of “chemical” drugs is relatively well defined and allows production of uniform large quantities, biologics “have a complex production process that tends to yield small quantities.”<sup>14</sup> Frequently with biologics, the manufacturing process itself, not just the chemical makeup, is subject to patent protection. This and the complexity of the properties of the

<sup>13</sup> Morrow, Thomas and Felcone, Linda. 2004. Defining the difference: What Makes Biologics Unique. *Biotechnol Healthc.* 2004 Sep; 1(4): 24-26,28-29. Accessed February 4, 2016 at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564302/>

<sup>14</sup> Morrow and Felcone. 2004.

therapy make it extremely difficult for competitors to bring a “generic” version to market. In early 2015, the FDA approved the first biosimilar drug to an existing biologic, but since that time no others have been approved.<sup>15</sup> These drugs often have delicate chemical structures that require careful handling and storage: some treatments cannot be shaken or exposed to light and many require precise temperature control. In addition, many biologics must be administered by health care providers in infusion centers or doctors’ offices.

The high cost of these drugs, the careful handling and storage requirements, and the requirement for many to be administered by professionals has led to another major change in the pharmaceutical market: specialty drug designations and specialty pharmacies.

“Specialty drug” is a term with no precise definition, but which generally covers a range of very high cost drugs and those with special storage or administration requirements. With many insurance plans, these drugs are considered the highest drug tier, with the highest cost-sharing requirements for patients. For individual market insurance plans in Colorado, these can have copays exceeding \$1,000, though the total price of the treatment far exceeds this amount. Medicare Part D enrollees can experience annual out of pocket costs for specialty drugs that are more than \$10,000. A Kaiser Family Foundation study found that median out of pocket costs for Medicare Part D enrollees taking one of three hepatitis C specialty drugs range from \$6,516 to \$7,153 in 2016,<sup>16</sup> and that in 2016, out of pocket costs in the Part D program can reach as high as \$11,538 for a single drug.<sup>17</sup>

In 2004, these drugs represented 19 percent of all spending in the United States on pharmaceuticals. By 2014 they represented one third of all spending and some estimate this will increase to a half of all drug spending by 2024.<sup>18</sup> In 2014, the high price of new specialty drugs to treat hepatitis C had a large impact on federal spending on Medicare Part D: \$4.5 billion.<sup>19</sup> Some fear that the growth in spending on specialty drugs will have catastrophic effects on the financial stability of the Part D program, and will not only impact those who are taking the drugs, but also the price of premiums for all participants.

The cost and requirements of these drugs have led to the development of a relatively new breed of pharmacy: the specialty pharmacy.<sup>20</sup> Along with the increases in specialty drug spending, these businesses saw their sales increase from \$20 billion in 2005 to \$78 billion in 2014. Many of these pharmacies offer more services than standard pharmacies, including individualized patient education and the pharmacies often report better patient adherence with therapies. With the high cost of these services and therapies, many specialty pharmacies are owned directly by PBMs, which then restrict patient access to non-owned pharmacies. This can help to greatly reduce PBM costs and therefore reduce insurance costs for these expensive drugs. However, within this market, there is usually just one manufacturer for specialty drugs and patients often have access to only one pharmacy, greatly reducing consumer choice and competition.

---

<sup>15</sup> New York Times. Jan 7, 2015. For First Time, F.D.A. Panel Approves Generic Copy of Costly Biologic Drug. Accessed February 4, 2016 at: <http://www.nytimes.com/2015/01/08/science/fda-panel-vote-biologics.html>

<sup>16</sup> Kaiser Family Foundations. December 2, 2015. It Pays to Shop: Variation in Out-of-Pocket Costs for Medicare Part D Enrollees in 2016. Accessed February 9, 2016 at: <http://kff.org/report-section/it-pays-to-shop-variation-in-out-of-pocket-costs-for-medicare-part-d-enrollees-in-2016-findings/>

<sup>17</sup> NPR Health, Inc. December 3, 2015. Specialty Drugs Can Prove Expensive Even With Medicare Coverage. Accessed February 9, 2016 at: [http://www.npr.org/sections/health-shots/2015/12/03/458216778/specialty-drugs-can-prove-expensive-even-with-medicare-coverage?utm\\_source=npr\\_newsletter&utm\\_medium=email&utm\\_content=20160209&utm\\_campaign=npr\\_email\\_a\\_friend&utm\\_term=storyshare](http://www.npr.org/sections/health-shots/2015/12/03/458216778/specialty-drugs-can-prove-expensive-even-with-medicare-coverage?utm_source=npr_newsletter&utm_medium=email&utm_content=20160209&utm_campaign=npr_email_a_friend&utm_term=storyshare)

<sup>18</sup> New York Times. July 15, 2015. Specialty Pharmacies Proliferate, Along With Questions. Accessed February 9, 2015 at: <http://www.nytimes.com/2015/07/16/business/specialty-pharmacies-proliferate-along-with-questions.html>

<sup>19</sup> Washington Post. March 29, 2015. New hepatitis C drugs are costing Medicare billions. Accessed February 9, 2016 at: [https://www.washingtonpost.com/national/health-science/medicare-spent-45-billion-on-new-hepatitis-c-drugs-last-year-data-shows/2015/03/29/66952dde-d32a-11e4-a62f-ee745911a4ff\\_story.html](https://www.washingtonpost.com/national/health-science/medicare-spent-45-billion-on-new-hepatitis-c-drugs-last-year-data-shows/2015/03/29/66952dde-d32a-11e4-a62f-ee745911a4ff_story.html)

<sup>20</sup> New York Times. July 15, 2015. Specialty Pharmacies Proliferate, Along With Questions. Accessed February 4, 2015 at: <http://www.nytimes.com/2015/07/16/business/specialty-pharmacies-proliferate-along-with-questions.html>

Another market change within the specialty market is the growth of limited distribution networks, where the drugs are channeled by the manufacturer through a small group of specialty distributors and only specialty pharmacies working with those distributors can get the drugs.<sup>21</sup> These limited channels are used for a few important reasons, according to Drug Channels, a research and data web service focused on pharmaceuticals:

- Specialty drugs serve relatively small patient populations, so a manufacturer can efficiently reach the entire market with a limited number of channel partners.
- Specialty drugs have special handling requirements. Only distributors that meet a manufacturer's criteria are allowed to stock and dispense these therapies.
- Product security is also important. There is a risk these high-cost drugs could be diverted from intended channels and sold elsewhere.

In 2012, there was a case of counterfeit Avastin, a cancer-fighting drug, entering the U.S. market through physicians' office that bought it outside the limited supply chain to save money.<sup>22</sup> Each dose of Avastin can cost thousands of dollars, offering a lucrative opportunity to counterfeit. Avastin's manufacturer and others cite this example as a good example of the need for properly controlled distribution networks, so physicians know they are buying legitimate products. However, it could also be cited as an example of why more competition in these markets is needed.

Limited distribution networks for specialty drugs have also been used by some companies to greatly increase costs on older drugs and then limit access, essentially turning generics into specialty drugs. In the most high profile example of this, Turing Pharmaceuticals raised the price of Daraprim by 5,000% and limited its sales to an extremely closed network.<sup>23</sup> This plan took advantage of the closed-network distribution, originally devised to protect consumer safety, in a scheme to create a virtual monopoly and charge much higher prices. Turing's use of this strategy was not the first in the generics market, but it was the most publicized (and criticized).

---

### *Recent Ideas or Efforts to Limit Pharmaceutical Price Inflation*

In recent years, the United States has seen rising drug costs across the industry: innovator drugs, specialty drugs, and generic drugs. Public opinion polling done by Kaiser Family Foundation shows a large amount of public support for political action on the issue:<sup>24</sup>

- 72% think that the cost of prescription drugs is unreasonable.
- 73% think that pharmaceutical companies make too much profit.
- 76% favor limiting the amount drug companies can charge.
- 86% favor requiring drug companies to release information to the public on how they set their prices.

---

<sup>21</sup> Drug Channels. February 22, 2012. To Limit Counterfeits, Build a Solid Channel Strategy. Accessed February 4, 2016 at: <http://www.drugchannels.net/2012/02/to-limit-counterfeits-build-solid.html>

<sup>22</sup> Wall Street Journal. July 20, 2012. How Fake Cancer Drugs Entered U.S. Accessed February 4, 2016 at: <http://www.wsj.com/articles/SB10001424052702303879604577410430607090226>

<sup>23</sup> Suowiecki, James. October 12, 2015. Taking on the Drug Profiteers. The New Yorker. Accessed February 4, 2016 at: <http://www.newyorker.com/magazine/2015/10/12/taking-on-the-drug-profiteers>

<sup>24</sup> Kaiser Family Foundation. August 20, 2015. Kaiser Health Tracking Poll: August 2015. Accessed February 9, 2016 at: <http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015/>

With mounting public and political concern, there have been a number of efforts to require pharmaceutical companies to disclose information related to drug costs and profits to justify the price increases.<sup>25</sup> Legislation regarding drug production cost transparency has been introduced in a number of states but all such efforts have failed.

The issue of pharmaceutical pricing is complex and that there are no simple solutions. Many ideas have been raised as options for addressing a variety of issues around pharmaceutical drug prices, including:

- Increasing transparency of the costs of research, development, production, and prices
- Require pharmaceutical companies to submit all the information they submit to foreign regulators
- Increase comparative effectiveness research and utilization
- Require disclosure of results of trials
- Shorten the exclusivity period for patents (and other regulatory exclusivity periods)
- Ban advertisements and marketing to patients or both patients and prescribers
- Create nonprofit alternatives to for-profit research and manufacturing companies
- Allow Medicare to negotiate for pricing, possibly including negotiation with forced arbitration
- Compare pricing to other countries
- Benchmark allowed pharmaceutical prices to negotiated Veterans Affairs prices
- Permit importation from other countries
- Limit price increases to inflation for existing drugs
- Require companies to justify prices as proportional to value
- Change how providers are paid for drugs administered in-office
- Limit profit margins for pharmaceutical manufacturers
- Create a different approach to market incentives, such as with innovation prizes
- Require manufacturers of generics to allow others to test off of the original drug

---

### **HB16-1102– Drug Production Costs Transparency Requirements**

The advocates for this bill are seeking to provide more information to the Colorado Commission on Affordable Health Care and the Colorado General Assembly on the costs associated with the production and development of some of today’s highest cost pharmaceuticals.

The bill would require a detailed accounting of a variety of costs associated with individual drugs sold in Colorado that have a wholesale acquisition cost of \$50,000 or more per year. Other states’ efforts that have been unsuccessful had a threshold of \$10,000, which would have covered many more drugs. An AARP study of the 98 most commonly prescribed specialty drugs for older Americans found that the average annual retail price for these drug therapies was \$53,384.<sup>26</sup> The threshold in HB16-1102 is for the “wholesale acquisition cost,” not the retail price (which would be higher), so it is not known how many drugs would be covered by the bill.

For those drugs that meet or exceed the \$50,000 price threshold, the manufacturers would have to report to the Colorado Commission on Affordable Health Care detailed information regarding each covered drug:

---

<sup>25</sup> New York Times. July 23, 2015. Drug Prices Soar, Prompting Calls for Justification. Accessed February 4, 2016 at: <http://www.nytimes.com/2015/07/23/business/drug-companies-pushed-from-far-and-wide-to-explain-high-prices.html>

<sup>26</sup> AARP Public Policy Institute. November 2015. Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2013. Accessed February 4, 2016 at: <http://www.aarp.org/content/dam/aarp/ppi/2015/rx-price-watch-specialty-prescription-drug-prices-continue-to-climb-final.pdf>

- Total R&D costs, including R&D costs of any predecessor companies for the drug.
- Total costs of clinical trials and regulatory costs, including those paid by predecessor companies.
- Total costs of materials, manufacturing expenses, and administration.
- Total costs for R&D paid by other entities, including federal or state grants or subsidies.
- Other components of costs, including patents or licensing.
- Total costs for marketing and advertising to patients, physicians, or others.
- A cumulative annual history of increases in the average wholesale price.
- Total profit from the sales of the drug.
- Total costs of patient assistance programs, if any.

The manufacturers must report this information by August 1, 2016.

#### **Proponents**

- Kaiser Permanente
- AHIP – America’s Health Insurance Plans
- SEIU
- Rocky Mountain Health Plans
- Healthier Colorado
- Anthem Blue Cross/Blue Shield
- Colorado Education Association

#### **Opponents**

- PhRMA
- Genentech
- Novartis
- Gilead
- Pfizer

#### **Discussion**

---

##### **Reasons to Support HB15-1029**

- With pharmaceuticals making up 10% of all health expenditures (or as much as 20% of all expenditures based on other estimates), it is in the public interest to better understand what goes into determining the prices of pharmaceuticals. Currently, policymakers and the public have almost no information on how prices are set, yet must pay ever-increasing prices.
- High pharmaceutical prices increase costs for patients, while also raising costs for insurers who in turn must raise premiums, impacting consumers and employers. High pharmaceutical prices also significantly impact budgets of public programs like Medicaid and Medicare. Transparency into costs could bring additional attention to the issue and public opinion could influence price-setting.
- Some fear that if pharmaceutical prices continue their dramatic increases, soon only the very wealthy will be able to afford medications. The prices will exacerbate already existing health disparities based on income and wealth. More transparency in how prices are set will help policy makers and society at large better understand policy and market options for the provision of needed medications for the public good.
- High prices for pharmaceuticals are sometimes defended based on the value they offer patients and the health system. However, calculating the value of a drug is a complex and controversial issue, and value calculations have not been used to set other health services pricing. Moving into value

calculations for prescription pricing could create a precedent with serious unintended consequences. The current and immediate high prices of a mushrooming number of specialty drugs is unlikely to be sustainable for public or private health systems. More transparency in the pricing of drugs could allow all parties (not just the sellers) to level the playing fields for negotiation of price.

- With increased public awareness of the issues around drug pricing, policymakers are increasingly interested in stepping in to curb the high prices. However, with the dearth of information available on prices, the complex balancing of policy options is not being made as part of a fully informed decision-making process. Len Nichols, in an Issue Brief for the Center for Health Policy Research and Ethics at George Mason University, notes that the lack of data leaves one of three tough choices for policy makers and researchers, “(1) making educated inferences based on incomplete data, (2) reach judgments and develop an advocacy campaign based on truly scary list prices, or (3) writing defenses of the status quo based on data that are shared only with industry supporters...”<sup>27</sup>

### Reasons to Oppose HB15-1029

- This bill looks at costs related to a handful of high-cost drugs but fails to take into account value of the drugs. For example, the Hepatitis drug Sovaldi has a high price but could reduce health system spending by reducing the need for more expensive treatments, including organ transplant.

A December 2015 article in the *New England Journal of Medicine* titled “Measuring the Value of Prescription Drugs” looked at several competing schemes for measuring the cost effectiveness and value of new pharmaceuticals.<sup>28</sup> Comparing drug prices to cars, the authors note, “Consumers don’t ask dealers about a car’s manufacturing costs. Instead, they decide whether to buy a particular car by comparing its price and features to those of other vehicles, in the process spurring companies to develop even better alternatives.” However, the various frameworks available to look at cost effectiveness and value of therapies each face challenges with regard to subjectivity of value, overall systems budget impact, and other market-based issues not seen in other nations.

HB16-1102 does not seem to seek information on pharmaceuticals’ value of cost-effectiveness, only looking at detailing the costs and profit of manufacturers.

- The prescription pharmaceutical market is extremely complex and this bill only looks at manufacturer’s costs, not the interactions and transactions up and down the supply chain. For example, without factoring in rebates, the wholesale acquisition cost of a drug is not a good indicator of the actual price paid for a drug.
- A great deal of the information required to be reported is proprietary business information that the manufacturers desire to not release. Many business negotiations depend on this information and it could impact businesses to let the information be known to competitors.
- The cost to develop a particular drug has little to do with that drug’s price. Len Nichols, a health care economist at George Mason University: “The past R&D cost is really kind of a red herring. The current revenue doesn’t pay for past R&D; it pays for current R&D.”<sup>29</sup>

---

<sup>27</sup> Nichols, Lin. May 15, 2015. What Price Should We Pay for Specialty Drugs? Accessed February 5, 2016 at: [http://chpre.org/wp-content/uploads/2015/05/New-Pricing-Policy-for-Specialty-Drugs\\_5.12.2015.pdf](http://chpre.org/wp-content/uploads/2015/05/New-Pricing-Policy-for-Specialty-Drugs_5.12.2015.pdf)

<sup>28</sup> Neumann and Cohen. December 31, 2015. Measuring the Value of Prescription Drugs. *N. Engl. J. Med.* 373:27. DOI: 10.1056/NEJMp1512009

<sup>29</sup> New York Times. July 23, 2015. Drug Prices Soar, Prompting Calls for Justification. Accessed February 4, 2016 at:

<http://www.nytimes.com/2015/07/23/business/drug-companies-pushed-from-far-and-wide-to-explain-high-prices.html>

In an Issue Brief for the Center for Health Policy Research and Ethics at George Mason University, Nichols noted the case of Sovaldi, the Hepatitis C cure that launched with a \$80,000 price.<sup>30</sup> In that case, evidence suggests that it wasn't the past R&D that led to high prices, but instead the returns from the high pricing being used to increase present and future R&D.<sup>31</sup> Researchers on declining returns on investment for pharmaceutical R&D (Berndt et al.) noted "research and development costs are sunk at the time of product launch, and so they ought not to factor into the pricing decisions of a profit-maximizing firm once the product has been developed."

HB16-1102 requires drug manufacturers to submit a great deal of information on R&D and trials for particular drugs, under the premise that these costs drive the set prices. At stakeholder meetings, representatives of various pharmaceutical companies emphasized that their R&D costs cannot always be separated by drug, as R&D is done on a wide range of potential options, many of which do not result in successful therapies. This tends to support the points above by Nichols and others, that R&D isn't a clear cost that is factored into pricing, but instead it is the current sales that dictate how broad current R&D can be.

### **About this Summary**

---

This summary was prepared by Health District of Northern Larimer County staff to assist the Health District Board of Directors in determining whether to take an official stand on various health-related issues. The Health District is a special district of the northern two-thirds of Larimer County, Colorado, supported by local property tax dollars and governed by a publicly elected five-member board. The Health District provides medical, mental health, dental, preventive and health planning services to the communities it serves. For more information about this summary or the Health District, please contact Dan Sapienza, Policy Coordinator, at (970) 224-5209, or e-mail at dsapienza@healthdistrict.org.

---

<sup>30</sup> Nichols, Lin. May 15, 2015. What Price Should We Pay for Specialty Drugs? Accessed February 5, 2016 at: [http://chpre.org/wp-content/uploads/2015/05/New-Pricing-Policy-for-Specialty-Drugs\\_5.12.2015.pdf](http://chpre.org/wp-content/uploads/2015/05/New-Pricing-Policy-for-Specialty-Drugs_5.12.2015.pdf)

<sup>31</sup> Nichols cites: E. Berndt et al, "Decline in Economic Returns from New Drugs Raises Questions about Sustaining Innovations," 34(2):245-52 (2015),