How Veterans Are Affected by the High Cost of Specialty Drugs

by

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for the
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I. Introduction

Chairman Sanders, Ranking Member Burr, and members of the committee, I am John Rother, President and CEO of the National Coalition on Health Care (NCHC). I appreciate this opportunity to testify on behalf of the Campaign for Sustainable Rx Pricing regarding the high cost of specialty drugs and how our nation's veterans are affected by this growing problem.

The NCHC launched the Campaign for Sustainable Rx Pricing in May 2014 to call attention to high-priced prescription drugs – most notably, specialty drugs – and the impact these prices are having on consumers, employers, and taxpayers. The Campaign is supported by the more than 90 stakeholder members of the NCHC. Our member organizations include medical societies, businesses, unions, health care providers, faith-based associations, pension and health funds, insurers, and groups representing consumers, patients, women, minorities, and persons with disabilities. Collectively, our organizations represent more than 100 million Americans.

The goal of the Campaign for Sustainable Rx Pricing is to foster a national dialogue on the pricing of high-cost biopharmaceutical therapies, some of which are now priced at $1,000 or more per dose with total treatment costs of $100,000 or more. Prices at that level threaten access to care and result in much higher out-of-pocket costs, higher premiums, and higher taxes. We believe there needs to be a better approach to pricing that recognizes value and balances the interests of innovator drug companies with the interests of society and our health care system. We are calling on the leaders of the biopharmaceutical industry to engage with us in a dialogue about market-based solutions for ensuring that the U.S. health care system can sustainably pay for the innovation that is so vital to our health and well-being.

My testimony for today's hearing focuses on three broad topics: (1) the challenges caused by rising health care prices; (2) the role of specialty drug prices as a major component of the health care cost problem; and (3) market-based solutions, including a stronger commitment to transparency, that are needed to address this growing problem.

II. Rising Health Care Costs Are a Challenge for All Stakeholders

The high cost of health care is a significant and ongoing challenge for consumers, businesses, and government programs, including the Department of Veterans Affairs (VA) health care system.

According to the most recent data[1] from the Centers for Medicare & Medicaid Services (CMS), national health expenditures in 2014 are projected to total $3.057 trillion (a 5.6 percent increase over 2013), with $290.7 billion spent on prescription drugs (a 6.8 percent increase). Total national health spending in 2014 accounts for 17.6 percent of the nation's gross domestic product (GDP) and translates into per capita spending of $9,596. CMS further projects that national health spending will increase at an average annual rate of 5.7 percent over the 2013-2023 time period, with per capita spending reaching a level of $14,944 by 2023.

Rising health care costs are presenting challenges on multiple fronts. Working families and seniors face difficult choices when their budgets are pressured by medical expenses. Many businesses, both large and small, find that health care costs are undermining their ability to hire new employees, expand their operations, and compete in the global economy. Federal, state, and local governments – facing budget constraints driven by continually increasing health care costs – are forced to limit the resources they devote to other priorities such as infrastructure, education, and public safety.

The VA health care system – which serves nearly 9 million enrollees, with an annual budget approaching almost $60 billion[2] – also is impacted by rising health care costs. Because the VA serves patients whose medical needs tend to be greater than those of the broader U.S. population, its budget is disproportionately impacted by high health care costs, including new specialty drugs with extremely high price tags.

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[1] CMS National Health Expenditure Data, September 2014. http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html

[2] U.S. Department of Veterans Affairs, President's Budget Request for Fiscal Year 2015. http://www.va.gov/budget/products.asp

III. Specialty Drug Prices Are a Large Component of the Problem

Spending on specialty drugs represents a growing share of overall prescription drug spending and is increasing at a rapid and unsustainable rate. Addressing these cost trends is critically important to ensuring a sustainable health care system and achieving affordability for businesses and consumers.

Specialty drugs generally are defined as drugs that are structurally complex and often require special handling or delivery mechanisms. While these drugs have been ground-breaking in the treatment of cancer, rheumatoid arthritis, multiple sclerosis, and other chronic conditions, the cost of treating a patient with specialty drugs can exceed $100,000 annually. Their high costs and extended use are placing a significant strain on our health care system.

While only 4 percent of Americans take a specialty drug, the spending associated with these drugs represents a quarter of all drug spending in the United States, according to a 2013 report[3] by CVS Caremark. In a separate 2014 report[4], CVS Caremark concluded that spending on specialty drugs increased by 15.6 percent in 2013, compared with only a 0.8 percent increase in spending on traditional medications. A similar trend was reported[5] by Express Scripts, which has projected that spending on specialty drugs will increase 63 percent between 2014 and 2016. Additional research[6] by the PricewaterhouseCoopers Health Research Institute projects that specialty drug spending will increase from $87 billion in 2012 to $402 billion in 2020 – a 361 percent increase in eight years.

The role of specialty drugs as a major driver of drug spending is a direct result of their growing presence in the pharmaceutical market. In 2010, specialty drug approvals by the Food and Drug

[3] CVS Caremark, 2013 Insights, Specialty Trend Management. http://www.cvshealth.com/sites/default/files/Insights%202013.pdf
[4] CVS Caremark, 2014 Insights, 7 Sure Things. http://investors.cvshealth.com/~/media/Files/C/CVS-IR/reports/2014-cvs-caremark-insights-report.pdf
[5] Express Scripts, Industry Updates, April 8, 2014. http://lab.express-scripts.com/insights/industry-updates/report-specialty-drug-spending-at-lowest-rate-since-2007
[6] PwC's Health Research Institute, Medical Cost Trend: Behind the Numbers 2015, June 2014. http://www.pwc.com/en_US/us/health-industries/behind-the-numbers/assets/hri-behind-the-numbers-2014-chart-pack.pdf

Administration (FDA) exceeded traditional drug approvals for the first time, a trend that has continued each year since. In 2013, 19 of the 28 drugs approved by the FDA – more than two-thirds – were specialty drugs.[7]

Examples: Sovaldi and Harvoni

Within the past year, two new specialty drugs for treating patients with the Hepatitis C virus – Sovaldi and Harvoni – have entered the marketplace. These drugs provide important and effective breakthrough therapies for the treatment of Hepatitis C patients. But the manufacturer, Gilead Sciences, is demanding unaffordable prices that pose a serious threat to the pocketbooks of consumers, employers, government programs (including the VA health care system), and taxpayers.

Sovaldi, approved by the FDA in December 2013, is priced at $1,000 per pill and costs $84,000 for a 12-week course of treatment. Because Sovaldi is often prescribed in concert with other drugs, the total treatment cost sometimes approaches $150,000 for a single patient.

Harvoni, which received FDA approval in October 2014, is priced at $1,125 per pill and costs $94,500 for a 12-week course of treatment. This drug also is combined with other treatments for many patients.

Sovaldi is on pace to become the highest grossing drug in history, having generated sales of $2.27 billion in the first quarter of 2014 and $3.48 billion[8] in the second quarter. If this sales trend continues, Gilead essentially will recover its total investment in Sovaldi in the first year. Pharmasset, the company that carried out the research and development on Sovaldi, intended to price the drug at 43 percent of what Gilead is now charging[9]. Did Gilead purchase the company knowing it could more than double the price and pay for its investment in one year? Has an incentive for innovation been abused at the expense of taxpayers and patients?

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[7] "Specialty Drug Approvals in 2013." Express Scripts Insights. March 26, 2014. http://lab.express-scripts.com/insights/drug-options/specialty-drug-approvals-in-2013

[8] *Wall Street Journal*, Hepatitis C Pill Rockets Gilead Into Big Leagues, July 24, 2014.

[9] *The Fiscal Times*, The $1,000 Pill That Could Cripple the VA's Budget, by Erik Pianin, October 8, 2014 http://finance.yahoo.com/news/1-000-pill-could-cripple-104500188.html

We are concerned that the exorbitant price tag assigned to this drug reflects an abuse of the market power that is granted to pharmaceutical manufacturers under federal law. Under the Hatch-Waxman Act[10], manufacturers receive the exclusive right to manufacture and sell their products for a period of time so that they can be rewarded for their innovation and recover the costs associated with developing important new therapies. This system generally has worked well, producing effective treatments for many illnesses that were once untreatable. However, when a new medicine is considered more effective than previous therapies, the high demand for that product, combined with the market exclusivity, allows the manufacturer a great deal of market power in setting the price. In the case of Sovaldi, we believe that market power has been abused.

Implications for Veterans

The committee has indicated that the VA currently provides health care services to more than 170,000 veterans who have the Hepatitis C virus, and that tens of thousands of additional veterans are estimated to have Hepatitis C but have not been tested.

Recognizing that the VA serves a large number of veterans who may benefit from either Sovaldi or Harvoni, we are seriously concerned about the impact the unreasonable prices for these drugs will have on access to care for our nation's veterans. At a time when almost all government programs are facing tight budget constraints and operating with limited resources, it is critically important to ensure that the essential health care services we owe to the men and women who have served in uniform are not underfunded because the VA is forced to pay excessive prices for new specialty drugs.

Looking at the overall impact of the costs associated with Sovaldi and Harvoni, we have serious concerns that new specialty drugs with unusually high prices may place an unsustainable burden

[10] CRS Report for Congress, The "Hatch-Waxman" Act: Selected Patent-Related Issues, April 1, 2002. http://congressionalresearch.com/RL31379/document.php?study=The+Hatch-Waxman+Act+Selected+Patent-Related+Issues

on the VA health care system, result in many patients not receiving needed treatments and therapies due to budget constraints, and create the potential for even greater dysfunction down the road if they establish a pattern for future pricing strategies.

The Sovaldi and Harvoni Price Tags Are Not Sustainable

Innovative new drugs are not sustainable if the health care system cannot afford them. The IMS Institute for Healthcare Informatics has estimated that the total cost of purchasing Sovaldi for all 3.2 million Americans who are infected with Hepatitis C would approach $300 billion. This figure is roughly equal to the total amount spent in 2013 on all other brand name prescription drugs combined. *Kaiser Health News*[11] describes the problem with this explanation: "If all 3 million people estimated to be infected with the virus in America are treated at an average cost of $100,000 each, the amount the U.S. spends on prescription drugs would double, from about $300 billion in one year to more than $600 billion."

The increase in the number of exceptionally high-priced drugs threatens the sustainability of our health care system. This is particularly true for public programs, including the VA health care system, which serve disproportionately sicker populations who are more likely to need these new medications and are already straining under the cost of existing high-priced new medications currently on the market. With additional specialty drugs prepared to come down the pipeline, and without pressure on pharmaceutical companies to change their behavior, the health care system will not be able to withstand the coming onslaught of six-figure therapies.

IV. Market-Based Solutions Are Needed to Make Specialty Drugs More Affordable

The Campaign for Sustainable Rx Pricing is advocating market-based solutions for making specialty drugs more affordable. New approaches to rewarding innovation and pricing drugs

[11] Kaiser Health News, Who Should Get Pricey Hepatitis C Drugs, May 5, 2014. http://kaiserhealthnews.org/news/sovaldi-who-should-get-pricey-drug/

based on their value – along with a strong emphasis on transparency – are important first steps toward achieving this goal.

One solution is to encourage alternative payment and incentive structures for rewarding innovation in the development of new drugs and technologies. These types of payment strategies can improve access to new drugs while at the same time generating additional evidence on the value to patients of these new medications. As part of a broader value-based purchasing strategy, these alternative arrangements – such as outcomes-based contracting or reimbursing providers a flat fee for obtaining drugs, rather than a percentage of the drug's total cost – provide enhanced financial incentives for manufacturers of new drugs that are linked to standards for quality care, performance, and health outcomes. Greater use and availability of comparative effectiveness data is a key element in the future growth of these innovative payment arrangements.

On another front, we support enhanced flexibility for the VA to conduct pilot programs to explore new ways of assessing and pricing drugs based on their value. For example, the VA should be authorized to use the findings of comparative effective research to provide information to patients and providers about which drug regimens and treatments deliver the most value and which are less effective. Such information is highly beneficial to both patients and providers. Additionally, the use of value-based insurance design can help promote better outcomes and quality of care, while discouraging low-value, high-cost care through the use of financial incentives. By building on best practices in the private sector, the VA can improve access to high-quality and cost-effective treatments based on the best available medical evidence and clinical guidelines.

Promoting greater transparency in the pharmaceutical industry is another strategy that offers significant promise for improving the affordability of specialty drugs. Recognizing that a competitive market is the best place to create value and determine price, we believe that the drug manufacturing industry should commit to the following common sense principles for health care sustainability which would benefit patients and the entire health care system:

1. **Drug Manufacturers Claiming a Value Proposition for Their Products Should Provide Documentation of Such Claims.** Manufacturers should provide a clear basis for claims they make that drugs reduce costs elsewhere in the health care system. Such reporting should include the net effect of any savings relative to the cost of the drug. If the manufacturer is claiming system-wide savings relative to existing alternative treatments, for example, it should clearly define the populations and treatment alternatives for which they are claiming savings and provide substantiating data that can be independently validated. Studies by independent researchers also are needed to provide a more comprehensive assessment of the value of new products.

2. **Drug Manufacturers Should Make Price Increases More Predictable to Benefit Patients and the Health System as a Whole.** Price inflation of existing drugs has become a serious problem, with manufacturers routinely demanding double-digit price increases year after year and throughout a plan year. A robust discussion of drug price predictability needs to take place, with a particular focus on the impact to consumers.

3. **Drug Manufacturers Attempting to Launch New Products Should Disclose Likely Populations Served, Launch Price, and Any Value Proposition, in as Timely a Manner as Possible.** Manufacturers currently withhold this information until nearly the minute the drug hits the market, which unnecessarily impedes the ability of patients and the health care system to react to a drug's indications, value, and pricing. Providing this information earlier will allow the market to function more efficiently.

4. **Drug Manufacturers, Working with FDA, Should Make Available All Clinical Data to Help Third-party Researchers Examine Comparative Effectiveness and Value**. Various organizations, including the American Medical Association, have called on drug manufacturers to work with the FDA to make this information available. Facilitating another government agency (such as the Patient-Centered Outcomes Research Institute), or other responsible third party, to assess the impact a newly introduced drug would have on public and commercial costs in relation to the drug's ability to improve patient health would be beneficial for patients without resorting to distortionary government intervention into price

setting. Rather, adding a non-binding "cost effectiveness" component to a government agency's or other organization's mission would provide a credible assessment of a drug's overall value.

5. **Drug Manufacturer Participation in Organizations that Influence Coverage Decisions Should Be Transparent and Free from Conflict of Interest.** Many organizations play a role in influencing coverage, such as the drug compendia entities and United States Pharmacopeia (USP). To the extent that drug manufacturers and others influence data availability, selection of indications, and interpretation of evidence in drug compendia, they are also setting the standards for drug use and coverage. Critical, independent reviews should be required of the information submitted by drug manufacturers and any potential conflicts of interest should be disclosed to the public and resolved in advance of the review process.

V. Conclusion

Thank you again for the opportunity to testify on this important issue. As we continue to work with stakeholders in the private sector, the Coalition looks forward to continuing a dialogue with the committee about market-based strategies for ensuring that veterans – along with the broader U.S. population – have access to affordable specialty drugs.