

**TESTIMONY OF DR. RICHARD I. FOGEL, MD, FACC, FHRS
CHIEF CLINICAL OFFICER, ST. VINCENT, INDIANA,
A MEMBER OF ASCENSION**

**Before the
UNITED STATES SENATE SPECIAL COMMITTEE ON AGING**

**Hearing on
VALEANT PHARMACEUTICALS' BUSINESS MODEL:
THE REPERCUSSIONS FOR PATIENTS AND THE HEALTHCARE SYSTEM**

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Valeant Pharmaceuticals' Business Model:
The Repercussions for Patients and the Healthcare System
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Dr. Richard I. Fogel, MD, FACC, FHRS
Chief Clinical Officer, St. Vincent, Indiana, a member of Ascension

Good afternoon, my name is Dr. Richard Fogel. I am a practicing cardiologist and electrophysiologist and the Chief Clinical Officer for St. Vincent, a faith-based health system that is part of Ascension, the nation's largest non-profit and Catholic health system. St. Vincent is one of Indiana's largest employers with 20 hospitals serving 57 counties in central and southern Indiana. Ascension provides care in 24 states and the District of Columbia, where 160,000 caregivers and other associates are committed to delivering compassionate, personalized care to all, with special attention to those living in poverty and most vulnerable.

Thank you for holding this hearing today to explore recent hyperinflation in pharmaceutical pricing and how it affects both patients and care providers. As healthcare practitioners, we are at a transitional time in which we are moving away from fee-for-service reimbursement – receiving payment for each service to a patient – to a fee-for-value payment system – receiving incentives to make the system more effective and efficient. In this new world of “population health,” we see reimbursement flattening or even decreasing, pushing providers and consumers to be ever more vigilant about our spending and management of resources.

As Chief Clinical Officer of a 20-hospital system with 16,000 employees, I work hard to focus our providers on achieving what has been called the Quadruple Aim. The goal of the Quadruple Aim is to improve the health of populations; reduce the cost of care; and enhance the patient and provider experience. The Quadruple Aim serves as the foundation of our clinical work at St. Vincent and Ascension.

Unfortunately, rising drug prices are contrary to the goals of the Quadruple Aim.

Pharmaceutical prices in general are rising much faster than inflation, and prices for hospital-administered drugs are growing even faster than general pharmaceutical price inflation. A recent report from the IMS Institute for Healthcare Informatics estimated that U.S. drug spending increased by 8.5 percent last year – more than any other year in the past decade except for a double-digit spike in 2014. According to IMS, the increase in drug spending is much higher than originally thought due to increases in the cost of hospital-administered drugs, whose cost is rising faster than retail pharmacy spending.

In contrast to the overall 8.5 percent increase in drug spending reported by IMS, drug spending at Ascension has increased 11 percent over the last year. This resulted in an increase of \$73.9 million in our drug spending from February 2015 to February 2016.

Double-digit increases are not out of the norm. In fact, we have seen increases of 500 percent, 1000 percent and even up to 3000 percent on select products, both branded and generic. These cases have shown no observable market-related changes to justify triple- and quadruple-digit increases. Included in my testimony is a table with Ascension's top increases in mature drug costs. This table represents the spending on our older brand and generic drugs; it does not include the new or "blockbuster" drugs.

As healthcare providers, we can't provide the quality care that our patients deserve without the partnership of the pharmaceutical industry. It is important that we protect intellectual property and reward innovation. We understand that in certain circumstances the price of a drug may be at a reasonable premium when that drug represents a true clinical advancement or breakthrough in treatment. While we understand a steady, rational increase in prices, it is the sudden, unfounded price explosions in select older drugs that hinder us in caring for patients. While pharmaceutical price inflation is nothing new, the increases that we have seen in the last few years are simply unprecedented.

What I find particularly troubling is when drugs that have been around for decades – and whose formulations have not changed – are suddenly and steeply increased with no apparent justification.

As a cardiologist who specializes in electrophysiology, I have seen firsthand the impact of price increases in two drugs in particular: Isuprel and Nitropress. Isuprel is a drug that increases slow heart rates and has been used during procedures to treat heart rhythm problems for decades. Nitropress is used to acutely lower blood pressure in patients whose blood pressure has risen to life-threatening levels. I first used Nitropress as a medical student in the mid-1980s, although the drug was available for years before.

When Valeant Pharmaceuticals purchased these drugs in 2014, St. Vincent saw the unit price of Isuprel increase from approximately \$204 per vial to approximately \$1,265 per vial

for a 521 percent increase from 2014 to 2015. We saw Nitropress increase from about \$203 per vial to about \$729 per vial, a 259 percent increase from 2014 to 2015.

Combined, these two drugs alone resulted in a nearly \$12 million increase in cost to Ascension in one year and nearly \$900,000 to St. Vincent. Despite a significant reduction in utilization, the overall Isuprel cost increased 253 percent and the Nitropress total cost increased 81 percent.

I would note, however, that pharmaceutical price increases are not limited to only a few drugs. Ascension tracks cost changes on a weekly basis, and we are projecting no change in the 11 percent year-over-year inflation for the foreseeable future.

In an effort to mitigate such increases in cost, Ascension created a national therapeutic affinity group in 2013. This group consists of pharmaceutical leaders and physicians from our system across the nation. In addition to medication safety initiatives that improve outcomes and increase patient safety, these leaders feel it is imperative to also look for alternate therapies that provide effective care and also achieve savings for the system and those who ultimately pay for healthcare.

For example, Nitropress is an ideal drug to treat blood pressure issues in patients as it is very effective and very responsive. By adjusting the dosing by turning a dial up or down, we can precisely control a patient's blood pressure so it's where we need to it be. However, due to the sharp increase in pricing, we have worked to mitigate the cost and have turned to evidence-based use of other drugs, such as intravenous Nicardipine, which has a similar action. At St. Vincent, we have reduced the usage of Nitropress by 48 percent, and its use has been reduced by 47 percent across Ascension. That being said, we are still spending more on Nitropress than we did prior to the 2014 price increases.

Likewise, the use of Isuprel has been reduced by 43 percent at St. Vincent and by 52 percent across Ascension. While this kind of nimbleness should be applauded, it can't compensate for the significant increases in these two fundamentally important cardiovascular drugs.

To date, our therapeutic affinity group has taken on more than 70 such projects across our 137-hospital system. This work is not easy. It takes much time and effort to gather the data, create potential alternatives, socialize, move through an approval process and then implement. We will not compromise patient safety and will not recommend switching to a therapeutic equivalent unless we are convinced that the switch is evidence-based and will not have an adverse impact on patients.

What is disheartening is that all this work can be wiped out with a stroke of a pen by a pharmaceutical company with no equivalent patient benefit. Steep price increases, with

little or no justification, often following consolidation or change in ownership in the manufacturing rights to a drug, do not serve patients, but they do serve the new company's bottom line.

In the inpatient setting, insured patients are somewhat shielded from financial impact as hospitals are typically paid a bundled payment covering the entire hospital stay. The cost of drugs used during a hospital stay is paid out of that bundled payment, which means that when drug costs increase, this cost comes out of the hospital's pocket first.

Hospitals also generally shoulder the burden for those patients who are self-pay (or uninsured) through charity or uncompensated care.

That being said, it is important to realize that pharmaceutical cost increases have a real and measureable impact on the patient. In the longer term, an increase in pricing will be felt by all patients as increased costs will eventually contribute to higher insurance premiums and/or higher costs for patients. More immediately, our decreased margins affect our ability to provide other patient-centered services that we deliver as part of our mission.

For example, as we continue our journey toward population health, we look for ways to keep our patients healthier. One program that I am most proud of is our Rural and Urban Access to Health (RUAH) initiative, in which we send health access workers to our communities to assist those who are poor and vulnerable sign up for insurance and connect them to other community resources, including other healthcare services, food, transportation or housing. These efforts do not provide revenue for St. Vincent, but they are services we provide because it is the right thing to do for individuals in our communities. With less available care dollars, it is a greater challenge to expand these types of community benefit programs.

Another effort we have undertaken is to do our part to fight the opioid epidemic. With deaths related to opioid addiction now surpassing deaths by automobile accidents, I am passionate about exploring ways that our health system can improve our patient and community services related to addiction. Addiction requires long-term treatment and personalized care. It is expensive but crucial if we are going to begin to address our current crisis. But these programs require funding. Before creating such new programs, we have to consider budget implications. There is no way around that. Increasing budgetary pressures on providers from higher drug costs will impact the creation of these programs, which serve the most vulnerable members of our communities.

More broadly, it is also important to note that many small community and critical access hospitals operate on tight margins. In recent years, we have seen more of these hospitals close because the financing was simply unsustainable. While pharmaceutical inflation is not

the only factor in this burden, it is a significant factor, and left unchecked it will contribute to the closing of more community hospitals.

Recommendations

Pharmaceutical hyperinflation is an issue that has only become worse in recent years and is not expected to subside. On behalf of St. Vincent and Ascension, we appreciate the Committee's attentiveness to the issue, and we strongly support the policy solutions released earlier this week by the Campaign for Sustainable Rx Pricing.

The Campaign for Sustainable Rx Pricing is a nonpartisan coalition of organizations, finding bipartisan, market-based solutions to lower drug prices in the U.S., aiming to strike a balance between innovation and affordability. In this pursuit, the coalition has published market-based reforms that address the underlying causes of high drug prices in the U.S. through increased transparency, competition and value. These policy solutions were developed with the strong participation and endorsement of the American Hospital Association, as well as physicians, nurses, consumers, health plans, pharmacists and employers. A copy of these recommendations is included as an attachment to my testimony, and I would like to highlight some of these proposals.

Price Transparency: The Physician Payments Sunshine Act requires medical product manufacturers to disclose to the Centers for Medicare and Medicaid Services (CMS) any payments or other transfers of value made to physicians or teaching hospitals. Likewise, hospitals are required to submit cost and quality data to the Department of Health and Human Services annually. Since the true cost of pharmaceuticals remains so complicated, I recommend similar transparency be required for current and historical drug pricing.

Food and Drug Administration (FDA) Fast Track Approval for Drugs to Increase Competition: Hospitals can negotiate aggressively for better pricing on drugs when there is competition. But when there is only one source for a drug and there are no therapeutic alternatives, we have very little bargaining power. We can limit utilization to necessary cases, but there is no way around paying the increased price.

In such cases, it would be helpful for the FDA to create an accelerated pathway to bring competing suppliers to the market. For example, as many others have also noted, in some cases the first drug in a new class of drugs is approved on a fast track at the FDA in order to bring an important new therapy to market. This is a good policy; however, we would suggest that the FDA also approve the second drug in the new class on a fast track. Not only would this competition help bring down the cost of drugs by providing an alternative, it may also offer a distinct clinical advantage for certain patients by utilizing the second drug.

I understand that the FDA has been working to prioritize generic reviews in cases where there is only a sole-source generic, which I fully support. The existence of an accelerated FDA pathway to bring a competitor to the market just may serve as a deterrent to steep, unjustifiable price increases in an opportunity pricing model.

Protect the 340B Program: In addition to the proposals by the Campaign for Sustainable Rx Pricing, I would also urge your support for the 340B Program. This program helps safety-net healthcare providers extend services to low-income and vulnerable populations by allowing qualified hospitals, clinics and health centers to purchase outpatient prescription drugs at discounted prices. Ascension has 31 actively participating 340Bs nationwide.

Several of our St. Vincent hospitals in Indiana are eligible for the 340B Program. For example, in 2014, the St. Vincent Joshua Max Simon Primary Care Clinic served more than 62,000 patients and filled more than 66,000 340B prescriptions. Patients served at the clinic are charged for drugs on a sliding scale based on their income. Most of those served pay only 20 percent of the 340B discounted price, with the remainder covered by St. Vincent. Without the 340B Program, the Clinic would not be able to provide its patients the prescription medications they need at a cost they can afford.

At our health system, Via Christi in Kansas, a woman was diagnosed with a rare, typically fatal neuromuscular disease that affects only 1 in 40,000 people. The only medication available to treat her disease was investigational and costs about \$400,000 per year. With the 340B Program, the drug's price was reduced by one-third, and Via Christi covered the remaining cost.

At our St. Thomas Hickman Hospital in Tennessee, a patient suffering from bipolar disorder had been hospitalized multiple times because she could not afford her medications. The closest psychiatric hospital is 60 miles away from her home. Because of the 340B Program, the patient was able to obtain her medications free of charge from a local pharmacy. As a result, she has been able to remain well enough to stay out of the hospital.

I understand that some are calling for significant restructuring of the 340B Program. As pharmaceutical companies are increasing prices at an alarming rate, I can't think of a worse time to be thinking of cutting a program designed to make drugs more affordable for those at the lower end of the income spectrum.

Conclusion

At Ascension and at St. Vincent, we are dedicated to providing spiritually-centered, holistic care that sustains and furthers both individual and community health. We support solutions that keep drug prices low and provide important discounts to hospitals that serve those

who are struggling most. We look forward to working with Congress to develop and support solutions that improve the health of the population, enhance the patient experience and outcomes, and reduce the cost of care.