**Testimony of Steven B. Miller, MD, Senior Vice President and Chief Medical Officer, Express Scripts**

**House Energy & Commerce Committee**
**Hearing on "21st Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients"**

**June 11, 2014**

Chairman Pitts, Ranking Member Pallone, and Members of the Committee, I appreciate the opportunity to testify today. I am the Chief Medical Officer for Express Scripts. Express Scripts is the nation's largest pharmacy benefit manager, administering the benefits for more than 85 million Americans. Each day, we work to make the use of prescription drugs safer and more affordable. With the country facing hundreds of billions of dollars of prescription-related waste each year from costly drug, pharmacy and health choices, our mission remains as relevant as ever.

Today, we manage prescription benefits for tens of millions of Americans on behalf of thousands of clients, including health plans, large employers, small businesses and other plan sponsors. Employers, unions and government organizations throughout the nation rely on our services. We are committed to our members achieving better clinical outcomes and dedicated to delivering better financial outcomes for plan sponsors.

Innovative therapies are critical component of the prescription drug benefit. As these break-through therapies come to market, our clients, public and private, expect us to deliver innovative benefits to meet their needs and ensure appropriate use of these therapies. Critical to freeing up dollars in the prescription drug benefit to pay for these new cures is the ability to harness the use of generics—and in the future, biosimilars—where and when we can. Generics truly have been the success story of the past 30 years: driving innovation through competition.

To that end, Express Scripts supports a strong, fully-funded FDA, which is equipped to efficiently evaluate and approve new brand and generic medicines while appropriately ensuring patient safety. The Agency must have the resources to assure timely and predictable access to both brand and generic medications. We applaud the FDA for increasing the pace of drug approvals and providing increased information to payers and consumers about drug evaluations. We also support federal investment in biomedical research at the National Institutes of Health to ensure the US remains at the forefront of innovation and discovery. This is particularly important for basic scientific research.

The current system works very well to drive innovation, with more than 5,000 drugs in human trials for 74 distinctly different diseases[1]. Adding to the complexity for patients and payers is the manufacturer community and FDA focus on specialty medications. In 2013, 19 of the 28 approved new therapeutic drugs were specialty medications – nearly 70% of new drug approvals. For the last three years, specialty drugs have been the majority of FDA new drug approvals.

Some of these new specialty drugs approved in 2013 are remarkable:

- Eight new cancer drugs were approved, including oral formulations and gene-specific targeted therapies (e.g. Tafinlar® and Mekinist®).
- For the first time, medications were approved under the FDA's new Breakthrough Therapy expedited approval program (e.g. Gazyva™, Imbruvica™, Solvadi™)
- At the same time, 2013 FDA drug approval data shows some instances that fall short of true innovation:
- In anticipation of the loss of patent protection for an inhaled solution that treats respiratory conditions, the manufacturer launched a new formulation of the same product with a new administration mechanism.
- The FDA approved zero biosimilars.

Whether highly or mildly innovative, these advances come at an enormous cost to patients and payers. These new therapies cost tens of thousands of dollars per patient. The challenge to payers is made clear with one recent new drug approval: Solvadi™.

Sovaldi is a new oral treatment for hepatitis C, a debilitating blood-borne disease of the liver affecting some 3 million Americans. The launch of Sovaldi has been the most successful in the history of the pharmaceutical industry. In just the first quarter of 2014 alone, the drug generated sales in excess of $2 billion. It's projected to become the largest selling drug in the world by the end of this year. And while the cost of Sovaldi varies by nation, the cost for a course of treatment in the United States is $84,000, or $1,000 per pill. The cost is approximately $55,000 in the U.K. and Germany. In Egypt it is $900 for a full course of treatment, still less than the cost of one Sovaldi pill in the U.S.

Not every patient diagnosed with hepatitis C needs to take Sovaldi. Hepatitis C is typically a very slowly progressing disease. Some infected patients do not manifest serious symptoms for decades after infection. Many hepatitis C patients are "warehoused," a common practice among hepatologists who take a "watchful waiting" approach with caring for hepatitis C patients until there is a clear need for treatment.

---

[1] Pharmaceutical Research and Manufacturer Association. "Explore the Latest Progress on Medicines in Development." (2014)

Clinically speaking, Sovaldi is a breakthrough in reducing the amount of hepatitis C virus to undetectable levels, with a "cure" rate of over 90 percent. However, various analyses suggest that Sovaldi may not be worth the price. In fact a new study from the California Technology Assessment Group found that even over a 20-year time horizon, the cost-benefit is only about two-thirds of the original $84,000 cost.

The high cost of Sovaldi has created a tipping point in the dialogue about fairness in drug pricing. Payers are galvanized around this issue like none before. Many payers did not budget for such a high cost drug and are now having to make tradeoffs between covering the drug and covering other basic treatments for their plan members. State budgets, in particular, are taking on the brunt of the cost at a time when state budgets have already been significantly stretched, as a third of the patient population is uninsured, underinsured and/or are currently incarcerated.

To be clear, improved sustained viral response from Solvadi™ is valuable to patients worldwide. But should it be the US' role to pay the lion's share of this innovation? To be clear, innovations like this should be rewarded handsomely, but within the bounds of what the country and taxpayers can afford, and we believe the current price for Solvadi violates these boundaries. In the United States, where Solvadi's manufacturer has the most incentives available to promote innovation, Americans will pay more for the medicine than anywhere else in the world. Some of these incentives include:

Market exclusivity. In addition to the usual patent protections afforded to high tech products, brand drug manufacturers receive a period of exclusivity under the Hatch-Waxman Act (or BPCIA for biologic therapies), where they are protected from competition on their product. These exclusivities aren't challengeable in court. And they are uniquely American.

Breakthrough approval designations. Congress acted to encourage speedy approval of "breakthrough" medicines when it passed the Food and Drug Administration Safety and innovation Act in July, 2012. Since that time, drug makers have had the ability to seek a *breakthrough therapy* designation by the FDA to expedite the review of new drug applications that demonstrate substantial improvement over existing therapies. This expedited approval is above and beyond the *Fast Track* approval program and is in addition to Accelerated Approval and Priority Review programs at FDA.

Our free market to sell medicines. Unlike other nations, the new drug approval process doesn't include a cost-effectiveness comparison. Manufacturers are free to sell their medications at prices they determine without government intervention, validation or approval.

NIH support. The NIH supports drug makers with bench science, basic research, and supporting clinical trials.

The price of Solvadi should be insulting to lawmakers who have worked to foster innovation and encourage a marketplace in the United States for brand drug makers. The challenge before Congress today is whether more needs to be done to promote innovation. Any action that Congress considers should explore the need for an environment where America doesn't pay the lion's share of research and development worldwide.

Some additional ideas that the Committee and Congress should consider include:

Support NIH with additional funding. Drug discovery begins with the excellent work by the team at NIH. Their exploration of scientific cures is the backbone of new drug discovery. Congress should consider ways to support NIH with additional funding that will serve: drug makers, patients, and the payers who afford the cures.

Support the FDA. The FDA does an incredible job and needs to be as scientifically advanced as the most developed company they regulate. Additional FDA funding is essential to expanding review programs and speeding new drug approvals. Given the success of *Fast Track*, *Accelerated Approval*, and *Priority Review* programs, without compromising the safety and effectiveness of drugs, these hastened timelines could become the norm for new drug approval if additional funding is provided.

Reserve marketplace incentives for true innovation. Market exclusivity is invaluable to drug makers and it should only be granted to new drug applications that are substantially and significantly improved upon existing therapies. The goal should be for companies to direct funding to the innovative discovery of new cures rather than rewarding "me too" products. What better way to promote innovation than to more carefully grant monopolies to drug manufacturers? When these marketplace protections aren't guaranteed, manufacturers will strive to ensure their products are truly superior.

The balance between access to lower cost generic medicines and incentives to innovate new and better medicines as embodied by the 1984 Hatch-Waxman Act is working. Today we have more pharmaceutical and biotech companies than ever. Moreover, the industry is healthy and profitable.

Express Scripts is concerned by ideas that reward certain types of drug development with additional market exclusivity. Exclusivity is a marketplace incentive that perverts the commercial market for prescription drugs: it inhibits innovation; it artificially restricts competition; it affords the same reward to a breakthrough therapy as a less innovative product improvement. Moreover, it places the burden for funding this additional incentive solely on the backs of the payers of health care (employers, health plans, etc.)—rather than socialized equally by society through the tax code. Proposals that seek to expand market exclusivity in

any situation need to be approached very carefully and very narrowly to ensure it is the right solution to the underlying problem.

Chairman Pitts, Ranking Member Pallone, and other Members of the Committee, thank you for the opportunity to testify today.