

From: Abbey S. Meyers

[REDACTED]

[REDACTED]

[REDACTED]

To: Senator Chuck Grassley and

Senator Ron Wyden

Senate Finance Committee

[report\\_feedback@finance.senate.gov](mailto:report_feedback@finance.senate.gov)

February 16, 2016

Dear Senators Grassley and Wyden:

I sincerely appreciate your request for public input on the policy questions surrounding the high prices of prescription drugs, and how to increase transparency about pharmaceutical pricing policies. In the early 1980's I founded a non-profit charity committed to the identification and treatment of rare diseases, and development of "orphan Drugs" that had been languishing undeveloped because they were perceived to be unprofitable. The charity was a coalition of rare disease support groups that became known as the National Organization for Rare Disorders (NORD). As a result of their advocacy in 1983 the Orphan Drug Act was signed into law by President Reagan. The bi-partisan legislation was co-sponsored by Rep. Henry Waxman in the House, and Senator Nancy Kassebaum in the Senate.

I am writing this letter not on behalf of any organization or company. I retired from NORD in 2009 and I have been writing a book about Orphan Drugs since that time (*Orphan Drugs: A Global Crusade*, available on Amazon). This letter is written solely on behalf of myself because after 35 years of struggling with drug pricing issues I think I can provide helpful information. It is important to note since your 18 month investigation has centered on 2 drugs for hepatitis C, that the drugs in question (Sovaldi and Harvoni) are NOT orphan drugs because hepatitis C is NOT a rare disease.

Orphan drugs were historically ignored by the pharmaceutical industry because drug companies assumed that potential profits were directly related to the size of the market for a drug. Under the

Orphan Drug Act the FDA can designate a compound as an “orphan drug” only if it is for a disease or medical condition that effects fewer than 200,000 Americans. After the drug is designated as an orphan drug it becomes eligible for financial incentives including tax credits and 7 years of exclusive marketing rights during which no other company can sell the same drug (or biologic) for the same rare disease. Unquestionably, the exclusivity provision of the ODA is the most important incentive of the law.

Today we have more than 500 orphan drugs on the U.S. market. Many horrific, crippling and life threatening rare diseases are treatable today because companies know they will not lose money if they develop an orphan drug, and they will likely make decent profits. This is because they will have a 7 year monopoly for their treatment, during which no other company can compete and drive their price down.

Until recently, the most expensive drugs on the American market were orphan drugs. This was understandable because the limited market for each drug required higher prices to recoup costs, and most insurance companies were unlikely to insure large numbers of people with the same rare disease. But very high prices for treatments aimed at common diseases are puzzling but not unexplainable:

- 1) Our American economic system (free markets) does not permit our government to control prices for consumer goods.
  
- 2) When you sell a drug for a common medical condition such as hypertension, high cholesterol, etc., if you put a small profit on every pill you will likely earn billions in profit because millions of people will buy billions of pills. But if you sell an orphan drug to a small number of people (e.g., hemophilia= 10,000 boys, cystic fibrosis=25,000 people, etc.), each pill or injection will have a higher amount of profit attached to each pill. Thus orphan drugs tend to be expensive, and some manufacturers expect to earn profits on orphan drugs that are equivalent to profits earned on common disease treatments.
  
- 3) Until our government asserts a degree of control over prices for medical goods and services, Americans will continue to pay the highest prices in the world for drugs. Companies that develop drugs for common diseases have watched the prices for orphan drugs rise beyond comprehension, and now they are doing the same for common disease drugs. Sovaldi and Harvoni are drugs for a common, life threatening disease (Hepatitis C) and it demands premium pricing simply because they know the American government and insurers will pay for it since in

most cases it cures the disease. I cannot help being even more grateful that Jonas Salk did not believe the same way about his cure for polio.

### What Can the Government Do?

1- The Bayh-Dole Act, also known as the *Patent and Trademark Law Amendments Act*, was passed in 1980 to deal with intellectual property arising from research funded by the federal government. Under the law the Federal government retains “March-In” rights under certain circumstances when an invention has been developed using federal funds (e.g., grants or contracts). The Senate should re-visit the Bayh-Dole Act to insure that, when federal funds are involved in research, the government should retain powers to negotiate final pricing for the product.

2- The American generic drug industry used to be the most powerful “free-market” tool for medical cost containment. Normally, when a drug patent expired a generic drug would quickly get to market at 80% of the retail price of the branded drug. Slowly other generic copies would reach the market and within 3 years of patent expiry the retail cost of the generic drug would reach 15% to 10% of the original brand-name drug price. **Competition has been the most powerful economic tool of the free market.** But in recent years mergers and acquisitions of generic drug companies have greatly reduced competition, and in some cases has resulted in drug shortages of old drugs that have been on the market for decades. In general most of the generic drug industry is now located in India and China, and since FDA does not have enough trained personnel in those countries to adequately inspect factories, the availability of low cost generic drugs in the USA is greatly reduced. There are certain government agencies that are absolutely essential to the health and safety of the American public, and none is more important than the FDA. Nevertheless, FDA has historically been underfunded!

3- Americans pay the highest prices because we do not control drug prices, nor even negotiate for lower prices. Nevertheless, when drug manufacturers negotiate with pricing authorities in France, Spain or Greece, they never refuse to sell their drug to that country because the price those governments are willing to pay is too low. Why is the American consumer being abused in this way? Why is our government unwilling or unable to protect consumers at the most vulnerable time in their lives...when they are ill. When a drug company wants to sell its drug in Canada it has to tell the Canadian government the price that they charge for their drug in 7 industrialized countries. The Canadian government averages those prices and tells the drug company what their health care system will pay for that drug. The government does not ask...it tells the company what it will pay. The company has to decide whether to walk away or whether it will sell the drug for the average price that seven other countries pay.

I do hope that these suggestions will help you in your investigations. There are things that our government can do to reduce the escalating costs of pharmaceuticals and biologics. In fact, if the

government does nothing, the problem will become much worse very rapidly because other companies will follow suit.

Sincerely,

Abbey S. Meyers

████████████████████

Author of [Orphan Drugs: A Global Crusade](#) (available on Amazon)