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March 4, 2016

Senator Ron Wyden, Ranking Member
Finance Committee
United States Senate
Washington, D.C. 20510

Senator Charles Grassley, Member
Finance Committee
United States Senate
Washington, D.C. 20510

Dear Senators:

On behalf of the 1.6 million members of the American Federation of State, County and Municipal Employees (AFSCME), we are writing in response to the Finance Committee's request for comments about its recent report, *The Price of Sovaldi and its Impact on the U.S. Health Care System*. We are pleased that the Committee conducted this important investigation and appreciate the opportunity to respond to the report.

While the report was focused on the pricing of, and access to, Sovaldi, this drug is emblematic of a larger problem regarding pharmaceutical policy. As highlighted in letters from some state Medicaid directors, the alarm over extraordinarily high drug pricing is not limited to Sovaldi and other treatments for Hepatitis C. Public payers, insurance companies, employers and consumers are grappling with high priced drugs for many other conditions including cancer and chronic illnesses. This case study of Sovaldi demonstrates that our pharmaceutical policies are way out of balance. Current policies prioritize profit-making by the drug industry over public access to needed medicines and need to ensure that taxpayers, employers and consumers can afford them. Current policies allow aggressive pricing that keeps life-saving medicines out of the reach of many, threatens the solvency of Medicare and Medicaid and puts substantial financial burden on employers who provide health coverage for their workers.

Although not in the case of Sovaldi, the pharmaceutical industry generally justifies high prices as necessary to fund ongoing research. But there is virtually no publicly available data to verify their claims. A study by the Tufts Center for the Study of Drug Development is often cited to demonstrate the cost of research, but the data behind it was hand selected by pharmaceutical companies and has not been made available for public review. The study methodology has been criticized for overstating costs substantially.

We urge the Committee to take steps to rebalance federal pharmaceutical policy by putting greater emphasis on access and affordability for consumers, Medicare and Medicaid and the overall health care system. Below we have highlighted a number of proposals.

American Federation of State, County and Municipal Employees, AFL-CIO

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Lift the Ban and Require Medicare to Negotiate over Prices

The market for pharmaceutical drugs is distorted by imperfect information and monopoly power. But it is also distorted by the fact that Medicare does not negotiate with pharmaceutical manufacturers over price. Not only does this lead to unnecessarily high costs for the federal government but also for beneficiaries. Price negotiation is a good business practice that should be conducted by the Medicare program.

Reinstate Higher Rebates for Prescription Drugs in Medicare

Since the implementation of the Medicare Modernization Act, drug manufacturers are no longer required to extend discounts for those eligible for both Medicaid and Medicare. AFSCME urges that manufacturers be required to provide rebates for those who are dually eligible and for people receiving the Medicare Part D Low-Income Subsidy.

Allow Re-importation of Drugs from Canada

Re-importation of drugs from Canada is a way to create competition where there is little or none. We believe that safety concerns can be minimized by restricting the source of drugs and by providing the Food and Drug Administration with adequate resources and authority to ensure the safety of re-imported drugs. Any risk associated with re-importation, is secondary to the risk to Americans who forego prescribed medications or take less than the amount prescribed because they cannot afford it. Re-importation is a good short term solution until balance is restored to federal policies.

Ban Pay-for-Delay

Under pay-for-delay deals, brand name drug manufacturers pay generic firms to keep cheaper generics off the market. This anticompetitive practice keeps prices high at the expense of consumers, employers and taxpayers. The Federal Trade Commission reports that among the 160 drug patent dispute settlements between pharmaceutical companies in fiscal year 2014, 21 may involve pay for delay settlements covering 20 brand name drugs with total estimated U.S. sales of \$6.2 billion. We urge that pay-for-delay be banned.

<https://www.ftc.gov/news-events/blogs/competition-matters/2016/01/ftc-v-actavis-causing-pharmaceutical-companies-change-their>

Reduce the Exclusivity Period for Biologics

According to the Federal Trade Commission, a twelve year exclusivity period is not necessary to incentivize pharmaceutical companies to research and develop biologics. In fact, the FTC estimates that brand name biologics will maintain 70% to 90% of their market share for many years after introduction of a biosimilar. Given the absence of evidence that a higher exclusivity period is needed to encourage the development of biologics, it is irresponsible to continue a policy that puts taxpayers on the hook for billions in monopoly rents. We urge that the exclusivity period for biologics be reduced to five years, consistent with the exclusivity period for chemical drugs.

<https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf>

End Tax Write Offs for Direct to Consumer (DTC) Advertising

New Zealand is the only other developed country that allows pharmaceutical companies to engage in direct advertising to consumers. There is good reason other countries have prohibited such advertising. Research indicates that direct-to-consumer advertising increases pharmaceutical sales and surveys indicate that physicians fill clinically inappropriate prescriptions due to inquiries from patients prompted by drug advertising. DTC advertising is also likely to encourage demand for brand name drugs over less expensive generics. As a consequence, DTC advertising drives cost growth in Medicare and Medicaid. Advertising should be more closely regulated to ensure that accurate information is conveyed to consumers. In addition, we urge that tax write offs of DTC advertising be prohibited in order to compensate taxpayers for the growth in Medicare and Medicaid costs caused by DTC advertising.

<http://prescriptiondrugs.procon.org/sourcefiles/Impact-of-Direct-to-Consumer-Advertising-on-Prescription-Drug-Spending-Summary-of-Findings.pdf>

http://www.rwjf.org/content/dam/farm/articles/journal_articles/2009/rwjf49184

Transparency

Through payments for drugs made by public programs, directly funded research and tax credits for private research, the federal government makes an enormous investment in pharmaceutical research and development. But the public and policy makers know little about the research and development that taxpayers help to underwrite. Transparency is critical to enable sound policy making. Drug companies should be required to report the cost of research and development of individual drugs, including the amount funded by taxpayers; the cost of production; R&D spending for non-approved drugs; and marketing expenses for each drug. Pharmaceutical companies must also be required to report the amount spent on basic research.

Comparative Effectiveness Research (CER)

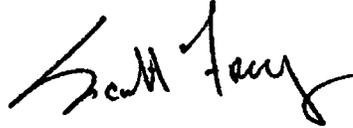
We need a greater investment in conducting research on the benefits of new drugs in comparison to existing treatments. In addition, CER conducted by pharmaceutical companies for regulators in other countries must be made available to payers in the U.S. We also support proposals to require drug makers to indicate on labels and in DTC advertising whether the drug provides any benefit, minor benefit or significant benefit over existing treatments.

Evergreening

One of the failures of current patent rules is that they encourage drug makers to make slight changes to existing drugs in order to receive a new period of market exclusivity and further delay generic competition. This not only directs research funds away from real innovation, but it drives up costs for payers. Patent rules must be revised to prohibit such anticompetitive behavior.

In conclusion, we would note that the pharmaceutical industry have pressed policy makers to insist that trade agreements require other countries to adopt U.S. patent rules. They argue that the U.S. is paying higher prices because other countries do not pay a fair price. But this report demonstrates otherwise. Drug makers will set their price based on what the market will bear. Even when Gilead understood that the price level would significantly block access, the company refused to reduce prices. It would be contrary to the evidence to think that higher prices for drugs in Canada and other countries will have any impact on the price of drugs in the U.S. market.

Sincerely,

A handwritten signature in black ink that reads "Scott Frey". The signature is written in a cursive style with a large, sweeping initial "S".

Scott Frey
Director of Federal Government Affairs

SF:BC:rf