March 4, 2016

The Honorable Orrin Hatch
Senate Finance Committee
Washington, DC 20510

The Honorable Ron Wyden
Senate Finance Committee
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The National Committee to Preserve Social Security and Medicare greatly appreciates the work of the Senate Finance Committee in bringing some needed transparency to Gilead Science Inc.'s pricing of its two blockbuster therapies for Hepatitis C, Sovaldi and Harvoni. The information gathered by the committee sheds light on a dynamic in the pharmaceutical market where the cost of drugs has become completely delinked from the cost of developing and producing them. The committee's findings in the context of a worrisome spike in drug costs indicate that policy makers need to reexamine the incentives in place to promote innovation. Policies designed to spur innovation should be more narrowly targeted toward stimulating *meaningful* innovation at reasonable prices that allow access to essential medicines.

Drug costs are very important to consumers, including seniors. According to a Kaiser Family Foundation tracking poll, 77 percent of Americans favor making sure that high-cost drugs for chronic conditions are affordable to those who need them. Sixty-three percent of Americans favor government action to lower the cost of prescription drugs.

For seniors, drug costs are important because of their impact on out-of-pocket costs and their potential to threaten the sustainability of Medicare and Medicaid. High drug prices are having a direct impact on beneficiaries' Part D costs. The ten most popular stand-alone Part D plans, representing more than 80 percent of prescription drug plan enrollment, will see average premium increases of 8 percent in 2016.

High drug costs impact the Medicare Part B program as well, as many high cost drugs, such as cancer drugs, are administered in physician offices. A Government Accountability Office study found that nearly two-thirds of new Part B drugs had expenditures per beneficiary in excess of $9,000 in 2013.

Due to Medicare Part B coinsurance, beneficiaries who use expensive drugs shoulder 20 percent of the costs of their drugs. And there is no out-of-pocket cap for Part B expenses. In 2013, beneficiaries' share of the cost of these drugs ranged from $1,900 to $107,000 per drug. While

many beneficiaries have supplemental insurance to help pay for their out-of-pocket costs, the impact on beneficiaries who need these drugs and who are without supplemental coverage is potentially devastating.

Without action, drug prices will continue to put pressure on the Medicare program. Total per beneficiary costs for the Medicare prescription drug program grew by almost 11 percent in 2014, driven largely by specialty drugs. According to the Centers for Medicare and Medicaid Services, total Medicare subsidies, known as reinsurance, paid to Part D plans with enrollees that have especially high drug costs have grown by more than three times the rate of premium growth.

Over the long term, these trends will continue to drive up costs for the program if nothing is done. Total Medicare Part B drug expenditures grew at an average annual rate of 4.4 percent from 2007 through 2013, at a much higher rate than inflation over that time. Things will only get worse as hundreds of expensive new drugs currently in development make their way to market.

The committee's report details the impact on state Medicaid budgets. Medicare and Medicaid are essential components of the social safety net for seniors.

The pharmaceutical industry often justifies the costs of drugs and the need for extension of various patent and non-patent monopolies that serve to drive these costs up because of: (1) the public good derived from innovation and (2) the expense of researching and developing drugs.

The Finance Committee's report uncovers information that substantially undermines both of these industry arguments. First, the report details the extent to which state Medicaid departments have been unable to treat individuals who need Sovaldi and Harvoni. Gilead's pricing for these drugs has created significant access barriers to these drugs. Further, the Finance Committee's report shows that Gilead specifically took into account that access would be more limited at the eventual launch price and that the company had considered a credible lower price ($34,000 less than its ultimate launch price) that would have resulted in many more patients being served.

The committee's findings also rebut the pharmaceutical industry's claims about prices being justified by the cost of new innovation. The cost of research and development for the drug was $62.4 million. Gilead purchased Pharmasset, the company that developed the drug, for $11.2 billion. It made $26 billion globally in the first 21 months after launch, a staggering return on investment for a drug it didn't even develop.

As a threshold matter, the costs of drug development need to be made more transparent. The public makes a huge investment in pharmaceutical spending and it has a right to see what it is getting for its considerable outlay. The Finance Committee notes that Gilead refused to provide complete information about the costs of developing the drug. Greater transparency is needed around pricing so that purchasers and payers can have a better understanding of what a reasonable price for a product is based on clinical evidence of effectiveness and reasonable return on the cost of development. The Finance Committee should monitor the implementation of various state laws that require that manufacturers divulge the costs associated with conducting clinical trials, the costs associated with manufacturing drugs and the amount of government

subsidies received for research. The committee should consider ways that Medicare and Medicaid could collect and use this kind of information to inform reimbursement decisions.

Sole source drugs create a particular problem for policy makers. As the Committee report notes, Medicaid was unable to negotiate for supplemental rebates from the manufacturers. The issue is particularly problematic for Medicare, which does not receive manufacturer rebates and is prohibited from direct price negotiation with drug manufacturers. The National Committee supports lifting this prohibition. That is why we support H.R. 4207, the Medicare Fair Drug Pricing Act, introduced by Rep. Jan Schakowsky, which provides such authority to the Secretary of Health and Human Services for sole source drugs.

The National Committee strongly supports policies that incorporate comparative effectiveness research into coverage and pricing decisions. These policies can create an incentive for manufacturers to produce products that generate genuine clinical advancement, and to set reasonable prices. Congress should, for example, consider legislation that would allow Medicare to return to its Least Costly Alternative policy, where Medicare reimburses at the cost of the least costly therapeutically equivalent therapy.

Greater care must be taken in providing patent and marketing monopolies. Overly long monopoly periods drive up prices and limit competition. Proposals that condition the length of exclusivity on reasonable pricing have merit. The National Committee supports reducing the exclusivity period for biologics to seven years. We oppose additional orphan drug exclusivity proposed in H.R. 6, the 21st Century Cures legislation, because it would add on to existing exclusivities. This type of exclusivity is not sufficiently targeted to new innovation and would inevitably drive up costs for existing drugs, many of which are blockbuster drugs subverting the policy goal of granting monopolies for the express purpose of stimulating research for orphan diseases. We believe that proposals to expand market exclusivity should only be used in extremely limited circumstances and only to reward drug companies for meaningful innovations.

The National Committee also supports efforts to promote greater access and use of generic drugs. We oppose pay-for-delay agreements between brand and generic manufacturers. We support efforts by the FDA to prioritize approval of generic drugs where there is no generic alternative to a brand drug. We oppose elements of the Trans-Pacific Partnership agreement that allow for evergreening of drugs. We also urge Congress to reject investor state dispute settlement and so-called Medicare “transparency” provisions in the TPP that would allow manufacturers to sue the US for reimbursement decisions under Medicare.

The public finances drug development through its financing of research and allowing tax write-offs for research and development. In addition, Medicare and Medicaid and the Veterans Administration are significant purchasers of drugs. The public has a right to expect a fair deal for the significant amount it pays for drugs. We applaud the Committee for its efforts to bring transparency to Gilead’s pricing of Sovaldi and Harvoni and look forward to working with it on the pressing issue of high drug costs.

Sincerely,

Max Richtman

President and CEO