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APhA

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[Submitted electronically via Report_Feedback@finance.senate.gov]

U.S. Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510-6200

Re: The Price of Solvaldi and Its Impact on the U.S. Health Care System [S. Prt. 114-20]

Dear Chairman Hatch and Ranking Member Wyden,

The American Pharmacists Association ("APhA") is pleased to submit these comments regarding the Senate Finance Committee's (the "Committee") report, *The Price of Solvaldi and Its Impact on the U.S. Health Care System* (the "Report"). Founded in 1852 as the American Pharmaceutical Association, APhA represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, physicians' offices, community health centers, managed care organizations, hospice settings, and the uniformed services.

We thank the Committee for the opportunity to provide comments on the Report. The advent of specialty drugs that can change, and even save, the lives of patients underscores the necessity of balancing the cost of these medications with their expected impact on patient outcomes. As the Committee continues its work, APhA encourages the Committee's consideration of the following issues.

I. The Benefit of Greater Transparency for Patients

APhA has long advocated for facilitating patient access to safe and affordable medications. Costly but effective medications like Solvaldi inarguably create new challenges for our health care system. However, the out-of-pocket cost sharing for a drug is even more important to patients than the average manufacturer price or some other relative cost assigned to a particular medication. Without some kind of insurance coverage or medication assistance program, most patients simply would be priced out of access to these high-cost medications. Demystifying a patient's insurance coverage through improved patient-plan communication of formulary coverage, as well as actual out-of-pocket costs, would empower patients to make informed choices about their drug coverage and providers to develop treatment plans which consider patient costs in addition to effectiveness.[1]

[1] APhA has consistently advocated for increased patient access to transparent, comprehensive information regarding their insurance plan's coverage of medications. Such transparency could significantly aid patients and their health care teams in

II. The Impact of increasing Access

It is important to note that improvements to transparency, predictability, and manageability of medication costs must be complemented by parallel moves to improve physical access to medications and medication-related services. Some high-cost specialty medications are subject to limited distribution arrangements that can complicate patient access and potentially raise costs.[2] Manufacturers cite the need for advanced clinical training and patient monitoring capabilities as reasons for using restricted networks to send specialty medications to certain provider settings or pharmacies. Pharmacists graduating today have a Doctor of Pharmacy (Pharm.D.) degree – a post-graduate degree that requires a minimum of six years of college to complete, with some programs requiring eight years. Moreover, with more medication-related education and training than any other health care provider and nearly 95% of Americans living within five miles a pharmacy, pharmacists are well-positioned and qualified to help increase access and lower cost by providing these types of medications.

In addition to narrow distribution networks arbitrarily and unnecessarily limiting patient access, Medicare Part D plans and pharmacy benefit mangers ("PBMs") create closed networks of pharmacies (or "preferred networks") where plan beneficiaries can obtain medications at discounted prices or reduced copay amounts. Some PBMs limit pharmacy participation in their networks, even when pharmacies are willing to meet network terms and conditions. Such restrictions not only deny true access and patient choice, they can adversely impact patient care. To ensure adequate patient access, plans and PBMs should have to contract with any pharmacy willing to accept the PBM's contractual terms and conditions for network participation (referred to as the "any willing pharmacy" requirement).

III. Optimizing the Impact of Medications

Highly complex medications like Solvaldi are very likely to be the new normal as scientific and technical innovation progresses. As the system adjusts to advanced medications that may command higher prices, patient care delivery must also adjust to properly support patients taking these complex medications. Pharmacists, with their advanced training in medications, are uniquely qualified to offer medication-related services that optimize the impact of patients' medications. Both CMS and the U.S. Department of Health and Human Services ("HHS") have recognized the value of pharmacists and pharmacists' services in optimizing patient outcomes in a cost-effective manner (*e.g.*, proposed expansion of pharmacists' medication therapy management programs).[3] The inclusion of pharmacists

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developing high-quality, cost-effective treatment plans. To that end, in recent comment letters to CMS, APhA reiterated the importance of transparency in the health care system. Specifically, we strongly supported CMS efforts in to enhance patient and provider access to clear, complete information regarding patient health care coverage—especially access to medication cost-sharing and plan formulary information. APhA encourages the development and implementation of policies that further enhance patient access to formulary coverage information and tools, such as out-of-pocket cost prediction calculators, to help patients translate and apply this raw information to real-world decisions.

[2] It is important to note that we refer here to drugs that are not restricted as part of an FDA-approved Risk Evaluation and Mitigation Strategy ("REMS") program. REMS programs restrict distribution on the basis of safety, not for financial or other reasons.

[3] *See, e.g.*, Centers for Medicare & Medicaid Services, *CY 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Programs; Proposed Rule*, 79 Fed. Reg. 1951 (Jan. 10, 2014); *See also* U.S. Department of Health & Human Services, *National Action Plan for Adverse Drug Event Prevention* (2014), *available at* http://health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf.

on a patient's care team can have a profound impact on overall quality of care[4], while increasing patient satisfaction and access to essential services, particularly in medically underserved areas ("MUAs").[5] To help ensure that the financial investment in high-cost medications translates to patient health gains, APhA encourages the adoption of strategies to increase patient access to pharmacists and their services. CMS's ongoing support for, and recognition of, the value of pharmacists' patient care services, including Medicare Part D medication therapy management ("MTM") and chronic and transitional care management services, highlights the benefits of providing access to these services.

However, at present, pharmacists face legal and logistical impediments to engaging fully the provision of these medication optimization services. Despite the fact that pharmacists provide essential services (*e.g.*, medication therapy management, health and wellness screenings, chronic disease management, immunizations administration, and assistance with care transitions to help manage medication use issues and avoid adverse drug events), Medicare does not recognize these services when provided by a pharmacist. As a result, Medicare beneficiaries' access to certain health care services and the contributions pharmacists can make to their health care and outcomes is unnecessarily limited. Enabling pharmacists to be better integrated into the patient's health care team, and to practice consistent with their education and training, will allow them to provide patient care services and maximize the value of medications, including high-cost and specialty medications. There is currently legislation, S. 314/H.R. 592, the Pharmacy and Medically Underserved Areas Enhancement Act, which provides access and coverage to pharmacists' patient care services to patients in medically underserved communities under Medicare Part B. The legislation, introduced by Senator Grassley, has been referred to the Finance Committee and has over 40 cosponsors.

Thank you for the opportunity to provide feedback on the Report and for your consideration of our comments. If you have any questions or require additional information, please contact Michael Spira, Senior Lobbyist, at mspira@aphanet.org or by phone at (202) 429-7507.

Sincerely,

Thomas E. Menighan

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs

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[4] *See, e.g.,* Michael E. Porter, Thomas H. Lee, *The Strategy that will Fix Health Care*, HARVARD BUSINESS REVIEW (2013), *available at* http://hbr.org/product/the-strategy-that-will-fix-health-care/an/R1310B-PDF-ENG; C.R. Preslaski , I. Lat, R, MacLaren, J. Poston, *Pharmacist contributions as members of the multidisciplinary ICU team*, CHEST (2013), *available at* http://www.ncbi.nlm.nih.gov/pubmed/24189862; American Diabetes Association,), *Effect of Adding Pharmacists to Primary Care Teams on Blood Pressure Control in Patients with Type 2 Diabetes: A Randomized Controlled Trial*, DIABETES CARE (2010), *available at* http://care.diabetesjournals.org/content/early/2010/10/05/dc10-1294.abstract.

[5] For example, immunizations in MUAs have increased due to increased patient access through pharmacists and pharmacies. Data gathered by one of the largest nationwide community pharmacy corporations indicates that over one-third of their influenza vaccines administered in 2013 were in pharmacies in MUAs; in states with the largest MUAs, they provided up to 77.1 percent of their influenza vaccines in these areas. Moreover, of all influenza vaccinations they delivered last season, 31 percent were during off-peak times (59 percent on weekends and 31 percent in the evenings), and approximately 31 percent of patients during off-peak times were age 65 or older, and 36 percent had underlying medical conditions. Notably, efforts to provide immunizations beyond those for influenza were complicated by lack of insurance coverage or recognition as in network providers. And there are many more providers with similar experiences.