



February 25, 2016

The Honorable Charles Grassley (R-IA)
Senate Committee on Finance
135 Hart Senate Building
Washington, D.C. 20510

The Honorable Ron Wyden (D-OR)
Ranking Member
Senate Committee on Finance
221 Dirksen Senate Building
Washington, D.C. 20510

Re: Senate Report: Price of Sovaldi and Its Impact on the U.S. Health Care System

Dear Ranking Member Wyden and Senator Grassley:

On behalf of the 13,500 U.S. members of the American Academy of Dermatology Association (Academy), the Academy appreciates the opportunity to comment on the Senate report titled, *Price of Sovaldi and Its Impact on the U.S. Healthcare System*. We recognize the importance of the overarching issues the Committee highlights in its report and commend you and the Committee for your continuing leadership to address this challenging component of our health care system.

Dermatologists diagnose and treat more than 3,000 diseases including many chronic inflammatory, multi-system, disabling and life-threatening conditions including skin cancer, which 1 in 5 Americans will develop in their lifetime, and psoriasis and psoriatic arthritis, which collectively affects 3.2% of the population. Therefore, the Academy would like to provide the following recommendations with regard to questions 4 and 5 presented in the request for comments.

What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?

The Academy supports the Committee's effort to focus on price transparency. Presently, there is no simple way to determine the price of a drug at the time of prescribing in the medical office. Patients are often unaware of the cost of a drug until they are at the pharmacy. If the patient is not able to afford the drug this can lead to a lowering in adherence to the treatment plan.¹ In 2013, 9% of medications were either not approved by a health carrier or never filled by the patient.² This lack of adherence to prescribed treatment is concerning and can lead to adverse outcomes.

¹ American Academy of Dermatology Association (August 20, 2015). Meeting of the Drug Pricing and Transparency Task Force. *Presented at 2015 Summer Academy Meeting*. New York City, New York.

² Aitken, M., Kleinrock, M., Lyle, J., & Caskey, L. (2014). Medicines Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the U.S. in 2013. *IMS Institute for Healthcare Informatics*. Retrieved from http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHL_US_Use_of_Meds_for_2013.pdf.

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Like many other physicians, dermatologists are concerned about the rising costs of treatment and its effect on patients. According to the IMS Institute for Healthcare Informatics when compared to spending on other “therapeutic classes” of drugs in the United States, dermatologic, oncologic, and autoimmune drugs have remained in the top twenty classes since 2010.³ Additionally, a recent study in JAMA Dermatology found that “of 19 [dermatologic] brand-name drugs analyzed, the retail prices of 7 drugs more than quadrupled” between 2009 and 2015. There is also concern about generic prices as the authors found that “selected generic drugs surveyed in 2011 and 2014 also increased a mean of 279%.”⁴

Due to increasing drug costs, some insurers are moving life-improving medications (such as biologics) into higher level “specialty tiers,” placing medically necessary treatments out of reach for patients. To this end, the Academy supports legislation such as H.R. 1600, the Patients’ Access to Treatments Act, which would limit cost-sharing requirements applicable to drugs in a non-preferred drug tier.

Another potential solution to help ease the burden is to explore whether the current data sharing capabilities in place would allow for drug pricing data to be available in electronic health records (EHRs). If the technology is available the next step would be to explore how to secure buy-in from insurance companies, pharmacy benefit managers (PBMs), and pharmaceutical manufacturers. This would be a long term solution, but it could potentially increase price transparency at the point of prescribing.

The Academy recognizes that drug pricing is a complex issue, but supports making publically available the methods in which drug prices are set today. One of the many important components in the drug pricing structure is the utilization of PBMs. The committee may want to explore current negotiations and rebate provisions employed by PBMs to ensure there is no conflict of interest when developing formularies. The Academy also supports more transparency in PBMs’ negotiations – both with manufacturers and with the plans for whom they manage their pharmacy benefits. The Academy does recognize that the report states that “members of Congress are forbidden by law to have access to information regarding price discounts and rebates agreed to by drug manufacturers as part of the Medicare and Medicaid programs.” Even with this provision, the Academy would recommend that Congress consider measures that would enable another agency, such as Centers for Medicare and Medicaid Services (CMS), to examine the negotiations and rebates.

Additionally, the Academy supports transparency in insurance coverage policies for drugs including copayment and coinsurance levels, as well as information as to how these levels and payment tiers are determined. To ensure dermatologists and patients have better access to pricing information in their respective plans, the Committee can work to require CMS to include language regarding drug formularies in the next Notice of Benefit and Payment Parameters (BPP) regulation. In 2015, CMS noted in its BPP final rule that at this time it had come to the conclusion to not have a mandate that insurers must list the co-pays and co-insurance on the formulary, but encouraged the parties to do so if possible.⁵ At present, patients have to compare their formularies and explanations of benefits to determine how much a particular

³ Aitken, M., Kleinrock, M., Lyle, J., Nass, D. & Caskey, L. (2015). Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014. *IMS Institute for Healthcare Informatics*. Retrieved from file:///C:/Users/ACook/Downloads/IHI_Use_of_Medicines_Report_2015.pdf

⁴ Miranda E. Rosenberg, BA; Steven P. Rosenberg, MD. *Changes in Retail Prices of Prescription Dermatologic Drugs From 2009 to 2015*. JAMA Dermatology.

⁵ Jost, T. (2015). “Implementing Health Reform: 2016 Benefit And Payment Final Rule, Consumer & Provider Provisions.” Health Affairs. Retrieved from <http://healthaffairs.org/blog/2015/02/22/implementing-health-reform-2016-benefit-and-payment-final-rule-consumer-provisions/>

drug will cost. This is a burden both for patients and their physicians as both parties seek try to determine the best and most affordable course of treatment. The Committee can work to ensure that it is mandatory for the plans to list this estimated cost sharing information directly on the formulary.

The Academy believes these measures may help to improve price transparency for new higher-cost therapies, while maintaining incentives for manufacturers to invest in new drug development.

What tools exist, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?

To address the impact of rising drug prices on Medicaid programs, the Academy recommends seeking input from state Medicaid Directors. The Department of Health and Human Services (HHS) recently hosted a pharmaceutical forum, which included state-level stakeholders. States are choosing a variety of approaches to address rising drug costs. In their attempts to address the issue, state Medicaid budgets are allocating larger percentages of funding to address rising drug costs, and they are doing so at the expense of other programs.

Another possible solution would be to encourage and empower CMS to provide additional information and educational resources to the states. One possible means of aiding the states would be for agency staff to develop a repository of easily accessible patient assistance programs and foundations available to assist states with access to pharmaceuticals.

The Academy supports the Senate Finance Committee's Bipartisan Chronic Care Working Group Policy options document on medication synchronization. Many insurance carriers now require patients to utilize step therapy protocol that requires a patient to fail a drug before eventually resuming treatment preferred by the physician, which can lead to adverse reactions or the patient not responding to the drug. For example, a patient who has responded favorably to a drug and then has been taken off of that treatment due to step therapy requirements imposed by an insurer may no longer respond well to that drug when the patient has the opportunity to resume treatment on that drug. Adherence to a physician's preferred treatment plan is critical for the patient's health. In order to improve medication adherence, the Academy supports requiring a study to determine how insurance plans could coordinate the dispensing of prescription drugs. Biologic therapy and other specialty medications are often needed to maintain improvement and reduce co-morbidities, thus improving patient outcomes, increasing patient productivity, and constraining health care costs. A streamlined process in which patients can receive all their prescriptions in one trip and obtain detailed directions for use from the pharmacist is a strategy which must be tested to see if it improves medication adherence while also lowering costs.

Conclusion

The Academy commends the Committee for its efforts to address the issue of drug pricing and encourages you to consider our recommendations. Should you have any questions, please

contact Christine O'Connor, Associate Director, Congressional Policy at (202) 609-6330 or coconnor@aad.org, and Ashley Cook, Specialist, Advocacy and Policy, at acook@aad.org.

Sincerely,

A handwritten signature in black ink that reads "Mark Lebwohl, MD". The signature is written in a cursive style with a prominent "M" and "L".

Mark Lebwohl, MD, FAAD
President
American Academy of Dermatology Association