



AMERICAN BENEFITS  

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COUNCIL

July 16, 2018

*Submitted electronically via <http://www.regulations.gov>*

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 600E  
Washington, DC 20201

**Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, RIN 0991-ZA49**

Dear Sir or Madam:

The American Benefits Council (“Council”) wishes to provide comment in connection with the request for information published in the Federal Register on May 16, 2018, by the U.S. Department of Health and Human Services (“Department”) entitled “HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs” (“RFI”).

The Council is a public policy organization representing principally Fortune 500 companies and other organizations that assist employers of all sizes in providing benefits to employees. Collectively, the Council’s members either sponsor directly, or provide services to health and retirement plans that cover more than 100 million Americans.

The Council appreciates the opportunity to provide comment with respect to the RFI, which touches on an area of critical importance for employees and their families across America.

Pharmaceutical drug therapies have played a significant role in treating and curing injury, illness and disease. They allow millions of Americans to overcome debilitating conditions, return to work after injury, illness or disease, and to live longer, healthier, more productive lives. America’s pharmaceutical manufacturers invest billions of dollars each year in the research and development of life-saving drugs. Given the reality

of scientific research, often an enormous investment does not lead to the development of a product that ultimately can be sold.

Although the benefits of pharmaceutical drug therapies can scarcely be overstated, these benefits often come with significant financial costs – to both participants and to payers in the health care system, including employer-sponsored plans. As evidenced in 2016 alone, private health plans spent more than \$142 billion on prescription drug coverage – more than ever before.<sup>1</sup> From 2013 to 2016, spending on prescription drug coverage grew more than any other category of health care expenses for individuals with employer-sponsored health coverage.<sup>2</sup> These costs continue to increase across plans. Of note, among employers with 500 or more employees, prescription drug costs increased by 7.6% in 2017 and are projected to rise by another 7.8% in 2018.<sup>3</sup>

As detailed in the RFI and in both the popular press and scholarly studies, employers, health insurers and other payers (such as states with respect to Medicaid and the federal government with respect to a variety of programs, including, significantly, Medicare, Tricare and the Federal Employees' Health Benefit Plan) have confronted significant expenditures for prescription drug coverage for enrollees as they seek to provide access to clinically effective and at times, life-saving drug therapies. These expenditures then result in increased plan costs and, often, increased health plan premiums.

In an effort to manage these drug costs, employers have sought to implement reasoned innovations and strategies designed to manage overall drug costs while still ensuring that their employees and the employees' dependents have broad access to needed drugs and services. Among the innovations and strategies pursued with regard to pharmaceutical drug therapies are:

- *Innovative Drug Formularies*: Development of drug formularies with tiered cost-sharing to encourage the use of less expensive drugs where medically appropriate.
- *Adoption of value-based insurance designs*: Implementing benefit design changes that lower or eliminate cost-sharing for high-value drugs and increase cost-sharing for low-value drugs.

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<sup>1</sup> See Peterson-Kaiser Health System Tracker, *Health Spending Explorer*, <https://tinyurl.com/y9moy7qq>.

<sup>2</sup> See Health Care Cost Institute, 2016 Health Care Cost and Utilization Report 14 (2018) (*hereinafter* "2016 Health Care Cost and Utilization Report"), <http://www.healthcostinstitute.org/report/2016-health-care-cost-utilization-report/>.

<sup>3</sup> See Mercer's National Survey of Employer-Sponsored Health Plans, *Mercer National Health Survey: Employers Finding New Ways to Hold the Line on Health Benefit Cost Growth*, Mercer (Nov. 2, 2017), <https://www.mercer.com/newsroom/mercernational-health-survey-employers-finding-new-ways-to-hold-the-line-on-health-benefit-cost-growth.html>.

- *Adoption of Step-Therapy Requirements:* An approach intended to control the costs and risks posed by pharmaceutical drug therapies by beginning medication for a health condition with the most cost-effective pharmaceutical drug therapy, and progressing to other, more costly or risky therapies only if necessary.
- *Use of Mail-Order Pharmacies:* Either encouraging or requiring prescription fills of certain pharmaceutical drug therapies (such as maintenance medications) via a specified mail-order pharmacy contracted with the employer's health plan.
- *Preferred Cost Sharing for Larger Prescription Fills:* Providing a preferred cost-share level, such as, a 90-day supply of a medication (as opposed to a 30-day supply), in order to reduce dispensing fees.

In addition to the above, the federal government has taken certain recent actions intended, in part, to help bring down drug costs in certain cases. For example, the Food and Drug Administration ("FDA") recently took steps to bring generic drugs to the market faster and in greater numbers.<sup>4</sup> The FDA's efforts involved steps to scrutinize use of the Risk Evaluation and Mitigation Strategies ("REMS") to prevent inappropriate actions to slow the generic drug process.<sup>5</sup> These efforts by federal regulators are important initial steps and should be part of a broader, collaborative effort among all stakeholders to help lower drug costs, while ensuring continued access to clinically effective – and cost-effective – pharmaceutical drug therapies.

The Council notes that pharmacy benefit managers ("PBMs") can serve as important partners to employer plan sponsors in negotiating lower costs and implementing strategies to bring better value to employers and employees. The Council encourages PBMs to increase their focus on the implementation and operation of programs and strategies designed to help employer-sponsored plans manage drug costs, while ensuring access by employees to clinically necessary drugs.

Nonetheless, prescription drug costs continue to represent a considerable portion of overall plan costs. As noted in the Health Care Cost Institute's 2016 findings, prescription drugs experienced a 24.9% price growth between 2012 and 2016,

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<sup>4</sup> See Anna Edney, *FDA Broadens Generic Drug Competition Efforts, Pressuring Prices*, Bloomberg (Nov. 9, 2017), <https://www.bloomberg.com/news/articles/2017-11-09/fda-broadens-generic-drug-competition-efforts-pressuring-prices>.

<sup>5</sup> See Steve Arnoff, *Healthcare Stakeholders Urge Senate to END REMS Abuse, Increase Generic Drug Competition*, Association for Accessible Medicines (Jan. 5, 2016), <https://www.gphaonline.org/gpha-media/press/healthcare-stakeholders-urge-senate-to-end-rems-abuse-increase-generic-drug-competition/#>; see also *Use of a Drug Master File for Shared System REMS Submissions -Guidance for Industry*, FDA Draft Guidance (November 2017), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM584202.pdf>.

accompanied by a 27% increase in prescription drug spending by employer-sponsored insurance plans over that same period.<sup>6</sup> And as cited by Murray Aitken for the IMS Institute for Healthcare Informatics, the average list price of branded drugs has similarly increased, at least 10% annually during the period 2012 through 2017.<sup>7</sup> These rising costs pose significant challenges for employers as they seek to continue to provide comprehensive, but cost-effective coverage for their employees and their employees' families.

Notably, in 2013, retail drug costs accounted for only 19% of employer plan benefits (and only 10% of overall U.S. health spending). By 2015, this number increased from 19% to 21%.<sup>8</sup> In light of projections that prescription drug spending will increase approximately 6.3% *per year* between 2016 and 2025 and the continued acceleration in prescription drug prices (up 4.4% in 2018, from 2.1% in 2017); employer-sponsored plans can expect similar increases.<sup>9</sup> This trajectory is unsustainable.

The issue of rising drug costs is complex, and necessitates the focused attention that the RFI acknowledges. The management of such costs in a coordinated and comprehensive manner involving all stakeholders is important to employer-sponsored group health coverage as well as public programs. The Council thus appreciates the attention of the Trump Administration ("Administration") to the issue of rising drug costs, as reflected in the RFI. The Council's comments and responses to the RFI follow.

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<sup>6</sup> 2016 Health Care Cost And Utilization Report at 14.

<sup>7</sup> See Murray Aitken, IMS Institute for Healthcare Informatics, *Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020* (2016), <https://morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf>; Neeraj Sood, PhD et al., Leonard D. Schaeffer Center for Health Policy & Economics, *The Flow of Money Through the Pharmaceutical Distribution System 1-2* (2017), [http://healthpolicy.usc.edu/documents/USC%20Schaeffer\\_Flow%20of%20Money\\_2017.pdf](http://healthpolicy.usc.edu/documents/USC%20Schaeffer_Flow%20of%20Money_2017.pdf).

<sup>8</sup> See Rabah Kamal & Cynthia Cox, *What are the Recent and Forecasted Trends in Prescription Drug Spending?*, *Peterson-Kaiser Health System Tracker* (Dec. 20, 2017), [https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-drugs-count-bigger-share-health-spending-many-think\\_2017](https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-drugs-count-bigger-share-health-spending-many-think_2017).

<sup>9</sup> See Centers for Medicare and Medicaid Services, *National Health Expenditure Projections 2016-2025: Forecast Summary* (2017), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2016.pdf>; Centers for Medicare and Medicaid Services, *National Health Expenditure Projections 2017-2026: Forecast Summary* (2018), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ForecastSummary.pdf>.

## **The Council supports rules intended to result in improved competition among drug manufacturers, wholesalers, retail pharmacies and PBMs.**

The Council's members are many of the nation's largest private sector employers. As such, they understand the realities of a competitive marketplace – notably, that the need to deliver best-in-class products at competitive pricing helps drive innovation in both product design and delivery. In this regard, increased competition with regard to pharmaceutical drugs should similarly help drive innovation in bringing both new drugs and lower-cost alternatives, including generics and other bioequivalents to the marketplace. Such competition has the potential to deliver significant benefits to payers in the marketplace, not only by improving the quality and efficacy of products, but also by lowering prices.

To that end, the Council supports policies intended to increase competition among all the players in the pharmaceutical drug space – including manufacturers, wholesalers, retail pharmacies and PBMs – provided that the laws and regulations that implement such policies are carefully designed to result in lower costs and better value for plans, while avoiding unintended consequences that could harm employers, plans or consumers. Increased competition could help to lower costs, or at least mitigate cost increases, that plans will face with respect to drug coverage while preserving – or indeed accelerating – innovations that bring life-saving products to consumers.

## **The Council supports increased drug price transparency that leads to lower drug costs and better value.**

The Department, in the RFI, specifically states that it is considering “new measures to increase [drug-price] transparency.”<sup>10</sup> We note at the outset that transparency is not an end in and of itself. The goal we share with the Department is to implement policies that lead to healthier Americans and lower costs. The Council's overriding approach to the questions posed in the RFI and the initiatives it contemplates is to explore and evaluate what tools are available to plan sponsors to lower drug costs for employers and consumers. It is through this prism that we view potential policy initiatives on which the Department seeks comment.

We also note that the issue of drug-pricing and transparency is complicated and involves many variables. Thus, a valuable outcome of this RFI process would be a better understanding of how different tools (*e.g.* rebates, coupons, etc.) are being used to lower cost for employers and consumers. An aligned objective should be to consider altogether new models and mechanisms to help achieve desired outcomes. This needed clarity will inform next steps in lowering drug prices in a comprehensive and effective way.

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<sup>10</sup> See 83. Fed. Reg. 22,692, 22,695 (May 16, 2018).

One common complaint in this area is that payers lack available data and transparency regarding the actual (versus “sticker”) price of many prescription drugs. Whereas the “price” of drugs is often reflected as an “average wholesale price” or “AWP,” published studies confirm that there are often wide disparities between AWP and the actual price paid by many payers across the system.<sup>11</sup>

Notably, with respect to consumer goods, there are many product categories that offer robust price transparency, and such information is often thought to lead to lower prices and better informed consumers. For example, car pricing services (such as those offered by Kelley Blue Book, Edmunds, and TrueCar, among others) provide realistic pricing information on new and used automobiles, and are popular with – and relied upon by – consumers when making their purchasing decisions.

Indeed, the U.S. health care system itself demonstrates how increased transparency can lead to better results for consumers and plans alike. More specifically, the system has seen increased transparency regarding the actual costs charged by medical providers, and/or amounts paid by payers in the system to such providers. This increased transparency has come about, in part, through the use of published Medicare reimbursement rates, as well as the development and use of various third party reporting agencies, such as FAIR Health. These innovations show that increased availability of cost information, if properly designed and carefully implemented so as to avoid unforeseen consequences, can help consumers (including employer sponsors and their employees) make informed and sensible purchasing decisions.

We seek increased transparency as it relates to furthering the overall goals of lowering costs and providing better value for plans, employers, and employees. As the Department considers “new measures to increase transparency,” we ask the Department to be cognizant of existing disclosures obligations that may already be applicable. For example, there exists a requirement under the Employee Retirement Income Security Act (ERISA) for an entity (generally imposed on PBMs or third-party administrators) to annually disclose to the plan (upon request) the aggregate rebates retained by the PBM where the plan and the PBM have agreed that such rebate amounts will be retained by the PBM as compensation for managing the plan’s prescription drug coverage.

The RFI poses the question: “Do PBM rebates and fees based on the percentage of the list price create an incentive to favor higher list prices (and the potential for higher rebates) rather than lower prices?” In the RFI, the Department has a specific section of questions focused on “[r]educing the impact of rebates.”<sup>12</sup> The Department states:

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<sup>11</sup> See, e.g., Neeraj Sood, PhD et al., Leonard D. Schaeffer Center for Health Policy & Economics, *The Flow of Money Through the Pharmaceutical Distribution System 1-2* (2017).

<sup>12</sup> 83 Fed. Reg. at 22,698.

“Increasingly higher rebates in Federal health care programs may be causing higher list prices in public programs, and increasing the prices paid by consumers, employers, and commercial insurers.” This is a very important question for the Department to examine in informing policymakers on strategies to lower costs for both public and private purchasers.<sup>13</sup>

Again, we stress that increased transparency itself is not the end goal. The end goal is reduced drug costs and better value for employers and consumers. In support of lower cost and better value, we hope this regulatory process will illuminate how rebates affect the price employers and consumers pay for drugs. Such clarity is critical to employers as they seek to manage drug costs. We encourage the Department and all stakeholders to take a holistic view of drug pricing, in which all the levers and practices that have an impact on how much plans and consumers ultimately pay are taken into account.

**The Council encourages the Administration to consider policy initiatives to allow and encourage the pharmaceutical industry to adopt value-based purchasing models.**

Many of the Council’s members have led the way in implementing innovative strategies designed to help transition the health system from one focused on volume to one focused on value. We encourage the Department to review a recent report published by the Council and Mercer, Leading the Way: Employer Innovations in Health Coverage, which outlines many of these strategies. One Council member featured in the report implemented a program that provides assistance and information to patients on specialty medications to improve adherence. The company’s team helped align the site of care to ensure that medications were being dispensed in a cost-effective setting – for example, at a patient’s home rather than a provider’s office – which in many cases also resulted in a better patient experience. This program has saved the employer millions of dollars.

This program and others that are focused on value-based insurance design and value-based payment reform have the potential to transform our system by realigning incentives that keep patients healthier – while at the same time lowering costs. These programs have begun to penetrate the pharmaceutical industry, but adoption is slowed by regulatory barriers that impede outcomes-based contracts that, for example, would

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<sup>13</sup> The Council is also aware of findings in years past by the Congressional Budget Office that, given certain market conditions, increased transparency regarding drug rebates may actually increase drug costs and lower competition. See Congressional Budget Office, “Increasing transparency in the pricing of health care services and pharmaceuticals,” 4 (Jun. 5, 2008) (“In markets where only a small number of firms operate, increased transparency would make it easier for those firms to observe the prices charged by their rivals, which could lead to reduced competition between them.”).

reimburse patients and payers if certain drugs do not work as indicated. As new drugs that treat and cure complex conditions come to the market it becomes even more critical to break down these regulatory barriers. Specifically, the Federal Anti-Kickback Statute, which has the laudable purpose of prohibiting actions that induce the purchase of items or services payable by a federal health program, can unintentionally limit the implementation of value-based contracts between manufacturers and payers that everyone would agree benefits consumers and the federal government itself. The Administration should create a new safe harbor or exception for value-based contracts, which could spur adoption of value-based purchasing across the private sector.

Additionally, as the RFI notes, Medicaid “best price” can also have a chilling effect on value-based contracts. If a manufacturer negotiates with a payer to refund the entire cost of a drug if it is ineffective for patients with certain health conditions, that manufacturer could be at risk for providing that drug at no cost to the *entire* Medicaid program. We urge the Administration to issue guidance or regulations to eliminate these barriers.

**The Council encourages examination of ways to spread more equitably the burden for incentivizing new drug development.**

The RFI notes that: “U.S. consumers and taxpayers generally pay more for brand drugs than do consumers and taxpayers in other OECD countries, which often have reimbursements set by their central government. In effect, other countries are not paying an appropriate share of the necessary research and development to bring innovative drugs to the market and are instead freeriding off U.S. consumers and taxpayers.” The Department seeks input on what can be done to reduce the pricing disparity and spread the burden for incentivizing new drug development more equitably among the U.S. and other developed countries. The Council encourages examination of this question and hopes it will yield both greater innovation in new drug development and lower prices for U.S. consumers, taxpayers and employers.

**The Council urges the administration to take action that would lower out-of-pocket costs for millions of employees with chronic conditions.**

The statutory preventive care safe harbor for Health Savings Account (“HSA”)-Eligible plans should be expanded to encompass drugs and services intended to prevent and treat chronic disease. Per section 223(c)(1)(A) of the Internal Revenue Code (“IRC”), an individual is not eligible to contribute to an HSA unless he or she is covered by a qualifying high deductible health plan (“HDHP”) and is not covered by other disqualifying coverage. Significantly, IRC section 223(c)(2)(C) provides that an HDHP does not cease to be a qualifying HDHP for purposes of the HSA rules solely because it provides certain preventive care services. Specifically, section 223(c)(2)(C) states:



SAFE HARBOR FOR ABSENCE OF PREVENTIVE CARE DEDUCTIBLE. – A plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for preventive care (within the meaning of section 1861 of the Social Security Act, *except as otherwise provided by the Secretary*).

(Emphasis added).

According to the Agency for Healthcare Research and Quality, 86 cents of every health care dollar spent in the U.S. is for patients with chronic diseases. As HSAs and HDHPs grow in use and popularity, individuals with a chronic disease would benefit from increased access to drugs and services intended to manage their conditions and, in many instances, prevent the onset of other conditions or co-morbidities. For example, treatment of diabetes through adherence to daily blood glucose monitoring and a proper insulin regime can prove to be incredibly effective not only in managing the diabetes, but also in avoiding the onset of other statistically-related conditions, such as circulatory issues, many of which are exacerbated by poor management of the underlying diabetes. While employers and plans would very much like the option to provide pre-deductible services to these individuals to help them manage their conditions and prevent the onset of other conditions or co-morbidities, the current regulatory interpretation does not facilitate these actions.<sup>14</sup>

Given the broad regulatory authority provided to the Secretary of Treasury in IRC section 223(c)(2)(C), the Council believes there is ample statutory authority for this Administration, via the Treasury Department, to interpret the preventive care safe harbor to encompass drugs and services intended to manage chronic conditions and/or prevent the onset of co-morbidities. Accordingly, we urge the issuance of new regulatory guidance intended to achieve this result. We believe it is not only supported by the statute, but is sound public policy in both helping individuals access critical care and helping to reduce plan costs. Implementing this policy is one way to quickly lower out-of-pocket costs for millions of Americans with a chronic disease.

**The Council supports efforts to improve drug pricing and reduce out-of-pocket costs for enrollees in publically-financed and administered programs, and urges the Administration to also consider employer-sponsored plans.**

Employer-sponsored plans have long been the backbone of the U.S. health coverage model – providing comprehensive and affordable health coverage to millions of working and retired Americans and their families. For years, employer-sponsored plans

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<sup>14</sup> See IRS Notice 2004-23 (“[P]reventive care does not generally include any service or benefit intended to treat an existing illness, injury, or condition.”).

have accounted for a majority of American healthcare plans.<sup>15</sup> In 2016, employer-sponsored plans covered 55.7 percent of the population; notably, more than double the number of people enrolled in Medicaid which covered only 19.4 percent.<sup>16</sup>

Employer-sponsored plans will continue to play an essential role in the provision of health care for the American worker and family. The Council is mindful of the importance of federal healthcare programs, and applauds the Department's efforts to consider thoughtful and meaningful reform with regard to such programs. Consistent with that undertaking, the Council urges the Department to take a holistic approach in this review that includes both federal healthcare programs and employer-sponsored health coverage. This will ensure that working Americans can benefit from improvements made to the system to expand drug access, and bring down (or at least better manage) drug costs.

**The Council urges the Department to consider the potential adverse effects that can accrue to the employer-sponsored system if new rules intended to bring down drug costs are focused only, or principally, on public programs.**

As noted above, the Council represents a broad array of employers who provide their employees with group health coverage. In that role, the Council notes that the overarching goal of any new Department rules should be to reduce drug costs for *all* health consumers – whether private sector employers, consumers or public payers like the federal government. Efforts to reduce drug costs on public payers should not – intentionally or inadvertently – come at the expense of employer-sponsored group health plans. If that should happen, employers and employees alike will likely incur even greater increases in overall plan costs as a result of drug coverage, with potential adverse effects on the pricing and utilization of essential coverage for American workers and their families.

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The Council applauds the great strides in science that allow millions of Americans to live longer, healthier lives. It is not a bad thing to spend more on prescription drugs when doing so adds value, cures diseases, lowers other health care spending, and keeps employees healthier at home and more productive at work. However, the market is not willing to accept the absence of appropriate price transparency nor situations such as were exposed concerning the EpiPen. Health care resources are finite. The nation needs

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<sup>15</sup> See Michelle Long et al., *Trends in Employer-Sponsored Insurance Offer and Coverage Rates, 1999-2014*, Figure 5, Henry J Kaiser Family Foundation (Mar. 21, 2016) [https://www.kff.org/report-section/trends-in-employer-sponsored-insurance-offer-and-coverage-rates-1999-2014-issue-brief/endnote\\_link\\_179214-1](https://www.kff.org/report-section/trends-in-employer-sponsored-insurance-offer-and-coverage-rates-1999-2014-issue-brief/endnote_link_179214-1).

<sup>16</sup> See Jessica C. Barnett & Edward R. Berchick, *Health Insurance Coverage in the United States: 2016* (Sept. 12, 2017) <https://www.census.gov/library/publications/2017/demo/p60-260.html>.

to spend scarce resources more wisely; and all consumers - employers and employees alike - need to know what they are getting for their money.

The Council commends the Department for seeking to bring about a better understanding of drug pricing and enabling lower drug prices. We recognize the complexity of the task. While addressing the implications of these issues for federal health plans is essential, it is equally important to address these matters for employers and the more than 178 million Americans with employer sponsored health coverage. We look forward to working with the Department and other stakeholders to bring the voice of employer plan sponsors to this all-important effort.

Thank you for considering these comments submitted in response to the RFI. If you have any questions or would like to discuss these comments further, please contact us at (202) 289-6700.

Sincerely,

A handwritten signature in black ink that reads "Ilyse Schuman". The signature is written in a cursive, flowing style.

Ilyse Schuman  
Senior Vice President, Health Policy