



Kaiser Foundation Health Plan
Program Offices

March 4, 2016

Hon. Ron Wyden
Hon. Charles Grassley
United States Senate
Committee on Finance

Submitted via email to: Report_Feedback@finance.senate.gov

RE: *The Price of Sovaldi and Its Impact on the U.S. Health Care System*

Dear Senator Wyden and Senator Grassley:

Thank you for the opportunity to respond to your investigative report, *The Price of Sovaldi and Its Impact on the U.S. Health Care System.*” (Hereinafter “Report”)

The Kaiser Permanente Medical Care Program is the largest private integrated healthcare delivery system in the U.S., with 10.3 million members in eight states and the District of Columbia.¹ Kaiser Permanente (KP) is committed to providing high-quality, affordable health care services and improving the health of our members and the communities we serve.

Our integrated delivery system includes the provision of pharmacy services as a purchaser, a prescriber (through our independent Permanente Medical Groups) and a dispenser of drugs.² As a system encompassing providers, hospitals, pharmacies, laboratory services and health plans, KP experiences multiple effects of high drug prices across most components of the delivery system, including both hospital and outpatient care settings. We see firsthand how these drugs can help our patients. However, we also have to bear significant burdens on resources and budgets. As a health system, we cannot ignore the growing impact of specialty drugs on our ability to provide affordable care. We hope our views and experience as an integrated system

¹ Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation’s largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 38 hospitals and over 600 other clinical facilities; and the Permanente Medical Groups, independent physician group practices that contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente’s members.

² KP pharmacies dispense over 93 million prescriptions per year. We operate 378 outpatient pharmacies, 38 inpatient facilities, 5 central fill/mail order facilities, infusion centers and a specialty pharmacy. Our national pharmacy program employs over 8,600 skilled team members system wide. Our 2014 prescription drug spend was \$5.8 billion dollars, of which \$5.4 billion was for outpatient drugs.

will offer a balanced perspective on the benefits and challenges of high-priced drugs like Sovaldi.

The Committee's thorough and well-balanced Report echoed many of our concerns with rising drug costs, and provided new information that has increased our understanding of how the prices of Sovaldi and Harvoni were set.

Introduction

As the Report reveals, Gilead's decisions about pricing Sovaldi were nontransparent and profit-driven, relying primarily on Gilead's predictions about what the market would allow, and designed for a rapid return on the Pharmasset purchase. Lack of pricing transparency is not unique to Gilead. Current pharmaceutical pricing practices make rational discussion of, or negotiation over, drug prices challenging because there is no objective baseline. Launch prices and price increases seem arbitrary, justified *ad hoc* by various arguments that have little to do with health outcomes, the cost of raw materials, or the public interest and more to do with meeting investor expectations that have ballooned out of all proportion.

The Report documents that Pharmasset estimated the production costs for Sovaldi would be *de minimus*, starting around \$1.00 per caplet, and falling with commercial scale production to less than 1.5% of the drug price, assuming a range of \$30-40,000 per 12-week course of treatment. Yet Gilead's vice president, responding to the Report, told the American Enterprise Institute, "To suggest that a cure for a disease like Hepatitis C should be priced at \$36,000. . . would put a huge disincentive on investing in cures for our industry." Yet Pharmasset, the company that actually conducted the research and made the R&D investment in this drug, determined that, given production costs, R&D, other associated costs and a more than respectable profit, \$36,000 did provide incentive enough.

As a mission-driven entity focused on providing high quality health care to our members, KP has a paramount interest in the development and approval of effective new pharmaceutical and biologic therapies. They are an integral part of 21st century medicine. But, as the price bar is raised year after year, we become more deeply concerned about how health plans can absorb rapidly escalating drug costs without major rate increases. A large part of our focus is managing the factors reflected in what we charge for coverage. When it comes to prescription drugs, we are losing leverage to an industry that should be our partner in delivering health care, but often acts as though disconnected from the larger health care delivery system and its concerns for rising costs. We believe that all entities in the system should be responsible for promoting affordability, but current incentives drive the pharmaceutical industry away from such cooperation.

Your Report can be a turning point in this vitally important debate if it leads to changes that more fully reflect the public interest.

Questions from the Committee

What are the effects of a breakthrough, single source innovator drug on the marketplace?

The last several years have seen monumental growth in the specialty drug sector of the U.S. pharmaceutical market. Specialty drugs are defined by Medicare as drugs costing at least \$600 per month, or \$7,200 per-patient-per-year (PPPY). Actual prices are more often in the range of \$40,000 to \$500,000 PPPY, with a few drugs costing up to \$1.8 million PPPY.

Health system spending on specialty drugs has been rising dramatically for more than ten years. In 2000, specialty drugs (at the time primarily biotech drugs) made up less than 10% of KP drug costs. With increasing approvals of new drugs and new indications for existing drugs, this sector had grown to 31% of total KP drug expenses in 2008 and then to 43% in 2013—even though specialty drugs are used by less than 2% of KP members.

From 2008-13, our five-year cumulative *non-specialty* drug expense has grown *less than 5%*. In contrast, KP specialty drug expense has grown by 72% over the same period. These numbers reflect our data before the approval of Sovaldi and the other newest Hepatitis C drugs, which greatly exacerbated these trends.

Within the category of specialty drugs, innovator single-source drugs have been the major cost driver for drug expenditures within KP, and across the market in general, for over a decade. The impact increases each year.

Hepatitis C drugs represented the fastest growing specialty pharmaceutical sector in 2014; early market analysts predicted global sales to be over \$20 billion by 2018. The reality of pricing excess rapidly outpaced this projection; in 2015 alone, sales of Harvoni and Sovaldi totaled over \$19 billion. This is due both to the extremely high cost of the drug and the large infected population. In 2014, our six-year projection showed Hepatitis C drug treatment alone would increase KP outpatient prescription drug expenses by larger amounts each year reaching about one-third of all prescription drug expenses in 2020 (holding other outpatient prescription drug expenses constant).

While Gilead can focus on product lines for specific diseases, we have a very different perspective. We have to absorb the cumulative effects of thousands of these pricing decisions across the pharmaceutical spectrum, to meet our obligation to treat all of our members for all of their medical conditions. The price of treatment for this one disease cuts deeply into the resources we use to care for all populations, and we see no end to the line of other manufacturers of breakthrough drugs whose expectations for higher and higher prices have been stimulated.

Diluting the sticker shock effect

Manufacturers take full advantage of their ability to exploit their monopoly power with each new drug introduction. The health care industry has witnessed higher and higher price bars for specialty therapies every year, with many drugs introduced at six or seven-figure PPPY prices. Over a decade ago, sponsors of new small-molecule oral oncology drugs, emboldened by price

levels for biotechnology agents, began to price their products in the \$20,000 PPPY range. Each subsequent year, new launches pushed the price bar higher, so that now the prices for most oral oncology agents exceed \$100,000 PPPY. Other drugs may launch at substantially higher prices.³

As health plans strive to keep costs manageable for their customers against constant upward market pressures, the drug industry pushes the price bar higher with each new introduction. High-priced specialty drugs have become an essential part of clinical care, so continued strong growth in that sector with no downward (or even leveling) move on pricing makes it less likely that the U.S. will be able to control the trend of medical expenditures.

Shifting target markets

In the past, innovative drugs that treated fairly small populations, some with orphan drug designations, were the few niche therapies that commanded extremely high prices. Such pricing levels were accepted because of their relatively manageable impact on health care budgets. However, pharmaceutical manufacturers have manipulated the rules for what counts as an orphan drug, and taken advantage of legal protections of the Orphan Drug Act. The Act's intent to ensure the market did not disadvantage small populations has been misdirected to leverage higher profit margins. Former Representative Henry Waxman, the primary sponsor of the Act, has been critical of the pharmaceutical industry for misusing some of the incentives the law provides.

In addition, the manufacturers have invested in broad-based marketing for drugs with narrow indications. For example, expensive PCSK9-inhibitor cholesterol drugs are approved for a small subset of patients, but will almost certainly be marketed to the larger, undifferentiated population with high cholesterol. Consumers may be misled into believing that this new drug designed for very few patients should replace their effective generic statins, but at a \$14,000 price tag rather than one measured in pennies. Health plans, patients and ultimately all other segments of the health care system will bear the consequences of such conscious overselling of a drug priced for a limited number of patients.

Also, the pipeline in some therapeutic areas has been shifting to target large populations where specialty therapies had not previously penetrated. Three examples aimed at high prevalence conditions are: (1) recently approved monoclonal antibodies for a segment of lipid management patients; (2) monoclonal antibodies in the near-pipeline for subsets of asthma patients; and (3) late-stage development of a monoclonal antibody for *Clostridium difficile*.

The Hepatitis C drugs take this to a new level, capitalizing on combining astronomically high prices, typical for orphan drugs, with high prevalence (around 3 million infected individuals in

³A new treatment for Morquio A Syndrome can range from \$600,000 to \$1.5 million PPPY. A new drug for generalized lipodystrophy can cost \$700,000 to \$1.8 million PPPY. A new drug for the rare condition hypophosphatasia can start at \$250,000 PPPY for an infant, increasing with body weight; if an adult is treated, the cost can be over \$1.5 million PPPY.

the U.S. and about 150 million worldwide). It is this aggregation of extremely high price and enormous target population that is leading us to the financial precipice.

Specialty drug prices continue to climb without justification after launch

Annual drug price increases often exceed general inflation rates, sometimes several-fold, without evidence of added value, such as clinical trial data that indicate improved outcomes or define appropriate use.

Existing specialty drug prices increase more on an annual basis than those of other drugs. For example, we have seen consistent, annual price hikes of 15-20% for multiple sclerosis (MS) drugs. Within KP, these have increased cumulative per-patient costs 358% over the last twelve years. The wholesale acquisition cost (WAC) for four available MS drugs in 2005 ranged from \$15-18,000 PPPY. By 2015, of more than a dozen drugs approved for MS, eight had WACs between \$70,000 and \$74,000 PPPY; the other four were above \$61,000. Yet, very little progress has occurred in treatment efficacy or safety among most of these drugs since 2005.

This intolerable rate of price inflation applies to combination therapies as well. The recent trend has been toward increased approval for – or off-label use of – combinations of specialty drugs. Once again, Hepatitis C illustrates how combination therapy can increase the burden. For patients with a less common genotype of the hepatitis C virus, combining Sovaldi with Olysio could be an effective therapy, but as the Report points out, this comes at a total cost of over \$160,000.

Defensive price increases

We also see price increases that are forward looking and defensive, most obviously with biologic drugs that face competition from emerging biosimilars. Humira and Enbrel have increased prices by 30% and 28% respectively in a recent 12 month period. This degree of price increase will negate discounts brand manufacturers will have to offer when biosimilar competition materializes. Unless biosimilars are willing to dramatically underprice the new, higher bar, they will not be able to gain a foothold against the brand names, and purchasers will realize no savings from competition. At best, any discounts achieved will do little more than return spending to pre-2015 levels.

Everything old is new again

One of the most prominent current pricing abuses involves the purchase of older drugs by manufacturers seeking greater profit with little additional investment. Turing Pharmaceutical's 5000% price increase of Daraprim is the archetype for this particular phenomenon, which is not limited to small molecule, non-specialty drugs.

Some manufacturers have started re-purposing older drugs as “specialty therapies,” often with a new high price with scant or inadequate clinical trial support for a new indication. For instance, dichlorphenamide, a carbonic anhydrase inhibitor used since 1958 for improving intraocular pressure, was re-launched to treat hyperkalemic or hypokalemic periodic paralysis.

By 2002, the earlier brand of dichlorphenamide, Daranide, cost \$100 to \$700 PPPY. The drug was owned by Merck until it was purchased by Taro, which removed it from the market. Taro

renamed the drug Keveyis, and repurposed it to treat hyperkalemic or hypokalemic periodic paralysis, rare diseases that occur in about 1 in 200,000 and 1 in 100,000 people, respectively. No other drug has been approved for these indications. FDA approval was based on two clinical studies with less than 150 participants. Taro then put Keveyis on the market, priced at \$100,000 to \$200,000 PPPY.

This sequence of events is becoming a pattern: Taro's costs for this new version of an old drug included basically: (1) acquisition of the product; (2) conducting the qualifying clinical trials, which led to (3) approval for use. Based on these factors, the company launched the drug at a markup of about 1,000% at the lowest end.

While this 1000% increase may look modest compared to the price hike Turing imposed on Daraprim, we know of no other industry where manufacturers can routinely expect to raise the prices of products that are decades old by such unimaginable percentages.

Reduced ability for buyers to influence the market

The tactics described above are possible because so-called "innovator" products face little if any competition from available similar drugs, which severely impacts the functioning of the market. Payers face high barriers to balanced negotiation when the prices of necessary drugs are unrestrained by any real competition. Simply put: there is no free market when it comes to prescription drugs.

This limited market is exacerbated by a number of related issues: restricted distribution; lack of biosimilars and generics; small target populations.

Competition even among closely comparable, therapeutically interchangeable agents is also limited due to the impact of the Omnibus Budget Reconciliation Act of 1990 "Best Price" Rule. This well-intended requirement limits the ability of otherwise well-positioned negotiators like KP to obtain highly discounted contract prices that would benefit their members. While providing a degree of security to Medicaid programs, the Best Price rule comes at a cost to the market. The rule perversely provides leverage to manufacturers, which they take advantage of at the expense of all consumers and other payers.

Contracting for discounts on innovator drugs is possible in less than half the sector; a degree of competition still exists for a few classes, e.g., drugs for rheumatoid arthritis, psoriasis, and Crohn's disease. Negotiation is limited when drugs have minor differences or comparative efficacy is undefined. For example, discounts on oncology drugs have been less frequent as their prices have skyrocketed.

In addition, manufacturers can and do create systems for restricted distribution, or invoke exclusive contracting practices. These practices can add to the cost of these drugs, impose barriers to integrated care, and eliminate negotiation over price. Finally, many contracts in this area do not guarantee a set price for a period of time, meaning that the drug company can raise Wholesale Acquisition Cost pricing at any time and increase the effective price for all purchasers.

Summary

Trends in drug development and marketing indicate that the specialty pharmaceuticals segment will rapidly consume over half of total drug costs and possibly exceed 60% by the end of this decade. Insurers and their contractors have reached their limit in seeking effective methods in this market to optimize the use of specialty pharmaceuticals. We cannot manage our way out of this situation. The trend is unsustainable.

Do the payers in the programs have adequate information to know the cost, patient volume, and increases in efficacy of a new treatment regimen?

Generally, data that would allow payers to assess these factors are not publicly available until after a drug comes to market. This is due to the universal efforts of manufacturers to block any efforts that would involve even the most minimal levels of scrutiny, both of the comparative effectiveness of their drugs, or what goes into their justifications for pricing a particular drug.

Pricing data

When it comes to any information that could justify a drug's newly announced price, which is especially important, we have been unable to identify little that counts as objective "data." As we have noted above, and as the Report abundantly illustrates, the pharmaceutical industry strongly resists disclosure of any data and analysis that goes into its pricing determinations – in Gilead's case, ultimately resisting even this Committee's requests for needed information.

Not only is this troubling from a purchaser perspective, but the lack of transparency is out of sync with the broader health care industry. Health care is heavily regulated; for example, health plans are required to be transparent so that our financial stability can be monitored and our patient expectations for care can be fully met. We work with physicians, hospitals, other clinicians, laboratories, etc. to ensure that our premiums are reasonable and sustainable. By contrast, the drug industry continues to resist any notion of transparency at all, even at the most basic level.

If pharmaceutical pricing practices were themselves reasonable, fair, consistent, and predictable, the rest of the industry could accommodate the lack of transparency (though it would still be out of line in this industry). But the pharmaceutical industry's pricing practices are none of these things; opaque pricing seems to be an entrenched feature of its business model, and its effects are multiplying dangerously.

Other data

Assessing the cost, uptake and improvement of new treatment regimens is challenging, not only because of inherent differences among drugs and patients, but also because the data to support evaluation of use in clinical practice are often not readily available. Many specialty drugs are approved based upon placebo-controlled trials, while head-to-head comparisons are rare or missing.

Also, approval may be based on trials that do not match real-world usage or conditions, including studies done in multiple countries where health care practices or populations are not comparable. For example, naïve-to-treatment patients may be included in studies from other

countries when most US patients may have had prior “disease-modifying” drugs. MS patients naïve to immunomodulatory treatments receive either drug or placebo in multiple medical centers (over 80 in some trials) located in multiple countries (over 26 in some trials) where care and even major endpoints, like MRI procedures, can vary widely among less- and more-developed countries.

Some target conditions lack outcomes metrics used in common treatment approaches – or lack outcomes metrics recorded as structured, retrievable data. Thus, post-marketing efficacy and safety of these drugs are not well-known. Conditions which might lend themselves to structured data and patient registries include at least the following: MS, RA, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn’s disease, paroxysmal nocturnal hemoglobinuria, generalized lipodystrophy, cystic fibrosis, and several rare and/or inherited diseases.

What role does the concept of “value” play in this debate, and how should an innovative therapy’s value be represented in its price?

“Value” is one of the most important considerations in any functioning market, but it is also one of the most easily subverted. As both a purchaser and a provider, KP has a unique role in this discussion.

The pricing of Sovaldi clearly establishes the problem. The current (and pipeline) Hepatitis C drugs could make universal treatment clinically possible. Gilead’s Executive Vice President Gregg Alton has acknowledged that sofosbuvir (and other drugs in the pipeline) have the potential to eradicate Hepatitis C globally in time. However, a substantial barrier is Gilead’s choice to price its first drug prohibitively high. Because of that, the Institute for Clinical and Economic Review (ICER) concluded in 2015 that Sovaldi and similar drugs represent “an overall low value to the health care system,” despite potentially being clinical game-changers. And one of the most important takeaways from the Committee’s Report is that the initial pricing decision for the first-to-market drug set the benchmark for the other Hepatitis C drugs that soon followed.

Gilead made its value case for Sovaldi by extrapolating the extreme treatment costs for a few individual patients to the entire population the drug could conceivably treat. This is cast as an argument based on data, but it is not.

Gilead argued that individuals treated now will avoid a future liver transplant – considered the most dire and expensive outcome for a chronic Hepatitis C patient. If this argument were as sound as it is dramatic, \$90,000 would certainly seem like a good deal compared to a transplant costing hundreds of thousands of dollars.

But this argument exploits the truly rare circumstance of a liver transplant to justify prices the majority of patients – not to mention the rest of society – will pay. Only between 1-4% of the U.S. population chronically infected with the Hepatitis C virus will ever need a liver transplant for complications of Hepatitis C. 95-99% will not. This argument treats the cost of 30-150,000 transplants as if they are a cost that would be necessary to treat everyone in the entire infected

population, and then uses that as a baseline “data” point in justifying the value of the drug, and thus its price. The actual cost for medically necessary transplants to those 30-150,000 people, if it were spread across all those who have the virus would yield a figure closer to the range of \$6,000-29,000 per individual – far less than the cost of a minimum 12-week treatment with the current Hepatitis C drugs.

Another argument used to justify the cost of many drugs, including those for Hepatitis C, is the societal value of continued innovation and investment in research and development. As a matter of policy, innovation and research on drugs is both valuable and vital.

However, in the absence of specific, verifiable data about what manufacturers actually spend on R&D, it is difficult to accept these numbers on faith as a true calculation of what these high priced treatments are worth. We have little if any information about which data roll up to the R&D amounts manufacturers report in financial statements. Claims that it takes \$2 to \$3 billion to bring a new drug to market have been repeated often, but such figures have been challenged as subject to influence by pharmaceutical industry funding, and based on various factors such as opportunity costs that proceed from dubious assumptions. Most reasonable people would support investing more to research new and effective drugs. But few would choose to invest in increasing manufacturer profit margins, direct-to-consumer or other advertising, or subsidizing global sales of the same drugs at much lower prices in other countries. Yet these may well represent a significant part of what we are investing in. At the very least, we do not know.

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

We are seeing many states introduce legislation that would, for the first time, impose a small measure of transparency on pharmaceutical pricing. Policymakers in states like California, New York, New Mexico, Washington, Oregon, Colorado, Massachusetts, Tennessee, Virginia, and others have begun to discuss this seriously as a policy direction. Such measures propose little more than requiring manufacturers of high priced drugs to reveal what factors went into the pricing, something health insurers and many others in the health care industry routinely do now. Such measures do not require price setting or anything remotely resembling price setting. They would not require prior approval of drug prices; confidential information in any filing would remain confidential (as state laws require now for other confidential business and proprietary information); no pricing decisions would be directly affected or preempted. The proposals simply ask for the data that would justify the cost of extremely high priced drugs. If those data are sufficient, nothing more would happen.

Such proposals may have the benefit of highlighting the extent to which public funding is used in the early stages of research that result in new drugs. This is certainly a matter of public interest, but it is often obscured. Another advantage of transparency is that it can help state and federal agencies understand the data that must go into their own determinations of value for money spent on these drugs.

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?

Innovative drugs should not be considered a luxury. To function well, it is important that the pharmaceutical industry make a reasonable, or even very healthy, profit. But the clinical need for these drugs, and the overall resource requirements of the various parts of the health care system demand a counterbalance to the drug industry's thirst for profit. When drug prices continue to climb to unheard of levels, those excess costs are borne by the entire system and are a key driver of medical inflation. When insurers establish actuarially sound rates, as required by law, those high drug costs are and must be reflected in rising premiums.

We know many drugs can be priced lower. As the Report notes, Gilead negotiated a \$900 course of treatment with Sovaldi for 80 countries around the world, acknowledging the critical connection between pricing and drug access. That connection is broken in the U.S. market.

Because of our laws on drug coverage and intellectual property, the U.S. plays a central role in subsidizing the world's pharmaceutical market. But at some point, the drug industry's exploitation of that taxpayer and societal generosity must have its limit, because the U.S. is subsidizing drug company profits on an unsustainable trend.

In that light, we propose some actions that could help to address the problems we see.

Thorough review of the legislation that affects the drug market in the U.S.

As the Report demonstrates, laws governing the drug market, while drafted with good intentions, can be applied for a manufacturer's disproportionate economic advantage. Gaps in the laws are routinely managed to leverage market advantage. Even when the statutes work as designed, unintended consequences have become the rule rather than the exception. A thorough review of the entire legislative scheme has never been as timely.

FDA authority over innovation

The scope of FDA authority is at the heart of some key problems. For example, manufacturers routinely seek approval for "new" products that are essentially old ones with incremental changes, like extended release formulations or combination regimens. The lack of a regulatory scheme to oversee these practices dilutes the fundamental reasons public policy encourages innovation.

For example, when Teva's MS drug, the market-leading Copaxone, was approaching patent expiration, a one-year trial was done to justify three weekly injections of a more concentrated formulation compared to the once-daily dosage which had been marketed for 17 years. The new concentration and dosing frequency were compared to placebo, but not to the longstanding formulation and dose. The company then drove patients to convert to the new product (with the longer patent protection) before a generic equivalent could be approved and marketed. If the new formulation were truly an advance – rather than a revenue protection move – it could have been compared to the company's own product and could have been brought to market many years earlier.

FDA's authorizing legislation could be modified to define "innovation" as distinct from "incremental improvement." A true innovation would require demonstrating a significant and clinically meaningful benefit in an improvement, as opposed to some statistical difference or simple equality of result. This might be an opportunity to rebalance public policy in favor of real innovation, while still leaving the market open to smaller advances that warrant reasonable rewards.

Another candidate for legislative review and modernization is the Orphan Drug Act, which provides incentives for the development of medications to treat rare diseases. Hundreds of orphan drugs have been approved under this law, helping patients who previously had no options, and demonstrating the value of this legislation.

However, existing incentives under this law have been exploited. Some orphan drugs have achieved blockbuster status, and over a third of orphan drugs earn more than a billion dollars a year. Some pharmaceutical companies have succeeded in creating new subcategories of diseases to meet the criteria for orphan drug status. Manufacturers can seek additional approvals for non-orphan indications, substantially expanding use of the drug, and abusing a statute designed to help small populations.

FDA could solve some of these issues under its existing authority by requiring additional information when companies seek orphan drug status, such as information about intended future indications. This, too, is an area where careful review of the law's fundamental underpinnings might require more specific changes to ensure that its original intent is not being subverted.

Another area that may benefit from review is biologics and biosimilars. While FDA approval authority was addressed in 2010, this sector has advanced rapidly, and a large proportion of the drug development pipeline consists of biologic drugs.

Existing law grants biologics a 12 year data exclusivity period. Given the rapid advance of these therapies, a shorter period would more strongly encourage market entry and uptake of biosimilars. We urge no more than seven years of data exclusivity. Like generic drugs before them, biosimilars have significant potential to expand treatment options and reduce costs through increased competition.

Address the Unintended Consequences of Medicaid Best Price

Under current law, Medicaid programs must get at least a 23.1% discount off of a drug's Average Manufacturer Price (AMP) or the "best price" any commercial entity is able to negotiate. This requirement was designed to protect Medicaid programs, but has evolved into a *de facto* floor for the inflated price of any drug. KP and other payers find their negotiating power undermined by this rule. While we appreciate the intent of the best price rule, it has led to market distortion, with the unintended effect of protecting drug makers' pricing leverage while constraining the ordinary market forces that we would otherwise rely on.

A better approach might be to increase the minimum rebate amount and discard the market-distorting "best price" provision, generating at least the same level of rebate savings for the

Medicaid program and public programs that benefit from the rebate system today. We acknowledge this is an extremely sensitive issue for state programs and other entities in the health care system. But we encourage thoughtful and balanced discussion about the intent of the rule, its effects on the market, and most importantly, its effective price protection for drug manufacturers, given the current and growing drug pricing crisis. We believe a different approach to meet the same goals could benefit all consumers.

Support and Protect Reasonable Utilization Management

When Sovaldi became available, it presented an extreme case that challenged attempts by the health care system to manage resources. Despite its clinical value and effectiveness, the drug's pricing was not designed to promote universal treatment. Quite to the contrary, it seems to have been designed to make universal treatment (or anything even close) economically impossible. The astounding price of the drug and its follow-on drugs required careful management, both by commercial health insurers and by public programs.

The pricing itself sets up a direct conflict with the health system goal of delivering appropriate care and avoiding care that is medically unnecessary. This is typically achieved by managing utilization and in some systems requiring prior authorization for treatment. Many payers take this approach with higher-priced, specialty drugs. Before a patient can receive a certain treatment, the patient must meet clinical criteria, such as having specific indications or failure of appropriate lower priced therapies or treatments.

Gilead is now making it clear that it will try to block the use of such tools. The company widely touts its patient assistance programs, which offer financial help for eligible patients who cannot afford coinsurance. But it announced that anyone whose insurer applied management criteria to determine eligibility for the company's drugs would be disqualified from assistance. This is a clear and harsh example of how a manufacturer can exploit patients in need to serve its own bottom line and thwart payers' efforts to manage resources.

But there is more. In recent months, public programs have been sued for not making these drugs available for every patient with the virus. The claim is that any attempt to manage use of these wildly overpriced drugs is unlawful; they must be provided by the state to every person qualified for public health care programs regardless of cost to the state.

It bears repeating that this situation hinges entirely on Gilead's decision to set Sovaldi's price where it did at the start. They knew their drugs, if universally available, could eradicate Hepatitis C. Gilead had a possible cure in its hands, but quite consciously placed that cure out of economic reach.

Mitigate Overblown Investor Expectations

As the Report shows, drug pricing decisions are made under the influence of bloated investor expectations, often fed by prior revenue and profit successes that exceeded predictions. Sovaldi is one stunning example, and has raised those expectations beyond reason.

There is little in public policy or current law that could directly alter this dynamic; public and legislative efforts to shed light on unjustified prices and their effects on the health care system

may help to address the interaction between arbitrary, skyrocketing drug prices and the consequent level of premium increases necessary to sustain health care in this country.

Drug companies should not be run like hedge funds. There is ample room in this industry for healthy profit and strong growth. The pharmaceutical industry is one segment of a larger health care industry that is of great public concern. Drug companies benefit from publicly funded scientific research and profit from the public's willingness to support generous intellectual property and market exclusivity protection in exchange for innovation. Hedge fund thinking about drugs is now in danger of threatening the financial sustainability of our industry. That fact should be reiterated in every discussion about rising health care costs.

CONCLUSION

The Committee's Report was a major step forward in our public thinking about drug prices. We are grateful to the Committee and thank the Committee and its staff for helping to shape the debate about a problem that has been under-examined for far too long.

We greatly appreciate the opportunity to respond. If you have questions or concerns, please contact me at 510.271.6835 (email: anthony.barrueta@kp.org).

Sincerely,



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