REVIEW ARTICLE

Breaking the Bank: Three Financing Models for Addressing the Drug Innovation Cost Crisis

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BACKGROUND: The introduction of innovative specialty pharmaceuticals with high prices has renewed efforts by public and private healthcare payers to constrain their utilization, increase patient cost-sharing, and compel government intervention on pricing. These efforts, although rational for individual payers, have the potential to undermine the public health impact and overall economic value of these innovations for society. The emerging archetypal example is the outcry over the cost of sofosbuvir, a drug proved to cure hepatitis C infection at a cost of $84,000 per person for a course of treatment (or $1000 per tablet). This represents a radical medical breakthrough for public health, with great promise for the long-term costs associated with this disease, but with major short-term cost implications for the budgets of healthcare payers.

OBJECTIVES: To propose potential financing models to provide a workable and lasting solution that directly addresses the misalignment of incentives between healthcare payers confronted with the high upfront costs of innovative specialty drugs and the rest of the US healthcare system, and to articulate these in the context of the historic struggle over paying for innovation.

DISCUSSION: We describe 3 innovative financing models to manage expensive specialty drugs that will significantly reduce the direct, immediate cost burden of these drugs to public and private healthcare payers. The 3 financing models include high-cost drug mortgages, high-cost drugs reinsurance, and high-cost drug patient rebates. These models have been proved successful in other areas and should be adopted into healthcare to mitigate the high-cost of specialty drugs. We discuss the distribution of this burden over time and across the healthcare system, and we match the financial burden of medical innovations to the healthcare stakeholders who capture their overall value. All 3 models work within or replicate the current healthcare marketplace mechanisms for distributing immediate high-cost events across multiple at-risk stakeholders, and/or encouraging active participation by patients as consumers.

CONCLUSION: The adoption of these 3 models for the financing of high-cost drugs would ameliorate decades-long economic conflict in the healthcare system over the value of, and financial responsibility for, drug innovation.

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Let us travel back in time to 2002. "Managed care" had been identified as the source of everything wrong with the healthcare system. Public furor over "skyrocketing" drug prices was reaching its zenith, with movements at the grassroots state and federal levels in support of the "reimportation" of cheaper drugs from overseas, and perennial outrage over the US healthcare costs was spreading from corporate buyers to the public at large.

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Why? Because in 2002, the nation's payers were in the process of radically reshaping drug benefit designs into what is now the predominant standard in health benefits. Under these new designs, patient copayments were pegged to old drug formularies and were newly organized into coverage "tiers," with those copayments tracking, albeit roughly, with prices charged by drug manufacturers.[1] Back then, "consumer-directed healthcare" as applied to the pharmacy meant that the more expensive a drug was, the more of that expense a patient should share.[2]

Between the late 1990s and early 2000s, most Americans who had health insurance went from full drug coverage, with little or no cost-sharing to highly struc-

tured benefit designs in health insurance coverage. By 2010, the number of Americans whose health insurance coverage included drug formularies was nearly 80%.[3] Some formularies were expansive, and others were highly restrictive. The result was patients' exposure to drug prices, and popular and political anger at the drug industry. The resulting zeitgeist was strong and pervasive enough to help pave the way for the passage of the Medicare Part D drug benefit. Part D represented more drug coverage for increasing numbers of Medicare beneficiaries, using those benefit designs, but with no price controls, centralized price negotiation, or reimportation. The public's fury over drug prices and the demonization of the drug industry slowly receded, aided by the influx of generic drugs in the 2000s.[4]

Thanks to a slow, steady rise over the past decade in the number and availability of specialty pharmaceuticals, the exact same debate has reemerged in 3 areas of conflict: drug prices, the cost of covering more individuals with an increasing need for drug treatment, and the complexity of coverage allocation. These points of conflict were not new in 2002, nor are they new today.

Since the 1990s, the manufacturers that develop and market new drugs have funded an echo chamber of scholars, papers, and industry events to explain the 3 things that payers least want to hear:

1. The complicated economics of drug discovery and development necessitate the drug prices that generate large profits commensurate with a drug manufacturer's entire enterprise risk

2. Expensive new drugs that preclude surgeries, help patients avoid hospitalizations, and/or offset other medical costs save the overall US healthcare system money and are worth their high prices

3. Innovative new drugs are the engine of medical progress, our best hope against what are still the most dreaded diseases, and ought to consume an ever-larger share of a functioning healthcare economy.

Employers, insurers, and health plan administrators charged with paying for new drugs operate a parallel echo chamber to explain the 3 things the drug manufacturers least want to hear:

1. Drug prices are too high

2. Too many new drugs are not new at all but are extensions of old drugs and/or are only marginally better than much older and cheaper drugs

3. Too many patients are receiving drugs that do not add value and, combined with skyrocketing prices, are bankrupting the US healthcare system.

Based on our professional experience, payers tend to bolster all 3 arguments by pointing to drug advertising and the hapless complicity of the nation's prescriber community.

KEY POINTS

- A surge in expensive specialty drugs has renewed efforts by payers to limit their utilization, increase cost-sharing, and to compel government intervention on pricing.
- Despite much talk by healthcare stakeholders about value and value-driven care, access to innovative specialty drugs is reaching a state of crisis, with payers and drug manufacturers each blaming the other.
- Innovative new treatments designed to address serious diseases in targeted patient populations represent the future of medicine.
- Financial models are needed to offer practical, durable results for the misalignment of incentives between payers who face high upfront costs of these important drugs and the rest of the healthcare system.
- This article proposes 3 models that offer solutions for paying for high-cost drugs, including amortization, reinsurance, and rewarding adherence with copay reductions.
- These 3 models work within or copy current marketplace tools for distributing immediate high-cost events across many at-risk parties and/or encouraging active participation by patients.
- Drug manufacturers, payers, and physicians need to collaborate to study the links between cost, benefit structure, policies, and payment, which dictate patient access to specialty drugs.

Like many perennial arguments in healthcare, in some cases, one side is right, and, in other cases, the other side is right; in all cases, each side believes the other side is wrong. When the 2 sides come together in public to discuss drug prices, overall drug costs, and the value of medical innovation, each accuses the other of bad faith and irresponsibility to the greater good of healthcare.

All the "happy talk" about value creation is rarely, if ever, translated into actual changes in the business practices of each stakeholder.

Meanwhile, in the Real World

Both sides of this debate have good reason to talk past each other: more than $87 billion in annual spending on specialty drugs is in play[5]; and for all the chatter in the healthcare industry about "partnering," "value creation,"

and "care optimization," the game is zero-sum. Neither side cedes its high ground, drug manufacturers keep launching new drugs, and healthcare payers keep launching new benefit designs, pushing an ever higher share of costs onto patients. All the "happy talk" about value creation is rarely, if ever, translated into actual changes in the business practices of each stakeholder.

In 2014, we were back to the top of the cycle. The drug industry found renewed hope in the form of specialty pharmaceuticals.[6] Specialty drugs are roughly defined as bioactive, large-molecule entities that involve highly specialized and sensitive manufacturing, distribution, and clinical administration.

Most specialty drugs are either injected by a provider or at least are delivered to patients in a controlled-care setting. Specialty drugs are used to treat serious, chronic, or life-threatening conditions; are typically priced significantly higher than traditional, small-molecule drugs; and generally do not have a low-cost generic equivalent.[7] The estimated annual costs for these drugs may be several thousand dollars to more than $100,000.[5]

The majority of specialty drugs are not discretionary and cannot be dismissed as mere lifestyle improvement drugs; many of these drugs represent significant medical innovations in their clinical realms.

A relatively small patient population uses specialty drugs, but the per-patient costs are significant. In 2012, specialty drug spending was approximately $87 billion in the United States, comprising an estimated 25% of the total drug spending and representing an estimated 3.1% of the national healthcare spending.[5] CVS Caremark identifies a key challenge of double-digit growth in specialty pharmacy drugs driving the overall rise in pharmacy spending, noting that approximately 3.6% of their members who use specialty drugs account for 25% of the plan's healthcare costs.[6]

The current cycle of conflict over drug prices and costs will keep stakeholders distracted for a time while the market grinds its way toward a new equilibrium. However, this cycle will most likely be of limited duration, because of the extreme cost factor associated with specialty drugs, critical differences in the clinical need for those drugs, and insurance coverage guarantees instituted by the Affordable Care Act (ACA).

The majority of specialty drugs are not discretionary and cannot be dismissed as mere lifestyle improvement drugs; many of these drugs represent significant medical innovations in their clinical realms. In many cases, these drugs are the only hope for seriously ill patients and represent true scientific breakthroughs. The extreme cost factor also pushes the rock of specialty drug costs against the hard place of out-of-pocket maximums that were put in place by the ACA, which seeks to expand coverage to those with no health insurance, as well as to ensure catastrophic coverage.

The larger part of the problem for payers may not be a specialty drug's high cost for a treatment course as much as the total growth of this cost in the aggregate. We now have new or relatively new specialty drugs to treat cystic fibrosis (ivacaftor [Kalydeco], at a cost of $294,000 per annual cost[8]); lupus (belimumab [Benlysta], at $35,000 per patient annually[9]); and multiple sclerosis (fingolimod [Gilenya], at $48,000 annually[10]). But these are specialty drugs for specific diseases, and they represent an epidemiologically contained part of the aggregate economic problem. The bigger economic threats associated with specialty drugs are those applicable to broader patient populations.

Currently, the archetypal example is sofosbuvir (Sovaldi), which has been proved to cure, not simply manage, hepatitis C infection, but at a cost of $84,000 for the treatment course (or $1000 per tablet).[11] This price inspires gasps among people both inside and outside the commercial and public payer communities, but those inside these communities understand that the greater economic issue is not sofosbuvir's price as much as the aggregate cost it represents for a payer's population. Because hepatitis C affects a large population and is communicable, this lightning rod is not a discretionary drug. There are few good reasons not to make sofosbuvir widely available to this patient population; for example, using rigorous utilization mechanisms to prevent access to a drug with sufficient clinical evidence of its efficacy in the absence of any other curative treatment is not reasonable from a business or a clinical perspective.

Sofosbuvir may be the lightning rod, but the storm rages on across the spectrum of specialty pharmaceuticals. How is a payer to parse the value of narrow innovations, such as ivacaftor for cystic fibrosis, versus larger population innovations, such as sofosbuvir for hepatitis C? To date, the response has been to lump all these innovations and their costs into 1 bucket, and to add a higher formulary tier for more expensive drugs, or a specialty pharmacy benefit, which is precisely what payers did in the early 2000s.

Back to the Future

Why should a payer pay for healthcare? The practical answer for any healthcare payer organization is that they have no good reason to pay. Individuals or their employers move from one payer to another, or they go in and

out of Medicaid, and all of a given payer's investment in their members' health "moves" with them. A big investment today in an innovative specialty drug will not reap long-term savings for most payers; the US healthcare system is not set up to provide healthcare payers with the upside of long-term savings, because there is no long-term in relation to private healthcare payers.

If a patient has the resources to overcome administrative obstacles erected by payers to deflect these forced investments, the payer ends up fully on the hook for the cost of the therapy anyway, a therapy with a diffuse economic impact that does not benefit the payer who pays, but the next payer and every payer thereafter, and either the patient's employer, a private disability carrier, or society at large.

This is the same problem we deferred a decade ago, when innovative drugs and their associated costs inspired the first round of cost-sharing. But the question is as acute and important as ever: how do we pay the upfront costs of innovation for any given patient when the benefits of that innovation accrue to almost everyone but the one initially tasked with paying?

Financing Fixes for the Economic Disconnect in the US Healthcare System

Is there a solution to this perennial "disconnect" between the interest of healthcare payers and the interests of everyone else? Broadly speaking, yes—by not asking the payer to pay for everything upfront, it may benefit everyone else.

There are 3 methods under which drugs can be financed to reduce their direct, immediate cost burden to payers and to other healthcare stakeholders with annual budgets:

1. The first method involves the amortization of an expensive drug's costs over time[12]

2. The second method advocates a carve-out reinsurance model, which is applied to high-cost drug treatment regimens, such as those for very high-cost or catastrophic illnesses

3. The third represents the reward of a declining copayment over time with the demonstration of patient adherence to therapy.

These 3 methods serve to distribute the cost burden over time and across the healthcare system, while matching the financial burden of the innovation to those stakeholders who capture their overall value. Further, these methods can engage patients to be more accountable in the mechanics of their medical care, particularly when their only treatment alternative is an expensive therapy. All these methods have been originated or suggested in recent months by others[13-15]; we have not invented them, nor are we announcing them here or purporting to model them in this forum.

Our goal in this article is to articulate these methods in the context of the historic struggle over paying for drug innovation, as summarized above, and to expose these potential solutions to the broader health policy community.

High-Cost Drugs Mortgages

The amortization of a high, front-end cost over time is a relatively simplistic model that has been in existence for a long time. In the United States, mortgage models for financing the purchase of property date back to the early 1900s.[16] Early home mortgages were difficult to secure, because many banks felt that it was too risky to lend more than 50% of an appraised home. Consequently, not many people could afford a mortgage.

To stimulate the marketplace and to offer protection, the National Housing Act of 1934 created the Federal Housing Administration and the Federal Savings and Loan Insurance Corporation to help make home mortgages more affordable while providing depositors in federal savings and loans with security.[16] The intent was to encourage private-sector banks to issue loans while the income from mortgage insurance premiums covers the cost of the program so that financial support would not need to come from the government.[16]

Financing mechanisms should be revised to take into account the elimination of downstream, long-term costs when a cure or a drug that leads to a cure comes to market.

Aside from the current political environment in Congress, one could imagine that applying this type of model to finance the cost of drugs and reaching into the economic territory long inhabited by new homes is not an unimaginable course of action. If the benefit of therapy is to extend a patient's life and/or to improve the patient's quality of life, then payments can and should be matched accordingly.

The idea of amortizing high-cost drugs over a period of time was first articulated in the context of cancer drugs in 2003,[13] but this idea has also emerged in numerous private discussions since the launch of sofosbuvir. In July 2014, Scott Gottlieb, MD, of the American Enterprise Institute (AEI), discussed the idea of amortizing high-cost drugs in a policy brief,[14] followed by an AEI panel discussion headed by Dr Gottlieb and titled "How Will We Pay for the Cost of Cures?"[15]

The AEI panel included Gregg H. Alton from Gilead Sciences; Dirk Calcoen, MD, from Boston Scientific Group; Mark B. McClellan, MD, PhD, from the Brookings Institution and former FDA Commissioner; and Dan Mendelson, Founder and Chief Executive Officer of Avalere Health, a health policy company. The panel

discussed the challenges related to paying for drugs that yield a cure, and generally reached consensus that financing mechanisms should be revised to take into account the elimination of downstream, long-term costs when a cure or a drug that leads to a cure comes to market.[15]

At the panel discussion, Mr Mendelson noted that pharmaceutical companies are interested in participating in and shaping value-based care models. He added that drug manufacturers would like to explore arrangements to manage populations of patients, including taking risk for health outcomes; however, they are impeded from doing so by the Best Price provision in the Medicaid Drug Rebate Program.[15] The program requires manufacturers to enter into a drug rebate agreement with the Secretary of the US Department of Health & Human Services.[8] In return, state Medicaid plans will cover most of the manufacturer's drugs.[8]

The rebate for innovator drugs is currently the greater of 23.1% of the average manufacturer price (AMP) per unit or the difference between the AMP and the best price per unit, and is adjusted by the Consumer Price Index-Urban based on the drug's launch date and the current quarter AMP.[8] As a result, if a manufacturer enters into a contract outside of the Medicaid program in which the price is less than that provided under the Medicaid Drug Rebate Program, a wholesale change in price would need to occur to ensure that the best price was offered to Medicaid.

In this reinsurance model, the economic challenge posed by high-cost drugs would be carved out from traditional insurance benefits.

The AEI panel proposed an implementation model that "would allow a payer to spread out the costs over the period during which it would accrue the benefits of the reduced downstream costs from disease averted."[14] Specifically, it outlined a model in which a healthcare payer enters into an agreement with a drug manufacturer, with terms that enable the payer to allocate the costs of the treatment in prescribed milestones, while the manufacturer allocates revenue on the same schedule or based on agreed-upon financing measures.[14]

One way to galvanize the effectiveness of this financing model would be to separate the total cost of a specific drug into discrete milestones, in which the milestones follow the patient across multiple payers and over time while tracking health outcomes. This would either neutralize the diffusion of economic benefits (as we referred to previously) or the payers' and employers' recognition that they lose the long-term savings derived from their payment for a high-cost drug when the patient changes insurers or employers, or goes in or out of the Medicaid program.[17]

In addition, if the prescribed health outcomes set forth in peer-reviewed clinical trials are not realized, milestone payments could be stopped before the payment for a full course of therapy. A medical team would then be consulted to make changes to the prescribed therapy, to see if any treatment alternatives should be considered to improve the health outcomes of the patient.

Potential Obstacles

Although amortization preempts healthcare payers from having to provide immediate lump-sum payments, this model has several obstacles that would need to be addressed before launching it to a large patient population. First, clear clinical milestones would need to be created for each drug candidate who meets the standard of "high cost." Second, the method for triggering payment for achieving the milestone, or not triggering a payment if the milestone is not achieved, would need to be designed. Although a milestone tracking tool could be integrated into today's rapidly evolving electronic medical record systems, it would be difficult to create the link from the electronic medical record to a payer's claims system.

As a result, an approach to test the amortization model is recommended. A demonstration project that surmounts this obstacle would occur within an integrated payer–provider system, such as the larger and more viable accountable care organizations emerging today, and could be used to test the model with a defined patient population that is prescribed a particular specialty drug, such as patients with hepatitis C who are receiving sofosbuvir.

High-Cost Drugs Reinsurance

The second financing model involves a form of reinsurance, also known as stop-loss coverage, but in the context of healthcare it would be applied only to drug costs. In this model, the high aggregate costs of drug treatment for an individual patient are borne by a risk pool of multiple payers. The reinsurance risk pool reimburses payers for the portion of claims incurred by high-cost patients, the same way reinsurance does now for very high-cost healthcare claimants in general.[18] The concept is not all that different from reinsurance today, but with a lower attachment point (ie, the amount an insurer pays until supplemental insurance coverage comes into effect) for specific high-cost drugs, or an individual aggregate amount for patients with total drug costs past an attachment point, for example, $25,000, or some other breakpoint around which specialty pharmaceutical costs tend to cluster.

In this reinsurance model, the economic challenge posed by high-cost drugs would be carved out from traditional insurance benefits. Individualized medication management techniques could be used before the patient reaches the need for catastrophic care management.[19] Reinsurance serves to mitigate the risk of covering very high-cost patients and is currently used as a part of Medicare Part D; however, reinsurance is scheduled to be phased out between 2014 and 2016.[18]

Exploring how this model could be redesigned to manage high-cost drugs moving forward could help to spread the drug cost over more stakeholders, while ultimately improving patient care through more vigilant medication therapy management.

This high-cost drug rebates model avoids the controversy surrounding who gets assistance, and whether such patients are circumventing the drug utilization management process put in place by payers.

High-Cost Drugs Patient Rebates

The third model involves rebates by a healthcare payer or a succession of payers to patients with large cost-sharing burdens for high-cost drugs after the completion of, or milestones along, a course of treatment. Currently, drug manufacturers sponsor copayment assistance programs to provide financial assistance to patients who are not able to afford their copayment and are covered by commercial insurance. Similarly, copayment foundations exist to provide assistance to publicly insured patients who are facing economic obstacles to their needed medications.

There has been discussion about whether a drug manufacturer's effort to assist with patient cost-sharing benefits an individual patient to the detriment of the larger patient population in the insurer's risk pool, by subverting the drug formulary and discouraging the use of less costly generic drugs.[20] For therapies that do not have less costly treatment alternatives, these programs provide much needed assistance.

This high-cost drug rebates model avoids the controversy surrounding who gets assistance, and whether such patients are circumventing the drug utilization management process put in place by payers. In this model, all patients would start with standard specialty drug tier placement and cost-sharing amounts. But as patients demonstrate that they are adhering to the therapy, and their health outcomes mirror the published clinical data, the copayment would decrease over time to reward patients for actively participating in their medical care.

For some chronic disease states, it may be foreseeable that the copayment would drop to $0 as an adherent patient decreases downstream healthcare costs for his or her then-payer. Furthermore, if health outcomes are not being realized, the patient's care could be reviewed to determine if a different therapy may be more appropriate, thereby introducing medical therapy management to patients before they become nonresponsive to treatment, or before their illness progresses.

Potential Obstacles

Obstacles exist for operationalizing the rebate model. As with the amortization model, electronic medical record and payer claims systems would need to be modified to trigger the reductions in copayments, or the model would be limited to integrated payer–provider systems (ie, working accountable care organizations).

A pilot to test the feasibility of this model would require an integrated payer–provider type of system, as well as investment in systems to track agreed-on health outcomes to payments.

A Call to Action

The goal of proposing these models in this context is to provide a workable and lasting solution that directly addresses what is now a perennial problem—the misalignment of incentives between payers confronted with the high upfront costs of innovative specialty drugs and the rest of the healthcare system. These models are market-derived and would and should be market-driven, and they do not require acts of Congress to take effect.

Innovative new treatments designed to address serious diseases in targeted patient populations represent the future of medicine. Traditional payment methodologies need to change to keep pace with medical innovation.

All 3 models are voluntary, and the introduction of one model need not preclude the other. All 3 models work within or replicate the current marketplace mechanisms for distributing immediate high-cost events across multiple at-risk parties and/or encouraging active participation by patients as consumers. The most feasible and expeditious way to implement these models is through existing channels in the healthcare system, and not through the creation of new entities.

These models on their own do not address the largest challenge of all, which is the need for drug manufactur-

ers, payers, and physicians to acknowledge that there is a problem and to work together in a collaborative way to create a feasible solution that can be put into operation. Agreement between these various stakeholder groups would be required to implement any of these models to explore changing benefit structures, as well as existing coverage and payment mechanisms. This is no small task, because it confronts traditional economic conflict and cultural hostility between these groups, and many cynics would say it is an impossible task to achieve.

These represent financial and insurance innovations pegged to the problem we are lucky to have—a surge of complex and expensive new medicines to fight diseases against which, until now, we were defenseless.

A possible instigator of this necessary change may not be either party, but the real third party that is ultimately responsible for funding the other 2 parties, the employer. As more employers are shifting risk to employees, many are investing in tools to help employees become more effective consumers of healthcare. There may be no inherent incentive for drug manufacturers, payers, and physicians to come to agreement in today's world, but perhaps the employers who ultimately pay for what they all do will be the impetus for the change required to give workforces access to the best possible medicine in a more economically rational way.

Innovative new treatments designed to address serious diseases in targeted patient populations represent the future of medicine. Traditional payment methodologies need to change to keep pace with medical innovation. For specialty drugs, amortized payment, reinsurance, and copayments that decrease over time with evidence of patient compliance are 3 ways in which payments could be redesigned to support the development of innovative new drug therapies, to make them more accessible to patients, and to enable medical management by payers.

However, the management of drug payment alone is not the panacea for improving public health. It is necessary to take this discussion further to create revised linkages between the 4 items that govern patient access to new drugs:

1. The cost of drugs
2. Benefit structures
3. Coverage policies
4. Payment.

Payment reform without changes to the overall cost of drugs, benefit structures, and coverage may create conflicting incentives that could nullify the intended aims of payment reform to reach the maximum quality, efficiency, and innovation in care.[21]

Conclusion

The implementation of the 3 models suggested in this article would ameliorate perennial economic conflict in the US healthcare system over the value of, and financial responsibility for, the large swath of medical innovations embodied in new specialty pharmaceuticals. These represent financial and insurance innovations pegged to the problem we are lucky to have—a surge of complex and expensive new medicines to fight diseases against which, until now, we were defenseless. ■

Author Disclosure Statement

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STAKEHOLDER PERSPECTIVE

Financing Drug Innovation: Cost versus Cure

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DRUG MANUFACTURERS: The pharmaceutical industry has a problem. The cost of developing new drugs has soared, but insurers are increasingly unwilling to pay the price that manufacturers charge. Sofosbuvir (Sovaldi), a breakthrough treatment that cures hepatitis C but has an $84,000 price tag for a 12-week course of treatment, is the poster child for this tug of war over who should pay and how much. As we enter an era in which advanced specialty drugs become increasingly important, will patients continue to have affordable access to potentially life-saving treatments, and will pharmaceutical companies continue to have the financial incentive to continue their expensive research programs?

POLICYMAKERS: In their current article, Kleinke and McGee point to an inherent defect in the way that we finance healthcare that threatens to choke off the development of innovative new pharmaceuticals.[1] Drugs that have a long-term payoff in terms of patient health are paid through insurance that takes a short-term view of the cost–value trade-off. Drugs such as sofosbuvir are investments in good health that pay off over the course of many years, but that require large upfront expenditures.

Kleinke and McGee suggest 3 reforms that could reduce the impact of those upfront costs on payers and keep specialty pharmaceuticals within reach of patients. Long-term loans akin to home mortgages would spread the financial burden of high-cost drug therapy over a period of years rather than requiring a single large payment in the first year. Reinsurance would spread the cost over everyone in the insurance pool rather than imposing an unreasonable financial burden on the patient. Requiring patient adherence to the therapy to qualify for a rebate adds a performance element to the existing rebate system, which spreads the cost over the patient population of the pharmaceutical company.[1]

These proposals are attempting to hit a moving target. Insurers are taking aggressive action to limit their financial exposure to high-cost drugs. Complicated multi-tiered drug formularies are proliferating, with specialty pharmaceuticals relegated to the fourth and fifth tiers that require sizable out-of-pocket payments by the patient.

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Avalere Health found that some health insurance exchange plans place all drugs used to treat complex diseases—such as HIV, cancer, and multiple sclerosis—on the highest cost-sharing tier.[2] For example, in 2015, 60% of silver plans place all antiangiogenic agents (which stop the growth of blood vessels in tumors) in the specialty tier.[2] To the extent that they have drug costs temporarily under control, insurers will not be eager to make more radical changes in the financing mechanism.

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ment approach for high-cost drugs cannot be overstated. To be successful, all payers and drug manufacturers would have to agree on the principles behind whichever scheme is chosen, and on the details. The former is difficult; the latter may be impossible without unprecedented cooperation between insurers and drug manufacturers, because a small change in almost any specification can be advantageous or disadvantageous.

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Defining which drugs are deemed "high cost," and establishing rules for how that list of drugs will change over time, will be the subject of permanent controversy. Similarly, deciding how much financial burden should be placed on the patient, and how to enforce payment obligations that may extend well into the future, will be critical to the success of a new financing approach.

Kleinke and McGee state that each of the financing models is market driven and would not require an act of Congress to take effect.[1] Regrettably, that is not likely to be the case. Medicare and Medicaid are the biggest payers in the healthcare system, and any changes in private financing will inevitably be subject to scrutiny, and ultimately approval, by the federal government.

The problem of high upfront costs is most obviously an issue for the pharmaceutical industry, but it reflects a broader problem in the healthcare sector. There has long been widespread agreement that we should better coordinate and manage the care of patients, which is essential if we are to fully account for the long-term benefits and offsetting financial burden of high-cost treatments, but few health insurance plans have been able to accomplish this successfully.

That may be about to change as we develop the capacity to track and analyze detailed information on patients and their care, over time, through "big data."[3] Health insurance plans will soon be able to tailor their policies with a longer-term perspective and demonstrate that cost-savings will result. This opens up employers as another potential ally to help change the financing mechanism, because a cost-effective investment in healthcare means a healthier and more productive workforce.

PAYERS/PATIENTS: Perhaps the biggest obstacle to the adoption of any of the new drug financing models is that they redistribute the cost but do not lower the price of a high-cost drug therapy. In each model, the upfront cost is spread more widely, so that it is not borne solely by the patient and his or her insurer. That is a sound insurance principle, but without lower drug costs, payers and the public are unlikely to find it acceptable.

Indeed, even with a system that spreads the financial burden of high-cost drugs over more people and over time, we will still "break the bank," unless more fundamental changes are made in the way we finance and deliver healthcare. ■

1. Kleinke JD, McGee N. Breaking the bank: three financing models for addressing the drug innovation cost crisis. *Am Health Drug Benefits*. 2015;8:118-126.
2. Pearson CF; for Avalere Health. Exchange benefit designs increasingly place all medications for some conditions on specialty drug tier. Press release. February 11, 2015. http://avalere.com/expertise/life-sciences/insights/avalere-analysis-exchange-benefit-designs-increasingly-place-all-medication. Accessed April 28, 2015.
3. Bates DW, Saria S, Ohno-Machado L, et al. Big data in health care: using analytics to identify and manage high-risk and high-cost patients. *Health Aff (Millwood)*. 2014;33:1123-1131.