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A Prescription for Savings: Reducing Drug Costs to Medicare

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Introduction

Mr. Chairman Kohl, Mr. Ranking Member Corker -- thank you for the opportunity to testify before this Senate Committee.

Over the past decade, the drug space stands apart from other segments of the healthcare industry in terms of how much the underlying business model has changed. The life science sector has undergone a fundamental transformation to focus on delivering more value and more basic innovation to consumers.

These economic tenets – value and innovation – are now firmly embedded in considerations of which new drug products and new companies get taken forward. In part, this transformed business model is a consequence of well-designed government policies that have made the marketplace for drugs more competitive.

Industry pipelines also have more new compounds in late stage development than at any time before. More of these experimental drugs are derived in part, or wholly from profoundly new areas of drug science such as regenerative medicine, genomics and proteomics, and humanized immunotherapies. More of these new drugs are aimed at fundamentally new targets and more address unmet needs in medicine. Many are targeted at niche conditions or smaller subsets of common diseases.

The price of creating this innovation continues to rise, in part because development costs have exploded. But the drug prices paid by consumers and health plans have – on the whole – moderated to a level closer to overall inflation. Generic drug utilization has also reached all time highs. Nearly 75 percent of all prescriptions filled in the U.S. are for generic drugs, a number that will continue to rise.

These low cost generics are available only because investments were made in the original development of an innovative drug in the first place – a drug that subsequently lost its patent protection. This is a unique feature of the drug market that makes it one of the most competitive parts of the healthcare industry. The ability of innovative products to be brought forward, and subsequently be subject to generic competition once patents have expired, is also a feature on which public policy has become dependent. Low priced generic medicines are dependent upon the initial investment that made the original innovation possible.

Biologics, which represent some of the most breakthrough innovation taking place today, are also going to benefit from this cycle of innovation and generic competition. New legislation to create a pathway for follow-on versions of biologics will provide for more price competition in this technology segment. Taken together, there are many positive developments when it comes to competition in the drug industry, the delivery of value, and the ability of patients to access new technologies.

The economic framework for delivering value when it comes to new drugs is more firmly established than at any point in recent years as a result of competitive forces

that are sweeping the drug industry. The firm footing for this framework is also a consequence of the regulatory process. Medical products are one of the few consumer goods that must undergo pre-market approval before consumers can use them. They are one of just several products that must submit data demonstrating safe use and effectiveness to the government, and must undergo an extensive review process, prior to being cleared for sale. As such, compared to other consumer goods and even healthcare services, there is an extensive amount of information available about how medical products can be used most effectively.

But despite recent progress, challenges remain. There are still consumers who are priced out of healthcare. There are still cases where reasonable people could argue that a drug's price does not approximate the clinical value that is being delivered to an individual patient. The cost of developing drugs is rising at an unsustainable pace. New company formation in the biotech sector has dwindled. The overall cost of healthcare continues to rise. Too many diseases remain poorly treated.

So we must craft policies that provide proper incentives for new technology while making sure that we are getting more value for programs like Medicare.

Today I would like to outline some policies that I believe are working toward achieving these goals, in particular, the recent success of Part D. I would like to comment on some proposals to lower drug prices that are currently before this committee – proposals that I believe will undermine our recent progress, and otherwise create more ill effects relative to any benefits that they deliver.

Finally, I want to outline some proposals that I hope this committee considers. One of these is the idea of folding the medical drug benefit into the prescription drug benefit under the Medicare program -- merging the Part B and Part D drug schemes.

There are many challenges to this kind of scheme that would need to be carefully considered. It would not be a straightforward policy change. But properly designed, this reform would mirror changes taking place in the private insurance market. It could also foster greater price and brand competition, and reduce or eliminate peculiar constructs that have the potential to get in the way of making sure patients are getting the most clinical value out of the drugs they are prescribed.

Part D, Price Competition, and Consumer Benefits

Any discussion of policies that have worked to bring more price competition to the prescription drug market, and lower overall spending, has to begin with Medicare's "Part D" prescription drug program. Competition between more than 1,000 drug plans has resulted in costs that are substantially less than what was first envisioned, wider use of generic medicines than at any time, and discounts on branded drugs that have facilitated access and helped save money for seniors and taxpayers.

The Congressional Budget Office originally estimated that Part D would cost taxpayers $551 billion between 2004 and 2013.[i] The actual cost was much less. Federal outlays for the drug program, netting out premiums paid by enrollees and Medicaid payments made by states, totaled $214 billion through 2010. By 2013, we will have spent a total of $375 billion on the drug program. This sum is 32 percent less than what the Congressional Budget Office originally estimated.

A new report from the IMS Institute for Healthcare Informatics -- titled "Medicare Part D at Age Five: What Has Happened to Seniors' Prescription Drug Prices?" – tells part of the story. It shows the experience of drug prices in the major therapeutic drug classes that are used by seniors. The report finds that inside the Part D program, the average daily costs of therapy for eight of the top ten therapeutic drug classes fell on a sustained basis between 2006 and 2010.

Specifically, between January 2006 and December 2010, the average daily cost of therapy in the ten classes identified in the report declined by more than a third, from $1.50 to $1.00. With some widely used drugs coming off patent over the next several years, IMS projects that the average daily cost of therapy in these classes will continue to decline, reaching $0.65 by the end of 2015. This represents a cumulative 57 percent decline in the cost of these drugs since January 2006.[ii]

Critics argue that these savings are an artifact of one-time events, and not a result of increased market competition for how drugs are priced – competition that has been sparked by the Part D program. More specifically, they argue that the savings are really the result of lower than expected enrollment in the Part D program and a larger than expected number of costly, blockbuster medicines losing patent protection and becoming cheap generics. According to my AEI colleague Joe Antos, an economist who held leadership positions at both the Congressional Budget Office and the Centers for Medicare and Medicaid Services, neither factor accounts for the disparity between the CBO estimate and actual experience in the Part D program.

Antos observes that to gauge the size of the enrollment effect, one could multiply the additional number of people assumed by CBO (7.1 million, a number that has been relatively constant over time) by CBO's estimate of the federal cost per enrollee ($1,600) for each year. That totals about $92 billion through 2013, or only about 17 percent of the cost difference.

If anything, this is probably a conservative estimate. That's because many of the people not enrolled in Part D probably choose to forgo the drug insurance because they are not on any expensive, chronic use medications.[iii] In other words, their annual cost would be much less than the $1,600 figure. Thus they don't view the drug coverage as representing a good deal for them.

In short, overstated enrollment could be said to contribute to some of CBO's original prediction of higher costs. But clearly other factors are more important.

Moreover, comparing Medicare's spending trends with that of the entire health sector shows that the slowdown in drug spending inside the Medicare program was greater than the slowdown in drug spending outside the Medicare program. Antos notes that this suggests that an expiry of patents, which benefited all consumers equally, cannot explain the smaller-than-expected cost of the Part D program.

Competition between the Part D plans has to be a significant factor in the lower-than-expected cost of the program. CBO and the Medicare actuary don't take full measure of these competitive impacts because they don't have actuarial experience measuring these effects. Competitive behaviors such as: discounting by drug companies eager to secure preferred placement on drug plan formularies; drug plans that squeezed margins to gain market share or ran their plans as a loss leader for entry into other business segments; or drug plans that aggressively pushed generic substitutes as a way to lower premiums, cut costs, and boost profits.[iv]

As Mr. Antos notes in a recent article, had Part D been structured like traditional fee-for-service Medicare, then none of this would have happened. If we paid for each individual prescription the way we pay for each individual health service, there would be no incentive for drug plans to encourage the use of generics over brands. Indeed, economic and political incentives would drive out low-cost drugs in favor of products with higher profit margins in a cost-plus payment environment.[v]

Part D: Delivering Benefits System Wide

The economic benefits of Part D's competitive structure aren't confined to the Medicare program. They spill over into the rest of the commercial market, partly as a result of the additional discounts that prescription drug plans are able to secure for their members – discounts that apply across a drug plan's entire book of business. This delivers additional savings to consumers of private health insurance.

According to one recent estimate, on average, Part D has lowered retail prices for non-Part D commercially insured patients by 5.8 percent. The estimated external cost-savings to the entire commercial market amounts to $2.6 billion per year.[vi]

The authors found that the larger the number of Part D beneficiaries an insurer enrolled, the steeper the discounts a plan was able to secure. Enrolling an additional 100,000 Part D beneficiaries enables an insurer to negotiate 2.1 percent lower prices for non-Part D seniors (5.4 percent lower for generics and 0.3 percent for brands) and 1.8 percent lower prices (3.7 percent for generics and 0.35 percent for brands) for non-seniors enrolled in commercial plans that also participate in Part D.

Overall, Part D lowered retail prices for non-Part D elderly by 8.5 percent (19 percent for generics and 0.9 percent for brands). Part D likely led to bigger price discounts on drugs commonly used by the elderly. This is why elderly enrollees not in Part D realized larger price declines than the commercially insured non-elderly.[vii] The experience in Part D might have also had implications for the commercial drug

market's use of generics. The shift toward generics among the elderly in Part D may have caused physicians to change prescribing behaviors for all their patients.[viii]

In addition to the direct economic savings realized by the price competition that has ensued as a result f Part D, the increased drug utilization among seniors that resulted from Part D has also helped to improve health outcomes among the elderly, saving money for other parts of the Medicare program.

One recent study[ix] found that for conditions sensitive to medication adherence, hospitalization rates for Medicare beneficiaries declined more in states that saw the biggest coverage gains due to the implementation of Part D, relative to states with smaller Part D-induced changes in drug coverage. Comparing changes in hospitalization rates from 2005 to 2006 and 2007 (relative to changes among the near-elderly, who did not experience a change in benefits), Part D reduced the overall rate of hospitalization by 20.5 per 10,000 (4.1 percent), or by 42,000 annual admissions across eight medication sensitive conditions that were studied.

The authors speculated that if the results were extended to the entire over-65 Medicare population this would represent an aggregate reduction of 77,000 annual hospitalizations across those eight medication-sensitive conditions. Part D did not affect incentives for hospitalization, so any changes related to Part-D induced changes in drug coverage are likely due to changes in underlying health status.

Another study found that while enrollment in Part D was associated with increased direct spending on prescription drugs; other healthcare savings compensated for much of these outlays. Specifically, groups of enrollees that had no or minimal drug coverage before the implementation of Part D had reductions in other medical spending that approximately offset their increased spending on drugs.

That study found that after two years of enrollment in Medicare Part D, enrollees that had no drug coverage had increased their monthly drug spending by $41, but that outlay was roughly offset by a decrease of $33 in their monthly medical spending. The authors speculate that this was due to the fact that increased use of medication led to improved control of chronic illnesses. The same fact was observed for beneficiaries who had some drug coverage, but not enough to provide a full range of prescription benefits. For example, those seniors whom previously had a $150 quarterly cap on drug spending increased their spending by $27 once they enrolled in Part D. This was offset by a decrease of $46 in their medical spending.[x]

Proposals Being Considered by this Committee

These are some of the positive developments from policies that were put in place with this Committee's help less than eight years ago. As budget pressures mount, however, we are forced to consider additional ways we can make sure Medicare is continuing to get value for what it spends on drugs. I want to take a moment to provide some thoughts on a few of the proposals that I expect we will discuss today.

Some of the same data that I cite above, demonstrating the health benefits that accrue to patients from their appropriate use of prescription medicines, also underscores why issues of access are so important. While the price of drugs, and access to them, are distinct policy issues, in a world of mounting deficits and finite resources they cannot be divorced from one another. So as we discuss ways to ensure continued access to affordable drug coverage, we also need to take measure of the cost of developing medicines in the first place, how drugs are priced as a result, and how we make sure we continue to bring new drug innovations to market.

First, I want to comment on some of the recent proposals to import pharmaceutical price controls into the Part D benefit. These include recent suggestions to extend the Medicaid Best Price to the dually eligible Medicare and Medicaid beneficiaries who are enrolled in Part D, as well as those receiving a Low Income Subsidy (LIS). These mandatory rebates are a form of drug price controls that serve to distort market prices. The more that price controls creep into the Part D program, the more we erode the commercial forces that have made that market highly competitive.

One example: mandatory rebates create a strong incentive for companies to launch drugs at higher prices in anticipation of the payments that they will have to provide to the states and the federal government. These rebates also discourage additional discounting. Moreover, as more beneficiaries come under these kinds of tacit price control regimes, it will erode the ability of health plans to use competitive negotiations to move their market share and improve profit margins. This will, in turn, reduce their incentive to try and drive hard bargains with drug companies.

Once the Part D plans become fully commoditized insurance products – a reality hastened by the introduction of price controls into this market – plans will have little incentive to compete by negotiating discounts with drug makers. The Part D plans will, in essence, become price takers rather than price negotiators.

As Antos notes in a recent working paper that he co-authored with Guy King, if proposals for mandatory rebates in the Part D program are adopted, patients will ultimately bear the cost. Higher-income seniors who are not eligible for Medicaid or other Part D subsidies would feel the immediate impact. As drug plans respond to the new financial and regulatory incentives, enrollees who qualify for Medicaid or other low-income subsidies also could find fewer attractive options. The plans that continue to offer coverage to LIS enrollees without an additional premium are likely to have tighter formularies and less access to newer or more expensive drugs.[xi]

I know members of this Committee have also considered proposals to expand the authorities of Medicare to enable the Medicare program's staff to take clinical criteria into consideration in how they make payment and coverage decisions. I am talking here about constructs such as Least Costly Alternative authority.

In particular, some have postulated that these authorities could be combined with the capacity for CMS to demand clinical information, or develop its own clinical studies and comparative effectiveness research, to turn the coverage process into one resembling the FDA approval process – where CMS uses its interpretation of clinical data to make more granular decisions about what it choose to pay for.

There is nothing inherently wrong with a payer carefully judging the clinical data supporting the use of a particular medical product or service to determine what it will reimburse. But there are some things very particular to Medicare that makes the program no ordinary payer, and its decisions no ordinary matter.

One problem is that CMS has no tradition of making these kinds of decisions. As a consequence, it has little capacity to engage in these kinds of judgments. But the issue is larger than just hiring a bunch of clinical experts to make these decisions.

If Medicare were to engage in making clinical judgments about new technology at the time of first introduction, to deny reimbursement in cases where the clinical data is still not firmed up, it would undermine the way innovation unfolds in life sciences. In many instances, much of the innovation takes place post-market as new technologies are introduced and demonstrate additional benefits from real world use. Demanding early lifecycle demonstrations of value, however measured, skews heavily against this sort of post market innovation. Yet it's this post-market experience that is a big part of how clinical medicine has historically advanced.

We should consider how past treatments that we now recognize as profound advances would have fared under an LCA policy. We should also consider how such a construct would affect future decisions. An LCA process would invariably skew investment decisions, creating a binary hurdle that new technology would need to clear, much like the FDA approval process. This would invariably discourage investment decisions; not only because of the hurdle itself but the fact that the novelty of this requirement would mean that it would hard for investors to handicap this new hurdle. Investment shuns uncertainty, and this creates plenty of ambiguity.

The interplay of LCA authority with IPAB would present particular problems. IPAB could effectively confer CMS with LCA authority, in a wholesale fashion or around specific products or services. Yet IPAB was purposely constructed to be opaque and unaccountable. These elements were designed into the agency's constitution. The ability of this new agency to target individual services, products, and procedures with little accountability would create a high degree of uncertainty in the marketplace and represent a fundamental unfairness to Medicare stakeholders.

In addition, Medicare is not an ordinary payer. Its decisions are widely followed in the private market. It often sets a ceiling on what private payers are willing to cover.

As such, Medicare has a disproportionate impact on what patients in the U.S. will have access to. In turn, the program's practices are widely tracked in the Venture

Capital community and on Wall Street, where investors carefully weigh how they believe Medicare will treat a new medical product when making decisions to invest in a new technology in the first place. In short, the decisions Medicare makes have wide impact. They reverberate through the entire healthcare sector.

As a consequence, it is important that Medicare is more transparent, more judicious, more rigorous, and yes, in many cases more generous, in how it covers new technology. Medicare's coverage process serves as a de-facto gatekeeper to what patients will have access to in many cases. If we want new technology to advance and its application be optimized through ordinary clinical practice, Medicare has to allow new technologies to reach the market in the first place.

Yet the proposals that have been put forward would turn the coverage process into a more opaque, less rigorous construct. For example, some proposals would allow these decisions to be meted out by an independent and largely unaccountable advisory board. Others would see CMS relying on comparative effectiveness data that is not rigorous enough to form the basis of firm clinical judgments and would be summarily rejected by FDA if it were used as the basis of a regulatory filing.

Innovation in the Balance

We need to continue to pursue policies that aim to deliver more value for Medicare beneficiaries. But we must also consider the impact of these policies on investment in new drug development and continued life science innovation. The economic model that has fueled the investment necessary to endow the U.S. with the lion's share of the world's life science activity remains fragile, and is more in doubt than perhaps ever before. As we consider steps to implement policies that affect how drugs are priced, we should understand that biotech investment model better.

The cost of drug development has gone up significantly. Even while total R&D spending by a consolidating industry still continues to rise, and venture flows have remained level, the number of experimental drug programs that are being funded by this spending has shrunk. The result is that while the existing pharmaceutical industry consolidates, and acquires successful biotech firms for their products, the amount of new biotech company formation has fallen off sharply. There is a long lag time between investment in an early-stage venture and the payoff in terms of a late stage drug candidate. But make no mistake, these business trends will eventually show up in the form of fewer drugs being put into late stage development.

This phenomenon is worth considering, because the policies we are discussing here today could have implications on the investment model. New costs could further erode the ability to fund new drug development ventures, and start new companies.

Many of the costs are regulatory. According to some recent analyses, the actual direct costs of the clinical development of a new drug can approach $500 million.[xii] [xiii] The cost of some recent development programs have topped $1 billion in direct

costs for new cardiovascular drugs, a therapeutic class that often requires especially large trials as a result of clinical and regulatory factors. One example is the new super aspirins approved for the treatment of stroke and acute coronary syndrome.

The new antiplatelet drug Brilinta was compared to Plavix in a trial that enrolled 18,624 patients hospitalized with acute coronary syndrome during a median treatment of nine months.[xiv] A similar drug, Effient, was studied in several significant trials. The largest of these studies enrolled 13,608 patients and compared its effects to the blood-thinning effects of Plavix in patients with a threatened heart attack or an actual heart attack and about to undergo coronary angioplasty.[xv]

Trials of this size are mammoth economic investments, not only to the drug makers but also to society.[xvi] Each patient enrolled in a pivotal study adds more than $30,000 to the cost of the trial. A single pivotal trial can easily top several hundred million in direct costs. These costs get baked into the retail price of the drug.

Combine the increased cost of development with some other factors that are affecting the biotech investment model.

First, more of these regulatory costs are front-loaded. In other words, proportionally speaking, the spending on early stage development has risen more sharply than the cost of late stage development.

Second, the "value creation" stage in life sciences has been pushed out much further as a result of regulatory uncertainty that has increased the risk of late-stage failure. Before a novel phase II drug asset had substantial value, and biotech companies could raise capital around reaching such a milestone. Now a company must often take a promising new drug candidate into phase III clinical trials to be able to monetize the development program by selling the asset or raising capital from the public markets to fund its continued development. This means that raising the capital to fund development programs has become more difficult, and expensive.

Finally, layer on top all of this the declining patent life of new compounds. The average duration of intellectual property protection around new molecular entities is continuing to decline (it's now less than 13 years) as a result of recent policies aimed at encouraging generic competition and generic drug entry.

This is, in short, a perfect recipe for undermining a field of scientific innovation: Front load the regulatory costs, push out the value creation stage, and diminish the window in which entrepreneurs have to earn back a return on their investment.

Arbitrary policies to impose controls on certain prices, or penalize certain drug classes and individual compounds, impose more uncertainty and discourage investment capital from flowing into this industry. It drives up the cost of development by increasing the cost of capital needed to fund new innovations.

Now don't get me wrong. The news isn't all-bad when it comes to our vibrant life science industry. It's just that the investment model that has endowed the U.S. with a vibrant life science sector is fragile. The creation of this industry is one of our singular achievements. It has been the result of private and public capital and it is something that we should be mindful to preserve as we debate policies about how we try and influence the pricing of the products that result from these endeavors.

It's true that venture capital continues to flow into the life sciences. People are still making big bets on new science. Data on venture capital flows into various industries are tracked by an annual survey jointly published by Price Waterhouse Coopers and the National Venture Capital Association. The good news is that venture capital money continues to flow into life science ventures. These investments accounted for nearly 30 percent of the $21 billion invested in venture-backed companies in 2010. Moreover, the returns on these investments have been strong over time, a reason why investors continue to make bets on new drugs. [xvii]

But there is a cautionary tale. It is something that can be observed anecdotally from those who follow the biotech industry. Nearly 60 percent of biotech initial public offerings from the past four years are trading below their issue price versus about 30 percent of tech IPOs. Moreover, post-IPO, the performance has been dramatically better for the IT companies than it has been in Life Sciences. IT companies that get public tend to be more mature business with revenues and often-significant earnings; in biotech, most companies remain cash burning for a very long time, precisely because the development programs have become so long, and so costly.

This difference in IPO results is important. Healthcare companies usually require substantially more money to get to an answer than other kinds of venture capital investments. To fund a new drug program these days can cost about $200 million of capital to get to a "value creation stage" where investors can monetize a successful endeavor. As a result, some smaller venture capitalists are exiting this space. Even bigger firms that can write bigger checks are nonetheless often looking at new models of investing that don't require new company formation. Rather than start a new biotech company to develop a new concept or a family of promising drug companies, some investors are looking to fund drug development in a one-off fashion, creating virtual companies around individual compounds.

The result is much less new company formation, less big bets in the life science sector. As the great lions of the biotech industry – Genentech, Genzyme, Millennium – are themselves absorbed by larger pharmaceutical companies, there are fewer new biotech companies being formed to create the next crop of great American life science companies. The great hubs of biotech start-ups such as San Diego are starting to look more like biotech ghost towns. This will have an impact on employment in this sector, and it will eventually have an impact on pipelines.

Proposal: Merging Part B and Part D

Policies that encourage more price competition, and more clinical competition between similar drugs attacking similar diseases or targets, can help drive more value for beneficiaries while encouraging the sort of scientific competition that could lead to more, not fewer, opportunities for new innovations. Which gets me to the idea of merging Medicare's drug and medical benefits – folding its Part B program for drugs administered in the doctors' office into the Part D program.

There is good clinical and economic rationale for providing drugs under a single, unified program. Many private plans have already merged the drug and medical benefits. Folding Part B into Part D could provide substantial savings to Medicare. The savings would be a result of greater therapeutic substitution between oral and injectable drugs as well as more price competition between similar drugs.

Doctors would no longer have to choose an injectable therapy over an oral alternative because of concerns about whether a patient can afford a co-payment. With more oral agents competing with injectable agents to target the same biological mechanisms and same diseases, there's no reason why artificial economic constructs should be weighing on decisions about which drug to employ. These decisions should be based solely on the clinical question of what's best for patients.

It's true that there are many drug targets that are best attacked in injectable drugs. But for those that can be approached by both oral and injectable agents, there are plenty of reasons why injectable drugs often have advantages owing to their ease of use for the patient, and the lower cost to Medicare of administering a drug orally. Paying for drugs under one policy scheme would level the playing field and make scientific considerations the only factor in how to attack a particular disease.

Now moving Part B into Part D is enormously complex, and full of potential for damaging, unintended consequences. It would need to be considered carefully. It is also not worth doing if it only invites more temptation to import price controls into the resultant drug program. This is a competitive reform, but it will only work to lower prices and drive more high value use of drugs if drugs are allowed to compete with one another in reasonable and competitive market-based framework.

Moreover, not all of this savings would actually accrue to Medicare. Some of it would need to be used to help offset the rise in premiums and out-of-pocket costs incurred by beneficiaries in the form of higher Part D co-pays and program costs. Medicare would also have to create new physician payment codes to compensate doctors directly, at a fair and sustainable rate, for the cost of infusing drugs in their offices.

Conclusion

Right now, the custom of paying doctors by allowing them to keep a spread on the drugs they infuse creates incentives for all of the wrong kinds of behavior – higher launch prices, more use of the costliest biological drugs even when there are

cheaper alternatives, and a penalty for companies that discount their medicines by ultimately increasing the cost to the physician who chooses to infuse a cheaper drug.

The drugs that are in late stage development right now, and that have been launched in recent years, are perhaps more promising than at any point in recent memory. The Wall Street Journal recently took note of this trend in a recent front-page news article.[xviii] "Because developing drugs takes many years, changes in how companies approach the process take a long time to show effects," the paper reported. "Today's new-drug output appears to mark the beginnings of a payoff from a research reorientation the industry began undertaking several years ago."

This innovation is by no means a sure bet. The model that has made our life science successes possible remains in doubt. The decisions that we make about how we regulate the development of these products, and pay for their costs, have direct and prompt effects on whether or not these endeavors get undertaken in the first place.

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[i] These costs, projected at the outset of the program, were expected to be offset by an estimated $142 billion in lower federal payments to state Medicaid programs

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[iv] The average profit a pharmacy earned on generic drugs is $2.25 higher than for brands

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