Health Reform Accelerates Changes In The Pharmaceutical Industry

ABSTRACT The Patient Protection and Affordable Care Act makes major changes to the Medicare prescription drug benefit, reducing drug costs for many seniors and increasing rebates and other costs for industry. Although these changes will affect prescription drug costs and pharmaceutical companies’ profits, they are unlikely to alter the trends already reshaping the pharmaceutical industry. By participating in crafting health care reform, instead of opposing reform as it did in 1993, the pharmaceutical industry avoided some potential threats to revenues and made accommodations that limited the overall federal costs of reform.

Despite representing just 10.1 percent of overall national health care spending, pharmaceuticals had a central role in the politics and policy of the recent debate over health care reform. Pharmaceutical companies that make brand-name drugs remain highly profitable by most measures, but many signs of stress emerged in the decade prior to the passage of the Patient Protection and Affordable Care Act of 2010. Profits from companies’ existing products were slashed when patents expired and competition from generic drugs quickly eroded sales. Drug safety challenges rocked the industry. In addition, brand-name companies faced tougher price regulation from governments worldwide. In the United States, increased competition among health plans and pharmaceutical benefit managers also cut into companies’ profits.

In response, the brand-name companies have engaged in a furious round of consolidation. Pfizer absorbed its longtime rivals Wyeth and Pharmacia; Merck merged with Schering-Plough. These moves were designed to cut costs and acquire pipelines of promising compounds, and they resulted in job cuts even in research and development positions. Companies are re-orienting their research to seek new medicines in areas that offer more pricing flexibility, including cancer and other serious conditions for which there are currently few effective treatments.

In addition to traditional pharmaceutical companies, the biotechnology industry has also suffered. This sector consists of a few large companies with major products and many small companies with ideas and hopes for major new drugs. They have all been hit by the current economic slowdown and the associated reduced supply of investment capital.

The story has been quite different for generic drug companies such as the industry leaders Teva, Mylan, and Watson. In the United States, the acceptance and use of generic medicines has expanded greatly. Generics now make up 75 percent of all prescriptions but only 21 percent of prescription drug spending.

For the pharmaceutical industry, health care reform will occur within this already changing and challenging environment. This context helps explain the extraordinary political role that pharmaceutical companies played in the legislative debate that preceded the enactment of the Patient Protection and Affordable Care Act—a role very different from the one they played in 1993–94, when the Clinton administration tried and failed to enact reform.
The Deal
If the health reform debate was a political poker game, the brand-name drug industry entered 2009 with a poor hand. The industry was closely associated with Republicans after years of political support and perceived partnership in enacting the Medicare Prescription Drug, Improvement, and Modernization Act and its Medicare prescription drug benefit in 2003. Six years later, with Democrats in control of the White House and both chambers of Congress, the brand-name industry perceived that it had few powerful allies to help block reform provisions that were not in its interests.

PROVISIONS ALREADY UNDER CONSIDERATION
A number of such provisions opposed by the pharmaceutical industry were actively under consideration. President Barack Obama campaigned on the promise to rein in drug company prices by having the government negotiate bigger discounts for prescription drugs purchased through Medicare Part D. Rep. Henry Waxman (D-CA), chair of the House Energy and Commerce Committee, proposed requiring companies to pay new rebates on medicines purchased for low-income Medicare beneficiaries. And the president and many members of Congress had long sought to legalize the importation of medicines at lower, government-regulated prices from Canada and other countries.

As a result, the brand-name industry faced the prospect of a year of relentless criticism from Democrats and their supporters, along with further erosion of already weak public and political support. Recalling the long-term damage to the industry’s reputation that followed its opposition to the Clinton health care plan, industry leaders were reluctant to be depicted as scapegoats and enemies of reform—labels that were pinned on health insurers instead.8

With few attractive alternatives, the brand-name industry was willing to consider a rapprochement with Democratic leaders in the hope of limiting the possible harm from a new health reform law. And so a deal was struck. For the Obama administration, the agreement guaranteed that the brand-name pharmaceutical companies would not reach into their deep pockets to fund efforts to oppose reform.

ANNOUNCING AN AGREEMENT On 22 June 2009, President Obama announced an $80 billion agreement among the industry, the administration, and Sen. Max Baucus (D-MT), chair of the Senate Finance Committee.9 Negotiated behind the scenes, primarily by Senator Baucus, the details of the agreement became clear only later that summer, after the Finance Committee’s health reform bill was unveiled.

The agreement led Senator Baucus and the Obama administration to oppose drug importation and new rebates on drugs for Medicare beneficiaries. In exchange, the industry made a series of pledges, including to provide a mandatory 50 percent price discount on drugs purchased by beneficiaries of the Medicare drug benefit who were affected by the coverage gap, or so-called doughnut hole, of the Part D program. Created to help lower the projected federal costs of the program, the coverage gap means that with the exception of low-income beneficiaries, most Medicare beneficiaries must pay 100 percent of their drug costs after their annual prescription spending exceeds $2,830. Medicare drug coverage resumes when individual annual drug spending reaches $6,440. Just under one-quarter of all non-low-income beneficiaries experienced some spending in this gap in 2008.10

In addition, the agreement included a substantial increase to the mandatory “rebates” on sales of prescription drugs to the Medicaid program. In effect, these are forced price discounts. The industry agreed to raise the Medicaid drug rebate from 15.1 percent to 23.1 percent of the average manufacturer’s price for brand-name drugs (limited to 17.1 percent for certain clotting factors and drugs approved exclusively for pediatric use). Perhaps more significant, the industry also agreed to extend the rebate obligations to drugs used by Medicaid enrollees in Medicaid managed care organizations. These drugs had previously been excluded on the theory that the private plans would negotiate their own rebates. Now, plans may continue to negotiate rebates on top of those required by the new law.

Furthermore, the agreement included substantial and unprecedented annual fees, collected like a tax, to help offset the cost of expanding coverage in health reform (see Exhibit 1). The underlying notion was that the industry would in effect be “taxed back” some of the additional profit it would make as millions more people became insured and, arguably, used more prescription drugs. The fee is set to raise $28 billion during the first ten years of health reform and is based on each company’s share of sales to federal government programs. Makers of generic drugs face no similar fee.

POLITICAL RESPONSES This multiprong agreement was far from universally popular among Democrats and was in fact roundly critiqued by Obama’s ally Henry Waxman, the House Energy and Commerce chair. It was also opposed by several Republicans, including Sen. John McCain (R-AZ).11 Yet the ensuing months of debate failed to alter the basic elements of the agreement, and it made its way into the final reform legislation largely intact.

Indeed, in the final health reform legislation,
## Key Pharmaceutical-Related Provisions Of The 2010 Health Reform Legislation Affecting Medicare And Medicaid

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<tr>
<th>Provision</th>
<th>Target</th>
<th>Impact</th>
<th>Financial impact</th>
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<tr>
<td><strong>MEDICARE</strong></td>
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<td><strong>Coverage gap discount:</strong> beginning in 2011, brand-name drug manufacturers to provide a 50% discount on drugs purchased in Part D coverage gap</td>
<td>Part D beneficiaries in coverage gap</td>
<td>Will reduce costs for Rx purchased in coverage gap; should increase use of brand-name Rx initially but will lower manufacturer revenues from Rx sold in coverage gap</td>
<td>Estimated to cost brand-name manufacturers $32 billion over 10 years in net cost of new discounts and increased sales; estimated federal cost is $17.8 billion over 10 years*</td>
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<td><strong>Coverage gap subsidy:</strong> phased in over 10 years, a subsidy of 25% for brand-name drugs, 75% for generics purchased in the coverage gap, for Part D plans</td>
<td>Part D beneficiaries in coverage gap</td>
<td>Including brand-name discounts, will limit all cost sharing in standard Part D plans to 25% for brand-name and generic Rx</td>
<td>Estimated federal cost is $19.8 billion over 10 years*</td>
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<td><strong>Coverage gap rebate:</strong> 2010 only, $250 payment to any Part D beneficiary who has drug expenses in coverage gap</td>
<td>Part D beneficiaries in coverage gap</td>
<td>Will provide some immediate help to those with costs for medicines in coverage gap</td>
<td>Included in estimate for coverage gap subsidy*</td>
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<td><strong>Retiree drug coverage tax changes:</strong> beginning in 2013, reduces amount employers can deduct for providing Rx coverage to retirees by amount of federal subsidies they receive for such coverage</td>
<td>Retirees of approx. 3,500 employers that receive federal subsidies for providing retiree Rx coverage</td>
<td>Long term, could cause some employers to end retiree Rx coverage and lead more retirees to join Part D plans</td>
<td>Estimated to save $4.5 billion over 10 years†</td>
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<td><strong>Reduced Part D premium subsidy for high-income beneficiaries:</strong> beginning in 2011, raises Part D premiums for them</td>
<td>Beneficiaries with incomes exceeding $85,000 a year for individuals and $170,000 a year for couples</td>
<td>Increased cost to a subset of beneficiaries, possible abandonment of coverage</td>
<td>Estimated to save $10.7 billion over 10 years*</td>
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<td><strong>Cost sharing for preventive services:</strong> beginning in 2011, no cost sharing for such services covered by Medicare</td>
<td>All Part B beneficiaries</td>
<td>Should encourage more use of preventive services, early diagnosis, treatment</td>
<td>Estimated to cost $800 million over 10 years‡</td>
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<td><strong>MEDICAID</strong></td>
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<td><strong>Minimum rebate increase:</strong> beginning in 2010, raises min. rebate to 23.1% on brand-name and 13% on generic Rx</td>
<td>Drug companies providing Rx to Medicaid</td>
<td>Will reduce revenues from brand-name Rx that pay min. rebate; will reduce generic company revenues</td>
<td>Estimated to generate $38.1 billion in savings over 10 years, to accrue to federal government‡</td>
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<td><strong>Rebate extension to managed care:</strong> companies must pay rebates to states on Rx purchased through risk-based, MCOs</td>
<td>Drug companies providing Rx to Medicaid through MCOs</td>
<td>Will reduce revenues from sales to Medicaid enrollees; may lead some states to add drugs to managed care plan services</td>
<td>Included in the estimate for minimum rebate changes above</td>
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**Source** Author’s analysis. Notes This exhibit has been abridged for space. An unabridged version is available as Appendix Exhibit 1, which can be accessed by clicking on the Appendix Exhibit 1 link in the box to the right of the article online. FDA is Food and Drug Administration. MCO is managed care organization. *Congressional Budget Office. Letter to Speaker Nancy Pelosi [Internet]. Washington (DC): CBO; 2010 Mar 18 [cited 2010 May 27]. Available from: http://www.cbo.gov/ftpdocs/113xx/doc11355/letterno_co הנוכ_2010.pdf 1 legislator’s amendment in the nature of a substitute to H.R. 4872, the “Reconciliation Act Of 2010,” as amended, in combination with the revenue effects of H.R. 3590, the “Patient Protection And Affordable Care Act (PPACA),” as passed by the Senate, and scheduled for consideration by the House Committee on Rules on March 20, 2010 [Internet]. Available from: http://www.jct.gov/publications.html?func=download&id=3672&chk=9363318c356952fc6096748d291e2f9c&no_html=1 2 See Note 1 in text.

the agreement to provide a 50 percent discount on drugs for beneficiaries in the Medicare Part D coverage gap was not only preserved, it was sweetened. Congress pledged additional government subsidies that, when combined with the mandated company discounts, will close the coverage gap by 2020, so that beneficiaries at that point will pay only their plan’s standard 25 percent copayment on drugs (see Exhibit 1). Although generic drug manufacturers were
not required to provide discounts to individuals in the coverage gap, the law does include provisions that will reduce the cost of generics to beneficiaries. Increased subsidies to prescription drug plans will enable them over time to reduce beneficiaries’ cost sharing for generics in the coverage gap, from 100 percent now to the standard 25 percent by 2020. This change is likely to add momentum to the shift to generics that has occurred since passage of the Medicare Modernization Act.

Impact Of Changes
For patients, health reform will mean more coverage. That in turn will mean more coverage for pharmaceuticals in the required benefit packages of insurance policies available through state exchanges beginning in 2014. As noted, many Medicare beneficiaries will face lower cost sharing in the coverage gap starting next year. And in the long term, patients broadly will gain access to lower-cost versions of today’s biologics.

Other Health Reform Provisions
FOLLOW-ON BIOLOGICS Another set of changes in the new health reform legislation will also have a major impact on the pharmaceutical and biotech industries. The changes will create a new pathway for the approval of competitive versions of biological medicines, also known as biologics. These include drugs such as Herceptin, a monoclonal antibody used in fighting breast cancer, and erythropoetin, a protein that stimulates blood production. These “large molecule” biologic medicines, unlike their “small molecule” chemical counterparts, are not easily copied. But until health reform was enacted, the Food and Drug Administration (FDA) had no legal authority to approve a new biologic without requiring full clinical trials. The practical effect was that any biologics approved thus had a permanent franchise, in stark contrast to the booming generics market for small-molecule drugs.

The new law, however, creates a regulatory pathway for the FDA to approve so-called follow-on biologics—those with properties similar to existing medicines. The exact requirements for approval of follow-on products are to be worked out by the regulatory agency, but they are likely to require less extensive testing than would be required for a brand-new biologic. The law also grants a twelve-year period of so-called market exclusivity to the medicine’s original creator. During this period, competitors cannot use the data generated in producing the original product to produce a competing product.

Just how long that period of exclusivity should be was the subject of considerable debate during the months and years that preceded the enactment of health reform. The biotechnology industry views the twelve-year period as a barely sufficient amount of time for it to recoup the investment in product development and therefore serve to encourage continued research. On the other hand, many outside the industry view the period as excessively long and unnecessary. For now, the impact of these provisions on the prices that manufacturers will get—and that insurers and patients will pay—for these specialized and often very expensive products remains unclear.

NEW INSTITUTIONS Pharmaceuticals will also come under the influence of two new institutions created by the Patient Protection and Affordable Care Act. A new Patient-Centered Outcomes Research Institute is charged with funding studies on the comparative effectiveness of a range of medical and health interventions, including medicines. Conclusions drawn from such studies could ultimately have a substantial although indirect influence on whether and what drugs will be covered by health plans, and what prices purchasers will be willing to pay. Many in the pharmaceutical industry are concerned that the institute’s studies will ultimately curb innovation and keep drugs off the market. Still others think that the institute’s structure under the law—as a nonprofit, nongovernmental institute with a broad-based board of stakeholders—will enable it to strike a balance more favorable to innovation over time.

Still another new entity created under health reform, the Independent Payment Advisory Board, could have a far more direct impact on pharmaceutical coverage. The advisory board will have substantial authority to force changes in policies under Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP) to meet mandated cost reduction targets. That could include changes in Part D that could further ratchet down the prices for drugs.
Many of the massive changes discussed in this article began to reshape the pharmaceutical industry decades before health reform. Because of the much lower cost sharing, that increase will not compensate manufacturers for the cost of the 50 percent discounts.

**Cost to Industry** There’s no doubt that $105 billion over ten years will represent a sizable cost to the industry, but in context, its impact should not be overly burdensome. U.S. brand-name prescription drug sales totaled more than $226 billion in 2009. The Centers for Medicare and Medicaid Services (CMS) Office of the Actuary estimates that during the first ten years after the enactment of health reform, total public and private pharmaceutical spending will equal $3.4 trillion, the vast majority of which will be for brand-name drugs.

At the same time, it is practically impossible to estimate other effects of the legislation on the pharmaceutical and biotech industries. It’s unknown whether expanding the number of people with health coverage will lead to greatly increased pharmaceutical sales, especially given the fact that some of the newly covered are likely to be healthier than the current covered population. In addition, although many millions of Americans will gain coverage through Medicaid, their drugs will come with mandatory rebates that are even larger than before. One estimate of the increase in brand-name sales projects them to be a mere $11 billion over ten years—a tiny increment compared to existing sales.

Undoubtedly, the impact of the law will vary by industry sector and by company. The ability to license follow-on biologics could prove a boon to some makers of generic drugs but may also create new opportunities for brand-name companies with the expertise and technology to compete for this new market. For makers of generics, the new law should not alter in any major way the existing trends toward more use of generic medicines as brand-name medicines’ patents continue to expire and their makers continue to struggle to invent new medicines that are better than their old ones.

**Conclusion** In sum, many of the massive changes discussed in this article—consolidation, pricing pressures, and competition from generics—began to reshape the pharmaceutical industry decades before health reform. After reform, the fate of brand-name companies will remain tied to their ability to increase research productivity, to adapt to increasing pricing pressures, and to reduce their reliance on the U.S. market. In economic terms, the impact of the health reform law on them is arguably modest. Only the course of implementation and future legislative debates will determine whether the law will fundamentally change the future of the pharmaceutical sector’s patients, payers, and companies.
NOTES


