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Impact of the New US Health-Care-Reform Legislation on the Pharmaceutical Industry: Who Are the Real Winners?

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Abstract

Over the past two years, the US pharmaceutical and biotechnology industries were preparing themselves for passage of some type of health-reform legislation with a clear appreciation—and concern— about the enormous impact any law would be likely to have on the structure and viability of the research-based industry. Now, with final passage in March 2010 of the patient Protection and Affordable Care Act and its companion "quick-fix" and budget bill, the Health Care and Education Reconciliation Act, it is a good time to take a look at how the industry fared and assess how the various provisions of the health-care reform bill might affect the industry's long-term prosperity and growth.

This task is made somewhat complicated, of course, by the fact that certain provisions will not take effect for several years, others will require significant rule making and implementation programs by the US Department of Health and Human Services, and still others may never see the light of day. In fact, legal actions, foot dragging at the state level, or party-in-power reversals could cause significant delays or major revisions to the legislation. Nonetheless, there is much that can be gleaned from what is currently included in the new law.

For the sake of this Commentary, we consider separately the impact of the legislation on large, generally multinational pharmaceutical companies (Big Pharma) and on small, start-up, and mid-tier pharmaceutical and biotechnology companies (small and mid-sized enterprises, or SMEs). Let us begin with Big Pharma, keeping in mind that SMEs, especially the biotech start-ups, do not operate in a vacuum; for example, 50% of investment in biotech and 25% of biotech revenues came from Big Pharma as of the early 2000s (ref. [1]).

At first blush, Big Pharma looks like a big winner in the new world of health-care-reform law. Having agreed early in political negotiations to contribute any-where from an estimated $80 billion to $105 billion in fees, rebates, and discounts to help move the legislation forward,[2,3] Big Pharma managed to avoid punishing provisions on at least a half dozen big-ticket items that had been held over the industry's head for most of the past decade, and it seemed certain to find its mark with the change of political parties in 2008. In exchange for Big Pharma's support, both monetarily and politically, the legislation avoided contentious issues, such as drug reimportation, government authority to negotiate drug prices for

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CONFLICT OF INTEREST

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Medicare Part D, and prohibition of pay-for-delay deals between manufacturers of brand-name and generic drugs. These issues are unlikely to disappear, however, and may resurface as Congress begins debate on the 2012 reauthorization of the Prescription Drug User Fee Act.

There is also the matter of the market-place, where Big Pharma again appears to have fared well with the new legislation. Of the nearly 50 provisions of the health-care-reform law that affect drugs and biologics, approximately 20 are likely to have the direct or indirect consequence of increasing the volume of product sales. By adding 32 million formerly uninsured citizens to the ranks of new customers (at least putatively) and as much as $115 billion in new business over 10 years,[4] the legislation's impact on the industry's bottom line is likely to be significant. Of course, some of those provisions will also create or expand business for generics and biosimilars, mostly at the expense of Big Pharma. Moreover, another major economic downturn, like the one recently seen, or a costly public health emergency, such as a protracted H1N1 pandemic, could act as a clarion call for Congress to come to the rescue (again)—perhaps calling for support from Big Pharma's deep pockets.

Many of those 20 provisions of the law affecting sales volume also require the industry to discount prices (either directly or indirectly because of the differences in out-of-pocket price vs. the government price) or to give rebates (e.g., the basic Medicaid rebate for brands increased from 15.1 to 23.1%, retroactive to 1 January 2010). Nonetheless, this trade-off still leaves the industry with a projected $10–35 billion profit over 10 years. It is worth keeping in mind, however, that speculative though it may be, what the industry will pay into the system is still more certain than what its payout will be, given the vagaries of predicting profits in the long term with point estimates. Moreover, some analysts believe that intervening events such as the rate of growth in health-care costs and the imminent insolvency of Medicare and Medicaid will force the government to play a more proactive role in controlling industry profits. The result, as some suggest, is likely to be that the "mandate for coverage increases the likelihood of substantive *discussions* about cost containment" [5] (italics added). Several provisions already in the law leave the door open for such discussions, including the Independent Payment Advisory Board, which can recommend cost control measures to Congress or enact them if Congress fails to take action, and a provision in the law that allows the Centers for Medicare and Medicaid Services the discretion to establish criteria for determining classes of drugs for which Part D plans would have to cover all or substantially all drugs in a class.[6] For example, there are currently six "protected" drug classes required for Part D plans; how restrictive the prerequisite will be for new classes can affect the reach of Medicare expansion.

Turning to SMEs, what will be the impact of the new health-care-reform law on this sector? Mostly it bodes well. SMEs will have to pay comparatively little up front, relative to Big Pharma, and will accrue significant and sustained benefits over the long term. For example, the prescription drug manufacturers and importers who sell products to government health-care programs will have to pay out almost $30 billion in fees over the next 10 years but pay on only 10% of sales up to $125 million, graduating to 100% for sales over $400 million; companies with total sales of $5 million or less will not be required to pay any fee.[6] Another estimated $30 billion will be contributed by the biopharmaceutical industry through deep discounts off the negotiated price of branded drugs to fill the Medicare prescription coverage gap, known as the "doughnut hole" (the final $20 billion of the $80 billion low-estimate pharma tally comes from the Medicaid rebate previously mentioned). Filling the doughnut hole is a major boon to Big Pharma but also to SMEs, because of the latter group's large and growing investment in the specialty-care marketplace. Under Medicare Part D, specialty-tier prescription drugs are typically composed of injectable, branded drugs with a minimum cost of $600 per month and are often indicated for special purposes such as enzyme replacement,

blood modifiers, and transplantation.[7] According to a new US Government Accountability Office (GAO) report, specialty drugs account for much of the out-of-pocket spending by Medicare recipients; the GAO determined that 55% of Part D enrollees who used at least one specialty-tier drug reached "catastrophic" levels of out-of-pocket spending, compared with only 8% of all Part D beneficiaries who filed claims but did not use any specialty-tier drugs.[8] Representative Pete Stark (D-CA), chairman of the House Ways and Means Committee's Health Subcommittee, had noted that the best way to address this disparity would be to fill the doughnut hole.[9]

A critical provision of the legislation, with substantial benefits for SMEs, awards a 12-year period of data exclusivity for new branded biologics, as part of a compromise for the implementation of a process for approving biosimilars (i.e., follow-on biologics). (This type of compromise approach is similar to that incorporated into the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch–Waxman Act),[10] which provided research-based pharma companies up to 14 years of exclusivity in exchange for a streamlined approval process for generic versions of small-molecule drugs.) The impact, however, is likely to be delayed. The US Food and Drug Administration (FDA) must first work out the scientific requirements and regulatory pathway, a process that is likely to be complicated and contentious despite 10 years of preliminary discourse and precedents in other countries. Moreover, few SMEs currently have products on the market, and fewer still have had products on the market long enough to be at risk for nearterm competition from biosimilars. It is worth keeping in mind, however, that— by some estimates—50% of the current global development pipeline for new medicines is composed of biotech drugs, and many of these are being developed by SMEs. By virtue of the new law, latestage biologics will have added value as promising candidates for outlicensing to Big Pharma or as better investments to venture capital firms, who may be incentivized to stay in the game all the way to market because of the possibility of substantial return on investment from product sales. And, of course, the same return-on-investment principle could hold for the SMEs themselves.

SMEs may also realize some of the same benefits that all small businesses will realize from the health-care-reform law—the freedom to be entrepreneurs and innovators. Offering health-care benefits will no longer be a major recruiting advantage for big corporations or big government. This is likely to facilitate the growth of start-ups and spin-offs, because academic investigators and other entrepreneurs will be able to attract and retain experienced personnel without fear of losing their health benefits. In other words, "job lock" will not hold would-be entrepreneurs captive but instead will allow them to venture out on their own, assured that they will maintain medical coverage— with or without a preexisting condition — for themselves and their families.[5]

SMEs are often considered the seedbed of innovation, and in recognition of this fact, the legislation has both direct and indirect incentives to stimulate innovation in this sector. An example of the former is the two-year Qualifying Therapeutics Discovery Project Credit program, which provides up to $1 billion in tax credits for research expenses in tax years 2009 and 2010 for companies with 250 or fewer employees. It might seem that $1 billion would not go very far among the estimated 1,000 SMEs in this category. Actually, though, only about 20% of these companies will be eligible for the credit; the rest do not have taxable income or they have other tax issues that disqualify them.[11] Similarly, for companies that are developing orphan drugs, there are numerous provisions within the act that lessen the impact of—or actually exempt the companies from—various fees, rebates, and discounts. SMEs have come to dominate the orphan-product development area in recent years.[12] Orphan-product research and development is another area of high therapeutic value and innovation, with the percentage of new orphan-product approvals receiving priority-

review status (indicating that the FDA considers them an advance over what is currently on the market) increasing from 35 to 50% for new molecular entities and 17 to 67% for significant biologics over the past decade.[13] Orphan-product research and development has become an important source of new therapies for unmet medical needs and is rapidly developing into a mainstream subsector. This is highlighted by the doubling in the number of orphan designations granted by the FDA in the 2000s—from just over 200 at the start of the decade to 400 at the end—and the fact that approximately one-quarter of new drugs and biologics approved by the FDA over the past few years have been orphans.[13]

Other provisions of the legislation reward innovation indirectly, through comparative-effectiveness research (CER) measures. The most notable example is the Patient-Centered Outcomes Research Institute, which will develop comparative clinical evidence and methodological guidelines "to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions" when comparing medical treatments to determine those that are most effective and appropriate. [14] In addition, the law commissions the preparation of a host of reports and studies intended to inform future legislative and executive branch actions. Among these is one that seeks to determine whether adding quantitative benefit and risk information to promotional labeling would aid decisions by prescribers, payers, and patients. It authorizes the FDA to make regulatory changes based on its findings. These measures will attempt to sort out the best choices among several putatively equivalent therapies in competitive markets, but it will also increase the demand for high-value therapeutics addressing unmet medical needs, a sweet spot for SMEs. Moreover, the legislation benefits developers of adult vaccines by exempting these products from cost sharing, paying providers for implementing preventive care (including immunization reminders and outreach to low-income communities), and allowing the Department of Health and Human Services or individual states to purchase vaccines at negotiated prices.[6]

Finally, the new health-care-reform law is expected to create new lines of business in areas as diverse as medical information technology, education, retail stores, and methods of delivery.[5] CER and implementation programs based on CER findings will certainly get a boost as already discussed, but disease management is likely to experience a resurgence as well. For example, under Medicare Part B, providers will receive payment for creating an annual personalized prevention plan, including a list of all regularly prescribed medications and scheduled immunizations, which will aid compliance. Also, the Agency for Healthcare Research and Quality is authorized to provide grants to implement medication therapy management services provided by licensed pharmacists as part of a collaborative approach to improve the treatment of chronic diseases.[6]

In general, both supporters and critics of the new health-care-reform legislation feel that Big Pharma will benefit from the law's provisions. Indeed, when Congressman Henry Waxman heard that PhRMA, the trade association of primarily large pharmaceutical companies, had paid out one-third of the over $200 million spent by all sides in the media wars leading up to the bill's passage, he commented, "They're certainly going to get a very high return on that investment."[2] But…are they? It may well depend on who "they" are. The grand-prize winners in the health-reform legislation may well be the SMEs. If so, then we all stand to benefit from the booster shot to entrepreneurship and innovation.

References

1. Engel S. How to manage a winning pipe line. R&D Directions 2002;8:36–41.
2. Fram, A. The influence game: drug lobby's health care win. ABC News. 2010. <http://abcnews.go.com/Politics/wireStory?id=10227447>

3. Nussbaum, A. Drugmakers' overhaul costs $105 billion, Leerink says (update 1). Bloomberg Businessweek. Apr 27. 2010 <http://www.businessweek.com/news/2010-04-27/drugmakers-overhaul-costs-105-billion-leerink-says-update1-.html>
4. Smith, L. Pharma's reform bounce: how big a boost will $80 bil. buy?. The RPM Report. Sep 21. 2009 <http://therpmreport.com/Free/db79ab7c-1c40-4fe6-bb90-9b3ee1f65b9b.aspx?utm_source=RPMel>
5. Health care reform: not ready to be discharged yet. Knowledge@Wharton; Mar 31. 2010 <http://knowledge.wharton.upenn.edu/article.cfm?articleid=2457>
6. Steinke S. Timeline of pharma provisions in health care reform. The Pink Sheet March 29;2010 72:7–12.
7. Hargrave, E.; Hoadly, J.; Merrell, K. NORC at the University of Chicago and Georgetown University for the Medicare Payment Advisory Commission. Drugs on Specialty Tiers in Part D. Feb. 2009 <http://www.medpac.gov/documents/Feb09_DrugsonSpecialtyTiers_CONTRACTOR_RS.pdf>
8. US Government Accountability Office. Medicare Part D: Spending, Beneficiary Out-of-Pocket Costs, and Efforts to Obtain Price Concessions for Certain High-Cost Drugs. Mar 17. 2010 GAO-10-529T <http://www.gao.gov/products/GAO-10-529T>
9. Yoest, P. Specialty drugs force high Medicare out-of-pocket costs. Dow Jones Newswires. Mar 1. 2010 <http://www.advfn.com/news_Specialty-Drugs-Force-High-Medicare-Out-Of-Pocket-Costs_41779029.html>
10. Drug Price Competition and Patent Term Restoration Act of 1984. Public Law 98-417 (enacted 24 September 1984).
11. Yang, W. BioCentury, The Bernstein Report on BioBusiness. Vol. 18. Mar 29. 2010 Splitting up the $1B R&D tax credit; p. A-7
12. Milne CP, Tait J. Evolution along the government-governance continuum: FDA's orphan products and fast track. Food & Drug Law J 2009;64:733–753.
13. Kaitin, K., editor. Tufts Center for the Study of Drug Development Impact Report. January–February. 2010 U.S. orphan product designations more than doubled from 2000–2002 to 2006–2008; p. 12
14. The Patient Protection and Affordable Care Act. Public Law 111-148 (Sec. 6301 Patient-Centered Outcomes Research, Part D–Comparative Clinical Effectiveness Research, Sec.1181 (c) Purpose).