

» MARKET CHANGERS

REFORM, CONSOLIDATION, AND GOOD CITIZENRY

Our experts featured in this issue identify healthcare reform, mergers and acquisitions, and corporate reputation as three of the many market changers that will impact how the industry does business in the future.

HEALTHCARE REFORM: WHAT'S TO COME?

The year-long legislative endeavor to create a healthcare reform bill that all sides will agree upon took a step closer to reality as the latest version of the bill headed back to the floor for further discussion. The Senate Finance Committee's version, which passed on Oct. 13, 2009, completely omits a public or government-run health insurance plan, and would spend \$829 billion over the next decade to finance the expansion of Medicaid. It also sets out to provide federal subsidies to 18 million people who do not have coverage, extends health insurance coverage to an estimated 30 million Americans, and excludes an estimated 20 million illegal immigrants.

Our experts discuss the pros and cons of the proposed healthcare plans and how these may shape the market and how the industry does business in the future.

Pricing is Biggest Pain Point

Several of the proposals to finance healthcare reform will negatively impact pricing and result in financial pressures for life-sciences companies. The life-sciences community has been actively involved in the healthcare reform debate in an effort to expand health insurance coverage and to help find meaningful ways to reduce healthcare costs without adversely affecting federal pricing policy. However, it is widely expected that healthcare reform legislation will include changes to Medicare and Medicaid pricing policies, particularly for the pharmaceutical industry, as a means to pay for healthcare reform and the corresponding expansion in coverage.

"While there will be downward pressure on prices and increased rebate rates, there is also a huge opportunity to capture the increasing

Paul Boni
Grail Research



"The recent spate of mergers and acquisitions will not fundamentally impact the industry in the coming year, nor will these moves address the fundamental challenges companies face, including the slowing of innovation, dry pipelines, and increasing pressure from payers."

pool of new customers," says Dave Womelsdorf, Americas advisory leader, life sciences, at Ernst & Young. "Given all of the moving parts in the healthcare debate, companies need to stay on top of the proposed changes and be prepared to strategically respond when reform is enacted."

Patent Exclusivity Could be Reduced

Drug companies will likely have to adjust their strategy for commercializing drugs based on biologics in the future. Congress is likely to create a new FDA framework for the approval of biologics in the final bill.

"The current proposal seeks to limit patent exclusivity of biologics to 12 years versus the current 17 years for small-molecule drugs," says Sam Chakraborty, senior director at SSA & Co. "If enacted, this may reduce future profits due to the release of generics earlier in the market."

The current compromise bill has a provision that would raise about \$13 billion a year from fees paid by three sectors: pharmaceuticals, health insurance, and medical devices, Mr. Chakraborty says.

"Published analyses show that the pharmaceutical industry would have to foot a relatively small bill of \$2.3 billion, even though it is probably the largest and most profitable sector within the overall life-sciences industry," he adds.



Joseph Baron
Extera Partners

"I predict that M&A among big pharma and biotechnology companies will actually slow down in 2010. At the same time, venture capitalists are struggling to determine the most appropriate exit for their portfolio companies."

Payer Markets Could Gain Clout

Payers are becoming more directive about the care their patients receive, and the growth of electronic medical records and e-prescribing may bolster their ability to intervene in physician decision-making.

“As health reform may reduce the degree to which payers can compete through their underwriting approaches, we may see large payers use their clout to integrate more tightly with physician practices, and small payers retreat to compact networks that will also feature close payer-physician alignment,” says Steve Wunker, senior partner at Innosight. “With the ranks of the insured growing substantially in the next few years, we should expect PCPs and many specialties to be capacity constrained, and they may welcome payer interventions that boost productivity.”

Pharma companies can either cooperate with and influence these initiatives, or risk being pushed into a less-influential role in typical practices, he says.

Impact on the Supply Chain

The proposed change will drive better access to healthcare for a broader population and will cause companies to change the way that they operate to become more cost-effective, says Bill Hook, VP of global strategy, Healthcare Logistics, UPS.

“This will have a significant impact on the healthcare supply chain, as companies will now have to look for ways to serve more markets; the challenge is knowing that change is coming, but not being able to predict exactly what that change will bring,” he says. “Although concentrated in the United States, healthcare reform will have global implications, with an impact on pricing, how companies operate, how they anticipate change, and how they drive efficiencies going forward.”

Technology Innovation Will Decline

“There will be an inevitable reduction in healthcare dollars, resulting in only the cheapest technologies being adopted,” says Tom Steinke, CEO of Minnow Medical. “More expensive technologies, while better, will be squeezed from the marketplace. Since new innovations generally start out as more expensive in terms of recovering the development costs, these will be strongly discouraged, resulting in a substantial reduction in new medical technologies. These new technologies will not be given the chance to mature and become cost-effective, reducing the number and quality of healthcare options for our aging

Carolyn Buck Luce
Ernst & Young

“With the patent cliff ever closer, 2010 will be a critical year for pharma companies to demonstrate that M&A efforts have delivered value to shareholders.”



Dr. Ryo Kubota
Acucela

“Companies that can find access to capital through partnerships or M&As while also identifying a true collaborator will be the most successful.”

GLOBAL RISKS FACING LIFE SCIENCES

- One in four respondents believes that their entire company will have to change to address future risks; more than three-quarters recognize that their companies will have to undergo a major transformation, at least in some parts of the organization.
- 30% of executives surveyed from pharmaceutical R&D companies say their companies will have to change completely to face future risk.
- In Western Europe, where markets have experienced slow growth since 2001, 31% of responding executives call for a complete makeover of their companies.
- 82% of executives surveyed from biotechnology companies say that major changes will be needed in some or all parts of their company to address future risk.
- In the United States, nearly one in five survey respondents predicts that their organizations will have to undergo a wholesale transformation to address future risk.
- When asked to identify where they believe risk will rise most sharply in the next 10 years, respondents highlighted the areas of pricing and sales; marketing; regulatory affairs; talent management; and R&D.
- 40% of executives surveyed said that one of the biggest barriers to effective risk management between now and 2015 is identifying and assessing emerging risks. Success will require companies to understand those risks and plan to execute against mitigating them.
- 36% of responding executives identified pricing and sales as a key concern when asked which areas are likely to see the sharpest rise in strategic risk between now and 2015. More than half of the respondents based in Western Europe agreed. Additionally, 25% of all respondents said that marketing would also be an area of sharply increasing risk.
- 41% believe that between now and 2015, salesforces will become more versed in economic issues and adept at selling the economic virtues of products to patients, physicians, and payers.
- Tougher sanctions regarding patient safety continue to increase the costs of innovation, making regulatory affairs another area where risk is expected to rise sharply, according to 34% of surveyed life-sciences executives.
- Talent management was identified by more than 70% of respondents as an area where risk would rise moderately (38%) or sharply (33%).
- Today, R&D is at the root of the life-sciences industry's need for transformational change; 26% of executives surveyed — 39% in Western Europe — say the risks associated with R&D are set to rise sharply through the next decade.
- 44% say over the next decade, most discovery and early-stage research will be conducted outside large life-sciences companies. This sentiment holds true in the largest companies — with 52% of executives from companies with revenue of \$15 billion agreeing — as well as across sectors; 58% of respondents from pharmaceutical R&D firms and 67% from biotechnology companies also agree.

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KEY PRICING AND FINANCING PROPOSALS

The following are the pricing and financial proposals in the healthcare reform bill that will have significant ramifications for the industry.

Government Price Negotiation

- Requires the Secretary of Health and Human Services to negotiate drug prices on behalf of the public insurance option and to establish formularies.
- Requires the Secretary of Health and Human Services to negotiate drug prices with manufacturers for all covered Medicare Part D prescription drugs.

Changes to Medicare Prescription Drug Benefit (Part D)

- Eliminates the coverage gap (commonly referred to as the “donut hole”) under the Medicare drug benefit on a phased-in basis over several years.
- Requires drug manufacturers to provide 50% discounts for brand-name drugs and biologics used by Medicare drug benefit enrollees until the “donut hole” is eliminated.

Changes to Medicaid Drug Rebates

- Increases the minimum manufacturer rebates for brand-name drugs purchased by State Medicaid programs from 15.1% to up to 23.1% of average manufacturer price.
- Requires drug manufacturers to pay rebates to state Medicaid programs for enrollees in Medicaid managed care plans.
- Requires drug manufacturers to provide rebates to Part D enrollees who are dually eligible for Medicare and Medicaid.

New Fees on Life-Sciences Companies

- Imposes annual fees on drug and device manufacturers allocated by market share.

Source: Ernst & Young



Sam Chakraborty
SSA & Co.

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Tom Steinke
Minnow Medical

“Most new technologies weren’t always cost-effective when first developed, but addressed small niches. Those innovations will no longer make it to market under new environment, eliminating their possible iterations that might prove quite useful.”

population, which will have increasing demands on our healthcare system.”

MERGERS & ACQUISITIONS

Some experts believe M&A activity in the pharmaceutical/biopharmaceutical arena is just getting started.

Nick Colucci, president and CEO of Publicis Healthcare Communications Group (PHCG), predicts that the next wave of transactions will be midsized companies — \$500 million to \$800 million in revenue — absorbing smaller entities with single products that

generate \$150 million to \$300 million in revenue.

“With enough revenue and shareholder value to go it alone, watch for a new wave of leader companies to emerge,” he says.

Ripe for the Picking

Nicholas Landekic, president and CEO of PolyMedix, says any small-to-medium-sized company that is generating revenue will have a big bull’s-eye on it.

“As patent expirations continue to deflate sales, big pharma companies will be increasingly willing to trade their balance-sheet assets for anything to prop up the income statement,” he says.

The recent spate of industry M&As has further blurred the line between pharma and biotech.

“While certain companies will be focused on digesting and integrating their recent acquisitions, others will opportunistically continue looking at acquisitions of novel technologies and commercial-stage products,” says Carolyn Buck Luce, global pharmaceutical leader of Ernst & Young. “With the patent cliff ever closer, 2010 will be a critical year for pharma companies to demonstrate that M&A efforts have delivered value to shareholders.”

Finding Value in Convergence

Mr. Landekic says fundamental changes must and will occur in company formation and financing.

“In recent years, most investors have shared the same obsession as the major pharma companies — looking for shortcuts to make a modest quick gain,” he says. “While this has sometimes worked — and investors optimistically focus on the successes — it often doesn’t. Developing a new drug is the ultimate high-cost, high-risk, long-term proposition in a highly regulated environment for the possibility of high reward. Seeking quick shortcuts conflicts with the fundamentals of the business and sets the stage for disappointment.”

Experts say too many companies have been created, and funded, with weak fundamentals in the pursuit of quick gains.

“The disappearance of many funds and the disappointing returns of many venture funds show that this must change,” Mr. Landekic says. “This will be painful, because an entire generation of investors has grown up looking for quick fixes and with impossibly short time horizons.

“In the long term, this will be healthy for the industry, because it will require a return to fundamentals — identifying unmet medical needs and developing new drugs with tangible advantages,” he continues. “There will be

fewer companies and drugs, but the ones that will remain will be higher quality. Medicine and the quality of healthcare will improve, and those funds that are able to get back to basics will enjoy improved returns as well.”

According to Bob Silvers, managing director at SSA & Co., the recent spate of mergers and acquisitions highlights the continued belief that mergers enable cost synergies and are insurance against expiring patents, since more drugs will be added to the portfolio by combining two companies into one.

“In addition, there is the idea that the combination of different functions such as sales and marketing and R&D of both firms will become stronger post-merger,” he says. “While these motivations often reflect at least the public rationale for mergers, the fact is that, more often than not, merging companies are not better off in the long term. A study undertaken at the Wharton School demonstrates that after three years, most companies that merged showed slower operating growth. Three notable examples — Pfizer, GSK, and AstraZeneca, all created by mega mergers — have failed to deliver the R&D output expected post-merger. With blockbuster drugs comprising roughly 50% of total sales, this failure presents a serious problem.”

According to Paul Boni, chief research officer at Grail Research, the recent spate of mergers and acquisitions will not fundamentally change the industry in the coming year, nor will they address the underlying challenges it faces, including the slowing of innovation, dry pipelines, and increasing pressure from payers.

“Designed to serve as cost-containment strategies, the majority of these mergers will simply buy the industry time, as consolidation allows companies to save money through continued reductions in head count across almost all functional areas, including marketing, R&D, and sales,” he says.

Adelene Perkins, president and chief business officer of Infinity Pharmaceuticals, says it will continue to be interesting — and critical — to review the process by which companies select partners.

“There are examples of partnerships, mergers, and acquisitions that are focused on near-term capital relief, however they may not optimally position the company for scientific innovation, product breakthroughs, or significant shareholder upside value going forward,” she says. “I hope that we start to see more companies focus on selecting the best partner that enables them to create meaningful value for patients and shareholders, rather than focus on the richest near-term deal.”

Consolidation, and not just mega mergers, will be a major trend, according to Daniel Zurr, CEO and president of Quark Pharmaceuticals.

“In my view, this means less entrepreneurship and less groundbreaking research for the industry, possibly leading to slower rather than quicker filling of product pipelines,” he says.

M&A activity might be a result of more than just reinvigorating pipelines: companies might be looking to re-evaluate their businesses.

Steve Wunker, senior partner at Innosight, says pharma companies often believe that their business model is broken, yet they struggle with defining what exactly their current model is, let alone what must be preserved as opposed to discarded for the future.

“Too often, they start this process by looking inward at what they do well, instead of defining what will underlie successful propositions in the future,” he says. “If we use the latter lens, we believe that pharma companies must evolve into firms that offer tightly integrated solutions to disease states. It is hard to commoditize that sort of integrated proposition, and it is much less susceptible than a molecule to patent expiry dates.”

Is There No End in Sight?

Joseph Baron, partner at Extera Partners, says the common wisdom is that M&A activity will continue unabated in the near future because pharmaceutical companies have a well-documented need to revitalize their pipelines. However, the financial crisis has dramatically changed the situation for innovative biotechnology companies.

“Now, big pharma is inundated with opportunities to partner and acquire companies, and at the same time pharma is consolidating, creating fewer targets for biotech companies looking for partners,” he says. “I predict that M&A among big pharma and biotechnology companies will actually slow down in 2010. At the same time, venture capitalists (VCs) are struggling to determine the most appropriate exit for their portfolio companies. VCs recognize that in the current environment they will be required to invest more heavily and hold their portfolio companies for substantially longer, which means these companies may need to advance their products much further into the clinic or even onto the market before a potential exit. These trends, taken together, could have an interesting effect on M&A activity. I think we will see more unusual biotechnology-on-biotechnology mergers in 2010. To make this work, biotechnology companies will require the skills to find value in these unusual combinations, determine how to extract the most value from these target acquisitions, and use the residual value to drive the merged company forward.”

“Mergers and acquisitions will continue and will be driven by excess capacity and slow-



Mark Stejbach
Tengion

“Mergers and acquisitions will continue and will be driven by excess capacity and slower growth in big pharma and depressed valuations in biotech.”



Steve Wunker
Innosight

“With the ranks of the insured growing substantially in the next few years, we should expect PCPs and many specialties to be capacity constrained, and they may welcome payer interventions that boost productivity.”

er growth in big pharma and depressed valuations in biotech,” says Mark Stejbach, VP and chief commercial officer at Tengion. “More importantly, creative collaborative partnerships will accelerate in the coming years. Large pharma companies will need to move beyond licensing as a means of simply increasing the number of shots on goal and expand their access to new technology platforms with the potential to generate significant advancements versus the standard of care.”

Ryo Kubota, M.D., Ph.D., chairman, president, and CEO of Acucela, agrees that successful partnerships and collaborations are key drivers in this type of economic climate and will continue to feed the industry, along with M&A activity.

“Creating new, important medicines requires not only cutting-edge technology and expertise, but also access to capital,” Dr. Kubota says. “Companies that can find access to that capital — through partnerships or M&A

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— while also identifying a true collaborator will be the most successful.”

Ms. Perkins believes the pace of acquisitions will accelerate for early-stage companies for which this is the most likely endgame.

“Later-stage companies with strong pipelines will have far greater flexibility in choosing between acquisition options or product partnerships,” she says.

CORPORATE REPUTATION

Companies rely on their reputations in the market to drive shareholder value, create partnerships, and embody trust with patients. When their mantle of corporate citizenry becomes tarnished, rebuilding confidence can be an uphill battle. To improve their standing in the community, industry experts say companies should focus on creating scientific and medical innovations and demonstrate that new drugs have clear patient benefits. They should

also improve the dissemination of information and marketing of products through the adoption of tighter industrywide standards.

“Success is built on the trust and confidence that stakeholders have in our medicines, relationships, and corporate integrity,” says Lisa Davis, VP of corporate communications for AstraZeneca US. “To maintain a strong reputation, it is important to focus on those elements and then ask: what more can we do to improve healthcare and society at large? Not only listening but acting on feedback from stakeholders is critically important to the difference a company can make in its reputation and in the health of families and communities.”

Making It Personal

“Companies must embrace innovation and explain how clinical efforts improve the human condition,” Mr. Colucci says. “Grounding messaging in patient-centric

efforts builds welcomed relationships, ensuring campaigns move beyond product profiles to expressions of health and wellness. Products are a dime a dozen, but brand treatments that drive health and wellness are precious.”

Todd Everhart, M.D., director, medical affairs, Americas, at Chiltern, agrees that pharma companies’ efforts need to be focused on the patients and communities they serve.

“The large pharmaceutical companies need to reach out to the community and their patients in a more personal way,” he says. “Community outreach, philanthropy, access and affordability programs, and so on will give the public confidence that these companies care about patients and their diseases. This will ultimately improve public image and future trial participation.” ♦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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