



Healthcare *and the* Political LANDSCAPE

Healthcare reform remains front and center within the political arena.

The major reforms contained in the Affordable Care Act are not scheduled to take effect until 2014, but the legislation faces legal and political challenges.

In March, the U.S. Supreme Court heard appeals related to the legislation, and the court's ruling is expected in June. Whatever the court's verdict, healthcare reform will be a key issue in the November presidential and congressional elections.

Experts say even if parts of the healthcare reform law are overturned, the momentum for change in healthcare will continue.

"Regardless of whether healthcare reform — and the individual mandate specifically — is overturned, reform will continue to move forward because it's clear we need to address healthcare cost issues, particularly with the changing demographics and the changing economy in the United States," says Peyton Howell, president of AmerisourceBergen Consulting Services. "Within the healthcare field there is wide recognition that changes to the system have to be made, particularly with more than 10,000 seniors a day becoming eligible for Medicare, and there is not a sustainable system."

She says states are continuing to work to create health insurance exchanges, which become effective January 2014.

Starting in 2014, if an employer doesn't offer insurance, individuals will be able to buy it directly in an Affordable Insurance Exchange, a new competitive insurance marketplace where individuals and small businesses

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can buy affordable and qualified health benefit plans.

"States have made investments and are continuing to make investments to be ready for the deadline," Ms. Howell says. "States have been working on improving their IT systems. Many of the states are looking at ways that could allow Medicaid-eligible families to use their smartphones to be able to seek eligibility and other information. Those advances are exciting from a patient-access perspective and are good examples of advancements regardless of what happens on the legal side."

Michael Coffee, chief business officer at

MediciNova, says the insurance exchanges are a positive.

"The concept makes sense, but the devil is in the details," he says.

There is also recognition that broader healthcare issues need to be addressed.

"There is a false dichotomy in the debate about healthcare," says Mathew McCreight, managing partner at Schaffer Consulting. "There is a lot of care being given to those without insurance. They seek care with late-stage issues or chronic problems that could have been addressed early on and much more inexpensively. There is a lot of potential for better performance in the system."

He says the problem is that stakeholders are only looking at their own piece of the healthcare delivery system.

"It's a classic divided view where everyone is working very hard, but the overall result is suboptimal," Mr. McCreight says.

Impact on Pharma

Ms. Howell says the pharmaceutical industry is likely to benefit from healthcare reform primarily through expanded access to care.

"No matter what form that takes, primary-care medicines will hopefully lower overall healthcare costs by allowing access to treatable medication," she says. "We might also see the pharmaceutical industry impacted by changes in the provider environment. The implementation of accountable care organizations is just a beginning-stage discussion about how we can better align care and provide more holis-



“It’s clear we need to address the cost issues of healthcare, particularly with the changing demographics and the changing economy in the United States.”

PEYTON HOWELL / AmerisourceBergen

tic care. This shift could create new types of customers, new prescribing patterns, and new types of resources that patients can access earlier. Over time, this will shift what types of products are used and when they are prescribed.”

Kenneth Tomaszewski, Ph.D., president and CEO of KJT Group, says cost-effectiveness issues will likely play an increasing role in healthcare discussions, but these issues won’t necessarily be picked up by the media.

“In the future, cost-effectiveness in pharma and across the health services industry will play a role,” he says. “We may even see discussions around whether cost-effectiveness should become a standard output for new drugs.”

Mr. Coffee predicts there may be greater accountability required by the pharmaceutical industry.

“The pharmaceutical industry can do a better job of quantifying product value, and companies will need to show their products are providing value,” he says. “Conventional clinical endpoints of quality of life may not be sufficient to demonstrate value. Cost avoidance is going to be key. Cost-effectiveness studies should evolve to the next level to demonstrate more clearly how drug therapies will lead to a reduction in costs going forward.”

Mr. McCreight says regardless of what happens at the Supreme Court, the pharma industry’s long-term success will be determined by how well they are able to negotiate in a highly competitive market.

“The global picture right now shows that economies around the world are struggling,”

FAST FACT

THE ANNUAL FEES RELATED TO THE U.S. AFFORDABLE CARE ACT THAT WILL BE LEVIED ON DRUG MANUFACTURERS WILL COST THE PHARMACEUTICAL INDUSTRY ABOUT \$30.8 BILLION FROM 2011 THROUGH 2020.

Source: Decision Resources

he says. “Since the government is such a big part of the payment system in the United States, there will be a continuing pressure to address the needs of government payers during a time when money is very tight.”

Punit Dhillon, president and CEO of OncoSec Medical, says pharmaceutical companies will have to provide a pharmacoeconomic component that is much more compelling.

“As a society, we can’t afford to have expensive treatments and expect that Medicaid is going to cover 100%, and that all potential patients will have access to these treatments,” he says. “Unfortunately, the costs that the nation is bearing for healthcare have been very significant. This has to be addressed and there has to be some level of fairness applied to the distribution of care. President Obama would like to roll back the Bush tax cuts and apply those funds to healthcare. This is a contentious issue and will be opposed by Mitt Romney’s camp.”

Mr. Dhillon says government rebate plans and pricing controls under the current healthcare reform plan have to be planned for by the pharmaceuticals companies, since ex-

pensive treatments are likely to be limited compared with less expensive alternatives.

“Premium-priced new therapies, irrespective of effectiveness, are likely to be slowed due to poor pharmacoeconomics,” he says. “Under this reform, companies may elect a more austere route, sticking to larger markets and indications instead of venturing out to orphan diseases, which are equally deserving of R&D for cures.”

Mr. Dhillon says the central rationale for the law is the cost of healthcare and the sustainability of the healthcare system.

“If we agree that cost is the driver of this platform, then the issue of cost impacts everyone involved — individuals, providers, institutions, and insurers,” he says. “Reimbursement on the cost of R&D of a drug will always have a huge impact on the business model of pharmaceuticals.”

Glen de Vries, president of Medidata Solutions, says there is also a lot of pressure from the payer world about how valuable pharmaceutical products are.

“These are questions about the ability to deliver effective care on a per-person or a per-dollar basis,” he says. “The fundamental disparity is that the healthcare industry isn’t doing an effective enough job of taking care of patients as individuals. Regardless of how legislation talks about it, there is a need for more effective and more valuable therapies. Ten years ago, we were talking about safety and efficacy endpoints. Now the conversation also involves value endpoints and whether a drug is going to move the needle of the health of the patient enough to justify its use.”

The industry also is likely to be impacted by additional expenses. Annual fees related to the U.S. Affordable Care Act that will be levied on drug manufacturers will cost the pharmaceutical industry about \$30.8 billion from 2011 through 2020, according to Decision Resources. Measures to close the Medicare Part D coverage gap will add another \$30 billion to the industry’s expenses, and Medicaid rebate increases are projected to cost the industry \$20 billion over the next 10 years. In total, the pharmaceutical industry’s support for this healthcare reform will add up to about \$90 billion through 2020.

Impact of Politics on Innovation

Mr. Dhillon says there are at least three issues that are likely to be impacted as November approaches.

“First, it is probable that government-funded grants for research in the industry will be largely affected,” he says. “Second, the issue of taxation on biopharmaceutical companies and drugs is a hot one this year, and will play a key role in the upcoming political debates.



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DR. KENNETH TOMASZEWSKI / KJT Group

Finally, there are the ongoing debates surrounding Social Security’s funding for Medicare and Medicaid. How much longer will these funds be available, and what might happen if and when they are depleted? Wide disagreement on this and other key issues are sure to make this election a key one to watch for all interested in these critical matters.”

Dr. Tomaszewski says the effects of politics on innovation could be detrimental in the sense that the public doesn’t have a strong understanding of how innovation works.

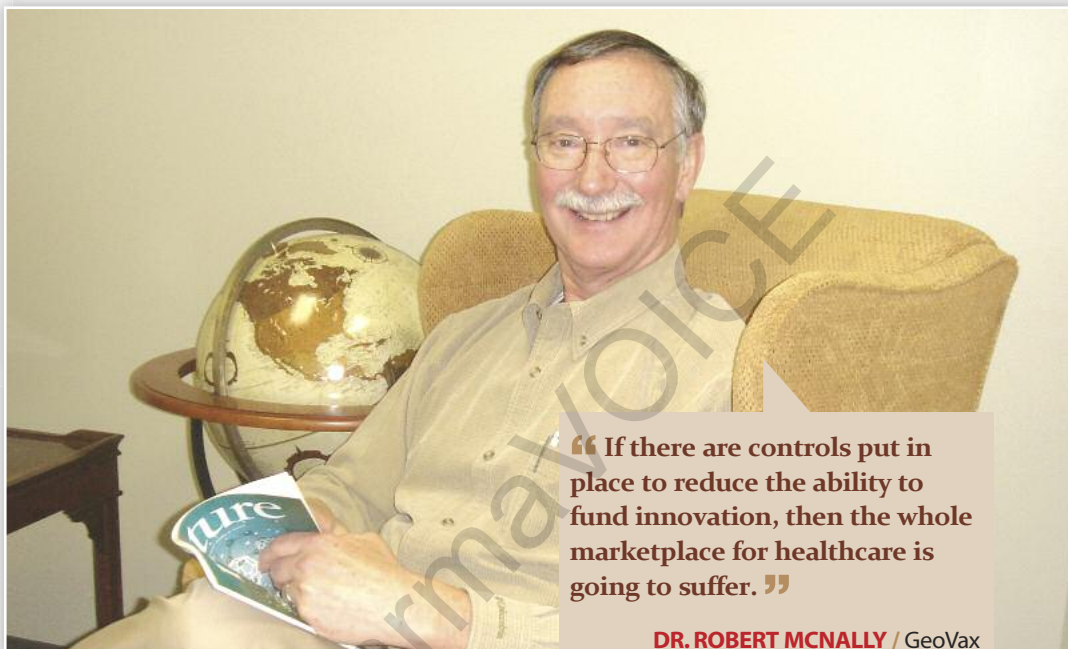
“Voters don’t necessarily have a strong understanding of how profit motives and the risks involved impact innovation,” he says. “I think there will be increased demonization of the drug companies.”

Robert McNally, Ph.D., president and CEO of GeoVax, points out the United States is founded on entrepreneurial spirit and innovation.

“Last year, we participated in an effort that was supported by the Bill & Melinda Gates Foundation and a subgroup called Research!America,” he says. “We lobbied for continued congressional support for the National Institutes of Health. But some members of Congress were not very supportive of any increases to the NIH budget and were reticent to discuss any changes. Those of us in the biotech arena benefit greatly from the support given by the NIH. It is the lifeblood for future innovation.”

Mr. McCreight says some people might point out that the long-term impact of politics will be stifling on innovation, but innovation, by its very nature, finds a way.

“Politics may either slow innovation down or speed it up, but innovation still happens,”



“If there are controls put in place to reduce the ability to fund innovation, then the whole marketplace for healthcare is going to suffer.”

DR. ROBERT MCNALLY / GeoVax

he says. “Ideally, there should be long-term incentives to help drive change on a longer-term basis.”

Mr. Coffee says while politicians are sensitive to demands of constituents, there are things that can be done so as not to stymie innovation.

“One of these is to make long-term invest-

ments in healthcare innovation more attractive,” he says. “Pharmaceutical research and development cycles are longer now than they’ve ever been. Therefore, investors in new companies and new therapies need to have an incentive to look at longer-term investments. This is an area in which politics could have an influence.” **PV**

EXPERTS



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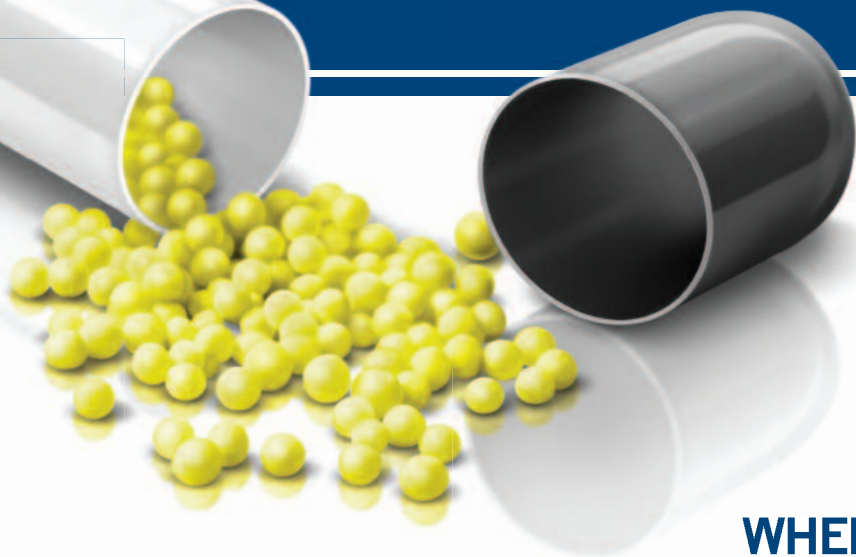
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