What healthcare reform means for Mich. pharma and medical companies

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In March 2010, President Obama signed the Patient Protection and Affordable Care Act into law followed by the Health Care Education and Reconciliation Act, which made some additional changes to the original legislation.


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This sweeping healthcare reform law promises to affect all stakeholders in the healthcare delivery sector in the United States and will also reach drug and medical device makers in Michigan.

Michigan companies will be subject to additional taxes and fees, but may also benefit from some of the law's incentive provisions.

Finally, as a consequence of the law's apparent shift toward value-based health outcomes and comparative effectiveness research, drug and medical device makers may approach future product development and commercialization decisions differently.

Mandated taxes, discounts and rebates

To help fund the law, brand pharmaceutical companies avoided price controls but will be required to make an estimated contribution of $80 billion in taxes and Medicare discounts and rebates. Big Pharma companies such as Pfizer will pay these costs based on market share starting in 2011. These costs will increase from an estimated $2.3 billion to $2.7 billion annually.

Drug makers will also be required to offer 50-percent drug price discounts to help cover the gap formed by the Medicaid Part D "doughnut hole."

Also starting in 2011, pharmaceutical manufacturers will be subject to an annual, non-deductible manufacturing fee allocated according to market share. The fee will not apply to companies with sales of branded pharmaceuticals of $5 million or less.

Medical device makers will face an annual excise tax of 2.3 percent based on sales starting in 2013. This will amount to $20 billion in additional taxes for makers of surgical devices, artificial hearts, hospital beds and the like.

These new taxes may be counterbalanced by increased sales due to increased consumer access to health insurance. The Congressional Budget Office estimates that as many as 15-16 million additional people could gain private health insurance, and another 16 million people will be included under expanded Medicaid coverage.

Generic drugmakers could benefit as more patients gain access to prescription and over-the-counter medicines, according to generic drugmaker Perrigo CEO Joseph Papa.

Market and tax incentives

This new legislation sets up a regulatory framework for approval of generic versions of biologic drugs (biosimilars), but brand biopharma companies gained a lucrative 12-year period of market exclusivity before facing generic competition.

According to Biological Industry Organization (BIO) CEO Jim Greenwood, this incentive will help to attract the massive investment needed for the discovery and development of new biologic therapies.

Generic Pharmaceutical Association President and CEO Kathleen Jaeger criticized the biosimilar provisions: "Simply put, the bill fails to infuse competition and choice in the healthcare system due to the excessive and unprecedented market exclusivity protections for the brand industry." According to Jaeger, the FDA was given the flexibility to create a workable biogenerics approval pathway, but "brand market exclusivity protections supplemented by rich patent protection…will keep affordable biogeneric medicines from patients for years to come."

This new legislation provides a tax credit for drug development companies with 250 or fewer employees. The "Therapeutic Discovery Project Credit" is a two-year temporary credit for qualifying investments made in 2009 and 2010 that is subject to an overall cap of $1 billion. The credit is designed to encourage investment in new therapies.

"Qualifying investments" means the costs for expenses directly relating to the conduct of a qualifying discovery project designed to: treat diseases via preclinical or clinical studies for the purpose of getting FDA approval; diagnose diseases or find disease biomarkers by developing diagnostics that can be used to make therapeutic decisions; or advance the delivery or administration of therapeutics.

Dean Zerbe, national managing director of the Alliant Group, writes in Forbes that the grant part of the new biotech credit is important for companies that are eligible for the tax credit, but don't meet tax liability or alternative minimum tax requirements.

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"During the summer, we have a strong, active, vibrant (student) research community," he said, noting the faculty keeps up research throughout the year.

Sinniah and colleagues from Calvin, as well as Brad Wallar at **Grand Valley State University**, received more than $208,000 from NSF for the purchase of an atomic force microscope, an isothermal titration calorimeter and a differential scanning calorimeter. That award was the college's third major research instrumentation proposal funded in the past year. Overall, Calvin received almost $1 million for the initiative.

The instruments will help the researchers and students study the interaction between molecules, which could help them find better ways for drugs to help patients, among other uses. With the most recent funding and past awards, the college has been upgrading its instrumentation from the 1990s with more sophisticated, modern equipment.

Sinniah received more than $55,000 in ARRA funds for a project studying enzyme inhibitor reactions, as well as nearly $45,000 from NIH to continue research he started while on sabbatical at the **University of Michigan**. The NIH funding will help offset some of his salary at Calvin so he can continue to oversee the research by Michigan graduate students, as well as bring some grad students and the research to Grand Rapids for his Calvin undergraduates to work on.

"For Calvin (students), they're able to collaborate with their colleagues at Michigan and see the broader research that goes on," he said.

Other programs recently garnering federal ARRA funds included:

- more than $487,000 to purchase a spectrometer for work by Eric Arnoys, David Benson, Chad Tatko and Amy Wilstermann
- $279,000 for a project involving a type of MRI scanning to investigate species and biomolecule identification for a project involving Wilstermann, Tatko, Benson, John Wertz and Randall DeJong
- more than $223,000 for diabetes research performed by Larry Louters
- $170,000 for Carolyn Anderson's work on synthetic peptides and Alzheimer's disease
- and $126,000 for Doug Griend's research on supramolecular structures, nanomachines and thermochromic material.

As much as possible, Calvin has placed an emphasis on purchasing equipment made in the U.S., in keeping with the intent of the ARRA funds of providing jobs and helping stimulate the U.S. economy, he said.

Another $185,000 from the NSF will support geography professor Deanna van Dijk's research and development of a geoscience course involving student research on Lake Michigan coastal dunes.

"One of the things we try to do is that we try to recruit students as freshmen and encourage them to go into research, get in a lab and work with their hands," Sinniah said. "It helps them find out early (whether they like science). When students start working early on research, it builds their confidence on course work and lab work. Just for that alone, it is a worthwhile task — to build that confidence early."

Sinniah said about half of Calvin's science students go on to graduate school, while a sizeable group goes into health-related studies, and the balance seek employment. **LW**

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Comparative effectiveness research and the shift toward value-based health outcomes

According to the nonprofit Kaiser Family Foundation, this legislation supports comparative effectiveness research (CER). CER evaluates the relative strengths and weaknesses of various medical interventions and seeks to ensure "value-based" health outcomes.

The law will establish a nonprofit Patient-Centered Outcomes Research Institute that will identify research priorities and conduct research that compares the clinical effectiveness of medical treatments in order to improve care quality and resource allocation as well as to reduce costs. The institute will build on the $1.1 billion that Congress budgeted for effectiveness research in last year's American Recovery and Reinvestment Act.

Industry Blogger Patricia Van Arnum notes the shift to value-based outcomes embodied in CER is likely to influence drug development. According to Van Arnum, clinical studies will still focus on evaluating a given drug's efficacy, but will also have to measure the effectiveness of a given drug compared to existing therapies."

New waters

Michigan drug and medical device makers will be entering uncharted territory as the many provisions of the new health reform law are implemented. It will be important for drug and medical device makers to monitor the post-health reform law business terrain as they make product development and investment choices.

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