Volume 6, Number 3 *March 2009*

SPECIALTY PHARMACY NEWS

News and Strategies for Managing High-Cost Biotech, Infusible and Injectable Products

CER Focus Should Be on Clinical Efficacy, But Will Plans Focus on Costs for Coverage?

The economic stimulus bill that President Obama recently signed into law has one provision that specialty pharmacy stakeholders are particularly interested in: comparative-effectiveness research (CER). And while many questions remain as to what the research's focus will actually be, scrutiny is almost guaranteed to fall on high-cost specialty drugs.

The stimulus bill signed into law by President Obama Feb. 17 (the American Recovery and Reinvestment Act of 2009), allocates $1.1 billion to CER. Of that total, $400 million will go to the National Institutes of Health, $300 million to the Agency for Healthcare Research and Quality, and $400 million to HHS. The HHS Secretary must contract with the Institute of Medicine to produce and submit a report to Congress by June 30 that recommends research and funding priorities after listening to industry stakeholders' input. The law establishes the Federal Coordinating Council for Comparative Effectiveness Research, a group consisting of 15 federal employees that will make HHS spending decisions on research.

"We need more comparative-effectiveness data," contends Derek van Amerongen, M.D., chief medical officer at Humana of Ohio. And patients need access to such data, he says. If someone is faced with spending thousands of dollars on a treatment, that patient needs to have the ability to find out what that money is buying him in terms of alternate treatments, he maintains.

"We welcome it, provided that they use science-based information," says Larry Hsu, M.D., medical director of Hawaii Medical Service Association, a Blues plan licensee. His plan, he says, always tries to look at the scientific literature available when assessing therapies.

Before the bill was passed, discussion among congressional members focused on whether the word "clinical" would be used in reference to the research. Including that word, argued proponents, would indicate that clinical outcomes and effectiveness were to be the focus of any research, rather than therapies' costs.

Although the Senate version of the legislation included "clinical," the final version of the bill did not. However, "just because the word is not in there does not mean the bill isn't greatly improved from where it started," contended Brent Del Monte, vice president of federal government relations at the Biotechnology Industry Organization (BIO), during a Feb. 26 press briefing.

Still, questions about the law exist. While CER is "important to the advancement of medicine,...the legislation is not as specific as I would have imagined," says Domenick Bertelli, a partner at Putnam Associates, a consulting firm for the pharmaceutical and biotech industries.

One of the biggest issues with CER, says Jarrett Bostwick, president of specialty pharmacy FactorHealth, is what will be done with the information that is gathered. "If it is in the public mainstream, there is concern pay-

ers may limit coverage options and reimbursement," he explains. Whether the data gathered must be placed in the public domain "is an unknown at this point," but the issue will need to be determined soon, he says.

Debi Reissman, Pharm.D., president of managed care consulting firm Rxperts, points out that language in the law indicates that it is not intended "to have the research direct any type of coverage or reimbursement decisions by payers."

Robert Hill, a partner at Reed Smith LLP, points to the language from the Feb. 12 *Congressional Record* page H1423 as "fairly illustrative" evidence of Congress' intent. "The conferees do not intend for the comparative effectiveness research funding included in the conference agreement to be used to mandate coverage, reimbursement, or other policies for any public or private payer," says the record. "The funding in the conference agreement shall be used to conduct or support research to evaluate and compare the clinical outcomes, effectiveness, risk, and benefits of two or more medical treatments and services that address a particular medical condition."

Nevertheless, says David Knowlton, president and CEO of the New Jersey Health Care Quality Institute and a board member of the nonprofit HealthWell Foundation, "Follow the money. It's all about money....And health plans will drive it." For instance, he says, take a situation where two hospitals are identical in quality. If an objective third party discovers that Hospital A charges tens of thousands of dollars more for a particular treatment than Hospital B does, and Hospital B produces outcomes that are equal to Hospital A's, why wouldn't a health plan want to use Hospital B? Or, says Knowlton, it would be like a school saying that it's doing a study to determine what the best education is for a child — but then saying that it's not going to do anything based on the data.

"There is going to be pushback," says Knowlton. "Let's not be naïve — of course they're going to use" the data. He adds that the legislation "is part of an economic plan, so they're saying up front that this is about the money."

"Our position is we support comparative effectiveness," said Jim Greenwood, president and CEO of BIO, at the media briefing. "We think it is a process when done well that can provide valuable information to patients and physicians." However, he said, "We are concerned about making coverage decisions" based on this research, as that "is not appropriate in the age of personalized medicine."

The *Congressional Record* passage on page H1424 seems to address this issue of personalized medicine: "Further, the conferees recognize that a 'one-size-fits-all'

CER May Represent Opportunity for Specialty Pharmacies

The American Recovery and Reinvestment Act of 2009 — the economic stimulus law signed by President Obama Feb. 17 — appropriates more than $1 billion for comparative-effectiveness research. Some specialty pharmacy industry stakeholders are leery that the research could effectively mandate treatments based on costs and view the provision as a potential threat (see story, p. 1). But one stakeholder sees a way for specialty pharmacies to play a big role in this area of health reform.

Instead of perceiving such research as menacing, "an interesting opportunity for specialty pharmacies is to get into the comparative-effectiveness world," says David Knowlton, president and CEO of the New Jersey Health Care Quality Institute and a board member of the nonprofit HealthWell Foundation.

Specialty pharmacies, he says, "are more likely to make patients compliant. And if patients are compliant, they will use less services."

Known for providing high-touch services to patients, most specialty pharmacies offer comprehensive patient support services that encompass everything from educating patients about their disease and therapy after an initial diagnosis to communicating with them about side effects that they should expect to coaching them about how to administer a drug.

When patients are adhering to their treatment regimens, the chances of downstream costs such as emergency room (ER) visits or hospital admissions decrease. For instance, Knowlton points to a diabetic, obese, asthmatic patient who visited the ER 135 times within one year. Once that patient, his condition and his therapies were properly managed and he was compliant with his treatments, "his costs plummeted," says Knowlton. Now imagine the costs if that patient were taking specialty drugs, he adds.

"Specialty pharmacies have a real opportunity if comparative effectiveness moves forward," Knowlton maintains.

Contact Knowlton through Maria-Christina Zajac at (201) 488-0049.

approach to patient treatment is not the most medically appropriate solution to treating various conditions and include language to ensure that subpopulations are considered when research is conducted or supported with the funds provided in the conference agreement."

According to Bostwick, concerns that the U.S. health care system's decision making would be transformed into a version of the U.K.'s value-based National Institute for Health and Clinical Excellence (NICE) are probably not realistic. That system is "such a different environment" from the U.S. in terms of the U.K.'s "approach to medicine and the way the government intervenes" that it's "hard to believe we'd gravitate" to this kind of system, he says.

"I am not sure we could ever get FDA or any branch of the U.S. government or regulatory body" to say that "this drug is not cost effective enough, so it will not be sold in the U.S.," agrees van Amerongen.

Reissman adds that "there is concern that spending could be based on research considered very academic versus more real world and useful to payer understanding of best-treatment courses. But I don't know if there is concrete evidence that this would or wouldn't happen."

One challenge, continues Reissman, is whether "the organizations given the funding are going to be looking at actually comparing Drug A versus Drug B head to head or something more global." For example, she says, would the timing of patients' treatments impact their outcomes? Would one group of drugs provide improved outcomes as opposed to another group of drugs? Do the outcomes of certain patient populations improve when they are treated by specialists as opposed to primary care physicians? Are there certain treatment pathways that are more successful in patients?

There is also the question of whether the research can utilize Medicare Part D data, says Bertelli. "This could be a huge database that could be mined."

"The concept [of CER] is not necessarily a bad concept from a public-policy standpoint," says Bostwick. "The sticky wicket depends on the therapies" that could potentially be affected. For example, he says, with biologic blood products such as intravenous

NEW FDA SPECIALTY DRUG APPROVALS

◆ **On Feb. 6, the FDA approved Atryn (antithrombin [recombinant]) for the prevention of perioperative and peripartum thromboembolic events in hereditary antithrombin deficient patients.** Developed by GTC Biotherapeutics Inc. and marketed by Ovation Pharmaceuticals Inc., the infusible is the first approved product derived from a genetically engineered animal created specifically for the drug. Atryn is created using the milk of a genetically altered goat. The FDA's Center for Veterinary Medicine also approved GTC's New Animal Drug Application, which is the first of its kind to regulate genetically engineered animals. The companies say the drug should be available in the second quarter of this year. Ovation did not respond to a request for pricing information. Visit www.gtc-bio.com.

◆ **On Feb. 27, the FDA granted approval to reintroduce Indevus Pharmaceuticals Inc.'s Valstar (valrubicin) for the treatment of bacillus Calmette-Guerin-refractory carcinoma *in situ* of the urinary bladder.** The drug, which is intended for intravesical administration in the bladder, was withdrawn from the market in 2002 because of manufacturing problems. Indevus, which recently agreed to be purchased by Endo Pharmaceuticals Inc., says it plans to market the drug in the second half of 2009. Indevus did not respond to a request for pricing information. Visit www.valstarsolution.com.

◆ **On Feb. 27, the FDA approved an IV formulation of the Schering-Plough Corp. drug Temodar (temozolomide) for the treatment of adult patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment, as well as for refractory anaplastic astrocytoma.** The FDA approved the oral form of the drug in 1999 for the same indication. A spokesperson for Schering-Plough says that the new formulation of the drug "will be launched as soon as possible." She adds that "the price will be determined at that time." Drugstore.com lists the price of five of the 5 mg capsules as $54.18. Visit www.temodar.com.

◆ **On March 3, the FDA granted another indication to Teva Pharmaceutical Industries Ltd.'s Copaxone (glatiramer acetate injection) for the treatment of patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.** Drugstore.com lists the price of one box of 30 pre-filled 20 mg syringes as $2,563.84. Visit www.copaxone.com.

immunoglobulin, "in the 1980s and 1990s there was significant concern with the potential for tainted supplies" from plasma-based products. What if CER demonstrated that newer synthetic, recombinant therapies were no more effective than older human-based products? Considering that "recombinant therapies can be two, three, four and five times as expensive" as the older therapies, he says, would payers force patients on the newer therapies to abandon those treatments in favor of the cheaper plasma products?

Bostwick also says that he foresees a lot of attention being given to chronic disease states such as rheumatoid arthritis and multiple sclerosis that have numerous — and expensive — therapies available and for which patient compliance is critical. Focus will also be on "debilitating chronic medical conditions" that impact large populations of people — particularly the aging baby boomers — such as Alzheimer's disease, he says.

Ultimately, to be effective CER "should involve all stakeholders," said John Taylor, executive vice president of health at BIO, at the briefing. "It will not provide benefits unless everyone has bought into this."

Hsu agrees that all stakeholders must be involved. He adds that the economic downturn may drive some public support for CER. "Because we're in a recession, it's the best time to talk about comparative-effectiveness research," he says.

Still, everyone who spoke with *SPN* agreed that it's too early to tell exactly how all of this will play out.

"It's very much a work in progress to figure out how the money will be spent and what impact the research will have," says Hill.

Contact van Amerongen at dvanamerongen@humana.com, Bostwick at jbostwick@factorhealth.com, Reissman at (949) 788-2909, Hill at (202) 414-9402, Bertelli at (781) 273-5480, Greenwood at (202) 962-9200 and Hsu at (808) 948-5179. Contact Knowlton through Maria-Christina Zajac at (201) 488-0049. To view the CER information in the stimulus law, visit www.aishealth.com/Compliance/HR1_comparative.pdf. ✧

For more information on the likely impact of comparative-effectiveness funding on health plans and PBMs, sign up for a March 24 AIS audioconference on the topic. The speakers are F. Randy Vogenberg, Ph.D., of EPS, LLC; Colin Roskey of Alston & Bird LLP; and Mark Rayder of Alston & Bird. Call (800) 521-4323 or visit the AIS MarketPlace at www.AISHealth.com.

NEWS BRIEFS

◆ **On Feb. 12, Walgreen Co. subsidiary OptionCare Enterprises, Inc. completed the purchase of CareMax Medical Resources, LLC.** Walgreens did not disclose terms of the transaction. The Tampa, FL.-based home care provider has seven locations in Colorado, Florida, Pennsylvania and Texas and provides infusion and respiratory care services, among other offerings. Contact Linda Lampinen at (847) 964-6726.

◆ **On March 3, BioScrip, Inc. posted a net loss for the fourth quarter of 2008 of $76.6 million, or $1.98 per diluted share, compared with net income of $2.5 million, or 6 cents per diluted share,** for the fourth quarter of 2007. It also reported fourth-quarter 2008 revenues of $366.6 million, up from $309.2 million. BioScrip posted a net loss for 2008 of $74.0 million, or $1.93 per diluted share, compared with net income of $3.3 million, or 9 cents per diluted share, for 2007. It also reported 2008 revenues of $1.4 billion, up from $1.2 billion. Visit www.bioscrip.com.

◆ **On March 4, Allion Healthcare, Inc. posted net income for fourth-quarter 2008 of $3.1 million, or 12 cents per diluted share,** up from $1.1 million, or 6 cents per diluted share, for the fourth quarter of 2007. The specialty pharmacy services provider reported revenues of $96.9 million for the most recent quarter, up 52% from $63.6 million. Allion posted net income for 2008 of $7.5 million, or 34 cents per diluted share, up from $3.3 million, or 19 cents per diluted share, for 2007. It also reported 2008 revenues of $340.7 million, up from $246.7 million. Visit www.allionhealthcare.com.

◆ **On Feb. 19, the FDA issued a public health advisory concerning Genentech Inc.'s psoriasis drug Raptiva (efalizumab).** Three patients contracted progressive multifocal leukoencephalopathy, a rare brain infection, and a fourth patient had a possible case of PML. All of the patients had been on Raptiva as a monotherapy for more than three years. Three of the patients have died. Genentech updated the drug's product labeling in October 2008 to include a "black-box" warning about life-threatening infections, including PML. European regulators have recommended suspending sales of the drug. Visit www.fda.gov/MedWatch/report.htm.