

---

# SPECIALTY PHARMACY NEWS

---

## Outlook 2009

### **Economy Will Impact Pharma Changes; Follow-on Biologics May Become Reality**

While concerns about the economic downturn have taken much of the focus off health care, this doesn't necessarily mean that 2009 won't see any major changes to the industry. *SPN* spoke with various industry stakeholders and found that specialty pharmacy and home infusion could very well see significant changes, many of them linked to the economy.

What it comes down to on changes to health care, contends Dexter Braff, president of The Braff Group, a health care mergers and acquisitions (M&A) company, is whether the Obama administration "will wait and pick a big fight or will engage in small skirmishes" earlier. For example, early on Congress could cut Medicare Advantage reimbursement by a certain percentage, or this could be part of some overall comprehensive health care legislation that happens later. He says there are reasons supporting either approach. "My guess is that they will go for something bold and wait," Braff tells *SPN*. "Anything to do with health care has so much energy behind it that they may not want to spend their negotiating currency on a couple of small items. This could delay the implementation of broad health care reform measures."

"When it comes to specialty pharmacy and home infusion, we see it as a mixed bag," says Braff. As a point of contrast, he explains that for Medicare home health, "we see the economic pressures as having a minimal impact on the industry for two reasons. First, the services rendered are nondiscretionary," so patients are not deciding to forgo them. Second, the federal funding for these services, "while under pressure, is not likely to substantially change." Based on his company's analysis, Braff says that Medicare home health will most likely "have a relatively uncompromised 2009."

Infusion therapy and specialty pharmacy have some similar aspects, he contends. "To a large extent, most services are similarly nondiscretionary." Funding, Braff says, "is more challenging. A goodly amount of reimbursement is from private insurers. As unemployment rates change," reimbursement may shift from private insurers to Medicaid, he explains. While there "may not be a huge fallout," he adds, "any

movement can be significant." In addition, as employers change their benefit plans, there may be "holes in reimbursement that could create opportunities for bad debt," he says.

#### **Medicaid Woes May Affect Reimbursement**

With more than 40 states projecting budget deficits in 2009, "we're greatly concerned...with any reimbursement from Medicaid," says Braff. For example, Medicaid is a large payer for the respiratory syncytial virus therapy Synagis (palivizumab).

According to Russ Bodoff, president of the National Home Infusion Association (NHIA), "We are concerned that the recession-prompted crisis in budgets of many states may lead to Medicaid reimbursement cutbacks, and we are concerned that already generally poor reimbursement and billing administrative obstacles confronted by home IV providers being able to service Medicaid patients may worsen and result in more denied access to IV in the home for them — and overall increased costs to the states as these patients will need to be serviced in institutions instead."

As companies struggle to pay health insurance costs, one particular demographic may be hit hard. "I believe we are going to see major shifts of retiree coverage from commercial benefits to Medicare Part D beginning in 2009 as a direct result of the economic turmoil we are experiencing," says Atheer Kaddis, M.D., vice president of managed markets at Diplomat Specialty Pharmacy. "I also believe Medicare Part D coverage will change over time, resulting in a much higher managed program with higher out-of-pocket costs for enrollees."

Expensive new specialty drugs are expected to hit the marketplace in 2009, says Elan Rubinstein, Pharm. D., principal with consulting firm EB Rubinstein Associates. With more employers putting a higher specialty tier into their drug formularies, more patients are going to be subject to a higher cost share, he says. The trend of shifting coverage of specialty drugs from the medical benefit to the pharmacy benefit will also mean more out-of-pocket costs for beneficiaries, he adds.

*continued*

## Will Home Infusion Coverage Gap Be Closed?

This may be the year for passage of a bill that closes the gap in Medicare home infusion coverage, says Braff (*SPN* 7/07, p. 1). Currently, only the drug itself is covered, but the administration and supplies needed to infuse it are not. He says he has heard that the home infusion industry may have “more of an ear with the new administration.” However, “the new administration will have its hands kind of tied with other things” that may push this legislation to the back burner.

Home infusion legislation “may be discussed, but I wouldn’t expect it to pass,” says Mark Armstrong, who is of counsel with the law firm Squire, Sanders & Dempsey, L.L.P., particularly because it may cost more money. However, NHIA points to a RAND Corp. study showing that for every dollar of Part D spending, there will be savings of \$1.63 to \$2.05 in Parts A and B. And more patients receiving therapy at home would lighten the load that falls to facilities providing infusion therapy.

“These are all valid justifications for it, but I don’t think it will be a winner,” asserts Armstrong. “It may be a priority issue. They’ll get started quickly in 2009 with legislative issues, but they can only do so much.”

Reversing the embryonic stem cell ban “will happen fairly quickly,” perhaps within the first 180 days, says Armstrong. “There is enough traction in Congress to get that passed.” Jim Greenwood, president and CEO of the Biotechnology Industry Organization (BIO), tells *SPN* that he “wouldn’t be surprised if this happens within the first week” of the new administration.

Expanding the State Children’s Health Insurance Program, which expires at the end of March, is next on BIO’s list of initiatives, says Greenwood. The organization will also focus on patent reform legislation.

The FDA has been the focus of a lot of attention the past couple of years, and 2009 will be no different. There will be a lot of scrutiny over who the new FDA director will be, says Armstrong. Neither he nor anyone else who spoke with *SPN* would venture a guess

as to whom President-elect Obama may tap for the position. Armstrong says that he “expect[s] Congress to provide additional funding to the agency.” The overseas FDA offices will add an additional wrinkle. It will be interesting, he says, to “see what involvement [the FDA] has with other countries and how drugs come in” to the U.S.

Most industry stakeholders agree that follow-on biologics legislation will be revisited in 2009. The issue might get some traction from the recently released Congressional Budget Office *Budget Options Report*. It estimates savings to federal health programs of \$8.1 billion between 2010 and 2019. If the legislation were passed and the Medicare Part B payment rates were modified so that the follow-on biologic had the same billing code as the reference product, savings for federal health programs would be approximately \$10.6 billion, it says.

Armstrong says he thinks a bill that creates an approval pathway for follow-on biologics could be passed this year and take effect in 2010. He adds that he expects the issue to be “addressed fairly quickly — maybe not within the first 180 days, but they could get a consensus around the issue fairly quickly.”

BIO “will support” follow-on biologics legislation, says Greenwood, but will insist that it’s done in a way that encourages biotech companies “to make the investments needed to provide cures.” He says he has spoken recently with Rep. Anna Eshoo (D-CA), who “is preparing to introduce legislation right away.” Eshoo and Rep. Joe Barton (R-TX) introduced H.R. 5639 in March 2008 (*SPN* 4/08, p. 12). That bill would provide potentially 14.5 years of data exclusivity for reference products, among other terms. The data-exclusivity period has been one of the sticking points for this legislation.

In addition, “there are going to be some concessions made with market exclusivity,” says Armstrong — “the 12-to-18-month range would be my guess.”

Contact Armstrong at (713) 546-3351, Bodoff at (703) 549-3740, Braff at (888) 922-5169 and Rubinstein at ebra@pacbell.net. ✧