
DRUG BENEFIT NEWS

Rx R&D Is Expected to Continue Slowdown; Government Policy, Generics Called Factors

With polls indicating large wins for Democrats on Nov. 4, some pharmaceutical industry observers contend that Democratic-favored policies supporting drug price controls and restricted drug access will dampen incentives for pharmaceutical research and development (R&D). But pharmacy benefit executives and consultants queried by *DBN* predict tough going for new drug R&D — and resulting outcomes and cost implications for health plans — regardless of which party controls the government.

Health plans and other Rx payers likely will continue to see few breakthrough products for chronic illnesses coming to market, they say. In 2007, the FDA approved only 17 new molecular entities and two new biologics, the lowest number recorded since 1983. Industry watchers say 2008 and beyond are on course for similarly low numbers of approvals.

One possible factor for the slowdown: Government and private-sector policies have raised the bar on reimbursing new Rx entrants, particularly in therapeutic categories that already have multiple treatment options, industry observers say. Meanwhile, most common conditions can now be treated with low-cost generic drugs, which are expected to continue flooding the market in the next few years, they add.

One health plan pharmacy benefit executive says that generic drugs, while lowering immediate costs, are raising the threshold on the entry of new drug products.

“With the tidal wave of blockbuster drugs that went generic in the last couple of years, most of the common disease states now have effective generic treatment options,” says Mark Gruenhaupt, clinical consultant for Argus Health Systems.

“If a manufacturer is going to develop a new drug for one of these disease states, they are going to have to jump over a higher bar than they did in the past, and also prove an even greater value over current options,” he tells *DBN*.

Proving this value may take the form of more outcomes studies or comparison studies, “not necessarily for FDA approval, but for uptake from payers,” Gruenhaupt says. “Because of this, it’s probably easier to show value in an untreated or undertreated condition.” This reality is evident in the number of biologics and cancer treatments currently in the pipeline, he adds.

Scott Gottlieb, M.D., a resident fellow at conservative-leaning think tank American Enterprise Institute (AEI), points out that some manufacturers, most notably Pfizer Inc., already have shifted R&D away from traditional drugs that treat common conditions, such as heart disease, to specialty biologics that treat rare diseases and unmet medical needs, such as cancer.

“The shift is driven in part by the industry’s critics in Washington, who have long maligned drug companies for targeting too many routine medical problems with drugs that were ‘merely’ tweaks on existing medicines,” Gottlieb writes in an Oct. 18 opinion piece in *The Wall Street Journal*. “Now these same detractors, led by House Democrats, are proposing controls on access to and eventually pricing of the specialty drugs as well.”

Price controls and drug restriction policies favored by Democrats will “distort financial incentives” that inspire pharmaceutical innovation, contends Gottlieb, who has held high-level positions at both CMS and the FDA under the Bush administration.

He points out that cancer drugs have only a 5% chance of making it through clinical trials and reaching patients. “Mobilizing capital to take on medical problems requires the promise of big returns for the few drugs that succeed,” he says. Historically, those big returns could come when a new drug mitigates or cures a previously untreatable problem. At this point, innovators may “re-price” the treatment, charging very high prices for administering the drug, Gottlieb explains.

This ability to re-price specialty pharmaceuticals is undermined by congressional Democrats' proposal to give Medicare the ability to negotiate specialty drug prices, or simply fix their prices by forcing companies to give Medicare drug plans the same deep rebates that are now mandated under Medicaid, he asserts.

Gottlieb argues that policies, which view health care as a commodity to be purchased at the lowest price, "could push drug development over a tipping point." The shift into the specialty Rx markets, meanwhile, isn't a measure of big drug makers' strength, he adds, "but a symptom of their decline, as they grope for a profitable niche amid increasing regulation."

Health Plans Affect R&D Incentives

Kam Ghazvini, chief operating officer and chief pharmacist at consulting firm **Global Pharmaceutical Solutions**, sees several reasons for the move to specialty Rx, including the increasing uncertainty about achieving a return on investment in primary-care drug development and the growing availability of generic drugs for treating common illnesses.

Health plans and PBMs continue to promote formula exclusions and other policies that deny coverage for certain non-specialty brand products, he says as an example of the challenges facing manufacturers.

"As more non-specialty brand products come off patent, common therapeutic classes will have several generic products available, making it difficult for pharmaceutical companies to position new products in the category," Ghazvini tells *DBN*.

Governmental or health plan/PBM policies that negatively impact pharmaceutical manufacturers' profit margins can jeopardize the R&D of new pharmaceutical drugs, he says, adding that this could harm health plans. Ghazvini warns that "a longer-term risk that could stem from stifled R&D is the increased need for hospitalization and other costly non-pharmaceutical treatment, which could drive higher overall health care costs."

Payer Policies Influence R&D

Gruenhaupt notes that government and payer policies have always influenced drug development. "Pharma companies must answer to their investors, so they will put the R&D dollars into treatment areas most likely to show a return," he says. "If government or payers are capping or restricting certain categories, those will eventually be avoided for the most part."

Meanwhile, if pharma is not able to bring in enough revenue, they will not be able to invest as much in the R&D needed to develop breakthrough therapies, he explains.

"That's why the big pharma companies are currently looking for a new model for drug development, because the current one is broken with today's spiraling health care costs and payer restrictions to control those costs," he explains. "They've already reached a point where they can't afford business as usual."

F. Randy Vogenberg, Ph.D., co-founder of pharmaceutical consulting firm Employer-based Pharmaceutical Strategies, LLC., echoes this point. Pharma's current business pricing methods and business model are "under serious attack as well as out of sync with societal thinking about their relative value," he tells *DBN*. "To date, pharma, including biotech firms, have not done a good job of establishing the economic value proposition for proper positioning of their products," he adds.

Vogenberg also asserts that the sharp economic downturn "creates a unique opportunity for R&D and marketing innovation to change the model, so that issues like pricing are brought back in line toward having more rational, defensible strategies that allow for meeting patients' needs going forward."

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