OUTLOOK 2011

EYE OF THE STORM

With a wave of mega-blockbusters set to expire in 2011 and with managed care increasingly in the driver's seat, pharmas will get another bite at the healthcare reform apple and refocus sales efforts on access, reports **Matthew Arnold**

With the fracas over healthcare reform over and gridlock descending on Washington, 2011 should be a far less exciting year for pharmas on the policy front. Not to worry, though – massive patent expirations should provide plenty of drama.

2010, says IMS Health's Michael Kleinrock, was "a bridging year between the economic crisis and the full wave of patent expiries."

Some $25 billion worth of drugs are set to lose US patent exclusivity in the coming year, including a pair of 800-pound earnings gorillas, Pfizer's Lipitor and Sanofi-Aventis and Bristol-Myers Squibb's Plavix, along with Lilly's Zyprexa and J&J's Levaquin. Those four products alone accounted for more than 93 million US prescriptions and $17 billion in US sales for the year to October. In addition, GSK's Advair Diskus will see some patents expire.

And 2012 is no better, with another $25 billion in US patent losses slated to hit, including exclusivity for AstraZeneca's Seroquel, Merck's Singulair and Takeda's Actos.

US sales growth will be static, at 3%-5%, IMS estimates. Global growth of 5%-7% will be driven in large part by a handful of new products for diseases like metastatic melanoma, MS and acute coronary syndrome, along with strong growth in emerging markets.

Growth in the US and Europe is being held down, in part, by cost-savings measures taken in response to the 2008 recession, which drained treasuries and continues to strain household budgets (a 2009 Kaiser Family Foundation survey found one in six Americans splitting pills to save money). In fact, some European governments are seeking to exploit the wave of patent expiries with policy changes aimed at maximizing the savings as those drugs go generic.

"In some cases I'd call it opportunistic, and I think it's smart when a country is thinking about how much money it has to spend on its whole population," says Kleinrock, who is director of thought leadership for the Americas at IMS Health.

In the US, no pain, no gain is the watchword for healthcare reform, with health plans ramping up the use of pre-authorizations and cost-sharing provisions. Gains from sales volume resulting from the law remain several years off.

"With the implementation of the new healthcare reform provisions, we expect managed care will continue to exert significant influence through cost controls that already have a major impact in determining which scripts are filled and which are switched," says Mark Spiers, president and CEO at Wolters Kluwer Pharma Solutions. "Early data also suggest that the increasing patient abandonment trend will continue and, if a slow economic recovery continues, we expect to see more patients walking away from their prescriptions at the drug counter."

PHOTO LEFT: i STOCK

Managed care ascendant

That means more emphasis on price promotions and offer-driven campaigns like BMS's Orencia effort from last year, in which the drug maker offered to cover patients' co-pays for the first six months. And managed care will eat up an increasing share of sales and marketing bandwidth.

"He who has the gold makes the rules and managed care is basically paying for most drugs," says Harris Kaplan, CEO of Healogix. "You have a small number of plans controlling the access channel in the US, and that's really reduced the need for the rep to come pounding on a physician's door twice a week in order to drive sales. Much more budgetary focus needs to be on making sure you have secured that top tier, because if you're trying to effectively market a drug in a territory where you don't have good managed care access, you're not going to get very far."

Also ascendant, says Kaplan, is pre-market development.

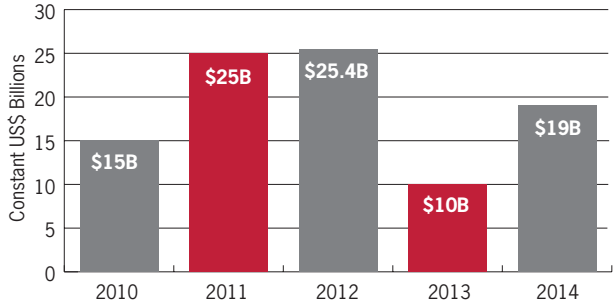
"Particularly as more compounds are sourced outside of big pharma, you're going to see a sea change in the amount of input marketing and commercial have," he says. Marketing, he says, should have a seat at the table from the moment a drug goes into phase III. "Pharma talks about having that kind of input earlier, but the reality is they don't fund it or staff it relative to the importance of the decisions being made," says Kaplan. "It's amazing how marketing is still seen as a giant SWAT team selling what's available today as opposed to letting marketing really craft that label."

That kind of early involvement will also be driven by the need to meet the data demands of managed care, says Nick Colucci, president and CEO of Publicis Healthcare Communications Group.

"Payers, insurance companies in particular, will want to see comprehensive value propositions backing up all claims of clinical efficacy and cost-effectiveness with rigorous data and peer-reviewed articles," says Colucci.

Revenue at Risk

Value of products at risk to generic competition from 2010 to 2014



Source: IMS Health, MIDAS, Market Segmentation, June 2010

"This means we have to start considering payer needs as early as phase II.

Healthcare reform rematch

The passage of the Patient Protection and Affordable Care Act was a relief after a year of wrangling, and a huge victory for then-PhRMA chief Billy Tauzin, who secured the industry a seat at the table for the drafting of the most far-reaching healthcare legislation in a generation. The result was a bill the industry could live with, if not without great sacrifice. Tauzin committed the industry to $90 billion in discounts that will help to fill in the Medicare Part D "Donut Hole," in effect fixing the most glaring flaw in another piece of legislation PhRMA pushed hard for. In exchange for that, and its support for the legislation, PhRMA got a law that excluded price controls, reimportation of drugs from Canada and elsewhere, curbs on marketing and other industry bugaboos. And even as they slash prices to come up with that $90 billion they promised the government, pharmas will almost surely benefit down the road from increased sales volume as the law brings tens of millions of formerly uninsured Americans into the healthcare system.

However, most provisions don't go into effect until 2014, and in the meantime, the new Republican majority in the House of Representatives has vowed to defund as much of it as possible—red meat for the base, perhaps, but Republican hostility toward the law could mean some changes at the margins, including a couple matters of importance to pharmas. PhRMA is itching to see a provision establishing an Independent Payment Advisory Board for Medicare hampered, fearing that the board, appointed by the president, could effectively impose price controls on the program. The board's recommendations for cost-cutting go into effect automatically unless Congress approves a bill making alternate cuts. PhRMA waged a furious but unsuccessful rear-guard action to kill the provision when it popped up late in the healthcare debate.

House Republicans could also take aim at the comparative effectiveness measures in the law, including the Patient Centered Outcomes Research Institute, a non-profit organization tasked with advancing comparative effectiveness research. Ex-FDA communications chief Peter Pitts says the board "provides the grease on the slippery slope towards formularies." Three of its 21 seats are dedicated to pharmas, with execs from Pfizer, J&J and Medtronic among the initial appointees. Congress could also pull the $1.1 billion allocated to the Agency for Healthcare Research and Quality for comparative effectiveness research by the law.

"That money will be radically reduced if not eliminated altogether," predicts Pitts, now of Porter Novelli and the Center for Medicine in the Public Interest. Pitts also expects "a very colorful season for healthcare hearings on the hidden codicils of healthcare reform," including a thorough grilling of interim CMS administrator Don Berwick, who has said nice things about the UK's National Health Service, setting off alarm bells in conservative circles.

5 biggest US patent expiries, 2011

Drug (Co.)	Disease	US sales '09
Lipitor (Pfizer)	High cholesterol	$7.1B
Plavix (BMS/Sanofi-Aventis)	Blood clots	$5.7B
Advair Diskus (GlaxoSmithKline)	Asthma/COPD	$4.6B
Zyprexa (Eli Lilly)	Antipsychotic	$2.7B
Levaquin (J&J)	Infections	$1.5B

Source: IMS Health

The elections dislodged several committee chieftains who have been thorns in the industry's side. In the Senate, Chuck Grassley (R-IA) is giving up his status as ranking minority member of the Committee on Finance to lead the minority on the Committee on the Judiciary. In the House, Henry Waxman, who routinely held Energy and Commerce Committee hearings on industry evildoing, will be replaced by a more pro-industry Republican as chair (at press time, Illinois' John Shimkus, Michigan's Fred Upton, Texas' Joe Barton and Florida's Cliff Stearns are in the mix), and the Ways and Means Committee will likely be chaired by Michigan's Dave Camp.

Of course, the elections won't have much of an impact on the FDA, where a number of former Waxman staffers have burrowed in, and industry shouldn't expect any letup in enforcement.

"If I were to start an agency in this environment, I would call it Dragnet," cracks Healogix's Kaplan. "Just the facts, ma'am. That's where everything is headed—you've got shrink-wrapped clinical evidence and you can either say it or you can't."

As Obama's FDA has staffed up and cracked down, enforcement letters have become an almost casual gesture.

"Warning letters are an immediate reaction and can be sent with a push of a button," says Publicis Healthcare chief Colucci. "Marketers need to be hyper-vigilant and turn around responses and justifications with haste and content to avoid triggering more aggressive Beltway engagement."

FDA's top lawyer recently said the agency would begin going after company CEOs for off-label marketing out of a sense that massive fines don't work as a deterrent and are simply written off as the multimillion dollar cost of promoting multibillion dollar drugs. In November, a Federal grand jury indicted a former GSK top lawyer on allegations that she lied to FDA about off-label marketing.

And industry hands in Washington anticipate another effort to pull tax exemptions for pharma marketing costs as members of both parties look for ways to cut costs without hitting individuals.

"No member wants to go into the next election having raised taxes on individuals or cut entitlements," says John Kamp of the Coalition for Healthcare Communication. "Every revenue option ever considered will be back on the agenda this year, and this is clearly one that will be considered."

And while the regulation-averse Republicans might seem more natural allies for the industry, the battle over healthcare reform created bad blood between the GOP and drug companies, which presumptive House Speaker John Boehner once slammed for "cutting a deal with the bully" and "helping him steal others' money as the price of protecting your own."

"There are some fences to be rebuilt," says Kamp. ■