
A NEW DA

The healthcare reform legislation inching toward the president's desk will mean big changes for the pharmaceutical industry, whatever its final form. **Matthew Arnold** takes a look at what's ahead

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Though better known for his jump shot, the president is also a chess player, habitually thinking several moves ahead and hard to faze. It shows in his healthcare game.

When he and his staff set out to move major healthcare reform legislation, they brought on board the grand masters of Congressional procedure, grooming former Senate majority leader Tom Daschle to head Health and Human Services and installing Rahm Emanuel, a pugnacious Democratic congressional enforcer as chief of staff.

They solicited the input of old bulls like John Conyers and Ted Kennedy. They sized up the major players—insurers, hospitals, doctors, seniors, labor and, of course, the drug industry. They secured the buy-in of all the big stakeholders well in advance—all except for the insurers, and even they got a dance or two.

PhRMA chief Billy Tauzin is nobody's fool, either. The wily former congressman and committee baron saw that the industry he represented faced powerful enemies in the president's own party and needed to claim a seat at the table if legislation was likely to pass. He came to the table prepared to make serious concessions. The Obama administration was eager to sideline a powerful lobby—the better to train their fire on America's Health Insurance Plans (AHIP).

From early spring through mid-summer, Tauzin attended five meetings at the White House, getting as much face time with the president and his staff as did AHIP's chief Karen Ignagni. Merck's Dick Clark, Pfizer's Jeff Kindler and Johnson & Johnson's Bill Weldon also made pilgrimages to Pennsylvania Avenue.

On June 19, PhRMA announced its members' intention to put $80 billion in cost-savings toward the health reform cause over 10 years, and to provide discounts that would halve the price of drugs to seniors in the Medicare Part D coverage gap—on the implicit condition that the legislation doesn't wring billions more out of the industry by imposing price controls.

Not everyone was happy with the agreement, of course. Liberals howled.

"PhRMA would like to see if they can get a bargain," said Rep. Henry Waxman (D-CA), who has Tauzin's old job as chair of the Energy and Commerce committee. "I think that PhRMA should contribute more than PhRMA wants to contribute." Across the aisle, House Minority Leader John Boehner (R-OH) accused Tauzin of "appeasement."

"When a bully asks for your lunch money, you may have no choice but to fork it over," said Boehner. "But cutting a deal with the bully is a different story, particularly if the 'deal' means helping him steal others' money as the price of protecting your own."

Coalition for Healthcare Communication chief John Kamp says Tauzin's bargain was a win-win for an embattled industry.

"Seniors really care about the donut hole," says Kamp. "Tip your hat to Billy Tauzin and the board of PhRMA for coming up with

that one. Good politics, good medical policy, good sense and good business."

Kamp is sanguine about healthcare reform, guessing it will deliver 15-30 million new patients, most in primary and chronic care, and strengthen the Medicare prescription drug benefit. On the downside, any bill that increases government's role as payor inevitably means increased pricing pressures on drug and device manufacturers in the long run.

Peter Pitts, the former top FDA flack who heads Porter Novelli's healthcare practice and the Center for Medicine in the Public Interest, says the deal is very good for pharmas—if it holds.

"It protects the non-interference clause that prohibits the government from negotiating Part D drug prices, hence avoiding the slippery slope to broader government-imposed price controls," says Pitts. "It takes drug importation off the table. It closes the donut hole, allowing Part D to pay for more on-patent drugs for more patients. And it maintains the status quo for dual eligibles."

While the Senate version of the legislation would respect the deal (Senate Finance chair Max Baucus, D-MT, brokered the agreement), the House version is another story. The House bill would nix the non-interference clause and impose mandatory rebates in Medicare Part D.

AstraZeneca CEO David Brennan said: "We said there were principles we didn't want to see violated. And if those principles—price controls, Medicare rebates, moving dual eligibles back from Medicare and back into the Medicaid discount program—if those things happen, I don't see how we could be supportive of the program."

Big brands teeter at patent cliff's edge

Last month, Novartis launched the latest big OTC switch of a blockbuster prescription brand that went off-patent with its roll-out for Prevacid 24HR. Drugs expected to go off-patent in 2010 include Effexor XR, Eloxatine, Cozaar/Hyzaar, Taxotere, Arimidex and Gemzac.

The patent cliff really hits in 2011, when brands with estimated combined sales of nearly $20 billion go off-patent in the US, including the biggest of them all, Lipitor. Other blockbusters set to lose exclusivity in 2011 include Seretide/Advair (both asthma and COPD indications), Zyprexa, Aricept, Levaquin and Lamictal XR.

Compounded by the dry spell in small molecule innovation and the overcapacity created by the latest round of mega-mergers, it points to still more shrinkage on the pharma side of the industry.

PhRMA chief Billy Tauzin knows his way around a big, unwieldy piece of legislation like none other. As chairman of the Energy and Commerce Committee, Tauzin was one of the prime architects of the Medicare prescription drug benefit before leaving Congress to head PhRMA. In his grand bargain with the White House and Sen. Baucus, Tauzin made serious concessions and contributed mightily to the cost savings target while strengthening the prescription drug benefit and soothing seniors

As of this writing, combined Senate legislation has just been unveiled and must pass several crucial votes before moving on to reconciliation with the House bill. A final bill is not expected to arrive at the president's desk before January.

"There's going to be a lot of horse trading," says Pitts.

As with the question of price negotiations, the House version's provisions aimed at fostering greater transparency on industry payments to physicians are more severe than the Senate's, which has industry approval.

Basically, the House version would impose more onerous reporting requirements on more types of healthcare professionals. In general, however, the so-called sunshine legislation has broad bipartisan support, and many companies have already moved towards compliance with its reporting provisions.

Shire's Michael Boken, senior director of marketing for Vyvanse, calls it a positive for the industry, one that will remove the taint of perceived influence-peddling.

"We've seen similar issues arise in other industries where corporate relationships are not disclosed and it can result in negative publicity for the entire industry," says Boken, citing the example of financial services. "Increased transparency always results in more ethical practices and less opportunity for misinterpretation by the media and the general public."

Greater transparency does mean greater scrutiny. "Management of new transparency will be one of the greatest challenges of the new decade," cautions Kamp.

Perhaps more important is the question of funding for effectiveness studies that the industry fears could be used to establish European-style formularies for federal programs.

"What's being discussed is government funding of clinical effectiveness rather than comparative effectiveness or its evil sister, cost effectiveness," says Pitts. "Where this is leading is toward a more European version of healthcare technology assessment. The current bills state that CMS cannot use these studies for reimbursement decisions."

Kamp takes a more jaundiced view, saying that while we're years from a British-style, NICE-esque system, we're headed that direction. The stimulus act, he notes, funded nearly a billion dollars' worth.

"Comparative effectiveness will take a decade or so to filter through the system, but like REMS, it promises to change the face of much

What healthcare reform will mean

FOR PAYMENTS TO PHYSICIANS:
Some form of sunshine legislation is in the cards. The only question is: Will it be the House version, with its unforgiving (some argue impossible) 2010 start date and more expansive reporting requirements, or will it be the Senate version that the industry has more or less signed on to? Under the Senate version, companies have until 2012 to put reporting systems in place and the types of healthcare professionals for which reporting is required are far fewer.

FOR FOLLOW-ON BIOLOGICS:
Both bills establish a pathway to follow-on biologics with 12 years of data exclusivity, meaning that would-be generic challengers cannot piggyback on the innovator's clinical trials data before year 12 of licensure. The patent litigation processes laid out in the Senate version are a little more complicated than those in the House version, but the bills agree on the broad strokes, and it's a big victory for the biotech industry, which sees it as a dramatic advance over the Hatch-Waxman Act governing drug patents.

FOR PRICING:
The Senate bill prohibits repeal of the non-interference clause for the Medicare prescription drug benefit, which essentially says the government can't directly negotiate drug prices for the program – one of PhRMA's conditions for supporting legislation. The House bill is another story. Should that version prevail, the industry could soon come under enormous pressure to lower prices. An alleged run-up in branded drug prices over the past year – up 9%, according to an analyst working for AARP – is sure to fuel support for the House bill, and Congressional powers have already demanded a GAO analysis of drug prices to monitor "anticipatory price gouging."

FOR COMPARATIVE EFFECTIVENESS RESEARCH:
Happily for pharmas, the legislation points towards clinical effectiveness research – studying how well drugs work for patients – rather than cost effectiveness. Both bills prohibit CMS from using such research to make decisions on which drugs to cover.

FOR MARKETING AND ADVERTISING:
Not much. Efforts to include provisions empowering FDA to place a moratorium on ads for new drugs or to pull pharmas' tax deductions on ad spend fell short in the House. Far short. Still, expect to see these zombie policies rise and lumber on again and again. In particular, look out for Sen. Al Franken's (D-MN) flesh-eating proposal to kill tax-deductability not merely for DTC but for all drug marketing, which would, if it ever passed, make pretty much any promotion of prescription drugs prohibitively expensive.

industry marketing," says Kamp. "Comparative effectiveness data may eventually be a required part of labeling and marketing."

One of the industry's triumphs in the healthcare reform fray was getting a provision authorizing a 12-year exclusivity period for biologics past Rep. Waxman's Energy and Commerce committee over his objections. That legislation, aimed at establishing a path for biosimilars or follow-on biologics, followed a major push by the Biotechnology Industry Organization. Similar language was adopted by the Senate.

"It seems pretty clear that there will be a legislative pathway that will extend patent protection and data exclusivity," says Pitts. "Follow-on biologics will need to undertake clinical trials and follow very precise good manufacturing practices. This means they will not follow the same price structure as small molecule generics. I predict they will be around 20%-25% of the innovator price. That means that there will be no windfall savings, and that the innovator companies can still turn a profit by continuing production and sales post patent expiry."

Taken altogether, these little changes to the incentives structure —increased government involvement meaning increased pricing pressures, comparative effectiveness research and movement towards increased generics access for small and large molecule compounds alike—point to more patients and greater stability in the short term and smaller profits in the long term.

While extending coverage to most of the uninsured and reining in some insurance industry excesses, the legislation really only tinkers with cost, but suggests gradual movement towards a more efficient and cost-effective system.

An analysis by McKinsey and Company that was picked up by *The New Republic* put it this way: "For many pharma/biotech and device companies, this will largely feel like a major acceleration and amplification of recent market forces over the next few years (i.e., rising payor influence, increasing development costs and commercial restrictions, intensifying pricing/margin pressures)—curbing overall industry revenue/margin growth and value creation."

Drug and device makers, McKinsey concluded, "will feel more significant pain" as a result of the legislation than will doctors, hospitals and payors, but that pain can be offset by greater R&D productivity if manufacturers learn to weed out unpromising candidate compounds earlier.

"Change, although uncomfortable, forces an organization to reevaluate its purpose, processes and people," says Joe Shields, product director for Enbrel consumer at Pfizer. "At the very least, this reform effort should help to wring unnecessary costs out of our current system and demand accountability from all sectors of the healthcare economy. At best, it will transform the system to proactively support prevention and wellness. Innovation in drug development and commercialization is more important today than it ever was."

And having long borne the brunt of Americans' frustration with their healthcare system, the industry might also benefit from a regime in which fewer people are looking for someone to blame for their high healthcare bills and insurance insecurity.

Of course, better coverage means fewer prescriptions left unfilled because the patient can't afford it, and that means better adherence and persistence.

"The end result will be more Americans having better access to healthcare," says Shire's Boken.

"And that may also lead to improved adherence to treatment and physician-advocated lifestyle changes that may improve overall health, preventing complications and resulting in cost savings to the healthcare system," he explains. "Manufacturers should benefit from more access to healthcare and increased adherence to treatment that may result from healthcare reform." ■