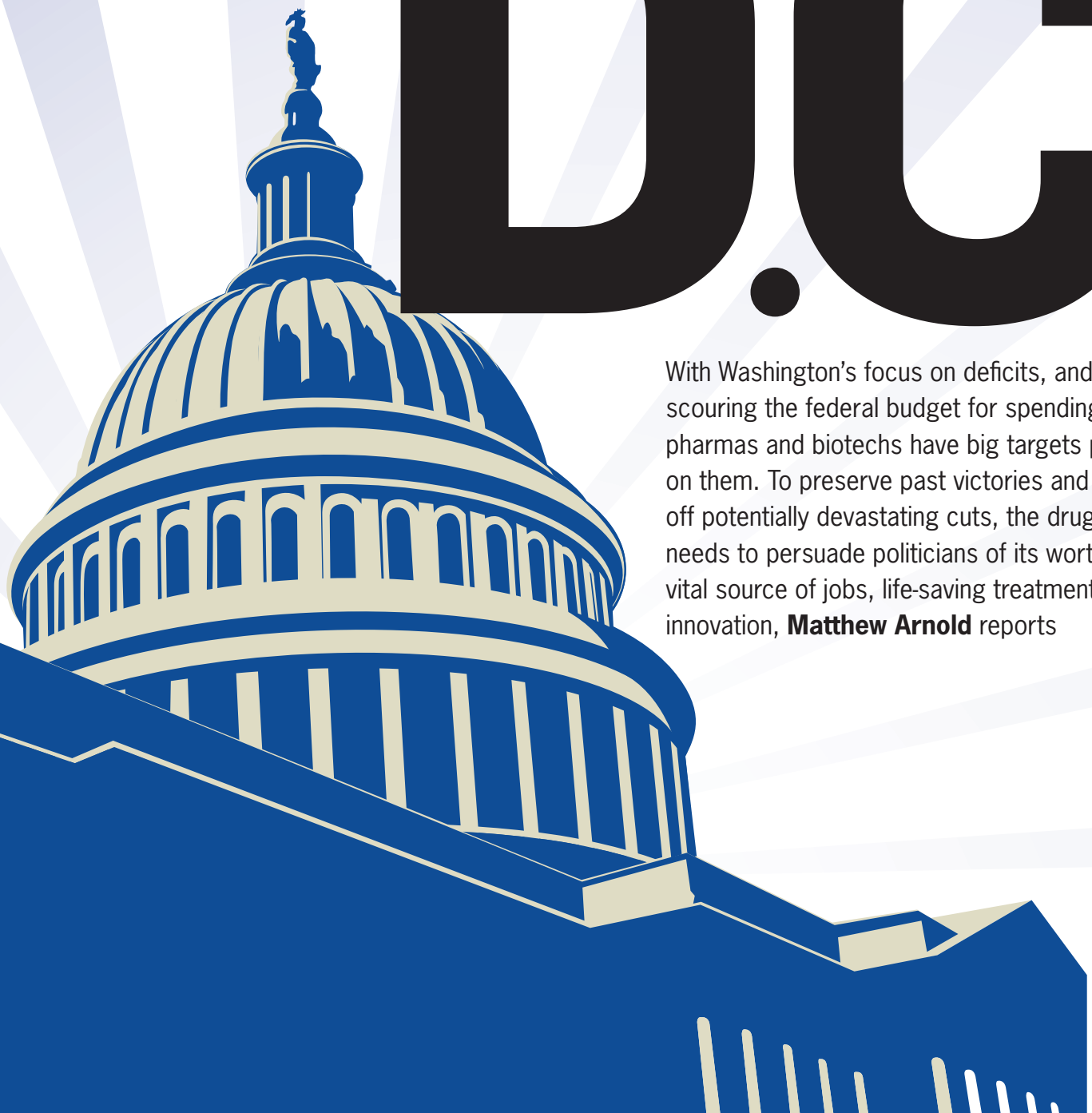
OUTLOOK 2012

DETAILING D.C.



With Washington's focus on deficits, and Congress scouring the federal budget for spending cuts, pharmas and biotechs have big targets painted on them. To preserve past victories and stave off potentially devastating cuts, the drug industry needs to persuade politicians of its worth as a vital source of jobs, life-saving treatments and innovation, **Matthew Arnold** reports

You might not realize it, but if you work in the healthcare industry, particularly in biopharma, and even more particularly in marketing for a biopharma company, you've been painted with a giant bullseye. Oh, don't go looking for it in the mirror – only lawmakers can see it, but it's there.

For months now, Washington has been gripped by deficit-cutting fever, and ballooning healthcare costs are the number one driver of non-discretionary spending in the federal budget. Republicans are determined to slash entitlements. Democrats are desperate for a grand bargain with cuts to social programs offsetting economic stimulus going into an election year. The drug industry looks like a huge potential source of revenue to lawmakers of both parties.

At press time, Congressional "Supercommittee" staffers were throwing around ideas including deep cuts to Medicare, eliminating the tax deductability of pharma advertising and Part D drug rebates that pharmas say amount to price controls.

The drug industry fields one of the most powerful lobbies in Washington, and however hidebound, PhRMA gets results. Over the past decade the industry has mostly gotten its way with the Medicare Part D prescription drug benefit, last year's Patient Protection and Affordable Care Act (PPACA), and most recently, patent protections on biologics and intellectual property protections in trade pacts. But the hunt for budgetary fat to cut threatens many of these gains, so pharma must make the case for itself as a source of good jobs and a center of American innovation right up there with the tech sector.

Did you know that the pharma sector supported four million US jobs in 2009—675,000 directly? Or that each pharma sector job supports four more in other sectors, from manufacturing to construction to contract researchers and child care providers? How about this: advertising-driven sales help support nearly 20 million jobs in the US.

You can expect to hear a lot more of these sorts of stats in the year ahead, as the biopharma and advertising industries make their case for why legislators should look elsewhere for their pound of flesh.

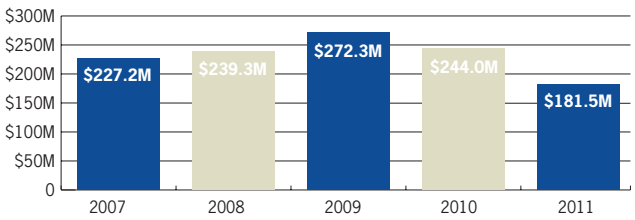
Sputnik and biotech

"We're starting to talk a little more about how it is that drugs are paid for in this country, and that gets to the value proposition," says PhRMA communications chief Karl Uhlendorf. "The fact is, generic utilization is approaching 80%. Plenty of folks think it should be a lot higher. There is a tipping point where in order to have future generics, you have to nurture branded drugs."

Merck chief Ken Frazier put that in economic perspective in a July *Wall Street Journal* opinion piece assailing the Obama Administration's efforts to cut federal healthcare spending through the Independent Payment Advisory Board and price controls on the Medicare Part D prescription drug benefit. "Merck, the company I manage, has over 40,000 people on its payroll in the US," wrote Frazier, "and while overall pharmaceutical employment here has shrunk in recent years, it still tops 650,000. These are high-quality jobs, with an average salary of more than $95,000. Biopharmaceutical research is skilled and labor-intensive."

Pharma in Washington

The drug industry fields one of the most powerful lobbies inside the Beltway (annual expenditures shown). Expect the rhetoric to ratchet up in the year ahead.



Source: Center for Responsive Politics (opensecrets.org)
* Based on pharma/health products lobbying activity through Q3 2011

The drug industry has found a surprising ally on these concerns in… the Obama Administration? In his most recent State of the Union address last January, Obama spoke of "this generation's Sputnik moment," a jarring call to invest in science and technology to maintain our national competitive edge, and the President has repeatedly made the case for the biopharma sector as a center of innovation in American industry. The White House has poured billions into early-stage drug development, ultimately meant to spur commercialization of new drugs by private industry, and the President has spoken of personalized medicine—in particular, the development of revolutionary individualized anti-cancer treatments—as being among the industrial moonshots he'd like to see US companies undertake.

The public seems to share the administration's appreciation of the industry's economic importance. In a recent PwC survey, six in 10 respondents said pharma and biomedical research is an important engine for economic growth.

All this talk about "winning the future," in part with innovative medicines, hasn't stopped the Obama Administration from making some proposals that industry leaders say could cost tens of thousands of jobs, but the President's remarks suggest an openness to industry concerns going into an election year in which the nation's grinding economic woes and widespread unemployment are top of mind at 1600 Pennsyvania Ave.

A thousand cuts

Chief among the industry's worries in Washington right now is a proposal by the administration, included in the jobs bill Obama proposed in October (and promptly voted down by Congress), to impose rebates on the Medicare prescription drug benefit that industry leaders say would

amount to price controls. That measure would cost up to 238,000 US jobs in pharma and related industries, according to the estimates of American Action Forum, a conservative think tank helmed by a former director of the Congressional Budget Office.

"Mandatory Part D drug rebates would put people out of work, increase costs for seniors and privately-insured patients, and slow research and development for new drugs," said Douglas Holtz-Eakin, who directed the CBO from 2003-2005.

The White House's Office of Management and Budget estimates that the measure would save $135 billion in federal expenditures over 10 years, but Holtz-Eakin's group says it would sock the drug industry for a dollar-to-dollar revenue reduction and make some meds too costly to produce.

Another administration move that has pharmas fuming is the White House's repeated efforts to reduce the period of data exclusivity for biologics from 12 years to seven. The biopharma lobby thought it had settled this matter last year, after it became a bargaining chip in healthcare reform negotiations. Then the administration revived, but ultimately dropped, the proposal as part of patent reform legislation which the President signed in September, Eli Lilly's John Lechleiter among the industry chieftains looking on. Now it's back on the table as a deficit reduction measure being kicked around by Supercommittee Democrats.

Another legislative zombie said to stalk the Capitol Building of late is the notion of yanking or cutting the tax deductability of pharma advertising. It might not stand up to a First Amendment challenge, says the Coalition for Healthcare Communication's John Kamp, but it might effectively shut down consumer advertising of prescription drugs while the wheels of justice grind away, and that would mean many jobs lost in both the pharma and medical advertising sectors.

"This could be the most damaging suppressant of economic activity ever," says Kamp, who fears that companies would respond to such a grab with an immediate halt to all advertising for the remainder of the year, followed by a flat 37% reduction, on average, in advertising expenditures going forward.

O, Christmas Tree

In Washington parlance, to "Christmas tree" is to garnish a must-pass piece of legislation with dozens of unrelated or incidental bills. Sometimes it's done to kill or hinder the "host" legislation, other times merely as an expedient means of sneaking otherwise un-passable bills through. The coming year's top Christmas treeing target is the reauthorization of the Prescription Drug User Fee Act, which is set to expire next September.

"The chairs in the House say they would like to move the legislation quickly and cleanly," PhRMA president and CEO John Castellani said in April. "The Senate will be a different story. We expect that since this is a healthcare legislation bill that must be passed, that a lot of other things will be added on."

PhRMA wants not only a clean bill, but one that speeds up approval times. Given the eagerness of the White House and Congressional Dems to stimulate economic activity, that might not be an impossibility, but in an election year with much else going on, it won't be easy.

The industry is also eagerly awaiting guidance from FDA on social media and from CMS on the "Sunshine" provisions of the PPACA. A first draft of what is likely to be one of several not-crystal-clear guidances on social media and Internet communications has been circulating at FDA for most of the year, held up over legal worries. The Sunshine guidelines, for which pharmas are supposed to begin collecting data on January 1, aren't very far along, and because CMS has much heavier lifting to do as it works to implement the PPACA, administrators have, as yet, offered no timeline for guidance—despite being taken to the woodshed by Senators Grassley and Kohl, who authored much of the legislation.

It's not all defensive plays for the industry in 2012, as FDA's policy regarding communication on off-label uses of approved drugs is being challenged on First Amendment grounds, and a recent Supreme Court case on commercial provision of prescription data is heartening industry lawyers, who see a potential disarming of the rationale behind the jaw-dropping settlements for off-label marketing of recent years. In that case, *Sorrell v. IMS Health*, the Court decided in June that governments could not prohibit commercial speech because they found it too effective. Several cases dealing more directly with off-label promotion are wending their way through the courts.

What's more, with healthcare reform passed and Wall Street raising public ire, pharmas are no longer America's most loathed industry.

"We are still in the post-Vioxx era," says Kamp, "but Congress doesn't care so much about pharma marketing. They care about food and drug safety. They care about the new medical device approval process. There's some discussion about conflicts of interest and whether that's slowing down approvals."

The ugly economy has taken some heat off pharma, but it's also a reflection of the industry's hard-won legislative victories of the past decade—Medicare Part D and the PPACA—having defused some of the public anxiety about healthcare costs, for which prescription drugs, with their substantial co-pays, have often borne the brunt.

Kamp notes that while the industry has taken a hit in the short term from give-backs built into the legislation, reputational gains, along with increased volume, will put the industry on firmer footing in the long run. "The best kept secret about healthcare reform is that if it keeps, it's a pretty good deal for pharma." ■

Top pharma/health lobbying clients, 2011*

The top 10 Biopharma firms and their trade groups have spent more than $70 million in 2011, the Center for Responsive Politics reports.

Rank	Client	Total
1	PhRMA	$14.1M
2	Pfizer	$10.7M
3	Amgen	$7.3M
4	Merck	$7.1M
5	Eli Lilly	$6.9M
6	BIO	$6.0M
7	Novartis	$5.3M
8	Johnson & Johnson	$4.9M
9	Bayer AG	$4.9M
10	AstraZeneca	$4.5M

Source: Center for Responsive Politics (opensecrets.org)

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