

R&D cuts by sponsors spur more collaboration, innovation

New strategies share pipeline activity costs

After decades of relentless increases, research and development spending by the top 12 pharmaceutical companies has leveled off at a collective \$70 billion annually since 2008.

Now, it appears to be headed for a controlled free fall. Pfizer is making the biggest retrenchment of all, having announced in 2011 plans to incrementally slash its R&D budget from \$9.4 billion to \$6.5 billion as its disease focus narrows. Other industry standard bearers, including AstraZeneca and GlaxoSmithKline, also have been ratcheting down spending.

Conventional wisdom holds that R&D spending is the mainstay of innovation, suggesting cost-cutting could have a detrimental impact on the innovation engine. But many industry insiders take a decidedly different view. Pharmaceutical R&D has never been wildly productive, finishing six decades with a per-company average of one new drug every six years, according to Bernard Munos, a former Eli Lilly executive who founded the InnoThink Center for Research in Biomedical Innovation. Through 2008, even top-performing Merck had a batting average of only .95 new drugs annually. In that view, Pfizer's three drug approvals in 2012 were likely a non-recurring statistical anomaly; so were the two approvals each for Astellas, Forest, Roche and Sanofi.

R&D has always been an inherently daunting enterprise, as evidenced

by the fact that only six of the large pharmaceutical companies that existed in 1950 have survived, according to Munos. It also, he said, consumes roughly 15% of revenue, well above every other industry sector. Yet smaller biotechnology companies routinely do more with less, out-licensing promising experimental medicines into big pharma portfolios.

Since 2004, large pharmaceutical companies have accounted for only about a third of all new drug output. Merger and acquisition activity has done nothing to fatten pipelines, Munos said, nor have process improvements done much to thin costs. The pressure to raise new drug output has companies turning out many medicines of tenuous clinical benefit, while soaring research costs are pushing prices to exorbitantly high levels few can afford.

To compound these challenges, a large share of R&D budgets are being spent on late-stage clinical trials that support aging blockbusters instead of funding breakthrough research for new cures, said Munos. It's time, he said, to rethink that strategy. Only about 20% of all drugs licensed to big companies become blockbusters. Under the Affordable Care Act, monetary success of drugs is also dependent on their ability to significantly outperform what's already on the market.

Major sponsors believe collaborative models will most effectively lower fixed costs while stimulating invest-

Pharmaceutical R&D spending

Year	Spending (U.S. billions)	Growth over prior year
2002	\$69.2	14.0%
2003	\$78.7	13.7%
2004	\$87.7	11.4%
2005	\$95.8	9.4%
2006	\$107.4	12.1%
2007	\$118.7	10.4%
2008	\$129.2	8.9%
2009	\$125.3	-3.0%
2010	\$127.3	1.7%
2011	\$131.7	3.5%
2012	\$132.5	0.6%

Source: EvaluatePharma, 2011

ment and innovation activity. Increasingly, they are collectively solving common drug development challenges, including finding disease biomarkers. But except "under pressure," they tend to "fiercely resist knowledge-sharing with their peers," Munos said. The quest for an Alzheimer's treatment has consequently become a multi-billion-dollar endeavor with 116 therapies under development.

In addition to poor R&D productivity and shifting reimbursement policies, lost patent protection cost the top 12 sponsors their steepest revenue loss in 2012, according to Burrill & Company's 2013 annual report on the life sciences industry. Pipeline success rates across every phase of development have been flat at best, with no discernible sign the trend is reversing.