Drugs, Industry, and Academia

This week, international academic and industry leaders, investors, and policy-makers participated in the Biotechnology Industry Organization’s International Convention in San Diego, a reminder that prospects for new drugs seem bleak. Only 17 new molecular entities were approved by the U.S. Food and Drug Administration (FDA) in 2007, a fall from 53 in 1996. Coincident trends worsen the situation: a decline in prescription drug sales, the flight of investors, corporate layoffs, and pricing inequities in advanced economies that fuse with demands from poorer countries to gain cheap and immediate access to new drugs.

The paradox is that this comes as high-throughput screening, combinatorial chemistry, and rationalized drug design have revolutionized the discovery of new drugs and their targets. Ironically, just as the conventional business model appears fallible, academia has been lured by funding to re-engage in translational science (moving basic research findings into clinical application). However, academia lacks features intrinsic to drug discovery and development: incentives for “team science,” relevant infrastructure, and the capacity for large-scale production. So, like star-crossed lovers, industry and academia face both challenge and opportunity. How might they reposition themselves to interact effectively and bring new drugs to the table?

Initiatives such as the Medicines for Malaria Venture and the TB Alliance exemplify shifting global alliances of academia and industry to collaborate on treating neglected diseases of the developing world, from drug discovery through development. Governments, the private sector, and philanthropies have responded altruistically to such enterprises. The keys have been focus, flexibility [such as with intellectual property (IP) rights], tight timelines, and sufficient resources. This model of cooperation might provide a blueprint for optimizing the interface between both sectors to speed drug development more generally.

The capacity of the academic sector for drug development is illustrated by its experience with vaccines and biologicals (such as inhibitors of inflammation). Moreover, discoveries of niche applications for compounds that have failed in their primary application by industry (such as compounds with a new use in reducing cholesterol) suggest that the revision of outmoded approaches to IP might enable such academia/industry interactions to expand further.

Academia and industry might explore models to interact that are unconstrained by IP. One example would be secure Internet chat rooms for industry chemists and academic biologists to become acquainted and hatch projects, whose specifics would only then determine the division of IP. Presently, IP agreements occur before an academic even identifies chemists in a company, let alone discusses science with them. Similarly, both sectors are investing independently in defining biological networks of genes and proteins for target selection and drug development. This effort might be more efficient as a precompetitive public/private partnership, leaving the subsequent selection of targets and the attendant chemistry to IP.

A major bottleneck in drug development is in human capital. Investigators who project their science across disciplines are fundamental to producing safe and efficacious drugs. Such integrated expertise is scarce. But recent initiatives, such as the Wellcome Trust’s Training Program in Translational Medicine and Therapeutics, are providing trainee experience across sectors.

Regulatory agencies need to be empowered with funds for inspections that meet global standards and for harnessing academia to explore claims of drug efficacy and safety, independent of the sponsor but respectful of proprietary interest. Labeling might also be revised to indicate drugs that are truly innovative, because approval might be accelerated for drugs that are the first to safely address unmet clinical needs.

What if political pressures that threaten to drive down prescription drug costs also depress reimbursements for health care delivery, the lifeblood of science in many U.S. medical schools? Both industry and academia are poorly positioned to respond in the financial landscape. Such a scenario might occur rapidly, just like the rise in the price of oil, and alter both the livelihood of academic research and the industrial approach to drug development. But a crisis can present opportunities if both sectors strengthen their relationship. The time to revise the building code is not when the earthquake strikes.

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