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Making Translation Work

BIOTECHNOLOGY'S LARGEST GLOBAL EVENT, THE BIO INTERNATIONAL CONVENTION, CONVENES at the end of this month in Washington, DC. BIO is a key forum for exploring partnering opportunities and discussing industry trends, investments, and policies meant to better the world. The gathering is timely because there is an increasing need for new therapies for relentless illnesses. In the United States, cardiovascular disease accounts for 34% of all deaths, and Alzheimer's disease afflicts one of eight Americans at age 65 (and nearly half of 85-year-olds). Treatments for these and other conditions are needed, but the U.S. Food and Drug Administration (FDA) approved only 21 new drugs last year, about half of the more than 40 drugs approved annually in the 1990s. New creative partnerships and regulatory procedures are needed if this is to change.

There are plenty of explanations for the slower approval pace, such as the complexity of chronic diseases and regulators' increasing aversion to risk. And even the harshest critics of biotech and pharmaceutical companies' pricing and marketing practices should recognize the importance of FDA policies and industry's R&D activities for the world in this era of globalization. Although translating lab discoveries into disease relief has always been challenging, the difficulty has intensified lately. Promising drug development projects routinely encounter the notorious "valley of death": a wasteland of business challenges that aborts academia's hopeful discoveries before industry's commercially savvy hands can deliver them to patients. And market forces, such as the flight of capital to less risky economic sectors, are broadening the divide between laboratory discoveries and a drug's debut.

Academic laboratories have long been ideally suited to unravel the causes of disorders. Needed now are creative programs that transcend the traditional technology transfer functions of nonprofit research enterprises to promote fruitful academia/industry partnerships for drug development, along with new scholarship in regulatory sciences and pharmacoeconomics. QB3 (www.qb3.org) is one promising example. This coalition of three University of California campuses has successfully introduced Innovation Toolkit (services and funding to aid entrepreneurial scientists), a startup incubator, and core lab facilities into a strong academic environment. This has produced new companies and private/public partnerships, such as one between the University of California, San Francisco, and Pfizer that breaks from tradition by creating the Center for Therapeutic Innovation, an open network of researchers designed to accelerate the pace of moving from discovery to proof of concept. Other encouraging partnerships are being launched in the United States and abroad, including Gilead Sciences with the Yale School of Medicine to explore cancer therapies, and F. Hoffmann-La Roche with three academic institutes in Switzerland for translational medical research.

Still, the biomedical sector needs to think more creatively about new methods for sharing and profiting from intellectual property. Confidentiality provisions of industry/academia partnerships can be adjusted to allow reasonable protection of commercial interests within strictly defined domains of joint activity, while leaving academicians ample space for open communication and publication. Elected representatives should fuel academia's discovery research with budget increases at the U.S. National Institutes of Health (NIH). And the FDA should adapt policies that reflect not only society's great need for new medicines but also the reality that risk is a continuum, rather than a yes/no question.

Change is under way as new efforts, including the FDA-NIH Joint Leadership Council and the National Cancer Institute's Clinical Trials and Translational Research Advisory Committee, bring together decision-makers from academia, industry, and government to address these needs. With ingenuity, new and better therapies can be achieved, but everyone must play a part in delivering the promising results of academic research to industry, and ultimately to the ailing patients who so urgently need relief.

— R. Sanders Williams and Susan Desmond-Hellmann

