Current Perspective

Innovation: Risky Business

The doubling time of medical knowledge is estimated to be less than three years. This new knowledge should be followed by new therapies to transform patient lives. As physician/scientists, we help drive such innovation at the clinic, in research and engineering labs, and in clinical trials. As ophthalmologist/clinicians, we depend on the resulting drugs and devices to provide the best possible care.

In retina I think of anti-VEGF drugs, OCT instrumentation, and intravitreal drug sustained-release technologies as examples that have revolutionized therapy and improved patient lives. And each of these continues to spawn new developments.

But the innovation cycle is threatened—by the cost of innovation itself.

National Eye Institute (NEI) funding has always been critical to innovation, from basic understanding of disease pathobiology and exploration of candidate molecules to phase 3 clinical trials. Yet the entire NEI budget was only about $674 million in FY2014—down from $820 million a decade earlier (in 2014 dollars).

Ophthalmology innovation depends heavily on industry research and development (R&D) funding. Alcon, a division of Novartis, spends nearly $900 million a year on R&D. Allergan—a company with nearly half of its business in ophthalmology—spent over $1 billion in R&D in 2014, with a plan to expand that in coming years. But consolidation in the ophthalmic industry may shrink the dollars available to fund innovation. For example, Valeant Pharmaceuticals, now engaged in a hostile takeover of Allergan, has announced its intentions to significantly reduce Allergan's R&D funding, if successful. While this may be a sound short-term business approach to cut costs and increase earnings per share, many would argue that it does so at the expense of future product innovation.

Finally, small private companies get most of their funding from the venture capital (VC) community. In 2013, ophthalmic VC funding was estimated to be about $400 million out of a total of about $4 billion in health care VC funding. Private philanthropy, nonprofit research investments, and angel investors also play a role.

And innovation is, by definition, risky business. Most new molecules fail to reach the market. The estimated cost of bringing a new molecule to market (accounting for both successes and failures) is between $800 million and $1.3 billion. This price tag emphasizes the need for big players—and also for new, less costly models of drug development.

This explains why some companies have as a major business strategy the in-licensing of already approved products. But that's not innovation. More commonly, companies in-license potential products that show promise but have not yet been finally approved by regulatory bodies. Though that approach is not fully innovative, the business acumen, clinical testing infrastructure, and regulatory experience of these companies optimize the chance that some of these molecules and devices will make it to market quickly.

As physicians, our objective is to provide the best possible care with appropriately efficient use of resources. At times, we shake our heads at the cost of new devices and drugs. But we also recognize the value brought to us and our patients by innovation—and the need to support those that make it possible.

NOTE: On Nov. 17, after this issue of EyeNet *had gone to press, Allergan agreed to be acquired by Actavis, thus avoiding a takeover by Valeant. The Actavis press release announcing the agreement noted that there would be "a meaningful commitment to research and development."*

DAVID W. PARKE II, MD
EXECUTIVE VICE PRESIDENT/CEO