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Dr Lindstrom serves on a number of Journal editorial boards, including *JCRS*, *JRS*, and *Ophthalmic Surgery*. He is the Honorary Editor-in-Chief of the *US/Chinese Journal of Ophthalmology*. He has co-edited seven books, published over 350 peer reviewed journal articles and 60 book chapters. His professional affiliations are extensive, including Liaison of the International Society of Refractive Surgery of the American Academy of Ophthalmology.

He is the recipient of numerous awards for distinguished service by national and international ophthalmology associations, including the LANS, Barraquer, and the first lifetime achievement award from the International Society of Refractive Surgery in October 1995, and also was honoured with another lifetime achievement award in October 2002, the Binkhorst Lecture Award from the American Society of Cataract and Refractive Surgery and the Bausch and Lomb Lifetime Achievement Award in April 2005.

There remain many unmet needs in Ophthalmology. This edition of *US Ophthalmic Review* discusses advancing skills and knowledge applied to three major sub-specialties: glaucoma, cornea and retina. The quest for new knowledge is a passion for many, and every new discovery is rewarding and intellectually stimulating. However, to provide true benefit to those suffering from diseases with no or inadequate therapy, the outcomes of research and development must be translated into reality through the creation of market-available treatments and surgical techniques. The chasm between basic science and clinically useful treatments is called by many the translational gap. The process of innovation, through what is called the innovation cycle, is what translates research to clinically applied reality. Crossing this translational gap requires the co-operation and collaboration of capitalists, entrepreneurs and scientists, for sure, but ultimately the major responsibility for success or failure of a new medication, device or surgical technique is dependent upon the practicing physician. They either adopt it widely and apply it to the benefit of their patients, or they do not. Those that capitalize innovation in America face great risks in the research and development phase, the regulatory approval phase and the market adoption phase when seeking a new solution for an unmet need. I am concerned that the risks and costs of this process are reaching the level where innovation could be suffocated in the US.

Disease, including blindness, is very expensive to society, and innovation is one of our best hopes to reduce the costs of health care and the lifetime burden of disease. Today, in America, the cost to obtain regulatory approval to market a new medical device often exceeds $100 million and a truly novel new drug can cost $1 billion or more. These costs precede the enormous cost of a market launch which, even with an approved product, can fail. The costs of management, scientists, marketing, sales, and infrastructure are significant, but these have been inflating for the past two decades at approximately 3 % per year and in actuality represent a barrier well accepted by the funders of innovation. The cost that has exploded in America is the cost to navigate the regulatory process both to bring a new device or drug to market, but also to provide the needed post-approval studies and post-market safety and efficacy surveillance. In addition, the risk of compliance with an ever increasing array of regulations and guidelines with the specter of severe monetary penalties is an ever more frightening reality.

Of course, we do not want a large number of ineffective or even dangerous products and treatments on the market, but many believe that the growing costs of the innovation cycle are on the verge of crippling one of America's great success stories. The medical device and pharmaceutical industry working in concert with innovative physicians and surgeons has transformed the treatment of glaucoma, cornea, cataract, and retinal diseases since I completed my Residency 35 years ago. I believe we are at a tipping point. The number of truly new drugs and devices coming to market each year is declining, and many of the major companies are simply creating incremental changes in currently available drugs and devices, rather than investing breakthrough and disruptive advances. It is important for we physicians to be aware of these issues and to advocate for continued investment in the next generation of solutions to today's persistent unmet needs. Our duty as physicians requires the proper application of today's treatments in the best interests of our patients, but also includes helping to delineate the remaining unmet needs, and advocating for and participating in the innovation cycle required to develop effective solutions. ■

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