

Promises Unfulfilled

Kenneth Davis, M.D.

NEW YORK—Advances in biomedical research have the potential to lead to unimaginable medical treatments. Our grandchildren should never experience many of the diseases that affected our grandparents. Yet in 2007 the FDA approved the fewest new drugs in nearly a quarter century. Last year was hardly better.

The problem lies in public policy and how it stifles innovation and risk taking. Academic medical centers around the country are patenting many potentially interesting drug targets and treatments, but these possibilities may never become reality due to a host of factors.

There is an enormous cost in discovering, testing, and gaining approval of novel drugs, and it is rapidly increasing. The drugs we would like to design, drugs that prevent disease, require many more years of testing, at far greater expense, than drugs of the past. Years of drug discovery and drug trials can leave inadequate remaining patent life and therefore provide no return on investment. Consequently, some great ideas that originate in our leading academic laboratories never find an industry partner to facilitate drug development.

To move from drugs that treat acute problems to drugs that prevent disease, we need changes in public policy that encourage innovation and provide adequate incentive. Current patent law discourages risk and innovation.

Simply put, we cannot treat all drugs as alike. The public good is not served by providing the

same period of marketing exclusivity to a drug that prevents the consequences of adult-onset diabetes and copycat drugs that treat seasonal allergies or erectile dysfunction. Generic substitution for drugs that offer little benefit over current treatments is to be encouraged, but a short period of market exclusivity for breakthrough medications is not in the public interest.

Congress must add flexibility to patent policy to take into account changing science as well as the public good. Breakthrough drugs with novel mechanisms aimed at diseases like diabetes and cancer that are especially burdensome to the health care system should receive longer protection. There should be disincentives for drugs that offer no benefit over existing pills.

The current growth in health care spending is not sustainable. However, often left out of the debate is the impact that truly

revolutionary therapeutics would have on the cost of health care. Imagine the cost of health care had there been no polio vaccine. Conversely, imagine the cost of health care if we could prevent diabetes.

We have the potential to leave our grandchildren with a great legacy of freedom from many of our most feared diseases and to harness the revolution in biomedical research. To do so will require wise, and even courageous, public leadership.

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