Medicine Could Reach For Stars, FDA Willing

by Ed Hudgins and Sam Kazman

When Bill Gates and Paul Allen founded Microsoft in 1975, they shot for the stars and succeeded.

More recently, Allen shot for the stars again. The two successful launches of his SpaceShipOne won the $10 million Ansari X competition for private manned space flights. This feat may ultimately do for private space ventures what Charles Lindbergh's crossing the Atlantic did for commercial aviation.

The success of these enterprises obviously depended on such factors as genius, guts, and foresight. It also depended on the less obvious absence of something—government regulation.

Yet this is something that both Gates and Allen may be forgetting in another field that they are entering—medicine.

Microsoft created new, innovative software that let us use computers for everything from word processing to e-mailing to superhero gaming. Its products created an explosive demand for personal computers, which in turn led to the ubiquitous Internet.

But little of this would have happened, let alone so quickly, if computers and software had been heavily regulated.

Regulatory advocates in that period routinely claimed government wasn't moving fast enough to "keep pace" with technology. A good thing, too—they intended this as a complaint, but, for consumers, government inaction was, and remains, a blessing.

On the other hand, until very recently this was not true of private space launches. In fact, if Allen had begun his space project at the same time he began Microsoft, it would have run into a lethal regulatory labyrinth.

Hurdles Lowered

Luckily, that did not happen. Telecom deregulation gradually opened the door to private space satellites. By 1998, with the enactment of the Commercial Space Act, many of the regulatory obstacles facing private space launches had been liberalized.

This brings us to medicine, a field in which both Gates and Allen have become major philanthropists. Gates has contributed billions to global health issues, including in July a $50 million international grant to fight AIDS and malaria.

Last year Allen gave $100 million to establish the Allen Institute for Brain Science. Its mission is to produce a comprehensive cellular map of the brain—the neurological equivalent of the human genome project.

The involvement of such figures as Gates and Allen in medicine should be an exciting prospect. Medicine, like computers and space flight, is a field rich in technological promise. Any day, it seems, a new scientific breakthrough could open the door to a world of new treatments for previously incurable conditions. If Gates and Allen manage to duplicate in medicine a mere fraction of their computer achievements, the health payoffs could be astounding.

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But this image may also be a false one. Medicine is pervasively regulated. Because of the Food and Drug Administration (FDA), with its inclination toward deadly overcaution, it can require 10 to 15 years and nearly $1 billion to create, test, and bring to market a new drug. In the wake of the Vioxx recall, that situation will get only worse.

New Thinking Needed

And that is only for the one in 5,000 drugs that succeed. How many "medical Microsoft" startups could survive such hurdles?

Men such as Gates and Allen may enter medicine, but whether they'll be able to revolutionize it is another matter. Consider how the heavily regulated field of biotechnology has produced hardly any billionaires.

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Jim Benson, CEO of Poway, California-based SpaceDev, signs one of the company's three hybrid rocket motors that would blast SpaceShipOne to win the $10 million Ansari X Prize.

What is to be done? The conventional wisdom is that massive government oversight is essential to assuring the safety and effectiveness of medical therapies. But Gates and Allen did not get to where they are by accepting conventional wisdom, and for that reason they should rethink just where to put their money and effort.

Devoting just a fraction of those resources to researching medical regulation, rather than medical science, could be incredibly fruitful. Advances in medicine may require difficult scientific breakthroughs. Advances in medical regulatory policy might only require the reframing of basic questions, such as the role of FDA.

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Is FDA really the only institution capable of evaluating new therapies? Are doctors and patients truly incapable of deciding whether to use experimental therapies?

Rethinking these issues, especially in the context of the very information technologies that Gates and Allen helped create, might well change the world.

Sam Kazman (skazman@cei.org) is General Counsel at CEI. Ed Hudgins is Washington Director of the Objectivist Center. A version of this article appeard in Investor's Business Daily.

Freeing the Biotech Revolution

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only on transparency, or predictability—even if it only delivers the predictability of research delays and unnecessary expense. Others have bought into the myth that a little excess regulation will assuage public anxiety and neutralize activists' alarmist messages. Defenders of excessive regulation have made those claims for decades, but the public and activists remain unappeased, and technology continues to be shackled.

The second strategy involves groups of scientists: professional associations, faculties, academies, and journal editorial boards. These organizations should do much more to point out the flaws in current and proposed policies. For example, scientific societies could include symposia on public policy in their conferences and offer to serve as advisors to government bodies and the news media.

Third, reporters and their editors can do a great deal to explain science-related policy issues. But in the interest of "balance," the news media often give equal weight to all the views on an issue, even if some of them have been discredited. All viewpoints are not created equal, however. Journalists need to distinguish between honest disagreement among experts, on the one hand, and unsubstantiated extremism or propaganda, on the other.

Fourth, biotechnology companies should eschew seeking short-term advantage and actively oppose unscientific, discriminatory regulations that set dangerous precedents. Companies that passively accept government oversight triggered simply by the use of gene splicing techniques, regardless of the risk of the product, ultimately will find themselves the victims of the law of unintended consequences as excessive regulation stifles them.

Fifth, venture capitalists, consumer groups, patient groups, philanthropists, and others who help bring scientific discoveries to the marketplace, or who benefit from them, need to increase their informational activities and advocacy of reform. Their actions could include educational campaigns and support of organizations that advocate rational, science-based public policy.

Finally, the government should no longer assume sole responsibility for regulation. Nongovernmental agencies already accredit hospitals, allocate organs for transplantation, and certify the quality of consumer products ranging from seeds to medical devices. Moreover, in order to avoid civil legal liability for damages real or alleged, it is in the best interests of the practitioners of agricultural biotechnology to adhere to sound practices.

Flawed, overly risk-averse federal regulation of the new biotechnology has slowed the rate of innovation in that crucial area of research. We need to find other, more scientific and efficient ways, to guarantee the public's safety while encouraging new discoveries.

Henry I. Miller is a Research Fellow at the Hoover Institution and an Adjunct Fellow at CEI. Gregory Conko (gconko@cei.org) is Director of Food Safety Policy at CEI.