Medicine Could Reach For Stars, FDA Willing
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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 as well-government regulation.

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

Microsoft created new, innovative software that let us use computers for everything from word processing to e-mailing to super hero 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.

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 goal 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.

But this image may also be a false one. Medicine is pervasively regulated. Because of the Food and Drug Administration, 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.

New Thinking Needed

That's 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.

What's 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 didn't 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.

FDA's veto power over new therapies has a gruesome side effect: Every approval of a new life-saving drug or device means that people died waiting for that approval to be issued.

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.