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Let Patients Decide How Much Risk They'll Take

By Kevin J. Tracey

Earlier this month, at a private conference for the CEOs of his portfolio companies, venture capitalist Vinod Khosla interviewed Google co-founders Sergey Brin and Larry Page, asking them if the company might jump into health care. "It's just a painful business to be in," Mr. Brin replied, later noting that "the regulatory burden in the U.S. is so high that I think it would dissuade a lot of entrepreneurs."

Mr. Brin is right. As a neurosurgeon-scientist and entrepreneur who co-founded a bioelectronic medicine company that deploys implantable technology to supplant drugs, I wish he were wrong. But rampant misalignment of incentives is hampering technology in the U.S. health industry.

Start with the Food and Drug Administration, which places the highest premium on "protecting the public health," according to the agency's website. The agency believes this goal is best accomplished through detailed oversight, ponderous review and ultimately control.

That doesn't work for entrepreneurs and investors, who want rapid returns on what they invest, at a pace faster than what the FDA allows. The pharmaceutical industry seeks large markets with high returns, and the major payers, including insurance providers, require evidence of cost effectiveness. Physicians and other prescribers have limited and dwindling resources to participate in research, and instead are encouraged to push standard treatment protocols, even when they are of questionable efficacy.

And the public, the patients, and the parents and children of the suffering, want treatment to be available, immediate and cheap; free if possible.

You don't need a postgraduate degree to realize the problem here. Members of Congress have proposed reforming the FDA in various ways, urging the agency to speed up its procedures. These are laudable efforts, but no government agency will ever be limber enough to mollify the Mr. Brins of this world.

Which is why it's time to try a new solution. The government and entrepreneurs should be allowed to carve out their own turf and let patients choose their own level of risk.

Consider the case of Goran Ostovich, a burly, 47-year-old truck driver from Mostar, Bosnia. Mr. Ostovich has suffered from long-standing rheumatoid arthritis and needed near-permanent bed rest. With his hands and wrists swollen and aching, he could no longer hold on to a wheel or even play with his small children. He tried a variety of medications. None worked.

When I met Goran at his doctor's office in 2012, however, he didn't seem at all afflicted with the disease. That's because, one year earlier, he had been offered the opportunity to be the first participant in a clinical trial of a new therapy based on my invention. He received a bioelectronic implant and rapidly improved. His mobility restored, he was soon back at work and even sustained an exertion injury from playing tennis.

Since news of this clinical trial's success became public, people from all over the U.S. stricken with rheumatoid arthritis have emailed, called and sent letters pressing for their shot at potentially effective—but not yet FDA-approved—treatments. Most wrote that they would gladly travel to Europe if it meant they could get access to the device.

That's exactly the point: Some patients are very willing to take a calculated risk, but misaligned incentives in the industry are driving potential stakeholders with new solutions out of the business.

While the FDA does a commendable job, there is no reason it should have the sole responsibility for access to lifesaving treatment. Institutional review boards and human-subject research protocols provide extremely high levels of protection overseeing clinical trials in the U.S. and Europe. These bodies have weeded out the charlatans in the industry, and the ultimate determinant of success will be patient satisfaction.

Mr. Brin and his colleagues took Google public under atypical rules, and to much fanfare. It is time to apply this kind of boldness to realign bioelectronic medicine research with clinical needs. Our patients deserve no less.

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Sergey Brin had it right: The health-care regulatory burden stops entrepreneurs from getting into the game.

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