

Over a decade ago, many leaders in the biomedical industry grew to dislike the risk that came with research and development for drugs. Since then, new drugs have been harder to come by, leading many to believe that biomedical companies need to return to the times of risk and innovation and start discovering new medical therapies again.

The industry used to be led by creativity and exploration; now, most biomedical companies function on the same processes they have used for the past 15 years. Cardiologist Andrew Marks, a founder of the Wu Center for Molecular Cardiology at Columbia University, claims that academic institutions and the National Institutes of Health have moved away from innovation, turning away from ideas with higher risk attached. According to the Council for American Medical Innovation, “[t]here is a palpable fear of new technology doing harm or costing more.”

Bernard Munos, founder of the InnoThink Center for Research in Biomedical Innovation in Indianapolis, Indiana, explains that “[t]he impact on innovation has been severe: new drug approvals have steadily declined; 22 of the 25 most prescribed drugs are now generic; [and] 78 percent of prescriptions were filled by generics in 2010 (up from 46% in 2001).” According to Jeremy Hsu, author of “Fear of Risk Threatens Medical Innovation,” the Food and Drug Administration received 45 applications for new drugs in 1996 and only 23 applications in 2010.

Yet, there are many new ideas in the works in the biomedical field today. Scientists currently could be exploring “synthetic biology, tissue engineering, nanotechnology, stem cells,” and more, Munos explained. Steve Burrill, President and CEO of Burrill & Co., said there are over 4,000 biomedical companies today, but the “financial criteria by which new drug candidates are assessed make it very difficult for the products of this new science to compete against ‘safe’

projects.” Burrill explained that returns on safer products come with less risk than financing the next “speculative breakthrough.”

More and more money is being spent on clinical trials instead of research and development. Drugs must go through three phases of clinical trials before they can be approved for use by the general public. According to Munos, “in 2010, the number of drugs entering phase I, phase II, and phase III were respectively 47 percent, 53 percent, and 55 percent lower than in 2008.” If the FDA requires only two phase III trials, how can this be? Companies don’t want to take the risk investing money in new research and innovation.

So what’s the solution? According to Munos, biomedical companies need to shift their spending from excessive clinical trials to “high-risk, unconventional discovery research,” which has produced most of the breakthroughs in the last century. Perhaps smaller companies are the wave of the future, as Munos explained that “since 2004, small companies have consistently outperformed big ones in the number of new drugs approved, despite much lower [research and development] spending.”

“Medical innovation should not be viewed only through the lens of cost containment,” said the Council for American Medical Innovation, because “the value of medical innovation in the United States outweighs increased treatment costs.” According to the National Cancer Institute, cancer survival rates increased from 50% in 1975 to 68% in 2002. The American Cancer Society reports that children with cancer are now almost twice as likely to survive for five years after their initial diagnosis as they were in 1975. All of this is because of medical innovation and discoveries. Enough worrying about risk – it’s time for the biomedical industry to get off the sidelines and get back in the game.