

Written statement of:

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Subcommittee on Health

Hearing:

“Reauthorization of MDUFA: What it Means for Jobs, Innovation and Patients”

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Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee, thank you for the opportunity to testify today. My name is Ross Jaffe. I am a physician trained in internal medicine who for the last 21 years has had the privilege of working to help develop innovative medical technologies. I am a founder and Managing Director of Versant Ventures, a California-based venture capital firm that focuses on investing in early stage medical device and life science companies to fund and guide their development of medical solutions for some of the most daunting diseases and afflictions facing patients today.

As a physician venture capitalist, I am increasingly facing a frustrating paradox, one that I never thought I would face in 21st century America. On the one hand, we live in a time of incredible opportunity for medical innovation. Our understanding of human physiology and disease grows almost daily. In addition to this new understanding of clinical problems, we have constantly evolving information technology, new and novel materials, and expanding engineering capabilities that enable smart inventors to conceive fascinating new products to solve important clinical problems. With the aging of the population and increasing pressure for healthcare reform, new and better technologies are critical to reduce the costs and improve the quality of healthcare. The potential for innovation in medical technology has never been greater.

On the other hand, as a venture capitalist I am forced to turn down investing in too many promising medical innovations -- technologies that you and I would want access to in order to help our loved ones if they needed them -- because it is difficult to predict how long and how much capital it will take to get a particular innovation approved by the FDA and into patient care. In this day and age of phenomenal medical innovation, regulatory uncertainty is the largest deterrent to venture capitalists bringing potentially valuable new technologies to market.

America currently leads the world in medical innovation through our unique medical device innovation ecosystem which has developed over the last fifty years. Most medical technology innovation comes from small, entrepreneurial companies, often fueled by venture capital, that take on the risk of promising science and, over time, transform ideas and research into critical technologies that advance science in areas of unmet needs for patients. I am sure that you have heard the statistics before: 80 percent of medical device companies have less than 50 employees, and 98 percent of the medical device companies have less than 500 employees.¹ If successful, these companies grow, create jobs, and deliver innovative devices and technologies to medical providers that improve patient care.

It is important to note where venture capitalists get their funding. Our investors are primarily university endowments, foundations, and pension funds. If we do our job well, not only do patients and physicians have access to innovative medical technologies and high-quality jobs are created, but universities can educate more students, foundations can fund more good works, and people can retire in greater comfort. This is an incredible win-win-win system that fuels medical technology innovation – a system which has allowed the United States to be the world leader in medical product development, manufacturing, and exportation.

While this medtech innovation ecosystem has traditionally worked very well, funding of medical technologies has slowed, largely because regulatory pathways are increasingly difficult to predict and unexpected regulatory delays increase the time and capital required to build companies. Increasing time frames and capital needs are causing many venture capital firms to move away from medical device investing, and many traditional investors in venture capital – the university

¹ “Medical Technology and Venture Capital: A Fruitful Yet Fragile Ecosystem,” MDMA and NVCA, June 2009, <http://www.medicaldevices.org/node/656>.

endowments, foundations, and pension funds that provide most of the capital to venture investors – are no longer putting their money with venture firms investing in the life sciences space.

This loss of capital has caused a dramatic decline in medical devices start-up funding over the last five years. In 2007, the MoneyTree report by Pricewaterhousecoopers and the National Venture Capital Association (based on data from ThomsonReuters) shows 116 early stage device companies raising approximately \$720 million in initial venture capital. Since then we have seen more than a 60 percent decline in the number of device companies receiving initial venture capital investment and more than a 70 percent decline in the amount of capital invested -- with only 55 new companies raising just under \$200 million in 2011.² This is the lowest level of medical device start up activity since 1996. What makes this data more troubling is that initial start-up company financings are a leading indicator for innovation and job creation in the medical device sector.

When you ask my venture capital colleagues why they are no longer funding new medical device start-ups, whether in formal surveys or informally, the answer is the same: unpredictability in the U.S. regulatory process makes it too risky to commit the capital required to build a company through to success. Since 2005, the time and capital it takes our companies to get a clear definition of the required regulatory path, negotiate pre-clinical and clinical requirements, and obtain an approval decision once a completed application has been submitted have risen dramatically. Small, venture-backed companies typically spend \$500,000 to \$2 million per month to operate as they prepare for clinical trials. A six to twelve month delay in getting to agreement with the FDA staff about a clinical trial design

² NVCA/PWC MoneyTree Survey, "VC Investments Q4 – MoneyTree – National Data", http://nvca.org/index.php?option=com_content&view=article&id=344&Itemid=103

issue, which is not unusual, can result in millions of dollars of extra capital that the company has to raise from investors to get through the approval process and into the market.

In a recent survey that the National Venture Capital Association³ performed, 42 percent of healthcare investors responded that they were decreasing their investment in medical device companies because of the increased time frames to regulatory approval. 61 percent of respondents noted that regulatory challenges with FDA was the primary factor driving their healthcare investment decisions, making this challenge by far the most commonly cited factor. As these investments are disappearing at home, they are moving overseas and into other emerging markets. The NVCA survey found that 31 percent of VC respondents expected to decrease healthcare investment in the U.S. while 44 and 36 percent expected to increase investments in Asia and Europe, respectively. I have included the entire report as an addendum to this testimony, but the message of this and other surveys⁴ is clear: The current regulatory environment is an increasing deterrent to investment in innovative medical technologies.

My venture capital colleagues and I would greatly prefer to have our companies do our development work here in the U.S., but the challenges of our regulatory

³"Vital Signs: The Crisis in Investment in the U.S. Medical Innovation and the Imperative of FDA Reform, NVCA and MEDIC, October 2011, http://www.nvca.org/vital_signs_data_slides.pdf

⁴ "FDA Impact on US Medical Technology Innovation", Dr. Josh Makower, November 2010, <http://nvcaccess.nvca.org/index.php/topics/public-policy/155-fda-impact-on-innovation-study-out-today.html>;

"Competitiveness and Regulation: The FDA and the Future of America's Biomedical Industry", California Healthcare Institute, February 2011, http://www.chi.org/uploadedFiles/Industry_at_a_glance/Competitiveness_and_Regulation_The_Future_of_America%27s_Biomedical_Industry.pdf;

"Comprehensive Analysis of the 510(k) Process, Northwestern University, May 2011, <http://www.inhealth.org/wtn/Page.asp?PageID=WTN004937>;

environment have compelled us to take most of our initial clinical work to foreign shores. We routinely seek regulatory approval and commercialize new products overseas ahead of seeking U.S. regulatory approval. It is now common for many innovative and often life-saving technologies – such as percutaneous heart valves – to be available to patients in Europe years before they are available here in the U.S. In our Versant portfolio, we have several examples of products approved and first commercialized in Europe -- a novel, leadless cardiac defibrillator; a novel treatment for chronic atrial fibrillation; a retinal implant to restore functional vision in blind patients; and a spinal implant – all approved overseas years before we could obtain regulatory approval and offer them to patients here in the U.S.

Fortunately, within the past year, the FDA has acknowledged how delays, indecision, and inconsistency are slowing innovation and driving product development overseas, and have committed resources to addressing these problems.

One recent guidance document that has the potential to improve the regulatory environment significantly is intended to make explicit the risk-benefit analysis used by FDA staff to make regulatory decisions in each pre-market application. Under the law, FDA is directed to assess medical technologies on the basis of whether the probable benefits outweigh the probable risks from the use of the technologies. Unfortunately, over the past few years many reviewers seem to be applying a different standard that weighs the probable benefits against any potential risk. This departure from the law is one of the key drivers that makes getting to agreement on pre-clinical and clinical requirements more difficult and time consuming. By making the assumptions behind the risk-benefit assessment for a new technology explicit, and documenting them for future reference, adoption of this guidance should improve the dialog between applicants and FDA staff.

While we await the finalization and implementation of this risk-benefit guideline, I am hopeful that this guidance will make a significant improvement in the transparency, consistency and accountability of FDA decision-making.

Beyond the administrative changes under consideration by FDA, I am cautiously optimistic that the user fee package that industry and FDA are developing will have additional process enhancements which will provide patients with timely access to safe and effective products. Medical device innovators simply need greater predictability in the review process if we are to attract future investment and lead the world in medical technology innovation. At the same time, resources alone will not solve FDA's problems. The additional funding needs to be accompanied by real administrative improvements and legislative reforms.

Currently, there are a series of bills before the House that may further improve the FDA situation. Rather than discuss specific bills, I would just highlight the potential value of legislative efforts that reinforce and clarify the "least burdensome" standards; streamline the *de novo* process; and revise conflict of interest guidelines to increase the ability of knowledgeable experts to participate in FDA decisions processes.

Let me be clear about one thing: We are not asking for increased regulatory predictability, consistency, and efficiency at the expense of patient safety. While some insist there is a tradeoff between encouraging innovation and protecting patient safety, the reality is that we need both. We need a regulatory system that is conducive to the timely development of innovative products that result in safer and more effective patient care than existing options. As investors, we pursue medical innovations precisely because they are better for patient care and are safer and more effective, preferably while also reducing overall healthcare costs. Many new

products we back are designed to specifically overcome limitations of existing technology, or to offer clinically valuable new solutions that improve patient care.

The public's health and our national economic competitiveness are compelling enough reasons to recognize the urgency of our challenges, but in the end it is in all of our individual interests to improve the transparency, predictability, consistency, efficiency, and effectiveness of the FDA. I am in an unusual role where I invest in innovative medical technologies which, I hope, I or my loved ones – or you and your loved ones – never have to use. But if we or any of our family or friends ever needs one of those technologies, we will be extremely grateful that it was developed, approved, and is available here in the United States. Getting the FDA regulatory system right so that it achieves its dual goals of assuring the safety and effectiveness of medical technology as well as encouraging innovation is of critical value to each of us and those we love.

In closing, I would like to reiterate just how fragile the U.S. medical technology ecosystem is, primarily as a result of the regulatory uncertainty at FDA. If the U.S. is to maintain our global leadership in medical technology innovation and our patients are to have timely access to the safest and most effective therapies available, Congress, FDA, industry and the medical community must work together on meaningful reforms to restore predictability, reasonableness and transparency to the premarket review process.

Thank you.

Addendum



Vital Signs

The Crisis in Investment in U.S. Medical
Innovation and the Imperative of FDA Reform

Key Survey Findings

October 2011

Summary

A 2011 study found that U.S. venture capitalists have been and will continue to:

- **Decrease their investment** in biotechnology and medical device start-ups
- **Reduce their concentration** in critical therapeutic areas, and
- **Shift focus away** from the United States towards Europe and Asia

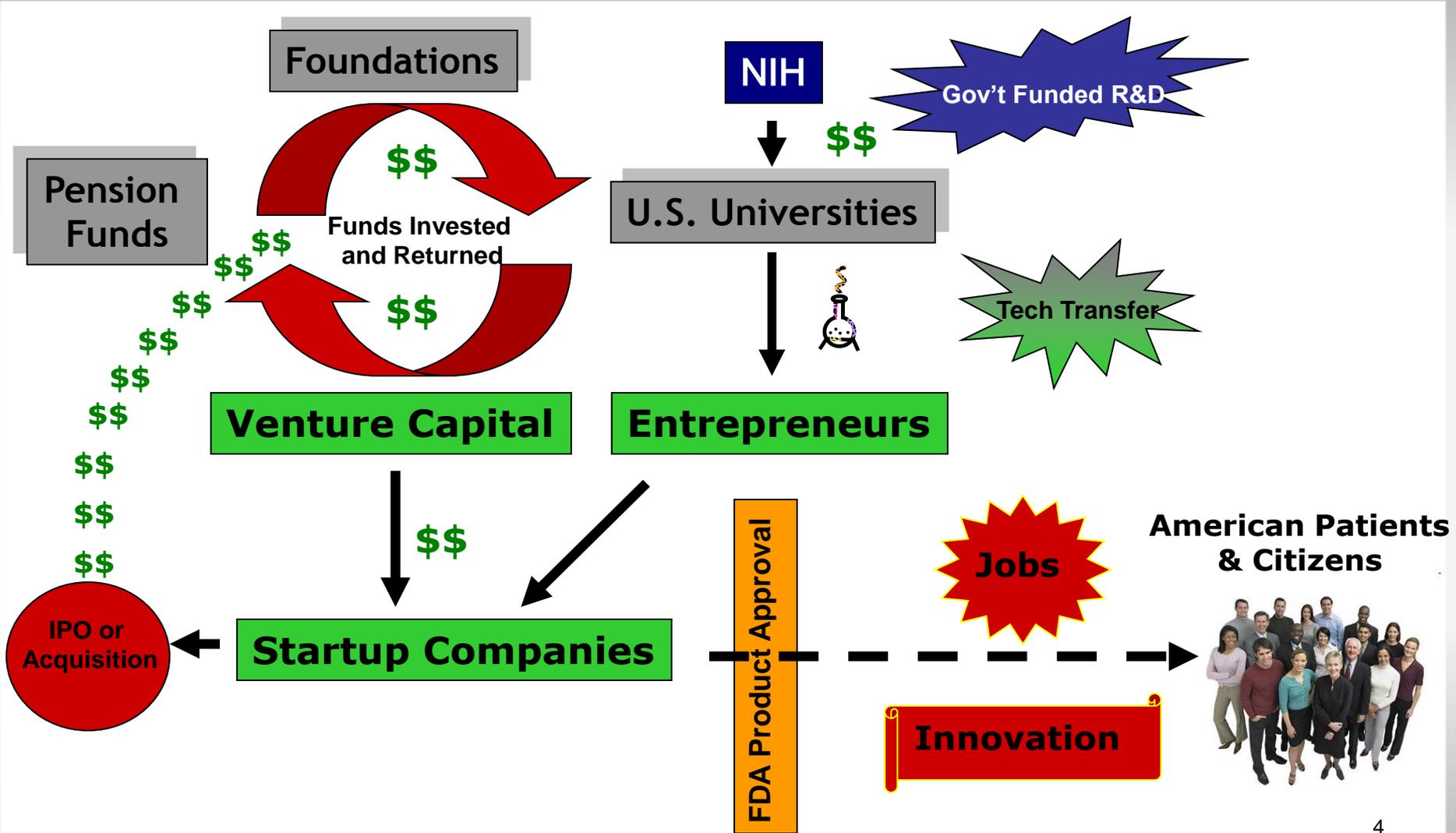
FDA regulatory challenges were identified as having **the highest impact** on these investment decisions.

We must act now or lose our leadership position in medical innovation, job creation and access to life-saving treatments in the United States.

Study Methodology

- **Online survey conducted July–September 2011**
- **Sent to 259 NVCA member firms investing in the healthcare sectors**
- **156 firm responses = 60% response rate = 92% of NVCA invested capital (2008-2010)**
- **Survey respondents accounted for \$10 billion of VC investment in healthcare companies in the past 3 years.**

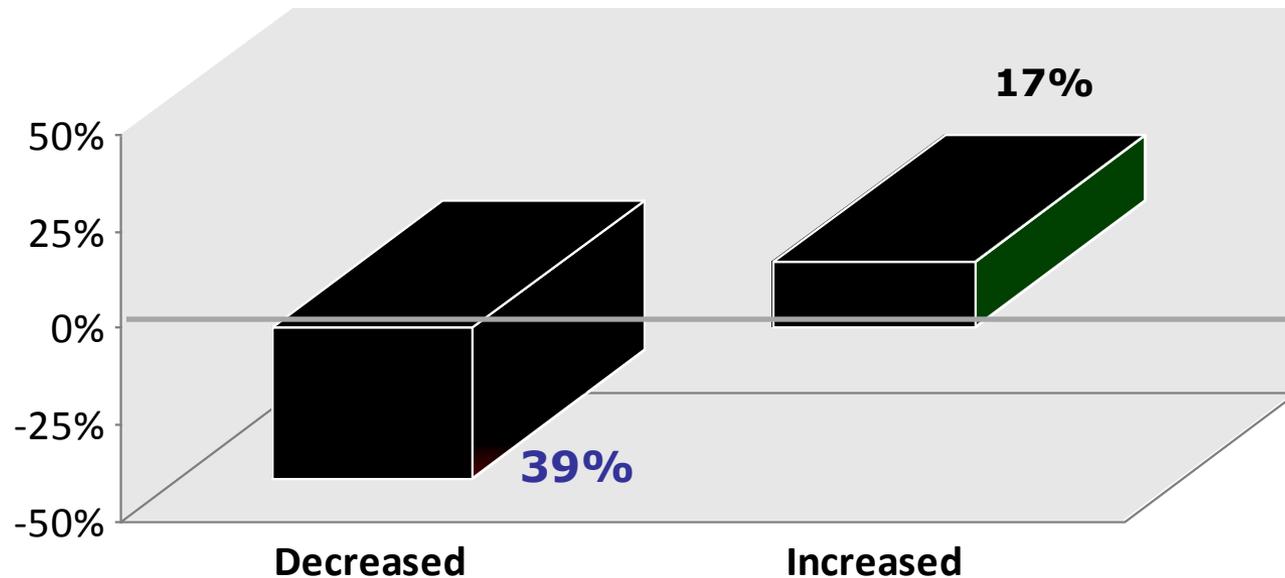
The Cycle of Innovation



39% of VC firms reported decreases in their healthcare investment in the past 3 years.

Past 3 Years - Change in Healthcare Investments

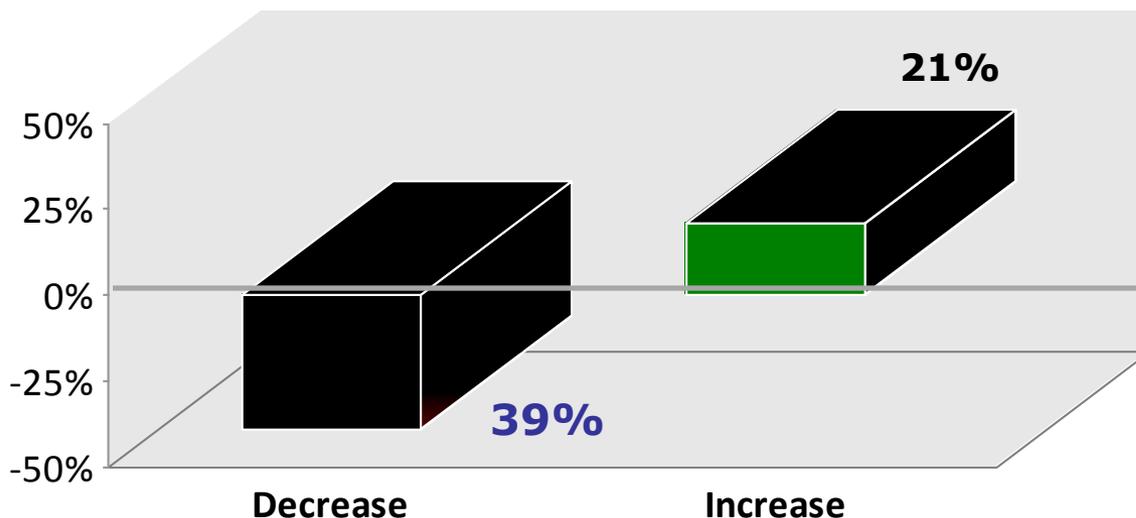
% of Respondents



Nearly twice as many VC firms expect to decrease their healthcare investment in the next 3 years.

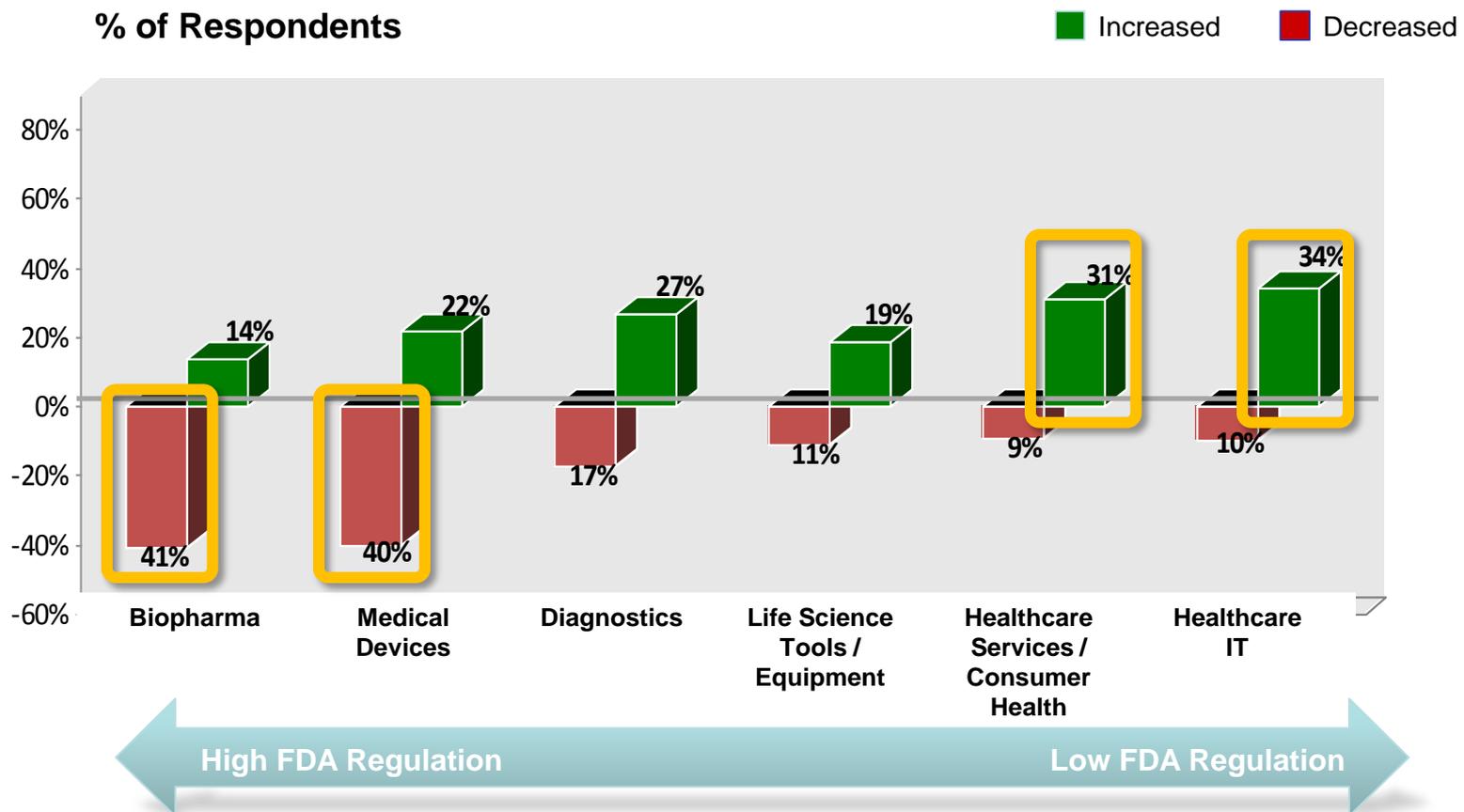
Next 3 Years - Expected Change in Healthcare Investments

% of Respondents



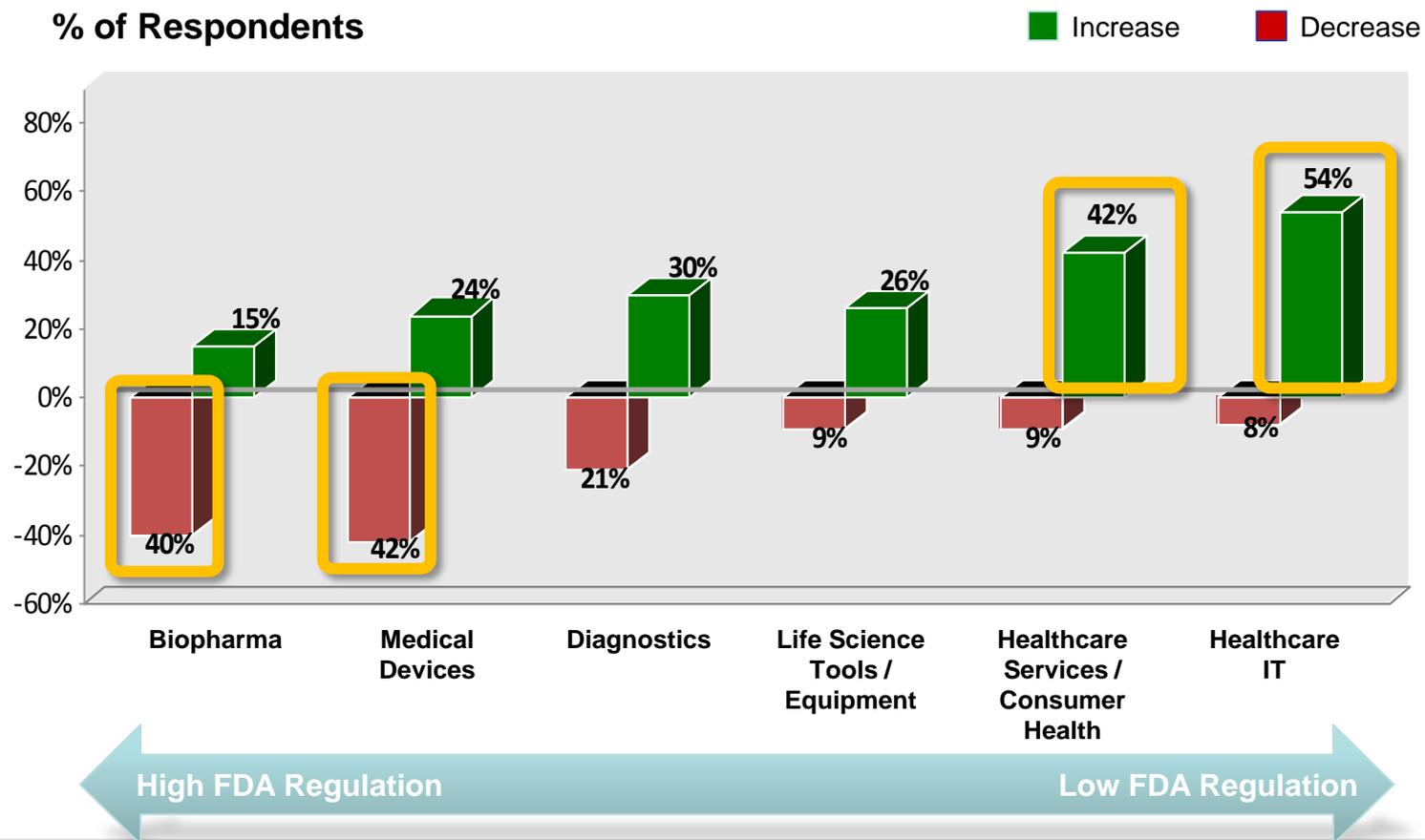
Within healthcare, venture investment has already shifted away from Biopharma and Medical Devices.

Past 3 Years - Change in Investments in Healthcare Sectors



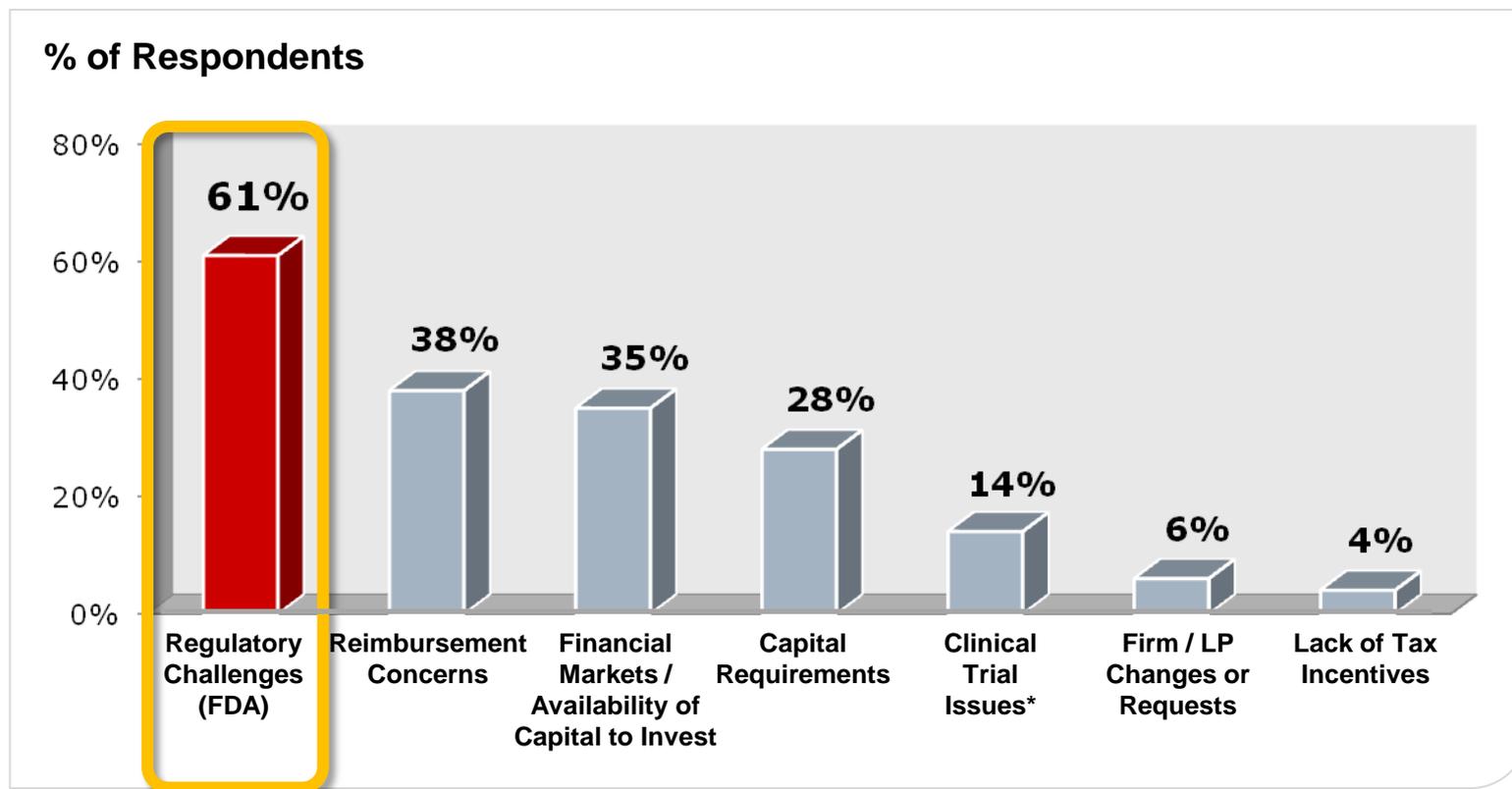
VC investment in Biopharma and Medical Devices is expected to continue to suffer.

Next 3 Years - Expected Change in Investments in Healthcare Sectors



FDA regulatory challenges are having the greatest impact on VC investment decisions.

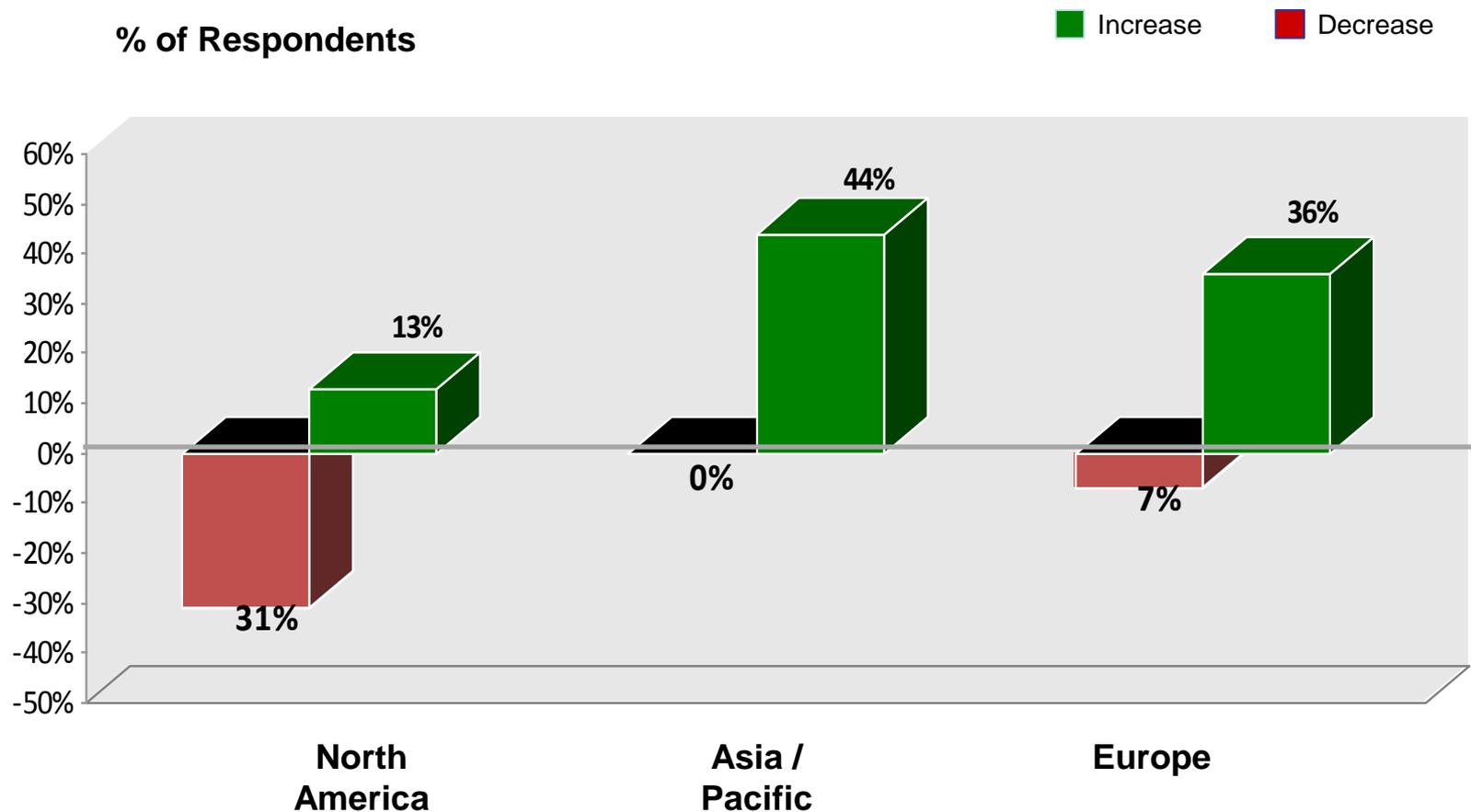
Factors Cited as Having the Highest Impact on VC Investment



*Unrelated to Regulatory Challenges

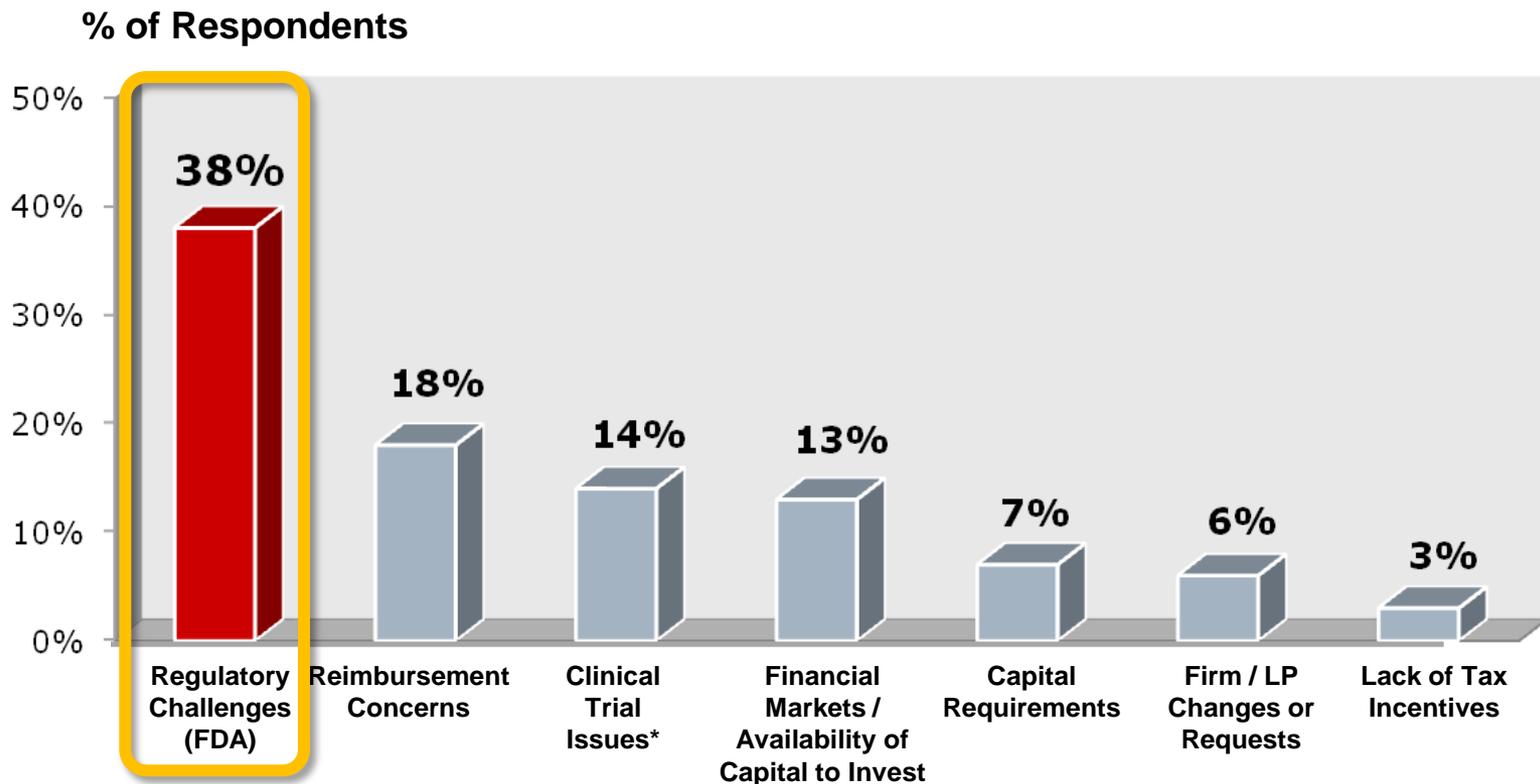
VCS expect to decrease healthcare investment in the U.S. in favor of Asia and Europe.

Next 3 Years - Expected Change in Healthcare Investment by Region



FDA regulatory challenges have the highest impact on VC firm decisions to shift investment overseas.

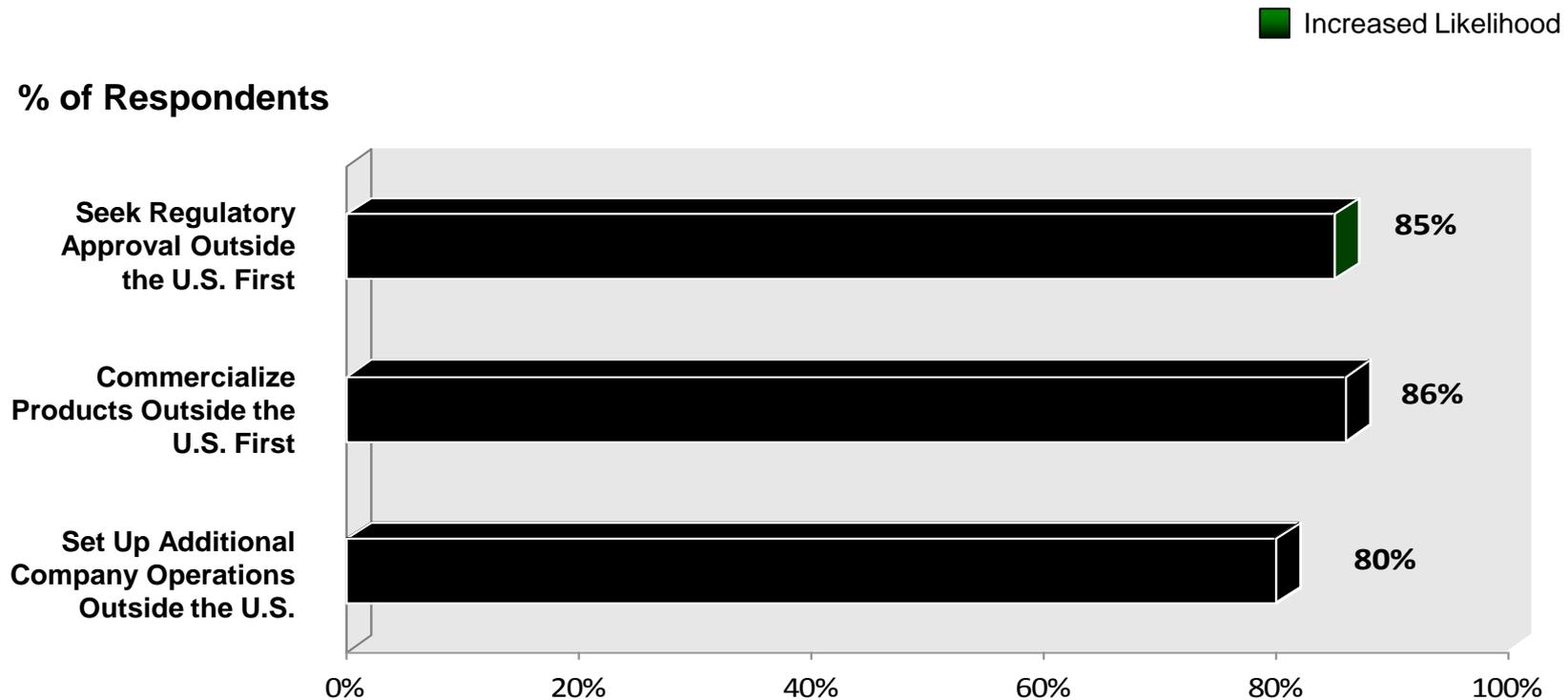
Factors Cited as Having the Highest Impact on Decision to Move Investment Outside of U.S.



*Unrelated to Regulatory Challenges

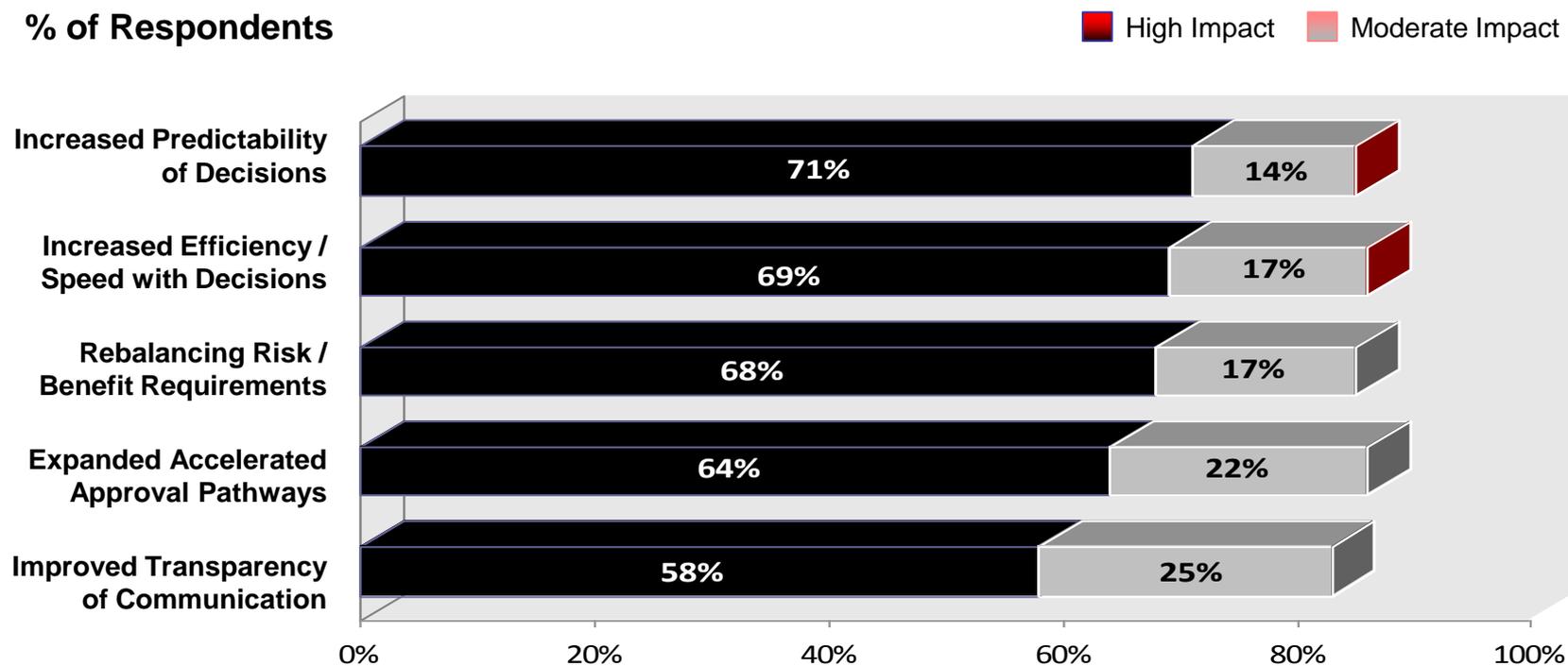
VC-backed companies are expected to increase operations outside the U.S.

Next 3 Years - Likelihood of Portfolio Company Decisions to Shift Outside of U.S.



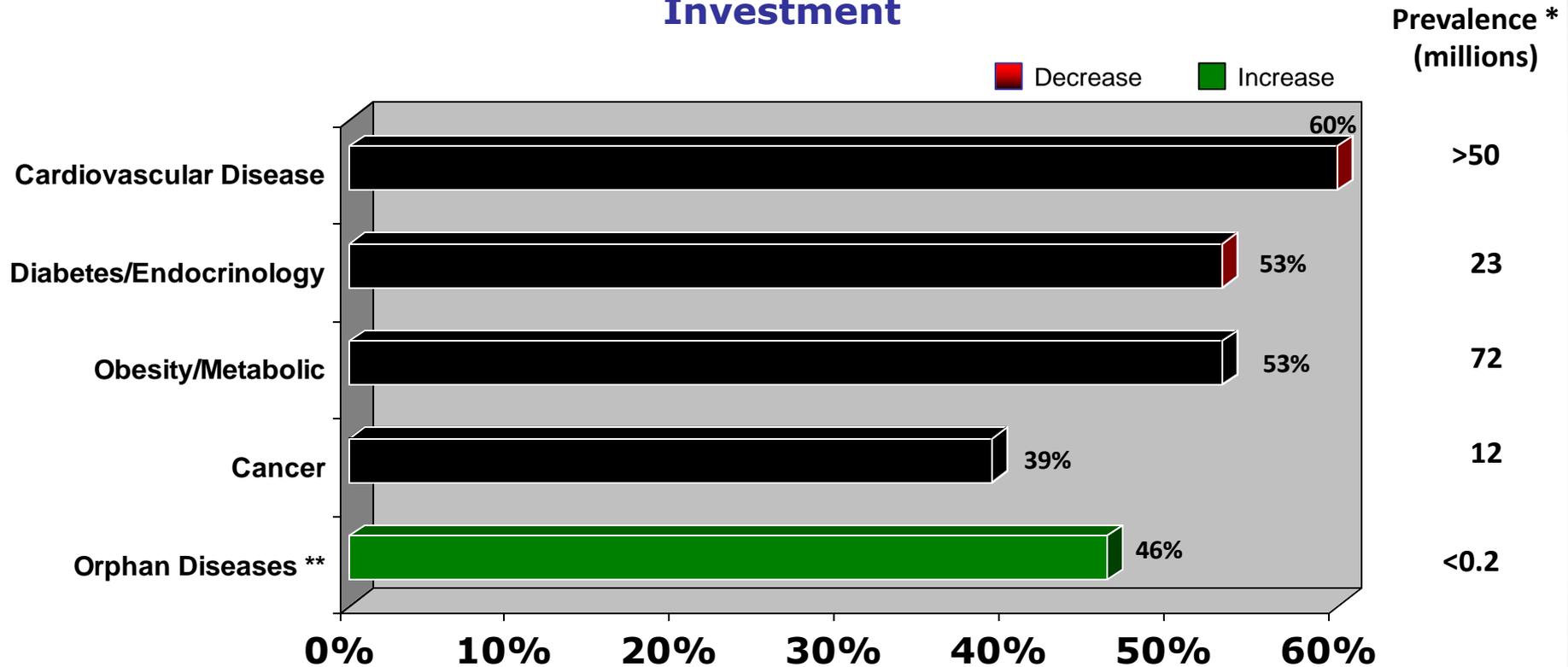
Meaningful FDA reform is critical to reversing these trends.

Expected Impact on Investments from Changes at FDA



Significant investment decreases in highly prevalent diseases with increases in orphan diseases expected.

Next 3 Years – Percent of Respondents Expecting to Decrease/Increase Investment



*Source: CDC; NIH; American Heart Association; American Diabetes Association; Surgeon General; American Academy of Neurology; American Lung Association; US Health & Human Services; National Cancer Institute

** See Report to Congress, *Improving the Prevention, Diagnosis, and Treatment of Rare and Neglected Diseases* in response to Public Law 111-80, Section 740

Implications

If the current situation is left unaddressed, the implications to U.S. patients and the economy are significant:

- **Many promising medical therapies and technologies will not be funded and therefore will not reach the patients that need them.**
- **Those that are funded may not be brought to market in the United States first, or at all.**
- **An estimated funding loss of half a billion dollars over the next three years will cost America jobs at a time when we desperately need employment growth.**
- **The U.S. leadership position in medical innovation will be placed in further danger and economic growth will suffer.**

Call To Action

MedIC priorities include the following:

- **Rebalancing benefit-risk assessments in the drug and device approval processes to appropriately reflect the value of new therapies to patients in need;**
- **Expanding the accelerated approval pathway into a progressive approval system for drugs, diagnostics and medical devices;**
- **Ensuring conflict-of-interest policies are not hindering patient access to new treatments; and**
- **Ensuring FDA is well resourced and endowed with state-of-the-art scientific tools, clinical input, processes and procedures**