

A FUTURE AT RISK:

Economic Performance, Entrepreneurship, and
Venture Capital in the U.S. Medical Technology Sector

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A FUTURE AT RISK:

ECONOMIC PERFORMANCE, ENTREPRENEURSHIP, AND VENTURE CAPITAL IN THE U.S. MEDICAL TECHNOLOGY SECTOR

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The statements, findings, conclusions, and recommendations are those of the authors and do not necessarily reflect the views of AdvaMed or AdvaMed Accel.

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Finally, any errors are those of the authors and represent no fault by any of the participants in these roundtables.

About AdvaMed

AdvaMed is the world's largest trade association representing manufacturers of medical devices and diagnostics—the medical technology industry. Its membership includes approximately 300 companies, two-thirds of them small companies with annual U.S. sales of less than \$100 million. AdvaMed member companies produce medical technology ranging from simple tongue depressors and blood pressure cuffs to the most complex imaging machines and cardiac and orthopedic implants and account for nearly 90 percent of the health care technology purchased annually in the United States and more than 40 percent purchased annually around the world.

About AdvaMed Accel

AdvaMed Accel is the division within AdvaMed dedicated to addressing the unique needs and challenges of smaller medical device and diagnostics manufacturers – the lifeblood of the medical technology industry. The only organization of its kind focusing specifically on the needs of the medtech industry's emerging growth companies, AdvaMed Accel works to create a policy environment more conducive to capital formation and innovation. For more information, visit www.AdvaMedAccel.org.

About Medical Alley

The Medical Alley Association is a state-based member organization serving the health technology community and works to promote Minnesota's Medical Alley by influencing policy at the state and federal levels, delivering actionable intelligence that informs decision-making and connecting members to peers, training and businesses. The Association's membership and supporting community extends throughout the world, employing more than 300,000 Minnesotans and many more globally. Founded in 1984, the Medical Alley Association has played a leadership role in growing Minnesota's Medical Alley for 32 years.

About MassMEDIC

The Massachusetts Medical Device Industry Council (MassMEDIC) is an organization of medical device manufacturers, suppliers and associated non-profit groups in Massachusetts and the surrounding region. Founded in 1996 by medical device company executives to establish a unified voice for the Bay State's vibrant medical technology sector, MassMEDIC has grown to become the largest regional medical device association in the United States, with over 350 members representing manufacturers, product developers, suppliers, research institutions and academic health centers.

About Tech Coast Angels

Tech Coast Angels is a non-profit angel investment organization founded in 1997. The nearly 300 members of TCA collaborate with each other on due diligence and then make individual decisions regarding potential investments. Its members invest in exciting companies in a wide range of industries including medtech, biotech, consumer products, Internet, IT, media, software and environmental, among others.

About Twin Cities Angels

Twin Cities Angels provides a formal organization for entrepreneurially-minded angel investors. Members share interests in: increasing their access to quality deal flow; leveraging their capital with greater investment clout from the combined dollars of the group; leveraging their time and expertise with other experienced members; making better researched and more intelligent investments through high-quality due diligence; increasing their knowledge about and how to make such investments; and socializing among like-minded individuals.

EXECUTIVE SUMMARY

Historically, America has been the world leader in medical technology. More than half of all global value-adding in medical technology manufacturing occurs in the U.S. The U.S. industry has been a singular bright spot as one of the few manufacturing sectors maintaining a positive balance of trade. Medical technology has contributed to impressive advances in health: Between 1980 and 2010, life expectancy increased by five years, fatalities from heart disease were cut by more than half, deaths from stroke were cut almost 60%, mortality from breast cancer was cut 31% and disability rates declined by one-quarter.

Despite these achievements, the future of the American medical technology industry is now at risk. It has been suffering from a steady decline of entrepreneurship for more than two decades. Entrepreneurs face tough, unpredictable, and uneven regulations and payments, as well as the difficult technical and clinical conditions built into the industry's foundation.

The industry is increasingly concentrated in a shrinking number of large players. All of those companies are scouring the globe for medtech innovation. With fewer startups in the system, the industry's dominant companies recognize the long-term threat to innovation represented by fewer companies fueling the industry's pipeline of innovation. All these factors represent a present and future threat to American leadership in the industry, to medical innovation and, ultimately, to patients.

The key data points supporting this troubling picture of the state of entrepreneurship in the medical technology industry include:

- The number of new medtech firms created each year has fallen by almost two-thirds, from 1,500 annually in the late 1970s and early 1980s, to around 600 in 2012.

- More than 30% of medtech firms are at least a quarter century old and more than half are more than 16 years old. This age distribution is typical of a mature rather than a dynamic industry and is markedly older than other high tech industries or even than businesses in the economy as a whole.
- Medtech's share of total venture capital has fallen from 13 percent in 1992 to four percent in 2014.
- Medtech's share of early-stage venture investment has fallen as well, from 10 percent in 1993 to three percent in 2014.
- During 2015, declining investor interest in device led to a drop in new company formations, and the majority of Series A rounds were less than \$5 million.

However, 2015 saw a significant pickup in early-stage activity, with five non-approved stage exits compared to one in each of the previous two years.

Policy changes are essential if the industry is to fulfill its potential for contributing to American economic growth and for the development of the new treatments, diagnostics and cures that the stunning advances in the life sciences of recent decades have made possible.

Key changes include:

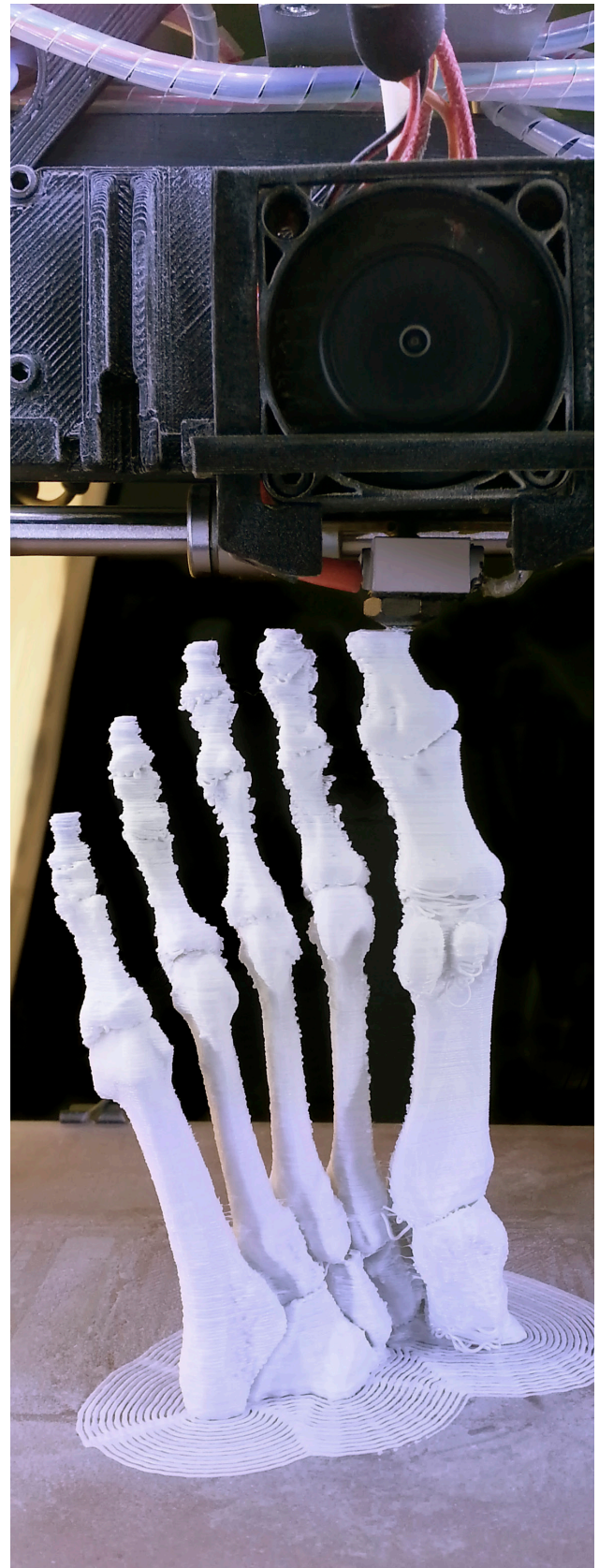
- A more consistent and timely pathway to FDA approval.
- Coding, coverage, and payment that is more timely and supports innovation—especially in the Medicare program.
- Tax and other policy changes, including repeal of the medical device tax, to encourage the flow of capital into early stage and start-up companies.

This report follows a series of roundtables around the country with entrepreneurs and early-stage investors in the medical technology sector. Roundtable participants were asked to give feedback on these long-term trends. Serial entrepreneurs pointed to tough, unpredictable and uneven conditions in regulations and payments, on top of an industry with difficult technical and clinical conditions built into its foundation.

Entrepreneurs painted pictures of challenging market conditions. Talent has been difficult to attract to an industry competing with other, less regulated industries. Engineering talent is in finite supply in the U.S., and the allure of other industries has exacerbated medtech industry shortages. With fewer start-ups in the system, the industry's major players recognize the long-term threat to innovation represented by fewer companies moving through the pipeline.

Stakeholders credit the FDA with working diligently to improve its performance from the low point in 2010 and appreciate the leadership's stated goal of making the U.S. the most attractive place in the world to introduce significant new products. At the same time, despite improvements, the process for review is often too slow and too inconsistent. The pathways for medtech reimbursement, by contrast, not only remain slow and uncertain but appear to be worsening. The total time involved in gaining FDA approval and insurance coding, coverage, and payment create delays on return on investment, even for successful products, that are unattractive to venture capital investors. The new medical device tax, currently under suspension through December 2017, has been an additional factor depressing investment in recent years.

Opportunity abounds, however, and leaders conveyed optimism throughout these dialogues. The convergence of non-traditional players in the health system presents great opportunity to mobilize for a new generation of innovations. Developments in consumer technology, the Internet of Things (IoT), Big Data and interoperability may all be driving influences in medtech in the next decade and beyond.



Entrepreneurs saw opportunity in consolidation as well. The current model of partnering in the medtech industry deserves attention both from stakeholders in the industry and from partners in government.

Incentives for structures such as R&D partnerships may help influence the amount of capital deployed from industry leaders into higher-risk innovations.

In addition to the transparency, predictability, and timeliness of regulatory and coverage decisions, direct steps to encourage capital formation may be an issue that would especially benefit from new government focus and action. American medtech sustainability requires fresh thinking from policy makers, particularly with regard to incentives encouraging private sector investment in industries considered of primary national strategic value, such as medical technology.

The U.S. medtech industry in its entirety faces the threat of losing its global position as the innovation leader. National economic competitiveness is at stake, and the risk is inherently greater than just U.S. primacy in medtech innovation. Continued decline in medtech start-up formation will impact the overall healthcare system and, ultimately, prevent the delivery of these innovations to patients.


PROJECT METHODOLOGY


This report is the result of direct dialogues with entrepreneurs and investors in the medical technology sector, and augmented by research from a range of industry analysts. Five roundtables were held in established regions of medtech innovation, including the San Francisco Bay Area, Orange County, California, Washington, DC, Minneapolis, Minnesota, and Boston, Massachusetts. Over 60 entrepreneurs, angel investors, venture capitalists and corporate investors participated in these sessions.

Roundtable participants were asked to give feedback on long-term trends, identify challenges and look forward to opportunities and solutions.

Simultaneously, data was collected from a variety of sources on medtech industry trends. Data from these sources does not always align due to source variability. Census Bureau data, for example, often lags by three years for general economic measures, and certain projects at the Census Bureau recur only once every five years. For that reason, the period covered in this analysis is generally the last two decades, and not always up to the same end date. Roundtable dialogues were merged together and participants de-identified, prior to filtering findings in conjunction with the long-term data.

Finally, the authors interviewed a number of industry leaders on the record, to provide further reinforcement and illumination of certain issues.





You may have an efficacious therapy but it costs so much money to bring it to market. [With these] regulatory realities, juxtaposed to the availability of capital, that's just too long a shot. You should be doing something else.

- **Corporate Investor**, Orange County Roundtable

THE CLIMATE FOR ENTREPRENEURSHIP

THE CLIMATE FOR ENTREPRENEURSHIP

Formation of new startups has declined by almost 70 percent since 1978. Similarly, since the early 1990s, the share of venture investment in early-stage medical technology companies has also declined from 10 percent of all U.S. early-stage investing in 1993 to three percent in 2014.

Declining U.S. startup activity together with falling early-stage investment combine to form a stark picture. U.S. venture investments have been on a downward trend since the early 1990s. The share of medtech venture capital activity occurring in the late stage has grown sharply in the last 15 years, meaning that risk capital has moved to more mature opportunities and exacerbated the challenge for entrepreneurs.

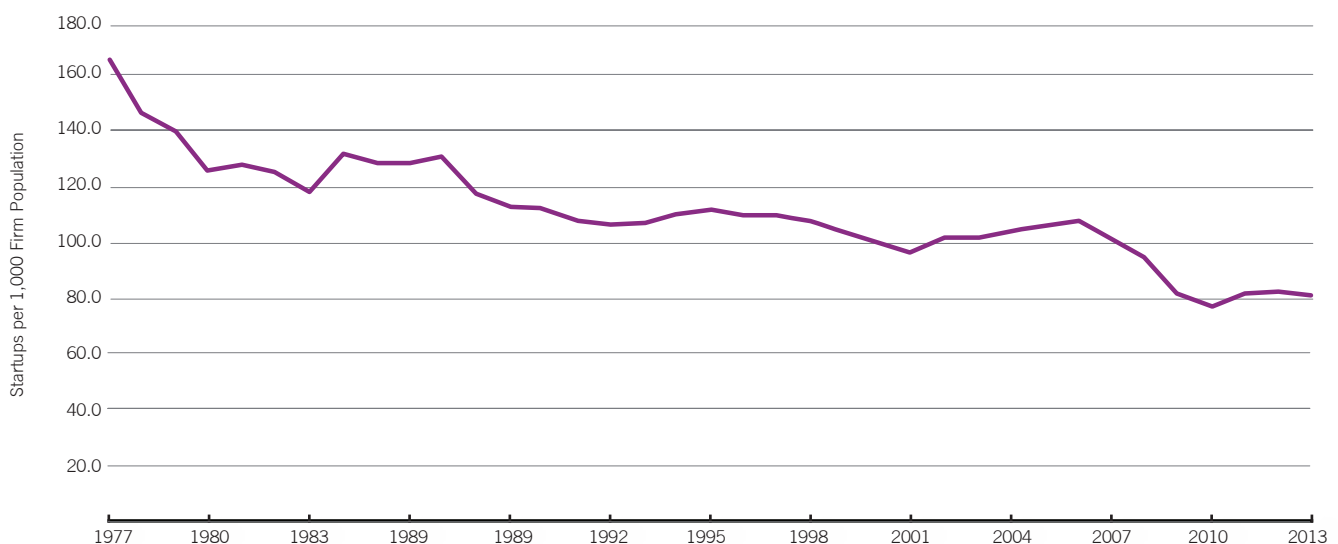
While the U.S. remains the world leader, the medical technology industry in the United States has been suffering from a steady decline of entrepreneurship over two decades. That decline represents a present and future threat to American leadership in the industry, medical innovation and, ultimately, to patients.

Serial entrepreneurs, angel investors, venture capitalists and corporate investors in medical technology were convened in five roundtables to discuss the environment for early-stage medtech innovation. Founders painted pictures of challenging market conditions.

Nationally, the climate for entrepreneurship is not as positive as it might seem. Media reports of the prosperity of the technology sector and the health of Silicon Valley have created the perception that the start-up ecosystem has been as vibrant as ever. The number of start-ups with billion-dollar valuations has risen dramatically. Initial public offerings (IPOs) have returned capital to investors, replenishing the limited partnerships that drive early-stage investment. Underneath these positive signs, however, new business formation has been in steady decline for more than two decades.

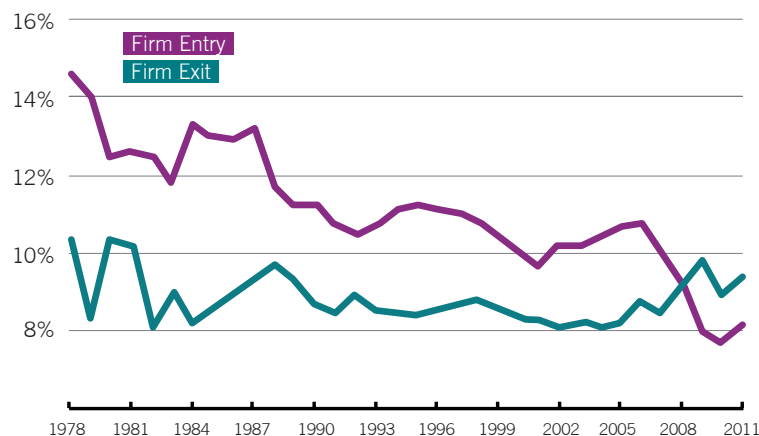
Released in August 2016, the Kauffman Index measured national trends in start-up activity in the United States. Start-up Density is the ratio of the number of new employer businesses divided by the total population (in 100,000s). The Kauffman Index demonstrates both the long-term decline since 1977 and the sharp decline since 2006 (Figure 01).

FIGURE 01
START-UP DENSITY IN THE UNITED STATES (1977 - 2013)



Source: 2016 Kauffman Index of National Trends in Startup Activity, kauffmanindex.org.

FIGURE 02
OVERALL START-UP TRENDS DECLINING (1978 - 2011)



Source: *Declining Business Dynamism*, Hathaway and Litan (Brookings, 2014).

FIGURE 03
NEW COMPANY FORMATIONS DOWN (1978 - 2012)

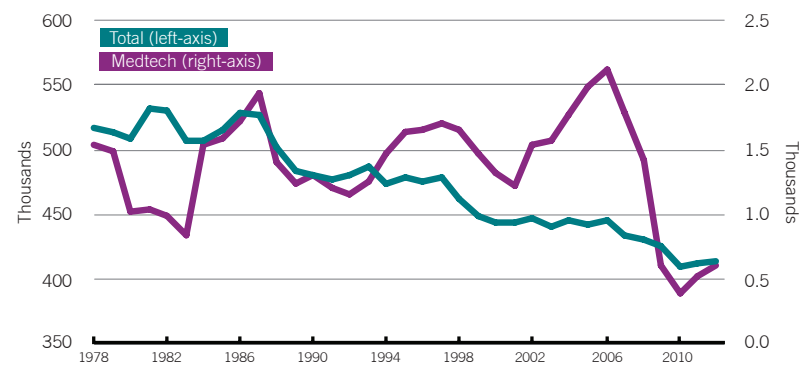
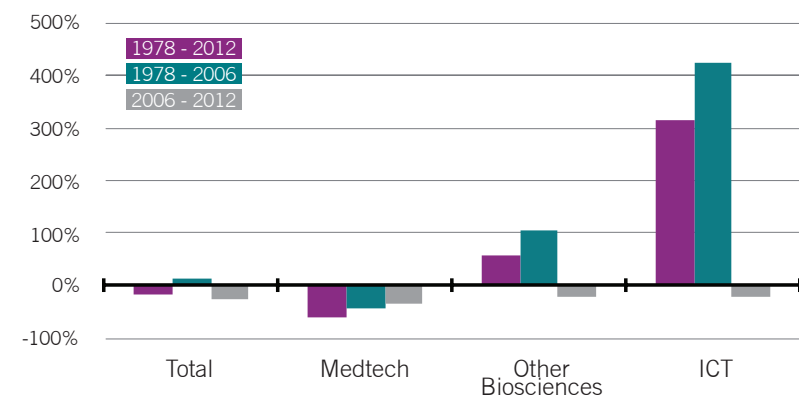


FIGURE 04
DELTA IN MEDTECH COMPANY FORMATIONS (1978 - 2012)



Source (Figure 03 & 04): Census Bureau, authors' calculations.

Released in 2014, the Brookings study “Declining Business Dynamism in the United States” looked at the rate of new company formation in the U.S. since the late 1970s. For all sectors of the economy, the rate of entry of new firms has fallen steadily since 1978 (Figure 02).

There is a similar pattern for medical technology, but the decline has been sharper. The number of new medtech businesses formed each year has fallen by almost two-thirds, with a stark decline since 2006, to around 600 in 2012 (Figure 03). For the private sector as a whole that number fluctuated around 500,000 new businesses formed each year, before the Great Recession.

Medtech start-ups have been persistently down compared with the total private sector and other technology sectors—both over the long-term and in the latest business cycle (Figure 04). Information and communications technology (ICT) start-ups have grown the most by far over the period.

The business start-up rate—the new firm share of total businesses—has fallen steadily since the late-1970s (Figure 05). This has been especially true for the medtech sector, where in recent years, less than five percent of firms were launched within the last year. While also down substantially for the private sector as a whole and for other technology sectors, their firm formation rates are still two-to-three times the rate for medtech.

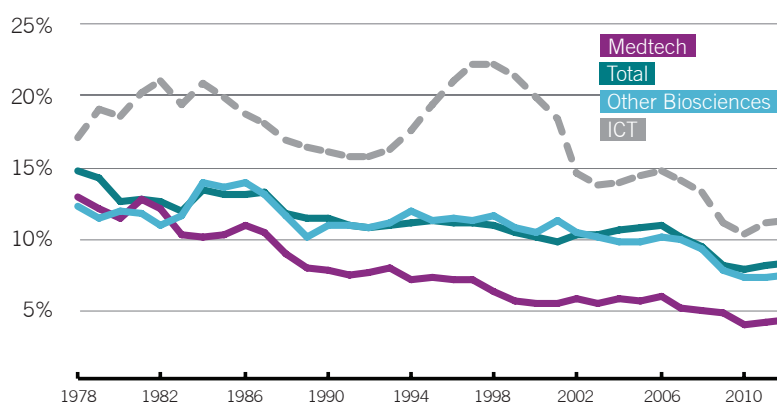
One mark of a dynamic industry is a high proportion of relatively young firms and a smaller proportion of aging firms. A relationship that runs in the other direction suggests a mature industry with limited growth prospects. The medtech industry is aging when underlying trends, including an aging population, increased demand in foreign markets and unprecedented scientific opportunities, should be sparking tremendous dynamism.

As displayed in Figures 06 and 07 to the right, U.S. industries as a group are aging, but the trend is heavily pronounced for medtech. More than 30 percent of medtech firms are at least a quarter-century old, and more than half are aged 16 years or more. Likewise, less than 20 percent are younger than 6 years. This is markedly different from the private sector and especially from other technology industries.

Three-quarters of medtech employment is accounted for by firms more than 25 years old, and 85 percent in firms 16 years old or more—a clear distinction from the overall private sector and the information and communications technology sector (Figure 07). Older firms tend to be less dynamic, flexible, and innovative.

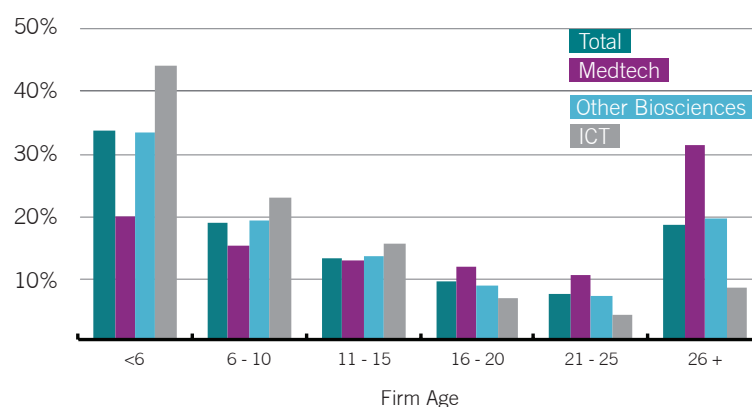
The decline in start-ups has become somewhat self-reinforcing, driving other negative impacts that have created additional drags on entrepreneurship.

FIGURE 05
RATE OF NEW BUSINESS FORMATION BY SECTOR (1978 - 2012)



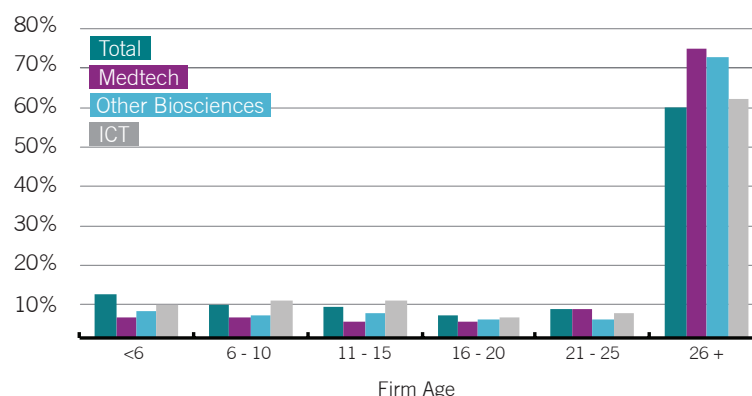
Source: Census Bureau, authors' calculations.

FIGURE 06
DISTRIBUTION OF FIRMS BY FIRM AGE AND SECTOR



Source: Census Bureau, authors' calculations.

FIGURE 07
DISTRIBUTION OF EMPLOYMENT BY FIRM AGE AND SECTOR



Source: Census Bureau, authors' calculations.

Talent, for example, has been difficult to attract to an industry competing with other, less regulated industries. Engineering talent is in finite supply in the United States, and the allure of other industries has exacerbated the medtech industry challenge.

“Years back all the best, brightest engineers went to aeronautics,” an investor at the Orange County Roundtable pointed out. “Now they’re going to IT. We’re missing a human resource component.”

“It goes even younger than that,” offered one corporate representative at the Orange County Roundtable. “You have app building competitions in high schools. It doesn’t even start at the university level, it starts much younger.”

Location has also traditionally been a factor given the medtech industry’s concentration in a small number of U.S. clusters. “I’ve been trying to help a start-up out of the University of Rochester,” offered an investor participating in the Boston Roundtable. “We raised \$2 million, but had to get a CEO from San Diego and he runs [the start-up] from San Diego. There’s just not [enough] talent.”

Though incubators have arisen in academic environments around the world, they haven’t necessarily changed the formula for success of early-stage companies. “Universities are trying to create revenue streams for themselves,” offered one entrepreneur at the Boston Roundtable.

“The physician-inventor has no idea what product development is all about,” offered another industry executive during the Boston dialogue. “The whole early product development piece is totally foreign.”

Others pointed to the role played by leading corporations in the medical technology sector. “A lot of [top corporations] are more focused on expanding to emerging markets with existing technology, than they are about new technology,” said one entrepreneur participating in the Minneapolis Roundtable.




“We don’t innovate well inside,” the entrepreneur said speaking of large companies, “and let’s really not spend money innovating outside.”

Participants also frequently pointed to competition for risk capital. “The perception is that the payoff will not be as great in medtech,” suggested one industry leader participating in the Boston Roundtable.

“Looking at seed and series A money that’s available,” one start-up leader said in Orange County, “it’s going to mobile apps. It’s going to cloud-based anything. I look at where money flows into a mobile app as compared to [medtech] and it just doesn’t make sense.” Industries perceived as simpler, more certain and quicker to returns have been pulling investor interest away from medtech over the last two decades.

Whatever the causes, the downward trend has lasted for more than 30 years in total. The U.S. medtech industry in its entirety faces the threat of losing its global position as the innovation leader. National economic competitiveness is at stake, and the risk is inherently greater than just U.S. primacy in medtech innovation. Continued decline in medtech start-up formation will impact the overall healthcare system and, ultimately, prevent the delivery of these innovations to patients.



I would counsel entrepreneurs to consider other projects that don't have the reimbursement challenges. This advice comes at the cost of discouraging some breakthrough innovation in healthcare, but that is what our system is already doing.

- **Steven Weinstein**, Novartis Venture Fund

THE CLIMATE FOR INVESTMENT

THE CLIMATE FOR INVESTMENT

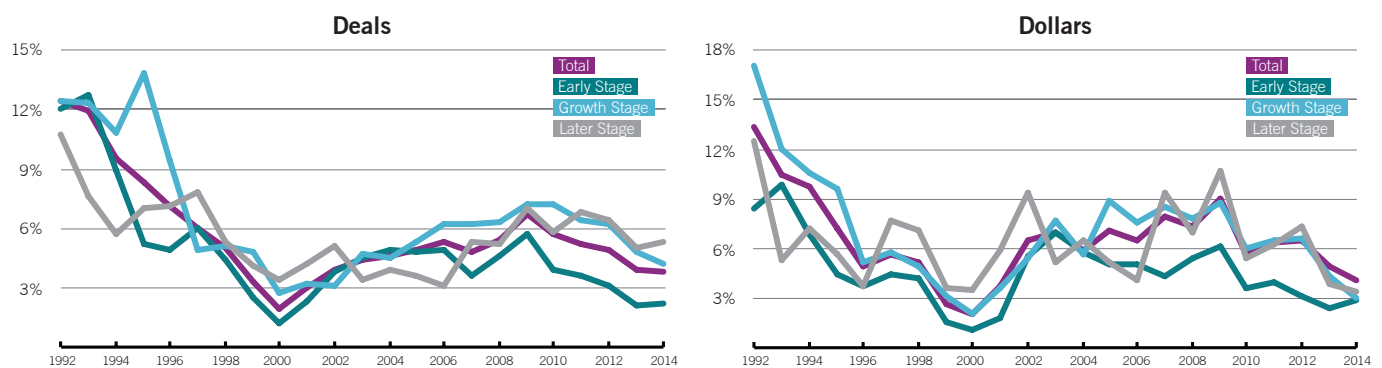
There has been a drastic capital flight from medtech since 1992. Venture capital investment in all medical technology companies has fallen from 13 percent of total venture capital investments in 1992 to four percent in 2014. As total investing has declined in medtech, the proportion devoted to early stage start-ups—the essential ingredient for development of new treatments and cures - has also declined, from 10 percent in 1993 to three percent in 2014 (Figure 08).

This capital flight has been caused by many contributing factors, and compounded by returns in sectors with simpler, more transparent markets. To investors, those returns have offered a safer environment – and one that has become a virtuous circle for replenishing venture capital funds. The better mobile and software funds have performed, the more their limited partners have come back to invest in new rounds.

“[As a] venture capitalist or the angel investor, your product is cash,” offered one entrepreneur during the Orange County Roundtable. “You’re going to apply that where you think you can get the quickest return for the best multiple. Right now medical device is not that space. If I were you, I’d be putting money somewhere else.”

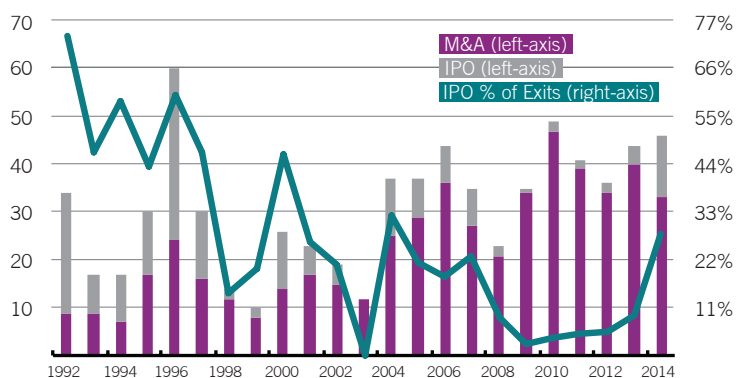


FIGURE 08
MEDTECH SHARE OF TOTAL VC, DEALS AND DOLLARS (1992 - 2014)



Source: VentureSource, authors' calculations.

FIGURE 09
MEDTECH IPO AND M&A TRENDS (1992 - 2014)

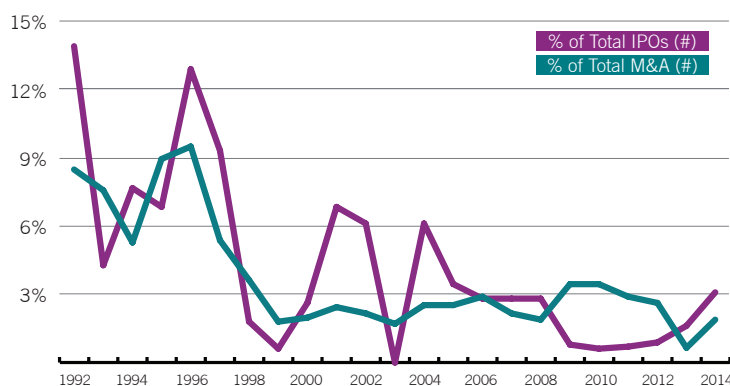


Source: VentureSource, authors' calculations.

Key avenues for investors to create return on investment are to sell equity either through an initial public offering (IPO) or to sell to another company, known as mergers and acquisitions (M&A). Collectively, these options are known as exits. Exits rebounded somewhat in 2014 (Figure 09).

Despite the steady flow of medtech M&A activity throughout the 2000s, there were relatively few transactions (trending around three percent) as a share of total VC-backed M&A deals. IPO activity followed a similar pattern—down sharply as a share in the 2000s from the 1990s (Figure 10).

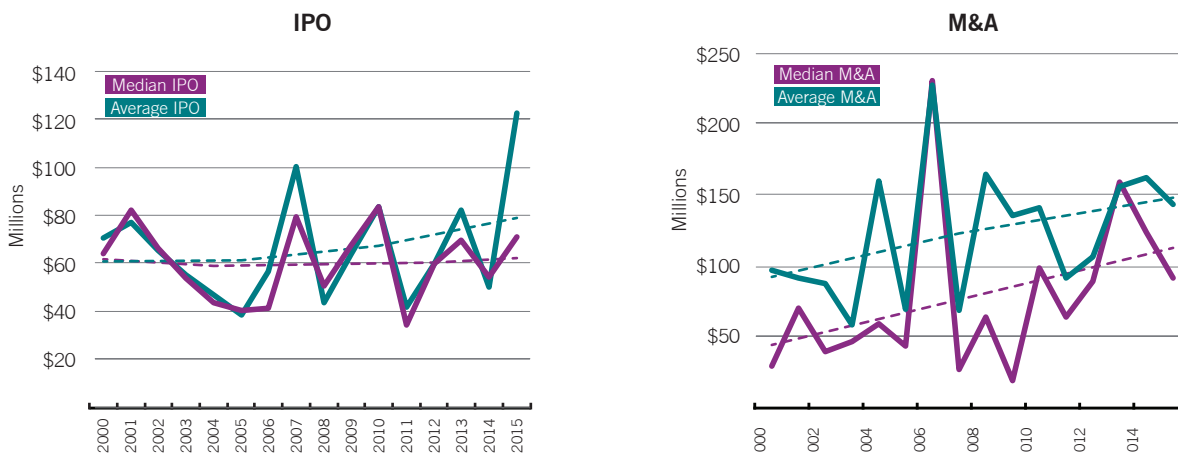
FIGURE 10
MEDTECH SHARE OF TOTAL VC-BACKED IPO AND M&A (1992 - 2014)



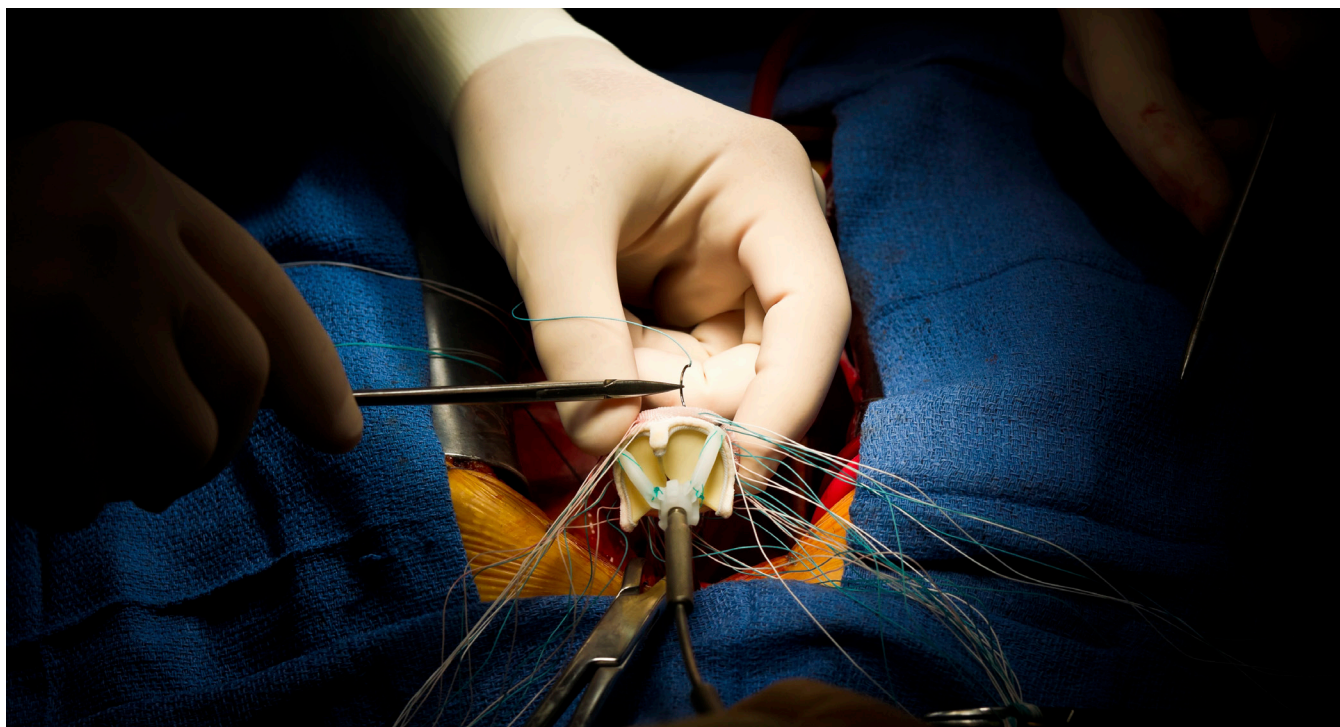
Source: VentureSource, authors' calculations.

Medtech exits have had median and average deal sizes of similar magnitude (Figure 11). During the last 15 years, average medtech IPOs have trended slightly higher, while average M&A deals have grown larger.

FIGURE 11
MEDIAN AND AVERAGE IPO AND M&A (2000-2015)



Source: Pitchbook, authors' calculations of total venture-backed and non-VC backed companies.



A CONVERSATION WITH AARON SANDOSKI, CO-FOUNDER & DIRECTOR NORWICH VENTURES, A VENTURE CAPITAL FIRM SPECIALIZING IN EARLY-STAGE MEDTECH INVESTMENTS.



MATT GARDNER: Medtech exits have been very different from those in the biopharma business model, where big pharma can hedge its bets much earlier with clinical-stage, phased deals with a combination of upfront dollars and milestone payments. Could this approach work in medtech?

AARON SANDOSKI: Structured deals work well when there are clear milestones. In pharmaceuticals, structured deals are typically used when a compound is still in the clinic. Drugs have a predictable path and events like filing a NDA and FDA approval are clear milestones that also correspond with significant value inflections. Most medical devices are different. The development and market launch are iterative processes with much ambiguity along the way. The area of devices where a pharma-like phased

approach is appropriate is a PMA device that has been clinically tested outside the U.S. The PMA submission and FDA approval are clear value-creating milestones that can be used for a structured deal.

MG: You've looked closely at exits. Is there an ideal time for large caps to buy in medtech? What happens to the price of acquisition after FDA clearance?

AS: If the large caps are thinking only about the short-term, then the ideal time to buy a company is when all the risk is gone and there is minimal negative impact on next quarter's earnings. However, if you take the long-term perspective, the ideal acquisition timing is very different—start-ups should be bought as they transition to commercial activities. Building a sales force and generating market traction at a start-up is very capital intensive. By our estimates it takes twice as much capital for a well-run start-up to gain market traction as it does to get the product to market. Yet, when we look at historical acquisitions about 2/3 of the value is realized at regulatory approval and 1/3 is realized after significant market traction. Acquirers typically already have the sales infrastructure, so they put zero value on what the start-up has built. Acquisitions that occur at the commercial inflection point instead of post-commercial success are good for everyone. Entrepreneurs avoid the highly dilutive commercial financing rounds and can move on to their next company sooner. VCs invest 1/3 of the capital for 2/3 of the reward. And since large caps pay 2/3 of the price of a commercial acquisition, they can acquire 50% more companies with the cash they have. Even if a few do not work out as planned, everyone, including the large cap, comes out ahead.

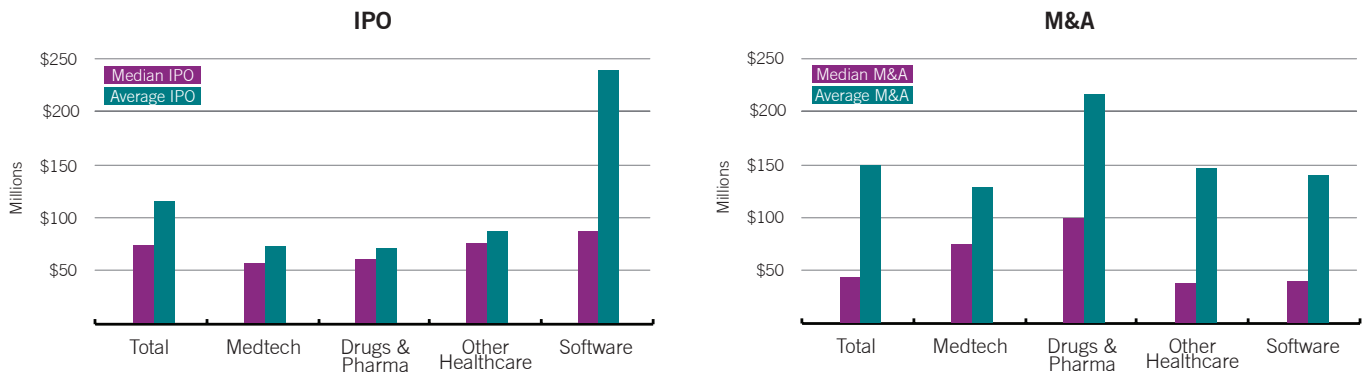
MG: Have there been “model exits” that you might point to as those that supported both winning innovations and a good outcome for investors?

AS: There have been a few model exits. One of our past portfolio companies, Rhythmia Medical, serves as a good example. The company had developed an Electrophysiology (EP) mapping system that was a major breakthrough in the field. The product was proven clinically, but had not yet filed for regulatory approvals in the U.S. and E.U. Boston Scientific was looking to build out its EP business and Rhythmia offered them a great platform. The acquisition was structured with an upfront that generated an excellent return for investors plus additional milestones based on regulatory, commercial, and sales activities. The reason the upfront was both palatable to the acquirer and very meaningful to the investors is because the company was pre-commercial and had raised a limited amount of capital at that point. Boston has been an active large cap when it comes to structured acquisitions at the commercial inflection point. Boston has also spent years in a state of turnaround. In a turnaround situation, the company's acquisitions tend not to focus on increasing next quarter's earnings by a small amount, but rather on how they can create a compelling longer-term company when the turnaround is complete. This may explain why it is the exception in the large caps.

MG: How do the current set of exits influence the climate for new investment?

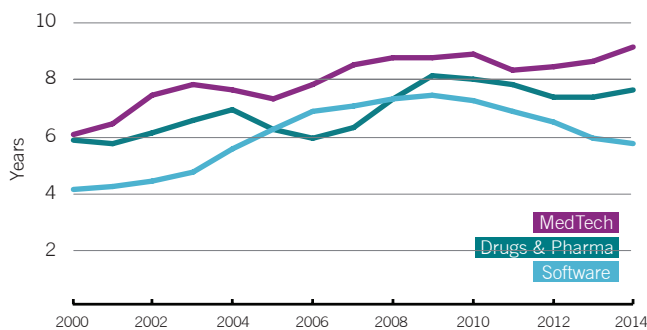
AS: In the past decade, a majority of start-ups were bought only after significant commercial traction. The large caps were focused on minimizing risk and short-term earnings dilution. This caused VC investment timelines to grow by years and led to large amounts of inefficient capital being deployed in commercial build-outs. The corresponding returns were insufficient for pension funds and endowments to want to reinvest when it came time for new medtech VC funds to be raised. The result has been a dramatic drop-off in the number of new medtech companies being funded in the past five years. Some of the large caps are starting to wake up to the fact that the acquisitions that drive their future blockbuster products are drying up. In just a few years the recent small crop of funded start-ups will be the mature start-ups and there will be 60-80% fewer potential acquisitions available for the large caps. If large caps switch their focus and acquire a majority of start-ups at the commercial transition point, a healthy ecosystem will re-emerge. Venture returns will improve causing capital to flow back to medtech and the existing capital will be redeployed to build new products instead of being used to build duplicative sales forces.

FIGURE 12
IPO AND M&A SIZES BY SECTOR (2000-2015)



Source: Pitchbook, authors' calculations.

FIGURE 13
TIME TO EXIT (2000 - 2014)

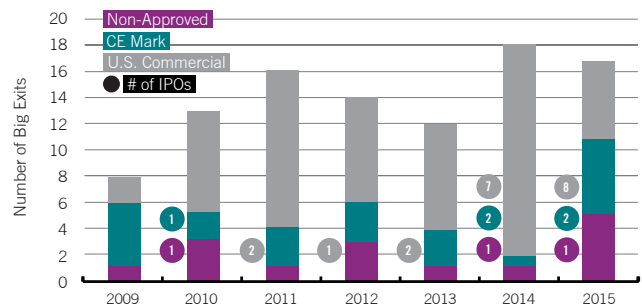


Source: Pitchbook, authors' calculations.

Typical medtech exits are relatively small compared with peers, and especially so for IPOs (Figure 12). Pharmaceutical M&A deals can be quite large and vary widely. The large number of small companies being acquired in the software industry pushes the industry average down despite large transactions in the sector.

Not only have medtech exits (IPO and M&A) been smaller relative to peers, but they have also taken longer. The median time to exit from founding is nine years, up from

FIGURE 14
INCREASE IN EARLY-STAGE M&A FOR VC-BACKED MEDTECH



Source: Trends in Healthcare Investments and Exits 2015, Silicon Valley Bank.

six years in 2000 (Figure 13). Software company exits have fallen by about one-third less to six years.

Though the long-term trend reflects an increase in time to exit, 2015 saw an unusual increase in exits for earlier-stage, venture-backed medtech companies (Figure 14). Industry veterans expect the shift in 2015 was a one-time event and does not reflect an overall change in M&A activity or a fundamentally different appetite among buyers.

A CONVERSATION WITH STEVEN WEINSTEIN, MANAGING DIRECTOR NOVARTIS VENTURE FUND, A CORPORATE VENTURE FUND WITH OFFICES IN THE BOSTON AREA.



MATT GARDNER: You were an investor in Sonitus Medical, which went through a shutdown following a negative coverage decision by CMS. What happened?

STEVEN WEINSTEIN: Sonitus Medical had asked CMS to provide a HCPCS code which is required of prosthetic/DME devices to be billable to CMS. Private payers use the same coding system. Soundbite Hearing System, Sonitus' product, was FDA approved to treat patients with single-sided deafness (SSD). Single-sided deafness is often due to a tumor or viral infection. CMS had already granted prosthetic status to Cochlear's BAHA device nearly a decade earlier. Sonitus' system was treating the same patient population, with the same indication, with the same mechanism of action (bone conduction). Both products were FDA approved to treat SSD. The two differences between the products

were that Soundbite was (1) a non-surgical solution (Cochlear's product requires a surgical post implanted into the skull), and (2) a less expensive therapeutic option than BAHA (when factoring in the cost of the surgery). The CMS decision to not cover the Soundbite System was the singular event that resulted in Sonitus' shutdown.

MG: Did you have any direct dealings with CMS that could shed light on this challenge for other entrepreneurs?

SW: My observation is that their processes are often defined by administrative definitions that are decades old, and they are often boxed in to outdated frameworks that cannot accommodate current medical innovation. Our process with CMS was ambiguous with no clear accountability as to who will make the decision and what criteria were being evaluated. Once decided, there was no accountability as to who made the decision and why.

MG: How did the CMS uncertainty impact Sonitus' ability to go out and seek coverage from other payers?

SW: The irony of the Sonitus situation, is that 95% of the addressable clinical need is with patients under 65 years of age, which are paid for with private insurance. Sonitus had been commercializing to patients and had been receiving payment from many private insurers. But, CMS controls the codes, so when CMS deemed Sonitus a "hearing aid," private payers followed suit. As hearing aids are not typically covered by private insurance, Sonitus' reimbursed market disappeared. Even though CMS beneficiaries only represent 5% of the market, CMS's decision eliminated a therapeutic option for all U.S. patients.

MG: Do you see a direct link between the opacity of reimbursement and the climate for medtech funding?

SW: Yes, the long, serial, foggy path to reimbursement, and the lack of a mechanism to encourage innovative products (which often will be first-in-kind and not fit existing reimbursement models/coding), is stifling the start-up medtech community and having a significant effect on the sector's ability to raise venture financing. Without clarity around reimbursement, investors and entrepreneurs are not willing to risk the technical, clinical and regulatory risks, to then fail in the last hurdle of reimbursement. Sonitus is a great example of this type of failure. The Soundbite is safer, less expensive, and offers patients a more convenient and less invasive therapeutic option. It generated very high patient satisfaction in the thousands of patients that were treated, but failed due to reimbursement. Nobody will begin to run a race if the last hurdle is too high, or ambiguous.

MG: Should CMS be expected to take such survival questions into account, when the potential death of a company carries the possibility of depriving patients of an innovative product? Do you have ideas for how this might be weighed?

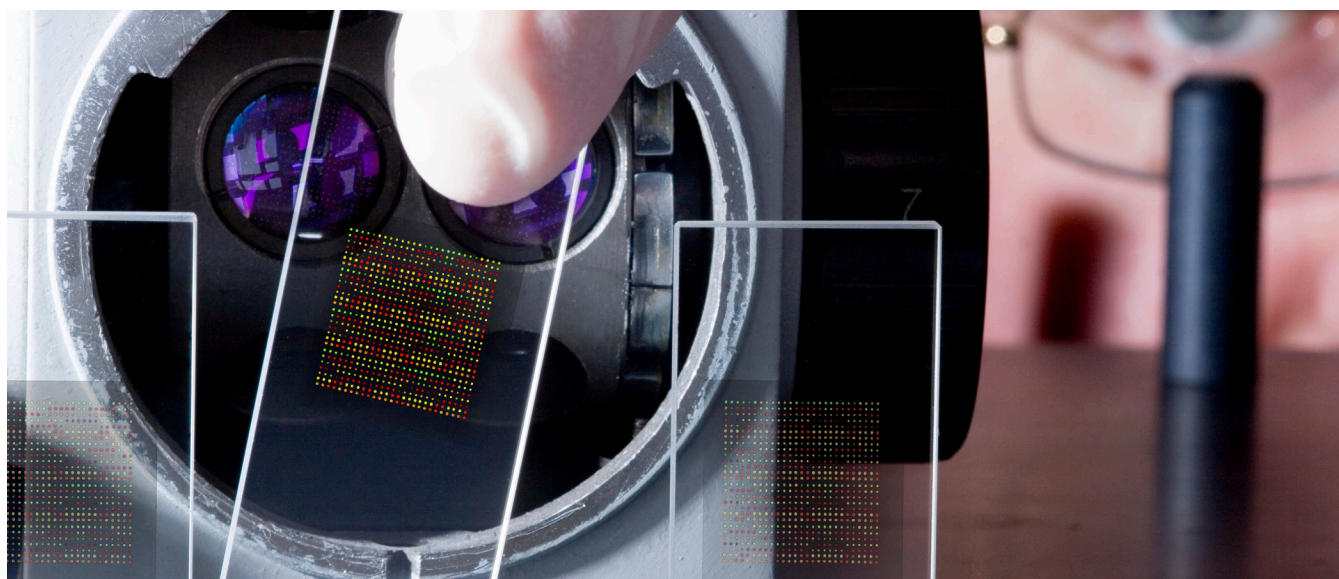
SW: I don't believe CMS should consider a company's potential failure as part of its decision making process. However, I do believe they should offer their beneficiaries the best, safest, and most cost-effective healthcare alternatives. In this case, CMS inexplicably chose to eliminate a safer, non-surgical, less expensive alternative. I think CMS should be responsible for making logical choices, and in this case, I believe they made the wrong decision. Personally, I believe they should work with academia and industry to promote innovation, as that is what makes our healthcare system robust, competitive, and results in better clinical outcomes. Unfortunately, I don't believe that is currently a focus.

MG: Would certainty about coverage have meant anything different to Sonitus? Would a faster response by CMS have made a difference?

SW: A faster "no" would have saved investors significant capital, and may have allowed the company to pivot. But, any "no" would have likely been fatal at some level.

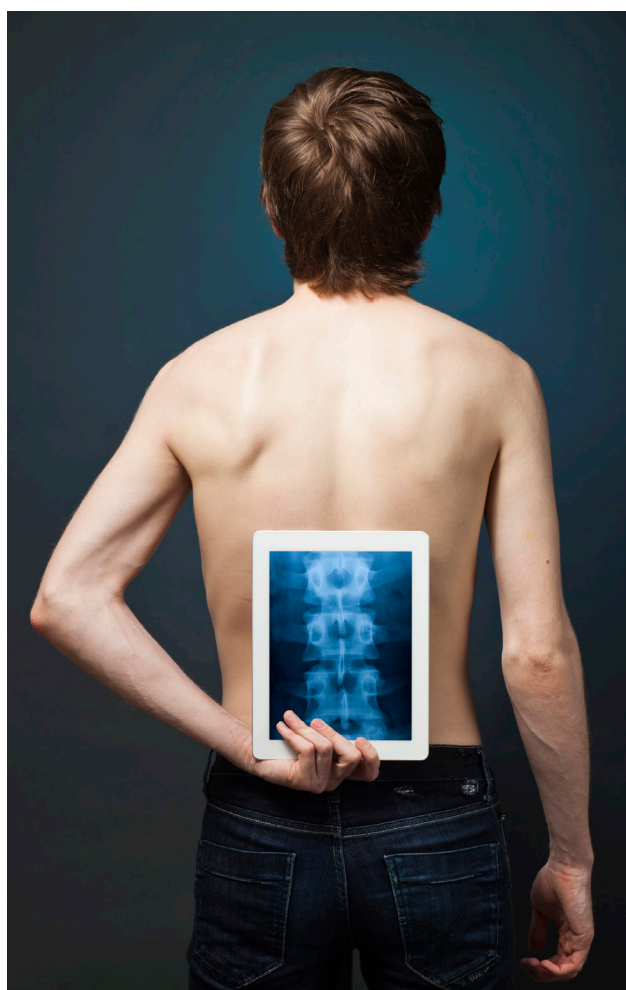
MG: If you were giving advice to other medtech entrepreneurs about reimbursement strategy, what would you recommend?

SW: If you have no choice but to pursue new reimbursement codes/coverage, be patient, and persevere. It is an illogical, political, and often painful process. Plan for it to take many years, and unfortunately you won't know if you have won until the race is over. I would also counsel entrepreneurs, personally, to consider other projects that don't have the reimbursement challenges. On a personal level, it may not be time well spent, given the opportunity cost of doing something else. This advice comes at the cost of discouraging some breakthrough innovation in healthcare, but that is what our system is already doing.




Several roundtable participants identified one area with an unintended impact on investment in start-up manufacturers. “If a physician advising an early-stage company works for a provider from which that company seeks adoption, the provider bars physician ownership,” said one Boston entrepreneur.

Hospital policies that limit business with certain companies with physician ownership, which have been put in place in an effort to prohibit doing business with physician-owned distributors, supply chain entities that raise real concerns under the health care fraud and abuse laws, have the unintended impact of also prohibiting business with legitimate start-up manufacturers.



The medtech business climate has been hard on investors. Returns have historically been smaller and taken longer in medtech when compared to other industries. Given a continuation of the same conditions, capital has no reason to return. “You look at venture capital returns,” suggested one corporate investor. “The vast majority of funds in this space have lost money in the past ten years. Why would you keep doing it?”

Recent trends show promising signals for investors in medtech (Figures 11 and 14). Still, the lure of software and other, less-regulated industries continues to influence the risk capital climate. “For one medtech or biotech, I could do fifteen fully funded app companies,” offered one angel investor at the Orange County Roundtable. “And I only need one of them to hit to pay that back.”



Financially constrained firms are less likely to enter new device markets as pioneers.

- **Ariel Stern**, Harvard Business School

THE CONTRIBUTIONS OF THE CURRENT REGULATORY ENVIRONMENT

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A recent study by the National Association of Manufacturers (NAM) assessed the total cost of the regulatory burden at more than \$2 trillion in 2012. In the context of the total U.S. economy, all sectors and all firms, the NAM study pegged the cost at near \$10,000 per employee. Unfortunately, the study also indicated that small business incurred costs 17% higher than the average firm, because the fixed costs of regulatory compliance are spread over a smaller amount of resources.

A 2010 survey conducted by venture capitalist Josh Makower, a General Partner at NEA and founder of medtech incubator Exploramed, identified critical points in failure in the regulatory review of medical technologies. Survey respondents cited changes in personnel and missing staff and advisors at key regulatory meetings with companies, all leading to delays. Ultimately, a 510(k) process required 10 months on average in the U.S. compared to 7 months in Europe, according to the survey, and a PMA process required 54 months in the U.S. compared to 11 months in Europe.

A recent economic review by Harvard Business School professor Ariel Stern identified the regulatory burden as especially significant for true pioneers as well as for smaller companies. “Pioneer entrants spend approximately 34 percent (7.2 months) longer in the approval process than the first follow-on innovator,” wrote Stern in her review. She also found that “financially constrained firms are less likely to enter new device markets as pioneers.”

Stakeholders credited the FDA with working diligently to improve its performance from the low point in 2010 and appreciate the leadership’s stated goal of making the U.S. the most attractive place in the world to introduce significant new products. At the same time, despite improvements, the process for review is often too slow and too inconsistent.

Even given the timely improvements by the FDA, entrepreneurs still found issue with the time to review. “Respectful of [FDA’s] effort to reduce the timelines and create more transparency, if we have an approval in 2016, we’re still six years behind Europe,” said one entrepreneur during the Orange County Roundtable.

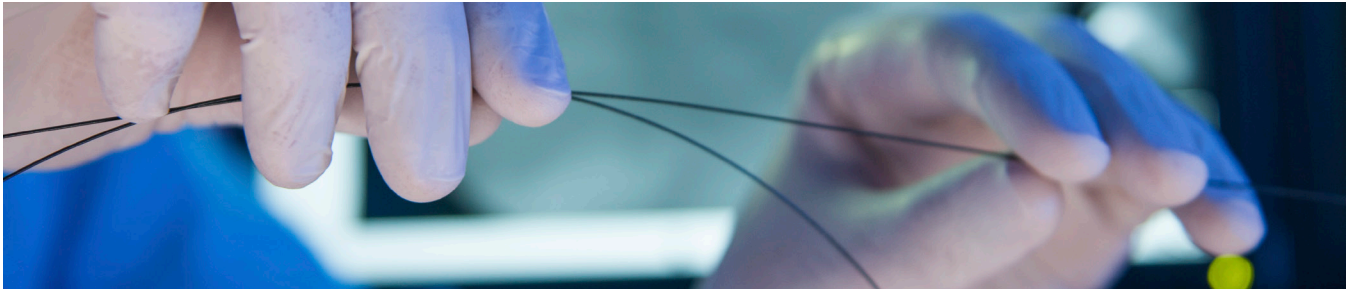


Only the most robustly funded start-ups could reasonably include [establishment of new codes] as a part of their strategic model.

- **Patrick Johnson**, Biophotas

THE CONTRIBUTIONS OF THE CURRENT REIMBURSEMENT SYSTEM

THE CONTRIBUTIONS OF THE CURRENT REIMBURSEMENT SYSTEM



With all the innate technical challenges facing medtech entrepreneurs, roundtable participants pointed to unpredictable and uneven conditions in regulations and payments as the greatest uncertainty in the industry today. Recent studies have shown substantially increased challenges to receiving positive coverage decisions from both Medicare and the private sector (Chambers et al, Health Affairs, February 2015). Even where coverage is ultimately granted, delays and inconsistencies are a formidable barrier to investment and to start-up company success. The rapid growth in provider risk-sharing arrangements have created situations where providers can be penalized financially for adopting new technologies, even when those technologies represent substantial clinical improvements.

Investors and entrepreneurs both cited the need for better predictability and visibility into time to market. Coverage decisions are often unpredictable and have no standardized pathway.

"Reimbursement, to me, is the biggest problem," said one investor during the Boston Roundtable.

"My fear is that CMS now is becoming the new FDA," said one Minneapolis Roundtable participant. "Yes, you get through the regulatory process but now there's just another big barrier."

Unfortunately, investors and entrepreneurs alike referred to CMS as just one aspect of the inefficiency endemic to coverage processes.

"We've had direct conversations with providers," said an investor at the Minneapolis Roundtable. "Decisions now are going to be based on committee, on what's going to be approvable before [they] put it in the system. Now you've got this chain that's FDA, CMS plus acceptance by the providers."

"It's a very complicated story," said one entrepreneur during the Boston Roundtable. "It's like a patchwork quilt out there. It's almost like trench selling. You have to go account by account to understand what their terms are. Each hospital, each state. The more I learn, the more I feel like I don't know."

"It's a long fight to fight," one investor added during the Minneapolis Roundtable. "The [venture] calculations are worse now because of reimbursement and because of adoption of risk-sharing arrangements by provider systems."

Many roundtable participants agreed on the need to prioritize action in the reimbursement system. "That would be number one on my list of things to get done," asserted a Minneapolis participant. "We want reimbursement to occur concurrently with FDA approval. We would like to have a provider consortium that works on adoption within healthcare systems that is somehow linked to that. If we got those two things done, the entire environment would change." The current paradigm for parallel review has limitations and would require modification to achieve this goal.

A CONVERSATION WITH MARTHA SHADAN, PRESIDENT & CEO ROTATION MEDICAL, A MEDTECH COMPANY HEADQUARTERED IN PLYMOUTH, MINNESOTA.



MATT GARDNER: You've been in leadership at big medtech companies, and now as CEO of an earlier-stage company. Has the reimbursement process been simple enough for a small company to generate sales?

MARTHA SHADAN: The reimbursement process is very complex. As a first time CEO, without a large staff responsible for this area, I have had to get educated. Do we apply for our own HCPCS code and if so, the long term value of doing so? What are the pros and cons of a miscellaneous code? Do we try for a Category 3 CPT code and pros and cons of doing so? [I] have gained an acute appreciation for the importance of account targeting given the variability in reimbursement based on geography, type of institution (hospital outpatient, ASC) and the payers' coverage terms.

MG: Do you have direct visibility into how and when each payer will make its coverage decision? Was the timeline predictable?

MS: The short answer is no. Each account contracts with multiple payers and typically will have terms specific to the provider or a network of providers. In addition, each payer can have different terms regionally. We are dealing with each provider on an individual basis.

MG: Which process was easier to understand, FDA clearance or getting coverage decisions from healthcare payers?

MS: FDA process is much clearer and seems less complex. There are multiple payers and the issues are further complicated by regional differences as well as differences in provider contracts with the payers.

MG: How has all of this impacted your ability to raise funding for Rotation Medical?

MS: Reimbursement concern was the number one issue for the majority of prospective investors.

MG: Do you see a direct link between the opacity of reimbursement and the climate for medtech funding?

MS: I believe that many deals do not get done because of reimbursement concerns.

MG: How do you see the reimbursement process differently now that you've been running a smaller company for several years?

MS: I was fairly 'insulated' from reimbursement issues when I worked at the large cap multi-national companies. Today, I have a greater appreciation of how much reimbursement can impact our success and how complex it can be given the multiple variables.


MG: If you were giving advice to other medtech entrepreneurs about reimbursement strategy, what would you recommend?

MS: Expect that early in commercialization, that there is not a 'silver bullet' and you will need to deal with each institution case by case. If reimbursement is denied, follow up to get an understanding on the reasons why. The decision [can] be reversed.



The time consuming processes were not the only issue with reimbursement. One investor in the Boston Roundtable pointed out the frequency of management mistakes with reimbursement issues. “I see companies with many different mistakes with reimbursement,” the investor offered. “Confusing coding with coverage. Doing a 510(k) path and not realizing that, when you come up for reimbursement,” your pricing will be influenced by the prices of existing products in that category.

Reimbursement resoundingly represented the most troubling web of challenges for the investors and entrepreneurs participating in these roundtables. From the murky CMS process, to the many and varied provider systems, to the management experience necessary to navigate a business through scale-up and commercialization, early-stage stakeholders identified not one, but many hurdles for the typical entrepreneur on the path to success.



Large caps are starting to wake up to the fact that the acquisitions that drive their future blockbuster products are drying up.

- **Aaron Sandoski**, Norwich Ventures

THE ROLE OF MAJOR INDUSTRY PLAYERS

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The medtech industry is increasingly concentrated in a shrinking number of large players. All of those players are scouring the globe for medtech innovation. With fewer startups in the system, the industry's major players recognize the long-term threat to innovation represented by fewer companies moving through the pipeline.

Medtech industry collaboration has typically taken the form of outright acquisition. Seldom have established companies formed partnerships with companies at pre-commercial stages, limiting the strategic options available to early-stage companies. Nuances and industry culture have made the conditions of partnering vastly different in the biotechnology sector versus the business development approach in medtech.

"A big pharma will buy a bunch of biotechs and two-thirds of them are going to fail," said one entrepreneur at the Boston Roundtable. "[If a big device company] buys one and it goes south, then they get crucified" as public companies.

"Bigger guys probably take less risk," said one corporate investor. Hypothetically, that investor offered the perspective of big company executives: "'Let's see this thing play out. I don't care if I pay five or ten times as much to make sure I know who the winner is.' As you get larger, it takes more to move the needle."

Limited options in venture capital have intensified the urgency among entrepreneurs to identify corporate strategic investors willing to share risk. "It tells you how bad it is, because people at very early stages are knocking on [the] door," said a corporate investor at the Orange County Roundtable.


Entrepreneurs and angel investors consistently pointed to the need for change in the role of big device companies. "Look guys, you need to pay attention, because in the next five years you aren't going to have anything to buy," said one entrepreneur in the Boston Roundtable.

"With the lack of funded Series A medtech companies, if you go out three years we have a whole period of time when there are literally not enough companies to buy," added an investor at the Boston Roundtable.

"I think it's harder for big companies," said one industry executive at the Orange County Roundtable. "Now if you take anything that feels like control [in ownership interest], you're running it through your P&L as a large company." That accounting has very real impact in terms of the way people will treat things."

"The only way to get that pipeline, and the only way for investors to get a good return," offered an early-stage investor during the Boston Roundtable, "is if the large companies buy companies [prior to] commercialization. I believe that solves everybody's problem."

The current model of partnering in the medtech industry may require adaptation. Incentives for structures such as R&D partnerships may help influence the amount of capital deployed from industry leaders into higher-risk innovations.



We want reimbursement to occur concurrently with FDA approval. We would like to have a provider consortium that works on adoption within healthcare systems that is somehow linked to that. If we got those two things done, the entire environment would change.

- **Investor**, Minneapolis Roundtable

**POLICY
IMPLICATIONS**

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Both the quantitative data and the unanimity among industry stakeholders on the nature of the problems suggest that the industry is facing a true innovation crisis. Without significant policy changes, the U.S. is unlikely to maintain its current world leadership and patients will be denied important medical advances that can lengthen and improve their lives.

While detailed policy recommendations are beyond the scope of this report, some general policy directions that need to be taken are clear:

- FDA processes must continue to be improved to reduce pre-submission time, time in review, and consistency of review;
- CMS especially, but private payers as well, need to create more transparent and timely pathways to coding, coverage and payment for FDA approved products, especially those that represent major clinical improvements.
- Mechanisms should be created to directly stimulate investment in start-up medical technology companies. These mechanisms could include tax changes such as pass-through of losses during the development stage to investors; better mechanisms at the NIH and other government agencies to fund R&D by start-up companies, growth in state-supported investment funds focusing on early-stage companies, and improvements in university and academic health center-based technology transfer programs to make them more attractive to investors. This should also include permanent repeal of the medical device tax to remove the concern that the first dollar of a start-up's revenue will be taxed.

SUMMARY

The medical technology industry in the United States has been suffering from a steady decline of entrepreneurship for more than two decades. Formation of new start-ups has declined by almost 70 percent since 1978. Similarly, since the early 1990s, the share of venture investment in early-stage medical technology companies has also declined from 10 percent of all U.S. early-stage investing in 1993 to three percent in 2014.

The pipeline is drying up.

That decline represents a present and future threat to American leadership in the industry, medical innovation and, ultimately, to patients.

The U.S. medtech industry faces the prospect of losing its engine for innovation. Of industries of national, strategic importance, certainly medical technology is a rare jewel, alongside other innovative industries contributing disproportionately to both the economy and well-being.

National economic competitiveness is at stake, and the risk is inherently greater than leadership in innovation. Continued decline in medtech start-up formation and investment will impact the overall healthcare system and, ultimately, make it impossible to deliver these innovations to patients.

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