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VC Asks Congress for New Medicare Policy to Help Medical Tech Startups

By Timothy Hay

America is still the world leader in creating new medical technologies that have the potential to save lives. So why is it so tough for the entrepreneurs and investors behind these new products to make a living here?



One reason, according to venture capitalists, is long, costly delays before getting new treatments to market, in some cases caused by health insurers dragging their feet when it comes to agreeing to reimburse doctors for using new medical products.

The hardships facing new medical devices and treatments was addressed this week on Capitol Hill, as the [House Committee on Energy and Commerce Subcommittee on Health](#) heard testimony from various players in the health-care industry, some of whom said they are having a tough go of it.

Among those who testified were prominent venture capitalists who focus on medical devices and biotechnology companies, and who spoke as members of the [National Venture Capital Association](#).

Mike Carusi—an investor with [Lightstone Ventures](#) and [Advanced Technology Ventures](#)—is among the most successful device investors in the industry, having spearheaded investments in hypertension treatment company Ardian Inc., acquired by [Medtronic Inc.](#) several years ago for more than \$800 million, the largest price tag the industry has ever seen.

But Mr. Carusi told Congress on Wednesday that he has not personally made a device investment for more than a year. And in scouting out new deals, Mr. Carusi is more likely than he was in the past to look outside the U.S., where the path to market is smoother and more predictable for new medical products, he said.

“I’m painting a picture of an industry still in crisis,” he said Thursday. Early-stage funding totals for medical devices are lower than they have been in 20 years, he added.

The main culprit in the downturn, he said, is the long and costly delays that device companies face before getting on the market.

And though the [Food and Drug Administration](#) has been identified in the past as a main cause of delays for emerging technologies, another bottleneck has occurred that is keeping startup companies in limbo while they hemorrhage money: delays in getting insurance companies to agree to reimburse for treatments involving new devices, Mr. Carusi said.

Though a good amount of reimbursement is done by private insurance companies that have their own calculus for making such decisions, [Medicare](#)—overseen by the government—remains the country’s largest payer.

“The government can encourage Medicare to be more transparent, and more predictable,” Mr. Carusi said. “The biggest challenge right now, with Medicare, is that we don’t know where the bar is [for reimbursement].”

Two of Mr. Carusi’s portfolio companies satisfied Medicare’s requirement on providing clinical data about their products, only to be turned away to go and get more data, and then to have the same thing happen again.

“ ... 5,000 patients’ [data] was not enough. We came back again with 10,000 patients. Not enough. We came back again with 15,000 patients. Not enough. ... The process appeared to be unending. My venture colleagues and I increasingly are facing this type of situation,” Mr. Carusi told Congress.

And since private payers frequently follow Medicare’s lead, the problem could snowball, he said.

The upshot, Mr. Carusi said, is that innovation and investment will be increasingly driven overseas, which will undermine America’s position as the world’s leader in new medical products.

Mr. Carusi and other VCs say the problem cannot be entirely solved by the government, but that certain steps could help the industry.

Among the measures that investors would like to see is a sort of interim reimbursement scheme, where Medicare could reimburse on a limited basis for the use of new technologies that are approved for sale, but stuck in reimbursement limbo, Mr. Carusi said.

“The government seems very receptive,” Mr. Carusi said. “The first step is always just acknowledging that there’s a problem. It’s still early days here, and some of the [proposed solutions] are still half-baked,” he said.

“But congressional leaders have been hearing from hospitals and everyone else, and they’re listening,” he said. “We are working on this mechanism for interim coverage.”

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