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TALKING POINTS

Alice Jacobs develops diagnostics that stand the test of time

Alice Jacobs, founder, chair and CEO of IntelligentMDx, has always sought out an accelerated course, which accounts for the imminent availability of an H1N1 flu test unlike any other available today.

The test IntelligentMDx is working on 'round the clock is the first to distinguish between novel flu, such as H1N1, and seasonal flu. As well, accurate results are ready in two hours vs. standard techniques such as culture, which can take days.

The test runs on standard DNA-detecting platforms commonly available in clinical labs, so there's no waiting time for the development of new equipment. Additionally, there's the potential to determine in just a few hours any resistance to the most commonly used antiviral medicine used for flu – unheard of today.

Most of the 110 hours a week Jacobs puts into her company – which she started when she was 25 and in medical school – are now focused on tightening up the timeline to get the H1N1 test out this fall.

But that doesn't mean she's delayed other plans for commercialization in her agenda. Jacobs and her team are still full-steam-ahead to introduce before the end of this year the market's first rapid, precise test for detecting hospital-acquired infections – the reason Jacobs incorporated IntelligentMDx in 2004.

"I had a very clear moment in my medical training when I immediately understood what was most needed," Jacobs relates.

Her epiphany happened in her third year at Harvard Medical School during a surgery rotation. One of the patients she was monitoring was a healthy man in the hospital for a routine operation. During the course of his hospital stay, he acquired a staph infection and died while Jacobs was in the room. Jacobs was the one to break the news to his wife and parents.

"That morning, I had gone down to the clinical lab to find out why we still didn't understand what was making him so sick, and I felt as though I had stepped back in time," Jacobs says. "I walked into a laboratory that was still using technologies from over one hundred years ago."

Jacobs knew from her research and experience – another result of her accelerated course – that there were advanced technologies in life sciences that were not yet applied to health care. The solution, she knew, was to figure out how to configure the life sciences technologies to work within the health care setting.

The experience Jacobs drew upon began with her time spent as a 16-year-old at Stanford University in the lab of Irving Weissman, the first to identify and isolate the blood-forming stem cell, and her introduction at that time to Leroy Hood, who performed the groundbreaking work on DNA sequencing that played a crucial role in enabling the human genome project

Hood, Jacobs says, introduced her to his concept of systems biology, which considers all scientific systems – bringing in physicists, chemists, biologists and computational scientists – for the most meaningful results in solving problems.

"IntelligentMDx is founded on that respect for systems biology, and we have incorporated that into our products and used inventions from basic science, from life science and clinical medicine to solve problems in human health," Jacobs says.

At the age of 19, Jacobs published her first peer-reviewed article. She graduated from Stanford University with degrees in biological sciences and art history. Thinking of a scientifically focused career, she thought medical school would give her a sense for the current state of medical knowledge.

"But then I realized that the real way to have an impact was to do what I'm doing now," she says.

Between founding the company and continuing with her studies, Jacobs overextended and seriously injured her back. Over the two-year recovery period from back surgery, until she could stand long enough to complete med school, she

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launched IntelligentMDx.

"Instead of watching daytime television, I built the business," she says. And when she did get to the point of finishing medical school while running the company, Jacobs at times felt like Wonder Woman. "I literally would change from my scrubs to my suit in my car. I didn't want the hospital to see me in a suit, and I didn't want my employees to see me in scrubs."

The problem was, Jacobs couldn't go home to change – home at the beginning was the office. She had kicked her two roommates out of her apartment and set up IntelligentMDx in the back two rooms, starting the company with three on board, then five and then moving into an office when there was enough staff. The company has moved again and is now headquartered in Cambridge with 28 on board.

At the start of IntelligentMDx, Jacobs built the team, was the principal inventor on most of the patents and fundraised – to date $26.5 million from private investors. "I speak three languages," she says, "science, medicine and business."

Her business training has been "trial by fire," so Jacobs has been careful to bring in seasoned people, including Leroy Hood as a board member. "The worst thing you can do is step on the same rake twice," she says.

Jacobs recognized at the get-go that the tests out on the market for the newly developed molecular diagnostics equipment were not necessarily the best tests, and so she set out to make a significant impact with the right set of parameters.

"That's one of the greatest challenges, particularly in our area of infectious diseases because we're chasing a moving target," she says. "Viruses and bacteria mutate to be able to survive in their environment, so you need to have an approach that allows you to account for those changes. It's not something you can just pull out of the literature to be robust now and also be effective down the road."

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> **Founder, chair and CEO**
> **of IntelligentMDx**

Building in flexibility and adaptability into the technology has already paid off. Knowledge about drug resistance that surfaced at the end of August has been quickly assimilated into the H1N1 virus test, Jacobs points out.

"Not only can we incorporate all of the complexities, but we can also make tests faster. The kind of development that we're doing normally takes months or years. The characterization of the resistance is something we have been able to do in 10 days," she says.

IntelligentMDx has already commercialized a product that allows for the customized monitoring of the buildup of certain viruses that can result in transplantation rejection, and so over the past year staff numbers have doubled in preparation for commercialization.

"The market demand for our test solutions has been more than we can accommodate, and so we have been trying to scale cautiously to accommodate that demand," Jacobs says.

With other products in the pipeline and plenty more to develop, Jacobs's ultimate goal is "to make clinically impactful molecular diagnostic products. We want to respond to the immediate needs and the broader needs of the medical community."

Now that IntelligentMDx is positioned for the next level, Jacobs spends most of her time strategizing. It's a difficult task, she says, in light of the uncertainties surrounding the debate over health care reform. Worried over the singular focus on cutting costs, she notes that without quality, everyone will lose.

"Quality health care can save money and save lives. Quality health care products such as ours emphasize getting things right up front, which allows major benefits down the road," Jacobs points out. "If you put patients first and quality health care first, you can actually have an impact on health outcomes and economics."

An example: Treating an infection when it initially presents might cost $200 to $300. Treating a downstream blood infection can cost $30,000.

With potential for making such a staggering difference in health care outcomes, Jacobs is relentlessly keeping to her accelerated schedule, despite any political debate qualms.

"All we can do now," she says, "is try our best to get things out as quickly as we can."