Shining the light on diagnostic shortcomings during the COVID pandemic reveals a stronger path for the future

Times of crisis can be highly informative by bringing to the forefront areas of weakness that, if addressed, can make us stronger. Outcome Capital recently sat down with industry expert Cathy Petti to discuss what the diagnostic industry can learn from the COVID crisis, not only from a scientific perspective to prepare ourselves for the next emerging pathogen, but also from a corporate level to gain a competitive edge in the marketplace.

Cathy Petti, MD

Dr. Petti is a health technology executive and in vitro diagnostics expert with a unique combination of operational, clinical, and entrepreneurial expertise focusing on molecular diagnostics, genomics, direct to consumer health, and artificial intelligence. She serves on the Advisory Boards for Pathogenomix, Life365, and Becton Dickinson and contributes her expertise to several global non-profit organizations and regulatory agencies. Dr. Petti has served as Global Head at Novartis Diagnostics where she expanded global markets for core products and built R&D teams for three de novo franchises. As Chief Health Officer at Ancestry, Dr. Petti built a direct to consumer genetic testing portfolio and served on the executive team leading to private equity investments at enterprise value of $2.6B. She founded MoDx.ai, a knowledge domain platform integrating diagnostics, digital health and AI, has led the ARUP Infectious Diseases Laboratory, and pioneered research in DNA sequencing. Dr. Petti currently serves as a strategic interim Chief Medical Officer providing companies with top-down market perspective, an extensive key opinion leader network, and tight relationships to life science investors. Dr. Petti holds an AB from Harvard University, an MD from Duke University, and is dual board certified in infectious diseases and medical microbiology.

Q: In your mind, what limitations concerning diagnostics has this crisis brought to the forefront?

A: Knowledge abounds in our industry, and early in this crisis we exposed one of our greatest vulnerabilities: the dangers of fragmented and siloed knowledge. COVID-19 has revealed a simple, inconvenient truth: the only "almost perfect" test is an autopsy and I think we all agree we would like to avoid that test as much as possible.

While we know that diagnostic tests are imperfect, the diagnostic industry has often failed to communicate those limitations to consumers and health professionals. Additionally, in our enthusiasm to deliver a diagnostic test, we can also forget to explain how a test result should be used to make health decisions. This failure to distribute our knowledge about testing to the general public reduces our credibility.

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Each test has specific value and the key for diagnostic companies is to identify that value, appropriately position the test to bring the most good to the right population, at the right time, to make the right intervention -- and then communicate that positioning to all parties, including the public.

Q: In your interactions with diagnostic companies -- both small and large in size – what are the missed opportunities or common mistakes that you have seen management teams make?

A: Great question. I think they fall into 3 categories.

Mistake #1: Not Emphasizing Strategic Thinking. Crises tend to accentuate inherent uncertainties in our businesses. Executives and boards thrive on making decisions based on thoroughly researched metrics and data. However, in times of crisis, data are often conflicting, inconsistent, and incomplete. We strive to make changes but unfortunately gravitate in times of crisis towards making tactical decisions because they are easier and perceived as less risky. Uncertainty demands leaders to focus on strategic thinking. Great executive teams are nimble, are not anchored by their assumptions, and are dedicated to strategic thinking about changing landscapes. Boards must remain dedicated to strategic thinking -- even more so in times of crisis.

Mistake #2: Not Approaching the Challenge Holistically. Many diagnostic companies have missed a major opportunity to learn how the stressors from this pandemic can inspire us to improve our overall infrastructure. Too many companies remain laser-focused on assay development without understanding the 360-degree lifecycle of a test. For example, innovative leaders understand that customers need solutions beyond the assays that

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include platforms to improve workflow efficiency from specimen collection to result reporting. Similarly, nimble companies are finding ways to adopt artificial intelligence technologies to improve inventory management and supply chains which are key in hospital settings that often run lean.

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Mistake #3. Not Strengthening Your Resolve. Crises have a way of magnifying our doubts and fears, and we have less tolerance for risk. Companies need to acknowledge these behaviors and find the discipline to re-evaluate why their core technology has value and identify areas to strengthen that value even when their technology may not be directly related to the pandemic.

In crises, companies need to resist the temptation to grab the shiny object and instead, stay true to their brand and founding principles. Questions that should be asked at the executive/board level are: Has the market disruption (e.g., pandemic) fundamentally changed our industry and is our technology obsolete? Or is our technology solid, our current application possibly less relevant, and other more relevant applications be targeted?

I go back to my original tenet: developing a technology is hard but identifying how and where to best use the technology is harder and even more critical.

Q: Specifically, from a diagnostic assay point of view -- what has gone well, where has the industry fallen short, and what are the most important unmet needs?

A: I think the industry has risen to the challenge in test development but has failed to explain the differences between test methods, test targets, and test platforms. We have learned that we need a complement of tests to meet specific needs of assisted living facilities, college dormitories, call centers, jails, inpatients, sports teams, and individuals in the community. We have fallen short in terms of communication, but we have time to dust ourselves off and commit to educating health professionals and individuals about the different roles testing can play in stopping disease spread, opening the economy and saving lives.

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Q: What impacts did the Emergency Use Authorization (EUA) regulatory designation have on the pandemic?

A: When I take care of patients in the hospital, I often use a non-technical term to communicate a difficult decision that must be made when the options all have inherent risks. I call that situation a "spicy pickle". This

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pandemic has been presenting spicy pickles and teaching lessons that influence every aspect of our industry: we are all learning. The EUA program has evolved into an effective tool to bring diagnostic products to market quickly with a reasonable degree of safety and efficacy.

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We are observing in real-time the difficulties in weighing the value of having tests available to the risks of those tests being imperfect. The EUA process has revealed the critical importance of post-market surveillance whereby regulatory agencies expedite the path to bring tests with public-health importance to market and when on market, the need for surveillance of diagnostic performance in real clinical settings.

Q: What are the key take-aways that you think every diagnostic company should think about?

A: This pandemic is shining a beautiful light on the diagnostic industry and while we had a slow start, I am hopeful that we embrace the unique opportunities presented by this pandemic. We are a dynamic industry and demonstrated to the world our pivotal role in the health ecosystem. Whether a company is a start-up or listed on the Fortune 100, we all may benefit from some reminders during a crisis:

1. Stay true to your core technology.
2. Spend more time thinking about the value you can offer along every link in the diagnostic chain. An assay is one step of the patients' journey. Each step is a potential opportunity for innovation and market disruption.
3. Remain open to changing your assumptions and hypotheses. Strategies are meant to be adopted and adapted.
4. Remind every member of your team on a frequent basis from the executive assistant to engineers to R&D scientists that what they do matters.

I am one of many healthcare professionals working in the hospital during COVID-19. The experience is humbling, and I am grateful for all the test developers and manufacturers who have quickly and effectively brought their products to market for healthcare workers to effectively do our jobs.

About Outcome Capital

Outcome Capital is a specialized life science and technology advisory and investment banking firm with a global reach, providing middle market innovative companies with a value-added approach to mergers and acquisitions and corporate finance. The firm uses its proven 'strategy-led execution' approach to value enhancement by assisting boards and management teams in navigating both the financial and strategic markets and in implementing the best path for success. Outcome Capital's strength stems from its unique ability to draw on its wide range of operational, strategic and investment experience, its expertise across the value chain, and its broad industry relationships.

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