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Alva10

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The annual listing of 25 companies that are at the forefront of providing Healthcare solutions and transforming businesses

Alva10

A New Realm in Diagnostics

One of the most prolific inventors of all times, Thomas Alva Edison, once said, "I have not failed, I have just found 10,000 ways that won't work"—something that deeply resonates with the diagnostics industry. To put things in perspective, Hannah Mamuszka, Founder and CEO of Alva10, sheds light on the fact that the diagnostics industry has long been attempting to make a real impact on patient outcomes, and, in doing so, has identified the 10,000 ways that can result in failure. Having spent more than 20 years in the diagnostics industry, Hannah is well-versed with the nuanced challenges that the industry faces. She emphasizes that the industry is in need of a radical transformation and reconfiguration to not just enhance patient care but capitalize on new opportunities for technological growth. This is where companies like Alva10 are making a difference. Named after Thomas Alva Edison, Alva10 is cutting through the clutter of the thousands of ways in which diagnostic tools won't yield the desired results, and is highly focused on demonstrating diagnostics as a viable means to make healthcare more efficient, improve outcomes, and lower costs. With an aim to move diagnostics to the forefront of precision medicine and optimize spiraling healthcare spend, Alva10 is unleashing the innovation that lies within the knowledge gap between healthcare purchasers and technology companies.

In an interview with CIO Applications, Hannah shares how her company's innovative business model is restructuring the relationship between health insurance payers and precision medicine technology companies to solve the largest clinical and economic challenges for payers and providers.

Could you share about your journey in the diagnostics industry and your role in the conception of Alva10?

As a molecular biologist, early on in my career, I had the privilege of working on a drug, which is now one of the top-selling drugs in oncology. While working on the drug, the FDA suggested developing a biomarker to discern the patient population that the drug should be administered to ensure safety. This became a big part of my job, and I spent about three years working on a fairly simple biomarker test to figure out who would respond to the drug. Later on, the FDA approved the drug without the biomarker test.

Hannah Mamuszka, Founder and CEO

However, the response rate of the drug was less than 40 percent, and it came with a hefty price tag. Back then, I approached the CEO of my company assuming we would pursue a strategy to use the test to find the patients most likely to respond. Of course, that didn't happen. When I think about it now, I realize that of course that isn't really the role of pharmaceutical companies- to develop diagnostics that limit their market- but the diagnostics industry hasn't been able to fulfill their role.

This is when I understood that we didn't have the diagnostic tools in the market to figure out who should receive a particular drug based on their biology. I have spent a majority of my career in diagnostics—both in pharma and at diagnostics companies, in the lab and on the business side—which enabled me to get to the root of the problem. Over the course of my decades-long stint, I realized that the most important aspect that has kept diagnostics away from the realm of healthcare is the market conditions surrounding reimbursement coupled with payers' lack of knowledge about the impact of diagnostics on both patient outcomes and payer economics.

We established Alva10 five years ago to change the payers' perspective on diagnostics. Payers often regard diagnostics as unnecessary and expensive. We helped the payers look at the big picture in terms of the benefits of diagnostics to downstream medical spend. Because of our efforts, payers now realize that diagnostics can be leveraged as a tool to control pharmacy spend, prevent adverse events, assess for risk, and really determine the appropriate patient population for different therapeutic options.

What are some of the challenges payers and diagnostic companies face, and how do you address them?

We partner with payers and communicate with them extensively about their areas of inefficient spending, high costs, and poor outcomes. Using their data, we are able to present the areas of opportunity where diagnostics are either on the market but not covered, and can be written into policy, or can be developed to address the concerns. Essentially, we work at the intersection of payers—defined as commercial insurance, Medicaid, Medicare, large employer groups, self-insured employers, retiree benefit groups—and diagnostic and technology developers.

We work at the intersection of payers—commercial insurance, Medicaid, Medicare, large employer groups, self-insured employers, retiree benefit groups, and more—and diagnostic and technology developers

We help payers recognize the disease areas that can specifically be addressed with diagnostic tools. In order to do that, we analyze their data in areas of spend, including pharmacy, claims, provider data, and a variety of other aspects and create a database, which helps us understand the key requirements of a diagnostic tool to be able to influence both patient outcomes and payer economics.

Can you explain what MATE™ stands for?

We work with payers to identify both the clinical utility value proposition required for the diagnostic and the level of evidence required for coverage—and then contractually commit to those standards. We term the level of evidence required for coverage, the MATE™—the Minimally Acceptable Threshold of Evidence. We have conceived of MATE™ as we realized there was no term to define the amount of evidence both sides would agree on. Diagnostic developers seek and receive regulatory approval from the FDA, which allows them to sell a test safely. However, until now, there has been no such threshold that defines the amount of data that a developer needs to get paid for the test. FDA clearance does not guarantee Medicare coverage or any commercial coverage.

Establishing the MATE™ allows the diagnostic developer to know how much data will be required for coverage, and the investor to know how much capital it will take. If the diagnostic doesn't have the data under the MATE™ agreement, there's no point in submitting for coverage. However, upon meeting the thresholds, they will be allowed a coverage policy at the negotiated reimbursement rate.

The other facet of that of course is the reimbursement rate. In our work with payers we build a budget impact model that allows us to assess the costs of currently managing a patient population. We then layer in how a novel diagnostic would impact the population through a variety of sensitivity analyses, and attribute a portion of the savings to the diagnostic, calculated on a per member basis. This gives us a justification for a calculation of a true 'value based reimbursement' rate, which we use in our payer contracts.

How has the ongoing pandemic impacted the diagnostics industry, and where do you envision heading toward in light of the recent developments?

I think COVID-19 has really highlighted the importance of diagnostics. From the lack of diagnostic tools in the initial phase to figure out who contracted the virus to still not having a coordinated national strategy on diagnostics, the importance of diagnostics has been elevated to a new level. Because of the lack of clarity around the reimbursement, the diagnostics industry struggled to take proactive steps in bringing the required diagnostics for COVID-19, including rapid tests, vial tests, PCR tests, and antibody tests to the market faster.

Our business is rapidly growing and accelerating as more payers, particularly employer groups, are realizing that diagnostic tools can be used as the means to dramatically improve care and rein in costs. With the advent of advanced diagnostic technology and integrated systems, we are noticing our customers to be much more proactive and savvy when it comes to data analytics, and this is going to create a huge shift in healthcare in the next ten years. Our goal is to create a financial ecosystem where diagnostic and healthcare technology can impact patient outcomes. CA