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Inside the Diagnostics Industry: Theranos Aims to Transform the Medical Diagnostic Industry

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After years of speculation, Theranos (Palo Alto, Calif.) last fall unveiled its revolutionary plan to reshape the future of laboratory testing. With a laser-sharp focus on lowering testing costs (always 50 percent or below Medicare reimbursement rates) and standardizing quality, the company's plans potentially hold benefits for stakeholders across the health care industry.

Patients benefit from the convenience of Theranos draw centers in Walgreens pharmacies and from the company's proprietary and patented infrastructure for processing microsamples (one-one thousandth the size of a typical blood draw). The company believes its quick return of precise results will provide enhanced efficiency and informative, longitudinal value for physicians and pathologists. Theranos also poses a disruptive threat to the laboratory industry through a transformative emphasis on transparency reflected in the company's commitment to both price transparency (all test prices are on the company's Web site) and publication of margin of error variation for aiding interpretation of test results.

The company's goal of deploying a national network of accessible testing centers is becoming a reality with the expansion of its Walgreens-based Wellness Centers to the Phoenix area in mid-November 2013, following the opening of the first center in Palo Alto in September 2013. Elizabeth Holmes, Theranos's founder and CEO, recently spoke to *DTET* about the unique infrastructure powering the company's pioneering vision.

Please tell us about how Theranos's proprietary infrastructure helps the company achieve its vision.

Our focus has been to build a high-complexity CLIA-certified lab so as to provide the level of oversight and quality that we think is really imperative to be able to provide data back to physicians for clinical decisionmaking. We focused on two things: to reduce the volume of blood that's required to run tests and to reduce the variance and the associated coefficient of variation. As you well know, so much of the error in laboratory testing comes from the preanalytic process where manual protocols or exposure of the sample to temperature or the amount of time before processing it can create variability—anything from the degradation of the analyte and its associated concentration to differences in the ultimate results that can be generated across lab locations. What we wanted to do was introduce a level of automation to that process that could help to minimize that variance and associated error and make it possible to do this testing on a microsample, while in a CLIA-certified framework. We have an infrastructure that can create very consistent data such that we can ultimately provide pathologists and physicians with more robust longitudinal data by helping to minimize variance and associated errors.

How did you decide on your initial test menu?

We had the opportunity as we built the company over the years to do a lot of work with pharmaceutical companies, having served as the infrastructure for their clinical trials. In that context we had the opportunity to develop some really sophisticated assays for markers that were used to characterize the efficacy or safety of a drug. If

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one were to provide those tests in the clinical care setting. I think there are a lot of questions about how they would or should be interpreted clinically. What we tried to do with this menu was to focus on tests that physicians know how to use so that we could provide the most value in the context of clinical care. What we did when we started to develop our lab was to focus on tests that are most commonly ordered by physicians and could provide the most clinical utility.

As molecular testing becomes more commonplace, even in primary care, will Theranos expand its menu to include these tests?

We have the opportunity to do that given the laboratory framework we have in place. The goal and hope in the industry is that [physicians' molecular] knowledge will be there in the future, and our goal as the laboratory is to provide those tests that can create the most utility for physicians when providing care to patients.

A focus on consumerism is infiltrating all aspects of health care including laboratory testing. With its Walgreens partnership, Theranos seems ideally positioned to address these changing expectations.

My motivation for starting this company and our mission is around being able to provide access to actionable information at the time it matters. There is an inherent goal there to be able to help ultimately facilitate early detection in any way we can.

When you think about access to actionable information, the first step is getting tested in the first place. As you know in the laboratory world today there is a huge percentage of patients, even when they are given a requisition to do a test, who don't do it. When you break down the research on why, there is a very big fear of needles that is right up there with heights and spiders and other very high-ranking human fears. People don't enjoy having a big needle stuck into them. Children, elderly persons, oncology and chronically ill patients, and others who are difficult to draw through traditional venipuncture not only go through tremendous pain in the collection process but also experience physical limitations around being able to get enough blood for the tests needed.

There are also issues of convenience with having to leave work to go to a location, not being able to do testing on weekends or at night, and long drives to get to wherever they are supposed to go to get tested. We established our partnership with Walgreens to allow people to do testing in a location that is most convenient for them and for the first time to be able to do testing during hours that fit their schedules. We designed a whole new environment in our centers, from check-in to microsample collection, with the aim of making the lab testing experience a wonderful one and getting people in and on their way in minutes.

Another aspect of access is the speed and turnaround time of results, to be able to get that information back to the physician such that it can be used at the time it matters most. Patients can now get a test in the morning and see their physician that afternoon and on the same day have that data. So in that one visit when the patient and physician are seeing each other, the information is there as opposed to having to go do a test, come back, do another test because it was out of range. We have created a framework that allows us to process these different tests from a single microsample draw, instead of multiple sets of different venipuncture tubes, and the physician can order comprehensive panels ahead of time with instructions that if a given analyte is out of range, then a set of specified follow-on tests should be run, all from the same microsample. Our mission is all about access to actionable information at the time it matters, starting with access to be able to get tested, and in doing so create a framework that provides the physician as early as possible with the most comprehensive biochemical information so they can make the best possible decision about how to take care of that patient.

You also believe price transparency improves access to testing. Please explain.

There are also issues around affordability of being able to pay for the test patients need to get. The transparency around cost is about access. We believe very strongly that people should know up-front, ahead of time, how much they will owe if they decide to buy a testing service. The work we've done makes it possible to not only know up-front how much the test will cost, but how much a copay or deductible is going to be. This is about access. We can make sure they are able to afford the test by making pricing available that it is the same no matter who you are or what type of

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insurance you have. We want to make sure that prices are low enough so that people can afford to do the tests they need.

Price transparency is a new concept for the health care industry. What has the reaction been?

I think it is very powerful. Today no matter what kind of insurance you have or don't have, you are going to have to pay out of pocket because you are going to have some type of deductible. How much you have to pay matters to a lot of people. Current practice is that you don't know when you go in how much you are going to have to pay and often you don't find that out until quite some time after the test. That can be really difficult. We have seen in the early days of our operation people who are coming to us who haven't gotten tested for a long time, but they are coming now because they know they can afford it. That is really important to us, getting back to the access point.

We also know that financially for Medicare and Medicaid that is very powerful because there is a great need to save money. We will help to realize savings that can be significant over time. That is an important thing in the context of being able to provide a footprint that can serve patients, while providing the lowest-cost testing.

The way we are billing, we are generally the lowest-cost provider around period, irrespective of network. Having a network with the lowest-cost provider seems to make us important to the insurance community. As we grow, that is an important part of our framework and our partnerships. But irrespective of which patient comes, we are billing the same and that rate is lower, as far as we have seen, than any other rate on the market. These prices are the same for both the payer and for the individual who has to pay out of pocket.

Your focus on transparency is not limited to prices but extends to margin of error. Please explain.

The margin of error variation is another element relevant for access to actionable information. The actionable information, in our minds, comes back to understanding the variance in testing. If a physician knows exactly what the variance is, if you are on the border of being in or out of range, that can help the physician or pathologist in the way in which they are interpreting that information. As we start to think about being able to minimize variance associated with preanalytical processing and by having a more standardized framework, we can confidently look at how laboratory data changes over time. The physician with this type of information and the margin of error variance has the opportunity to begin understanding change over time in a way that provides much more insight into the clinical significance of these values than they have when looking at in range or out of range with a single snapshot.

How will testing evolve in the coming years?

We think there is a huge opportunity, going back to the actionable information point, to begin to leverage what I call the movie instead of the snapshot in the way laboratory data is used. In the analogy I use, if I were to watch a movie I'd never seen before and you took one frame and said, 'OK, Elizabeth, tell me the story.' I would look at that single frame and have a really tough time telling you the story. But if you gave me a series of frames, I could begin to put that story together.

When you think about minimizing variance, minimizing preanalytic error, you have the opportunity to get very high-integrity information. If that infrastructure is standardized in such a way that that high-integrity information can be the same across locations, then longitudinally this data begins to be very powerful for the physician. During a visit physicians don't have to just look at whether the patient is in range or out of range but can start to look at what rate the patient is changing across visits. We think that information is going to be very powerful for pathologists and physicians to begin looking towards earlier detection and intervention. The goal is that if you can engage people in the testing process, so that they get the test when they need it, and you have this rich ability to look at that rate of change over time, you can use laboratory data in more actionable way

Side Box:

By-the-Numbers


Year Founded: 2003

Sample Volume: 1/1000th of a traditional draw

Test Pricing: Always lower than 50 percent of Medicare reimbursement

Walgreens Locations: approximately 8,200

Associated Data

 liz-holmes

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