Direct access testing, or DAT, is defined as consumer (as opposed to physician) initiated testing of human specimens (usually blood). DAT is also known as “direct-to-consumer,” “self-ordering,” or “patient-authorized” testing.1

With DAT, a person can walk into a lab and request the lab to run tests on drawn blood or fluids at his or her direction without a doctor’s order or prescription. DAT places the clinical laboratory professional in a direct provider relationship with the consumer/patient.

Proponents argue that DAT allows patients with chronic health conditions to track their health status more closely than their insurance will allow by being able to test without a doctor’s order. There are currently 26 states that allow DAT without any limits and 12 states that allow DAT with limits, such as restricting hospital laboratories from performing direct access testing, or only allowing tests that are classified as waived under CLIA.2 CLIA is the Clinical Laboratory Improvement Amendment which was established in 1988 to ensure that laboratories maintain quality standards to ensure test results are accurate, reliable, and delivered in a timely manner, regardless of where the testing is performed. The requirements are based on the complexity of the tests and not the type of laboratory where the testing is performed.3 Diagnostic tests are categorized as waived based on the premise that they are simple to use, and there is little chance the test will provide wrong information or cause harm if it is done incorrectly. Tests that are cleared by the FDA for home or over-the-counter use are automatically assigned a waived

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2AM. SOC’y FOR CLINICAL LABORATORY, CONSUMER ACCESS TO LABORATORY TESTING AND INFORMATION (July 2012), http://www.ascls.org/position-papers/177-direct-access-testing/139-direct-access-testing.
categorization. The CLIA regulations and standards do not differentiate between facilities performing DAT and facilitate performing provider ordered testing, therefore, all labs must obtain a CLIA certificate before conducting patient testing. It is interesting to note that the majority of the 26 states that have no limit on DAT do so because their state law is silent on the issue of whether patients may authorize laboratory testing for themselves, and not because they necessarily agree with the benefits of DAT.

According to Charles B. Inlander, president of the nonprofit consumer health-advocacy group, People’s Medical Society, the healthcare consumer has become the driving force for change in healthcare. He described today’s healthcare consumer as "empowered, educated, demanding, and critical of the healthcare system and providers." By placing the control of testing in the hands of the consumer, there is more empowerment and responsibility given to each individual. With greater empowerment, the consumer is more likely to increase his attention to his condition and become more responsible for managing his care. DAT can also be a useful in tool in enhancing the doctor-patient relationship because, equipped with a detailed history of testing, patients can better discuss their concerns intelligently and effectively.

Currently, while consumers may have the right to order their own tests, they also have to pay for them. Insurance companies as well as Medicare and Medicaid will not pay for lab tests that are not ordered by a physician. Lab tests are expensive, especially considering that the clinical laboratory industry is allowed to set their own prices, according to what the market will bear, to those who must pay out of pocket.

To a great extent blood testing has not changed much since the modern clinical lab emerged in the 1960s, despite the fact that during this time the laboratory testing

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industry has grown to have annual revenues of $76 billion dollars. According to Mitch Rothschild, the chairman of Vitals, an online portal that allows consumers to search for lower prices for medical services, “the lab-testing industry is ripe for a fresh challenger because the costs are high and unpredictable, while the services vary little from lab to lab.” According to Rothschild, his company has found that a basic blood panel test can range from about $120 to $600, depending on the lab an individual happens to walk into. With these high, unpredictable prices, consumers often choose not to get tested on their own and decide to wait until they either can see a doctor or until they are obviously ill. In most cases, patients will wait and go to their doctor’s office, so that their insurance can pay for the lab test, rather than pay a substantial fee out of pocket. Arguably, by not using direct access testing due to the high out-of-pocket expense that current labs are charging, the potential to self-monitor and detect conditions before they worsen diminishes.

Fortunately, a new company has thrown its hat into the clinical-laboratory testing field that hopes to make DAT much more affordable and, perhaps, revolutionize the blood testing industry. The company, Theranos, is based in Palo Alto, California and is headed by Elizabeth Holmes. In public statements Theranos has committed to the goal of substantially reducing testing costs by charging no more than half the Medicare reimbursement rate to an insurance company or to an individual who orders a blood test. Unlike the major labs, Theranos posts all of its prices publicly on their website. An example of how affordable their lab pricing is can be demonstrated by the price for a “panel”, or “set of tests”, relating to fertility costs.

Most consumers must pay out-of-pocket for fertility testing, even those with good insurance. The major labs can charge up to $2,000.00 for a fertility panel, while

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Theranos charges $34.95 for the same tests.\textsuperscript{10} According to Elizabeth Holmes, “women will be able to afford the tests ... be able to better manage the process and take some of the stress out of trying to conceive.”\textsuperscript{11}

Not only does Theranos promise financial savings to the industry, they have developed a technology that allows for most of the tests performed to be accomplished with just a few drops of blood from a pricked finger, rather than taking a vial or two of blood using a needle inserted in a vein, which is the current, common practice known as venipuncture.

What Holmes envisioned and what Theranos’ engineers ultimately built is a hand held device that uses a micro­needle to take a very small sample of blood, run a chemistry lab in its computer cartridge and transmit the findings to consumers.\textsuperscript{12} The software in the cartridge is the secret to Theranos’ innovative process allowing users to target certain biomarkers by changing out the cartridge that is programmed to test for certain markers.

There are still some specialty tests that Theranos hasn’t yet been able to miniaturize for use in its proprietary cartridge, so as to allow tests from mere drops of blood, but even then, their venous draws require much smaller samples than traditional labs. They also use much smaller needle, those designed specifically for collecting blood draws from children, creating a physical and psychological benefit to many patients. So whether it is a few drops collected with a finger stick, or the smallest venous draw sample possible, Theranos’ tests mean less blood; an easier, less painful, and a much more affordable process to the individual consumer.\textsuperscript{13}

In November of 2013, Theranos announced a partnership with Walgreens to test its product in a few states. A Walgreens in Palo Alto, California started offering blood


\textsuperscript{11} Caitlin Roper, \textit{This Woman Invented A Way To Run 30 Lab Tests on Only One Drop of Blood}, WIRED, (Feb. 18, 2014, 1:30 PM), http://www.wired.com/2014/02/elizabeth-holmes-theranos/.


tests within its premises in early 2013 and according to Walgreen executives, Theranos’ tests are much cheaper, quicker to do and a lot more efficient than traditional testing.\footnote{Mariella Moon, Walgreens to Offer Affordable and Needle-free Blood Tests in More Stores, ENGADGET (Nov. 18, 2014, 9:32 AM), \url{http://www.engadget.com/2014/11/18/walgreens-blood-tests/}.} A Theranos Wellness Center has already opened inside of a Walgreens in Phoenix, Arizona.\footnote{Theranos and Walgreens Expand Diagnostic Lab Testing to the Phoenix Metropolitan Area Business Wire, BUSINESS WIRE (Nov. 13, 2013 9:00 AM), \url{http://www.businesswire.com/news/home/20131113005513/en/Theranos-Walgreens-Expand-Diagnostic-Lab-Testing-Phoenix}.} Should this relationship prove successful, this could be the first of 8200 stores that will host a Theranos wellness center in either a Walgreens or Duane Reade store. A strong alliance with Walgreens would put Theranos within 5 miles of most Americans, which has been one of the company’s original goals since 2003.\footnote{Ken Auletta, Blood, Simpler, One Woman’s Drive to Upend Medical Testing, THE NEW YORKER (Dec. 15, 2015), \url{http://www.newyorker.com/magazine/2014/12/15/blood-simpler}.} Bringing high quality, affordable lab testing close to every American is what is needed for more participation in direct access testing. According to Holmes, “by making it possible to run laboratory tests from a tiny sample, children, elderly, and those with chronic conditions will now be able to afford regular testing and have a new experience without a fear of needles.”\footnote{Moon, supra note 14.}

Theranos has recently come under fire following a \textit{Wall Street Journal} investigation and series of articles from October 2015 to December 2015 which challenged the accuracy of the lab test results.\footnote{John Carreyrou, Hot Startup Theranos Has Struggled With Its Blood-Test Technology, WALL ST. J. (Oct. 16, 2015), \url{http://www.wsj.com/articles/theranos-has-struggled-with-blood-tests-1444881901}.} The Food and Drug Administration recently carried out an inspection of the Theranos facilities and determined that the vials used to collect blood were "uncleared medical device".\footnote{Food and Drug Admin., Theranos Inspection Report (Sept. 16, 2015), \url{http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm469395.pdf}.} According to Holmes the criticism is “what happens when you work to change things” and that she “was shocked that the \textit{Journal} would publish something like this when we had sent them over 1,000 pages of documentation demonstrating that the statements in their piece..."
were false.” Holmes’ recent struggles demonstrate the intrinsic tension between Silicon Valley and older industries that startups like Theranos threaten to disrupt.

Consumers have greater access to medical information than ever before through the internet. The American public has come to expect and demand the highest quality and quickest accessibility to healthcare. The public wants control over their medical care as well as reasonable cost associated with this excellent care. Right now, our healthcare model is set up so that insurance will only cover a test once a physician has ordered a test, usually when a patient has become symptomatic for a given condition. The concept of testing only once someone is already sick results in costly outcomes and limits individuals from fully taking ownership of their own health.

There are some concerns from those who oppose DAT, including arguments that physicians may lose control over patient management; those who suffer from hypochondria may over-utilize the system; and some consumers may not be able to interpret their results effectively. In the opinion of this author, these concerns are minor compared to the advantages of having a population that is more interested in their health and who is actively engaged in monitoring with affordability their own health.

Physicians will still be primarily involved in managing patient care, but hopefully will be advising patients who are better educated and prepared for their medical visits. With advancements in DAT and blood test technology, patients can soon bring historical data collected from tests they have taken themselves to their appointments, which will allow the doctor to make better recommendations about diagnosis and treatment options.

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