From: Elizabeth Holmes <eholmes@theranos.com>
Sent: Saturday, October 17, 2015 6:15 AM
To: kovacedm rileyb groughead wjperry@ snunnoffice@_ ; jimmattis kmatthews bfrist ; Bill.Foege ; Susan.Schendel xboies
Cc: Sunny Balwani; Heather King
Subject: RE: Statement from Theranos, 10/16/15

Thanks for this Dick.
That's correct – we are at an exact moment in time right now where we've just transitioned from operating under the traditional laboratory framework (governed by a law called CLIA) to the FDA framework. This is what the laboratories have been threatening to sue FDA about to prevent such a transition from being required for them. We are the first lab to do this.
Part of this transition means moving all operations from the CLIA quality systems to the FDA quality systems. By definition, it is not possible to operate under both policies at the same time, as they have different requirements.
We are currently waiting on clearances for our nanotainers (all our data was submitted to FDA). In order to effect this transition, we voluntarily decided and communicated to them that we would temporarily not use the nanotainer under the CLIA lab framework until we received clearance, and bring it up under the FDA framework (which by definition means it starts being used only once clearance is complete).
We hope to see those clearances soon, but of course can never put a date certain on FDA timelines. The nanotainers were cleared as part of our previous FDA submission for use with our device and first cleared test, so we have been through this process before. We have advocated aggressively for FDA to become the new standard for lab testing, and we are now completing that transition ourselves.
During the time we are transitioning the nanotainers operations, we are still able to use all our proprietary technology, including our devices, which were approved for use this summer based on studies with ~900 patient samples. Note the name Edison was the name of the company's very first device (not our current systems) – this is one of many incorrect statements by the former employee who communicated this information to the WSJ reporter.
We do not have a good % number right now of how many tests will be done on our equipment during this temporary period, in addition to our first FDA-cleared test, as we are literally in the middle of having just completed this transition and mapping that out now, and this will likely continually evolve, including as we get additional clearances. The significant point is that every test Theranos does and is doing is now fully compliant with the FDA framework.
Let me know if you'd like more background on any of the above, Elizabeth

From: kovacedm [mailto:kovacedm
Sent: Friday, October 16, 2015 5:00 PM
To: rileyb Heather King groughead _ wjperry
snunnoffice jimmattis kmatthews bfrist
Bill.Foege _ _ _. Susan.Schendel xboies(
Cc: Elizabeth Holmes <eholmes@theranos.com>; Sunny Balwani <sbalwani@theranos.com>
Subject: RE: Statement from Theranos, 10/16/15

That was well done.I am still confused,however,regarding my previous email.At this moment,how many of our customer submissions are being tested on lab equipment versus edison.?If I understand what is being said there is very little as we are focused on the FDA testing for edison and our nano tubes and not for active customers as we can't do both at the same time for some resaon

-----Original Message-----
From: Bechtel, Riley
Sent: Friday, October 16, 2015 06:03 PM Central Standard Time
To: Kovacevich, Dick M.; <mailto:hking@theranos.com>:
grougheac
snunnoffice
jimmattis
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Bill.Foege
Susan.Schendel
Cc: eholmes@theranos.com<mailto:eholmes@theranos.com>;
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Subject: RE: Statement from Theranos, 10/16/15

Directors,
For those who missed it, Elizabeth did a superb job on CNBC's Kramer "Mad Money" yesterday. Here's link...http://video.cnbc.com/gallery/?video=3000432502.
Riley

Riley P. Bechtel

From: kovacedm
Sent: Friday. October 16. 2015 3:12 PM
To: hking
wjperry
jimmattis
kmatthews
Bill.Foege
Susan.Schendel
Cc: eholmes@theranos.com<mailto:eholmes@theranos.com>;
sbalwani@theranos.com<mailto:sbalwani@theranos.com>
Subject: RE: Statement from Theranos, 10/16/15 [*EXTERNAL*]

So when blood is withdrawn in venous tubes do I understand correctly that the tests are then done on Lab like equipment and not Edison and those are sent to CLIA for testing while Edison is only being used for the FDA tests?

-----Original Message-----
From: Heather King [hking@theranos.com<mailto:hking@theranos.com>]
Sent: Friday, October 16, 2015 04:49 PM Central Standard Time
To: Kovacevich, Dick M.;
'jimmattis 'kmatthews 'bfrist@wfrist.com';
'rileyb 'Susan.Schendel

Cc: Elizabeth Holmes; Sunny Balwani
Subject: Statement from Theranos, 10/16/15

Dear board members,
Please find below, attached and here (https://theranos.com/news/posts/statement-from-theranos-2) our statement that was recently posted.
Best,
Heather
Statement from Theranos
PALO ALTO, CA (October 16, 2015) – We are disappointed to see that The Wall Street Journal still can't get its facts straight.
Our focus is on providing lab tests at transparent, unprecedented low costs and in more accessible ways, so that people can afford them and get access to actionable health information in time to do something about it. Actionable health information means testing done in accordance with the highest quality standards – those standards are FDA quality standards and our standards.
Here are the facts:
There are just 3 steps to Theranos' groundbreaking finger-stick technology.
1. Take a few drops of blood.
2. Put the blood in the Nanotainer™ tube.
3. Analyze the blood.
That's it. 3 simple steps. 1, 2, 3.
We sought out and asked FDA to review those steps for everything we do – like no lab before us. We asked for that engagement, and are glad to have it. We believe the model for the lab of the future is to take all tests through FDA review, and we have been working with them to do that for quite some time. Because we've always been committed to quality, to the best science, and to ensuring that innovation comes to health care. We are the lab of the future, not the lab of the past. It's about quality, it's about rigor, it's about clearly defined standards, it's about access for everyone – it's about your health.
Our current work with FDA is focused on the Nanotainer™ tube – the tube that collects those few little drops of blood in order to be able to run tests on tiny finger-stick samples: Step 2.
The FDA is putting our tube that transports the blood for our devices through its rigorous review process. That's what we are advocating for. During this process, we also made the decision to move our existing quality systems operations over to FDA quality systems completely, while we work with FDA for clearance on our tubes. This has been a long-term transition which we've now completed.
And here is one more fact. The Nanotainer™ and our devices have already been cleared by FDA for use with our HSV-1 test. FDA had to review and clear all our proprietary systems – including the Nanotainer™ tubes – in order to clear even this one test. Why? Because we're innovative. Because we are doing things differently. Now we're working with them on clearance of just the Nanotainer™ tubes across all tests. But it's the same tube. We've already met their rigorous standards in our first submission on our systems, and we'll continue to do so.
Our decision to engage with FDA at these unprecedented and transparent levels is, in and of itself, innovative. It is not possible to operate under the CLIA lab quality systems for Lab Developed Tests (LDTs) and the FDA quality systems at the same time. There is evolving policy and debate on this topic of regulating LDTs. Most companies would fight it, and they do. Big labs are threatening to sue the FDA over it. But we didn't. We said, we agree. We said, let's do this right. If we are going to advocate for the FDA regulatory framework, we should live by it as well. So we are.
As we continue with our transition to all FDA cleared or approved tests, we are now operating only under full FDA quality standards and systems. It's the right choice and the highest standard. And as of this exact moment, that means temporarily using a different tube – tubes for venous blood – so we can maintain the quality standards we have in our labs as we complete the clearance process on the Nanotainer™. Still smaller tubes, smaller samples, lower costs. So right now we are taking samples, transporting them, and running the tests. That is an FDA cleared process. That is our process.
Unprecedented transparency – in price and in submitting our data to FDA. Groundbreaking technology. Gold standard review. 1, 2, 3.

<https://theranos.com/news/posts/statement-from-theranos-2># # #