

To: Mattis, James N Gen MIL USMC USCENCOM CCCC-CCCC[james.mattis@centcom.mil]
From: Elizabeth Holmes
Sent: Sun 11/20/2011 7:13:01 AM
Importance: Normal
Subject: RE: Note for General Mattis in follow up to last night's dinner at George Schultz's house
Received: Sun 11/20/2011 7:14:00 AM

Dear General Mattis:

It was great to talk with you.

Thank you again for taking the time to connect amidst all that goes on in your days.

It is on us to drive forward to get a pilot.

We will do all it takes to make this happen and work through this process.

With my very best regards,

Elizabeth.

From: Mattis, James N Gen MIL USMC USCENCOM CCCC-CCCC [mailto:james.mattis@centcom.mil]
Sent: Saturday, November 19, 2011 7:32 AM
To: Elizabeth Holmes
Subject: RE: Note for General Mattis in follow up to last night's dinner at George Schultz's house

Good talking with you last evening, young Elizabeth. I will get some feedback from my guys but I intend to push hard for a parallel pilot project. Hope all goes well for you and thank you for the update. All my best, Jim

From: Elizabeth Holmes [mailto:eholmes@theranos.com]
Sent: Friday, November 18, 2011 2:51 PM
To: Mattis, James N Gen MIL USMC USCENCOM CCCC-CCCC
Subject: RE: Note for General Mattis in follow up to last night's dinner at George Schultz's house

Dear General Mattis:

I hope this email finds you well.

We had several visitors from CENTCOM to our site in California yesterday.

Whenever you have a moment -- at your convenience -- I would like to be able to briefly connect with you.

My office line is _____ and cell is _____. I'm in the office all the time and throughout weekends so please do not hesitate to try me at any time that might be convenient for you.

I very much look forward to it.

With my very best regards,

Elizabeth.

From: Mattis, James N Gen MIL USMC USCENCOM CCCC-CCCC [mailto:james.mattis@centcom.mil]
Sent: Monday, October 10, 2011 7:03 AM
To: Elizabeth Holmes
Subject: RE: Note for General Mattis in follow up to last night's dinner at George Schultz's house

Dear Ms. Elizabeth: This is a very big help—thanks for the fast and thorough reply. I think I understand your need for confidentiality and will do our utmost to stay in step with you on this aspect. This note will help guide us on the path ahead. Please don't hesitate to give us your thoughts as we push forward. All the best, Jim

From: Elizabeth Holmes [mailto:eholmes@theranos.com]

Sent: Sunday, October 09, 2011 10:57 PM

To: Mattis, James N Gen MIL USMC USCENTCOM CCCC-CCCC

Subject: RE: Note for General Mattis in follow up to last night's dinner at George Schultz's house

General Mattis: I've included the backgrounder on the regulation of our systems as mentioned in my note yesterday.

What we are doing is highly innovative and technologically disruptive; we worked for almost a year with Bill Schultz, former Deputy Commissioners of FDA who is now General Counsel of HHS, Peggy Dotzel, the former Deputy commissioner of FDA who succeeded Bill Schultz, and Jeff Gibbs, Former Head of Enforcement at FDA, to review our regulatory path and confirm that we are in every aspect in strict compliance with the law. As we are introducing a new model that brings a whole new level of, in our opinion, needed oversight and improvements in accuracy and quality and capability of tests collected at the point-of-service (and as a result disrupts many deeply entrenched old businesses that have not changed for a very long time in this space), we respectfully ask for your support in maintaining the confidentiality around this model until it becomes public through our national deployment in the US early next year:

Theranos is a federally certified high-complexity CLIA laboratory.

The federal certification for a laboratory is represented through the CLIA number which is displayed on the certificate itself.

Theranos' CLIA number is 05D2025714.

Federal certification is delegated to the licensing body of the state in which a given laboratory is headquartered. Upon approval and licensure, the state issues a certificate containing the federal CLIA number.

Licensure or approval as a high-complexity CLIA-certified laboratory means that the systems in the laboratory have been validated against national standards for every test that is run on those systems. As a CLIA-certified laboratory, the systems will continue to be tested by federal or accrediting agencies multiple times a year on an ongoing basis.

This ongoing testing is known as proficiency testing wherein every test that is run on a laboratory's systems must be validated against "blinded" samples provided by federal or national accrediting bodies with unknown concentrations of all tests that are run on a given system.

Each laboratory must report results back within a specified variability or Coefficient of Variation (CV) from a national standard for every test in order to maintain its license. This ongoing testing is not done on tests or systems which are waived or classified as CLIA-waived systems.

In the field, the systems used by the Theranos laboratory will be Theranos devices which include the disposable cartridges and associated software.

Theranos devices are classified by FDA as clinical analyzer systems. Clinical analyzers are regulated by FDA as what are called Class I devices as they are part of CLIA certified laboratories and overseen by trained laboratory personnel and pathologists on a constant and ongoing basis. Theranos' device classification by FDA can be found in Chapter 21 of the Code of Federal Regulations in section §862.2160.

As a CLIA-certified laboratory, the laboratory is legally liable for the accuracy of every result that it reports. This means that in addition to the controls, standards, and practices (such as Good Manufacturing Practices) required by FDA for Class I devices, Theranos devices are also subject to the ongoing testing, oversight, and regulatory obligations under CLIA certification.

Historically all point-of-care tests have been CLIA-waived tests which do not provide the accuracy and oversight associated with CLIA-certified tests. With advances in technology making it possible to do so, Theranos believed strongly that the additional

regulatory oversight and processing capabilities associated with CLIA-certification was fundamental to providing actionable data at the point-of-service and chose to introduce fully CLIA-certified testing capabilities at the point-of-service for the first time instead of applying for waivers for its systems.

Equally, companies in the medical testing space have traditionally sold equipment into clinical laboratories, including field hospitals. The laboratory becomes responsible for dealing with issues around the performance of tests run on the equipment, performance of controls for the tests, issues like temperature, environmental concerns, or shipping conditions affecting the reliability of tests and the controls for the tests, and the associated inaccuracies in test results and the costs associated with the laboratory's dependence on the quality of the manufacturer's product.

To bring the laboratory from the centralized infrastructure to the place where a patient is being stabilized or triaged and significantly reduce the cost associated with testing and providing care to patients, Theranos designed its systems to operate at the place the sample is collected or in the field.

These locations where blood has traditionally been drawn are classified as Blood Collection Sites under CLIA regulations. Rather than sell equipment into laboratories, Theranos provides its laboratory infrastructure as a service wherein its devices are used only for sample processing in Blood Collection Sites in strict compliance with the law and bits of data, rather than samples, are sent from its devices back to the CLIA-certified laboratory for real-time analysis, triage, and oversight under CLIA, again in strict compliance with the law.

This allows comprehensive oversight, quality, and professional analysis to be brought to tests run at the point-of-service, a capability which has not been possible historically through CLIA-waived medical devices which, as signified by the CLIA-waiver, do not have the same level of accuracy, quality, and oversight as CLIA-certified tests.

I have tried to keep this backgrounder as concise as possible and of course can go into additional detail in any area that is of value.

Please let me know if this helps to provide what we need for our next step.

With my best regards,

Elizabeth.

From: Mattis, James N Gen MIL USMC USCENTCOM CCCC-CCCC [mailto:james.mattis@centcom.mil]

Sent: Saturday, October 08, 2011 3:34 AM

To: Elizabeth Holmes

Subject: RE: Note for General Mattis in follow up to last night's dinner at George Schultz's house

Thank you for the fast response, Ms. Elizabeth. I'm trying to find a way to employ your device on a swift "pilot project" or "proof of principle" to expedite its entry to our forces. I need to show that the Theranos device is certified for use by whatever certifying agency is accepted at the Federal level. Any certification that you have from the appropriate Federal agency would be most helpful to expedite this effort.

Happy to hear that you're showing the device to the folks on board an amphibious ship. That class of ship carries large numbers of troops for extended periods, so I can see how your capability would be most useful on board.

All my best to you, young Elizabeth. Please send anything that would help open the doors to Federal/U.S. Military medical facilities. I can call you if we need to talk. Thanks! Jim

From: Elizabeth Holmes [mailto:eholmes@theranos.com]

Sent: Saturday, October 08, 2011 3:42 AM

To: Mattis, James N Gen MIL USMC USCENTCOM CCCC-CCCC

Subject: RE: Note for General Mattis in follow up to last night's dinner at George Schultz's house

General Mattis:. Thank you for this email. Please see attached.

Brief summary: Theranos is a high-complexity CLIA-certified laboratory. Theranos devices (which include the disposable cartridges and associated software) are sample processing units classified by FDA under 21 C.F.R. §862.2160 as Class I Exempt clinical analyzer systems.

Please let me know if it is of value to provide additional background on the above or our attached license.

I had the privilege to board USS *Bonhomme Richard* today to brief Vice Admiral Beaman, Major General Spiese, a large surgical team and others during Fleet Week. We had the opportunity to run a live demonstration of our systems in the operating rooms on board and tour the medevac vehicles on board. It will be such a privilege to be able to pursue the opportunity to deploy in your theater.

Thank you again for your note.

With my best regards,

Elizabeth.

From: Mattis, James N Gen MIL USMC USCENTCOM CCCC-CCCC [mailto:james.mattis@centcom.mil]
Sent: Friday, October 07, 2011 2:33 AM
To: Elizabeth Holmes
Subject: RE: Note for General Mattis in follow up to last night's dinner at George Schultz's house

Elizabeth: Good morning, hope all is well. Can you send me any data you have on the FDA or CLIA certifications of your device? We are pushing forward on our end and I see some specific opportunities in my theater. I need the reference material on certifications for us to take this forward.

I trust all is well with you. Thanks for any help you can provide. All the best, Jim

From: Elizabeth Holmes [mailto:eholmes@theranos.com]
Sent: Tuesday, August 30, 2011 1:11 AM
To: Mattis, James N Gen MIL USMC USCENTCOM CCCC-CCCC
Subject: RE: Note for General Mattis in follow up to last night's dinner at George Schultz's house

General Mattis,

I am honored and humbled by your email.

Your words on keeping hold of the unparalleled freedoms we enjoy in this land resonate so deeply with me. We are greatly indebted to you and the men and women risking their lives for our sacred homeland every day.

I look forward to receiving your letter. Thank you for your swift follow up. I got a call this morning from Colonel Erin Edgar with Christine Murphy who he is assigning to this project and will be following up with them with written background on our systems.

It will be an honor and a privilege to meet with you again and share background on our work and mission. I look forward to that next conversation.

Again, thank you for your inspiration.

With my very best regards,

Elizabeth.

From: Mattis, James N Gen MIL USMC USCENTCOM CCCC-CCCC [mailto:james.mattis@centcom.mil]
Sent: Sunday, August 28, 2011 10:24 AM
To: Elizabeth Holmes

Subject: Note for General Mattis in follow up to last night's dinner at George Schultz's house

Dear Ms. Elizabeth: It was a pleasure to meet you in San Francisco and to hear about your project. Thank you for your kind words—young folks like you remind me why we need to keep hold of the freedoms we enjoy in this land. I appreciate you taking the time to write. I thought the questions were very thoughtful, better even than the ones that I am asked when I testify in front of the Senate, smile.

Yesterday I signed off a note to you (old fashioned, I still use snail mail, smile) thanking you for discussing your project with me. Here is the information from my slow moving letter: our U.S. Central Command Surgeon (Colonel Erin Edgar, U.S. Army) will shortly be in contact with you and set up a visit. I want to swiftly follow up with you and try to determine if and how we could use your invention, one that has understandably seized a lot of attention.

I look forward to seeing you again and to hearing more about how you envisioned and crafted the effort to miniaturize into your invention such a complex process. That's the most exciting thing I've heard about in a long time, young lady, and I salute you for your vision, skill and persistence. If you ever write a book about how you did all this, I'll be first in line to buy a copy—your life is the stuff of adventure in a realm I seldom see.

Again, thank you for your note, young Elizabeth, and I wish you every success. Best, Jim

From:Elizabeth Holmes [mailto:eholmes@theranos.com]

Sent: Friday, August 26, 2011 9:16 PM

To: Sweeney, Kevin M RDML (S) MIL USN USCENTCOM CCCC-CCCC

Subject: Note for General Mattis in follow up to last night's dinner at George Schultz's house

Dear Admiral Sweeney, I received your email address from George's office as the appropriate vehicle of contact for General Mattis following last night's dinner. If you would forward the following message to him I would very much appreciate it:

General Mattis,

I want to let you know how honored I was to be able to meet you last night, and how inspired I was by your words, your integrity, and your service to our country.

As someone building a company with the mission of serving our country and our healthcare system, seeing you speak made a tremendous impact on me.

I hope to have the opportunity to meet you again.

As we scale at Theranos, we will strive to serve the men and women selflessly serving our country.

With my very best regards,

Elizabeth.

Elizabeth Holmes
CEO
Theranos, Inc.

Tel: 650.470.6111

Fax: 650.838.9804

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