Message

From: Christian Holmes [/O=THERANOS ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CHRISTIAN HOLMES]

Sent: 9/6/2013 5:16:18 PM

To: Jeffrey Blickman [jblickman@theranos.com]; Daniel Edlin [dedlin@theranos.com]

Subject: FW: Theranos website comments

From: Elizabeth Holmes

Sent: Friday, September 06, 2013 8:37 AM

To: Christian Holmes **Cc:** Sunny Balwani

Subject: Fwd: Theranos website comments

Begin forwarded message:

From: Kate Beardsley < kbeardsley@beardsleylawpllc.com >

Date: September 6, 2013, 7:18:01 AM PDT

To: Elizabeth Holmes < eholmes@theranos.com Subject: Fwd: Theranos website comments

I am forwarding the Hyman Phelps comments. If you want, we can get on the phone later today to discuss. Jamie gives her availability in the text.

Sent from my iPad

Begin forwarded message:

From: "Jamie K. Wolszon" < <u>JWolszon@hpm.com</u>>

Date: September 5, 2013, 10:02:46 PM EDT

To: 'Kate Beardsley' <kbeardsley@beardsleylawpllc.com>, "Robert A. Dormer" <RDormer@hpm.com>

Subject: Theranos website comments

Hi Kate,

Please find below my comments to the Theranos' website. Several of these comments repeat throughout the website, so I do not necessarily mention each instance. As discussed, they fall within the categories of substantiation for superlative or comparative performance claims, suggestion that consumer can order tests or receive results without involvement of physician. In addition, I do not think several of the claims apply to urine or other samples. I have a call from 9-10 am, but would be available from 10-1:30 or after 2:30 for a call.

Please remove references to "all" tests and replace with statements such as "multiple" or "several". It is highly unlikely that the laboratory can perform every conceivable test, both from a logistical standpoint and because the CLIA certification designates specific specialties of tests the lab performs. For a similar reason, replace "full range" with "broad range" Change "getting you answers" to "getting you and your physician answers" Ensure substantiation for claim "1/1,000 the size of" typical blood draw Does the "revolution" also apply to the urine and other samples? It appears that it really only applies to blood, although the other matrices are mentioned. Replace "faster and easier" with fast and easy Replace "highest quality" with high quality Ensure substantiation for "4 hours or less" Replace "amazing" with "very high" Why would fast necessarily lead to "highly accurate" "better more informed treatment"? What substantiation do you have for "have results to you and your doctor faster than previously possible"? Phrase "you and your doctor" in context of results implies that results are sent to patient at same time as doctor, which is inconsistent with several state laws. Replace with your doctor I doubt that most consumers will be familiar with the concept of coefficient of variance A CV of less than 10 percent could still be too high—it depends on the test Replace highest levels of accuracy with high levels of accuracy What substantiation do you have for the statement that human processing is the cause of most lab errors?

Can you use a less risky analyte than PSA?

- Change "we can help you see" to "we can help you and your physician see"
- Change "we're working to help better track chronic conditions" to "were working to help you and your physician"
- Change more precise to precise
- Change "provide insight" to provide "you and your doctor insight"
- Remove reference to early detection (particularly since you use it on the same page as PSA—the implication is that it can provide for early detection of prostate cancer, which is a risky claim).
- Add "once your physician orders a test" before "you can make an appointment or walk in at your leisure." Patient must have physician order or inconsistent with several state laws.
- Ensure substantiation for "it's a less invasive, and less painful experience"
- "system designed to let you know more, better and faster" should be "designed to let you and your physician." (Note that unlike the other claims, this states that it is designed to let you know faster as opposed to stating that it is faster)
- Change the more you know about what is happening in your body to "more you and your physician know"
- In the section about seeing the results, you need to revise to be clear that the physician sees the results, and then the patient can have access after the physician authorizes the results. Otherwise you will not be consistent with several state laws.
- Change complete to comprehensive
- Replace "most common panels to most specialized test" with common panels to specialized tests
- Ensure substantiation for dramatically lower
- Remove references to oncology and pediatrics—this increases risk
- You mention Walgreens. I assume they have consented to be mentioned?
- "even on your way to the doctor's office" could imply that you go before receiving the doctor's order.

- The bio for Samuel Nunn appears to be cut off
- Ensure substantiation for "unprecedented speed and accuracy"
- For "first and only" please remove only. Also, are you certain that you are the first lab to use any sort of microsamples? For instance, I have heard of labs running samples on blood spots from babies feet. Wouldn't that qualify as a micro-sample?
- Remove "knowing everything you need to know"
- Ensure substantiation for "lowers the risk of anemia"
- Change "most advanced" to "advanced"
- CLIA requires all high-complexity labs to undergo proficiency testing on a quarterly basis, so claim about proficiency testing could misleadingly imply that lab is doing something unusual.
- CLIA's highest certification also could be misleading as there are only three categories—waived, moderate and high-complexity. It is true that it is the highest certification, but several labs share this distinction.
- Also, I have yet to see a reference to California state laboratory license. Does Theranos have one?
- Ensure substantiation for size of dime claim
- Remove "unrivaled accuracy"
- Ensure substantiation for "diagnose sooner"

Jamie K. Wolszon

Hyman, Phelps & McNamara, P.C.

700 13th Street, NW

Washington, DC 20005

(202) 737-4299 (Office)

(202) 737-9329 (Fax)

jwolszon@hpm.com

www.hpm.com

Visit the HPM blog: www.fdalawblog.net

From: Kate Beardsley [mailto:kbeardsley@beardsleylawpllc.com]

Sent: Thursday, September 05, 2013 12:50 PM

To: Robert A. Dormer Cc: Jamie K. Wolszon Subject: FW: .COM PDF

This is the Theranos website that needs to be reviewed. It is scheduled to go live tomorrow night, so there is some urgency. I think we will need to get on the phone with the client once we know what we want to say. You can reach me at or at this email.

Thanks for taking this on on such short notice. I know it is a pain.

Kate

From: Elizabeth Holmes [mailto:eholmes@theranos.com]
Sent: Wednesday, September 04, 2013 7:05 PM

To: Kate Beardsley

Subject: FW: .COM PDF

PRIVILEGED AND CONFIDENTIAL COMMUNICATION

IMPORTANT — This electronic transmission, and any files transmitted with it are confidential and/or legally privileged information. This information is intended solely for the use of the individual or entity to which they are addressed. Any disclosure, retransmission, reproduction, dissemination or other use of the contents of this information by persons or entities other than the intended recipient is strictly prohibited. If you have received this email in error, please contact us immediately and delete all copies. Please note that any views or opinions presented in this email are solely those of the author and do not necessarily represent those of Theranos, Inc. Finally, before opening or using attachments the recipient should check this email and any attachments for the presence of viruses. Theranos, Inc. accepts no liability for any damage caused by any virus transmitted by this email. Our sole responsibility is limited to resupplying any affected attachments.

Theranos, Inc., 1601 S. California Avenue, Palo Alto, CA, 94304

650-838-9292 <u>www.theranos.com</u>

This e-mail is sent by a law firm and may contain information that is privileged or confidential. If you are not the intended recipient, please delete the e-mail and any attachments and notify us immediately.
