

**To:** Sunny Balwani[sbalwani@theranos.com]  
**From:** Elizabeth Holmes  
**Sent:** Thur 9/5/2013 10:30:44 PM  
**Importance:** Normal  
**Subject:** FW: .COM PDF  
**Received:** Thur 9/5/2013 10:30:46 PM

FYI. I am working on this with Christian and Yagi (you were copied on a forward of pieces of the below).

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**From:** Kate Beardsley [mailto:kbeardsley@beardsleylawpllc.com]  
**Sent:** Thursday, September 05, 2013 8:58 AM  
**To:** Elizabeth Holmes  
**Subject:** RE: .COM PDF

Elizabeth,

I haven't quite worked my way through the whole website, but I'm worried. Unless someone else has worked through this with you, the whole thing needs to be carefully reviewed. Here are a few of the general issues that need to be discussed:

- (1) It looks as if we are giving patients direct access to results. FDA takes exception to patient access to LDT results, and I think that a lot of states do too.
- (2) I think that, unless we mention the need for a prescription more often and more prominently, we risk being misleading.
- (3) There are rules on promotion directly to consumers that need to be checked.
- (4) There are many comparative claims. For example, every time you say "better" without specifying what it is better than, you are making a comparative claims at least to all market leaders. You must be able to substantiate these claims. I don't know if we have substantiation for all of these, but I am very worried that we are opening the door to big trouble from competitors. Also, words that end in "est" (e.g., highest quality) create parity claims at least as to all other market leaders. We need to be able to be sure that we can substantiate those as well.
- (5) When we get to FDA, we are going to want to make the case that this technology is equivalent to other technologies. Words like "revolutionary" and "breakthrough" aren't going to help.
- (6) I think there may be a bunch of claims that refer to the full battery of tests, but perhaps not to every test individually (e.g., results faster than previously possible). If this is the case, it needs to be clear what comparison is being made.
- (7) There are a number of claims that are potentially susceptible to multiple meanings (e.g., better diagnosis). These need to be tightened up.

Unless you have already had someone look carefully at this, we need to get someone involved in helping to vet this in real time. I proposed Jeff earlier, but there are other people we could use if you don't want him.

Kate

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**From:** Elizabeth Holmes [mailto:eholmes@theranos.com]  
**Sent:** Wednesday, September 04, 2013 7:05 PM  
**To:** Kate Beardsley  
**Subject:** FW: .COM PDF

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