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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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September 30, 2014

Dr. Jeffrey E. Shuren
Director
Center for Device and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Shuren:

Thank you for appearing before the Subcommittee on Health on Tuesday, September 9, 2014, to testify at the hearing entitled "21st Century Cures: Examining the Regulation of Laboratory Developed Tests."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Wednesday, October 15, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachments

Attachment 1—Additional Questions for the Record

The Honorable Michael C. Burgess

1. As you know I firmly believe that FDA lacks statutory authority to regulate medical practice albeit laboratory medical practice. Laboratory developed tests are a service and not commercialized devices performed in many labs. Do you have or did you rely on any legal opinion from FDA counsel and if so, will you produce that legal guidance?

2. LDTs have been instrumental in identifying and stopping the spread of infectious disease when FDA commercial kits are not widely available. Won't the FDA regulation lead to the dismantling of this important public health safety network? Aren't commercial kits approved by the FDA engineered so basically these can be performed at any laboratory in contrast to the skilled testing services offered by some of the most talented and experienced medical geneticists, molecular pathologists, and other medical specialists around the country?

3. The FDA has stated that it must regulate because of safety concerns. Physician groups have asked you for a clear, public assessment of the safety problems. To date, isolated examples have only been offered. Will you provide our committee with all internal FDA assessments of the harm that has been completed and were the basis for the agency's concern and proposed framework?

   We would also like the data and information you have to justify this proposed action, such as how many of these tests are performed daily, what is the extent of the harm, and have there been similar problems with FDA approved and cleared kits?

4. The FDA proposes criteria carve outs for tests that normally would be considered high risk. One of the carve outs concerns unmet needs, meaning no FDA approved commercial kits exists. You indicate that LDTs will be subject to the heightened regulation once a FDA approved commercial kit comes to market. This suggests that the safety and risk equation are changed by the approval of FDA commercial kits. It seems like you are trying to create market exclusivity where you do not have any statutory authority. How do you justify that LDTs, which require a lower level of oversight, overnight would require more—simply because the FDA has approved a commercial kit?

5. How many staff is available at the FDA and what is the estimated increased in workload? How many have experience as practicing physicians as opposed to career regulators or non-clinical PhD in the Personalized Medicine group of the FDA?

6. In Footnote 4 you state: *FDA generally does not exercise enforcement discretion for direct-to-consumer (DTC) tests regardless of whether they meet the definition of an LDT provided in this guidance. Therefore, the enforcement policies in this guidance do not apply to DTC tests, and the FDA's usual enforcement policies apply to DTC tests."*

   However, the NIH National Human Genome Research Institute website[1] indicates, "The Food and Drug Administration (FDA) has the authority to regulate genetic tests, but it has to date only regulated the relatively small number of genetic tests sold to laboratories as kits." Additionally, the Secretary's Advisory Committee on Genetics Health and Society, in direct contradiction to FDA's 'Footnote 4 Policy', reported[2] in 2010 that the "...FDA generally

[1] http://www.genome.gov/10002335

[2] http://osp.od.nih.gov/sites/default/files/SACGHS_DTC_Report_2010.pdf

exercises enforcement discretion for most LDTs, including DTC genetic tests developed as LDTs"

- All clinical laboratories and clinical lab-developed tests are subject to CLIA and state laws.

- In addition, under the new HHS direct access rule, all clinical laboratories must make individual test results available directly to consumers at their request, without going through a physician first.

- Moreover, requirements related to who is able to order a test from a clinical laboratory are subject to state practice of medicine laws, not FDA or CMS.

In light of these clear standards, I would like to understand better the 'Footnote 4 policy FDA has published, apparently for the first time. Specifically, please explain FDA's definition of a DTC laboratory test? How is a DTC test developed and performed by a clinical laboratory different than any other LDT performed by a clinical laboratory? I have been reading in scientific journals[3] and trade press[4] that disparate regulatory policies could be stifling US –based innovation and investment in clinical laboratories tests intended to provide consumers with their test information. Has FDA considered how the lack of regulatory parity among clinical labs created by the 'Footnote 4 Policy' might impact U.S. based clinical laboratories?

7. Are you not concerned that this will further erode support for those physicians who are offering new tests and treatments in academic medical centers that are saving lives?

8. Representatives of the FDA have publicly stated that the agency's intention was to issue three guidances governing LDTs: one outlining the regulatory framework, one outlining device reporting to the agency, and a third that would address quality standards and areas where oversight by FDA and CMS under CLIA overlap. The July 31, 2014, FDA notification only included the first two. Will the FDA be issuing additional documents or guidance explicitly addressing the overlap with CLIA?

9. The Committee has also heard that the FDA may be working with a third party organization on additional documents in regards to LDTs. Will you outline what additional materials the FDA may be developing on LDTs and other third parties the agency is working with in that regard?

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[3] Nature 505, 286–287 (16 January 2014)

[4] http://venturebeat.com/2014/08/29/blueprint-genetics-raises-3-9-million-to-bring-genomic-diagnostics-service-to-the-u-s/

Attachment 2—Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

The Honorable Renee Ellmers

1. Please provide the committee the tests that have shown inaccuracies that lead the FDA to address this issue.