

**Laboratory Testing Services Are Not the Practice of Medicine:  
A Response to Paul D. Clement & Laurence H. Tribe**

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The Food and Drug Administration (the “FDA”) asserted authority in October 2014 pursuant to the Food, Drug, and Cosmetic Act to regulate Laboratory Developed Tests (“LDTs”) by issuing a Draft Guidance document.<sup>1</sup> In response to the guidance issued by the FDA, Paul D. Clement and Laurence H. Tribe published a paper as counsel to the American Clinical Laboratory Association entitled, *Laboratory Testing Services, As the Practice of Medicine, Cannot Be Regulated As Medical Devices*.<sup>2</sup> Clement and Tribe argue that the FDA lacks authority to regulate LDTs because LDTs are not medical devices, but rather the practice of medicine, and any regulation of LDTs necessarily interferes with the practice of medicine.

Regardless of whether the FDA has authority over LDTs as medical devices, the position taken by Clement and Tribe regarding LDTs as the practice of medicine is fundamentally flawed. The FDA is not proposing to regulate how physicians use LDTs when practicing medicine; rather, the FDA is proposing to regulate the development of the LDTs through its pre-market review. Clinical laboratory testing, whether through approved assays or LDTs, is not the practice of medicine nor has it ever been viewed as such historically. Clinical laboratories provide relevant information as a tool for the physician to use, but the LDTs themselves are not the practice of medicine. It is the

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<sup>1</sup> U.S. Department of Health and Human Services and Food and Drug Administration, Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories, *Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)*, Draft Guidance, October 3, 2014.

<sup>2</sup> Clement and Tribe, *Laboratory Testing Services, As the Practice of Medicine, Cannot Be Regulated As Medical Devices*, ACLA available at <http://www.acla.com/wp-content/uploads/2015/01/Tribe-Clement-White-Paper-1-6-15.pdf> (last accessed January 27, 2015).

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act of the physician in diagnosing and treating the patient by using all available information and tools at his disposal that is the practice of medicine.

Clement and Tribe have taken an uncontestable fact, that all laboratory testing provides critically important information to a physician, and engaged in a play on words to conclude that the tests cannot be regulated because the FDA cannot regulate the practice of medicine. At the root of the argument, Clement and Tribe contend that because LDTs provide critical information to doctors, they are “part and parcel of the practice of medicine.”<sup>3</sup> Then, because they are “part and parcel” and integral to the decision-making process of the physician, the LDT itself is a “medical service.”<sup>4</sup> By then describing the LDT as a “medical service,” they overreach further to conclude that the LDT is the practice of medicine.<sup>5</sup> But this artful wordsmithing, converting the provision of useful information to being “part and parcel,” to then being a “medical service,” and by extension the practice of medicine, reaches too far. LDTs are part of the provision of laboratory services, and the right of the federal and state governments to regulate laboratory services has never been in doubt.

### **I. Regulation of Laboratory Developed Testing Services by the FDA Does Not Constitute Regulation of the Practice of Medicine**

To support their argument that LDTs are the practice of medicine and as such cannot be regulated by the FDA, as opposed to CLIA '88, Clement and Tribe rely on the historical and now statutory language that the FDA was not intended to interfere with or regulate the practice of medicine.<sup>6</sup> There are two fundamental flaws in this argument. The first is that the FDA is not seeking to regulate how physicians use LDTs post-market; rather, the FDA targets the development of LDTs pre-market. The second flaw is that they acknowledge that the use of LDTs may be regulated by CLIA '88. If they are correct, however, that such development and/or use of LDTs is the practice of medicine, then it is also outside the jurisdiction of CMS under CLIA '88.

#### *A. The FDA is Seeking to Regulate the Development Not the Diagnostic Use of the LDTs by the Physician*

Clement and Tribe overlook the distinction between regulating the tools and information used by the physician and the physician's practice of medicine, arguing that regulating the tool, here the

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<sup>3</sup> *Id.* at 4.

<sup>4</sup> *Id.* at 4, 11-13.

<sup>5</sup> *Id.*

<sup>6</sup> Clement and Tribe, *supra* note 2, pp. 4 – 6, 11-13; 21 U.S.C. §396; 37 F.R. 16503 (August 15, 1972).

LDTs, is interference with the practice of medicine.<sup>7</sup> This argument has been historically dismissed by Congress and the courts.<sup>8</sup> Rather, it has been found that Congress did grant the FDA power to regulate and control the *availability* of drugs, devices and biologics that are then used by physicians in order to protect health and safety.<sup>9</sup> Congress does not and has not authorized the FDA to regulate the use by the physician of the available tools, because that is the practice of medicine.<sup>10</sup> This is expressed most clearly by the FDA, wherein it states,

Thus, although it is clear that Congress did not intend the Food and Drug Administration to regulate or interfere with the practice of medicine, it is equally clear that it did intend that the Food and Drug Administration determine those drugs for which there exists substantial evidence of safety and effectiveness and thus will be *available* for prescribing by the medical profession...the Food and Drug Administration is charged with the responsibility of judging the safety and effectiveness of drugs and the truthfulness of their labeling. The physician is then responsible for making the final judgment as to which, if any, of the available drugs his patient will receive...<sup>11</sup>

The practice of medicine involves deciding which legally available medicines, devices and other tools should be used to diagnose and treat one's patients, not which tools will be legally available for use. For example, the FDA evaluates the safety and efficacy of the labeling requirements for drugs but does not regulate the off-label use by the physician. Here, the FDA is seeking to regulate the development of LDTs, i.e. their pre-market approval, not the post-market use of them by the physician.<sup>12</sup>

Clement and Tribe accurately describe an LDT as a “methodology or process” with the understanding that it is developed by a single clinical laboratory, by use of general purpose and

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<sup>7</sup> Clement and Tribe, *supra* note 2, p.12 (Clement and Tribe also argue that LDTs are part and parcel of the practice of medicine such as consulting “an up-to-date, peer-reviewed medical journal” but clearly the author of an article on a general subject is not practicing medicine nor could the author be held liable for medical malpractice for treatment by the patient whose doctor consulted the article).

<sup>8</sup> *U.S. v. Evers*, 453 F.Supp. 1141 (Ala N.Div. 1978), *aff'd* by 5<sup>th</sup> Cir. (1981); *Linder v. U.S.*, 268 U.S. 5 (1925); *U.S. v. Regenerative Sciences, LLC*, 878 F.Supp.2d 248 (D.C. Cir. 2012); *U.S. v. Algon Chemical, Inc.*, 879 F.2d 1154 (3d Cir. 1989); *see also*, *U.S. v. Loran Medical Systems, Inc.*, 25 F.Supp.2d 1082 (C.D. Cal. 1997).

<sup>9</sup> 37 FR 16503 (August 15, 1972).

<sup>10</sup> 21 U.S.C. §396; 37 F.R. 16503 (August 15, 1972); *see also*, Juliana Han, *The Optimal Scope of FDA Regulation of Genetic Tests: Meeting Challenges and Keeping Promises*, 20 HARV. J.L. & TECH. 423, 434-5 (Spring 2007).

<sup>11</sup> 37 FR 16503, 16504 (August 15, 1972) (*emphasis added*).

<sup>12</sup> The Draft Guidance by the FDA primarily seeks to regulate the pre-market approval, except that it requires the post-marketing reporting of adverse events. The reporting of adverse events, however, does not cause the regulation and pre-market approval of LDTs to be the practice of medicine or interference with the practice of medicine. In fact, adverse reporting is a common requirement and is done for drugs as well. *Draft Guidance, supra* n. 1, p.15, 19.

analyte specific reagents, to establish a specific testing protocol that is then used to inform the physician when the physician is diagnosing, treating and prescribing for his patient.<sup>13</sup> Significantly, when developing an LDT, the laboratory does not have the relationship that bears on a particular patient as one would in the practice of medicine. This collaborative yet distinct and divisible relationship was recognized by a federal court in New York in *Price v. Benedict Community Health Center*.<sup>14</sup> In *Price*, the deceased's estate brought a malpractice suit against a hospital and laboratory, after the laboratory performed and incorrectly analyzed a pap smear. The Court in *Price* found that the case sounded in medical malpractice against the laboratory, but noted that "the services rendered by [the laboratory] *pertained specifically to [to the patient]*...[the laboratory] was not performing a general duty, but...was engaging in conduct that bore a substantial relationship to the rendition of medical treatment to a particular patient, *to wit*, [the deceased]."<sup>15</sup> The Court in *Price* distinguished the conduct of the laboratory in interpreting the slide and providing services directly to a patient from other cases where, for example, a hospital failed to properly safeguard its blood supply, noting in the latter that "blood collection and screening practices do not bear a substantial relationship to the rendition of medical treatment to a particular patient."<sup>16</sup>

Here, the development of LDTs by a clinical laboratory is more similar to the safeguarding and screening of the blood supply than to the practice of medicine, because it is not related to the rendition of medical treatment to a particular patient. By developing an LDT, the clinical laboratory is not exercising professional judgment by diagnosing a particular ailment of a particular patient and recommending treatment. Rather, the clinical laboratory is developing a process to make available information that a physician can then use for these purposes.<sup>17</sup> The LDT, as Clement and Tribe acknowledge, is a process or method to identify and report information. The development of that process or method is not the practice of medicine, nor is it even the performance of a laboratory test for a particular patient. It is simply the process that the laboratory must go through, pre-market, to establish the validity and utility of the test, *before* it is available for use. The proposal in the Guidance by the FDA is not to regulate the practice of medicine but to regulate the pre-market approval of LDTs, similar to imposing requirements to screen blood or label drugs, as opposed to the post-market use of the blood or drugs by the physician. It is this fundamental difference between the practice of medicine and the

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<sup>13</sup> Clement and Tribe, *supra* note 2 at p.4; *see also*, HHS, *supra* note 1 at p.5.

<sup>14</sup> *Price v. Benedict Community Health Center, Inc. et al.*, 1998 WL 743707 (N.D.N.Y. 1998)

<sup>15</sup> *Price v. Benedict Community Health Center, Inc. et al.*, 1998 WL 743707, \*5 (N.D.N.Y. 1998) (*emphasis added*).

<sup>16</sup> *Id.*, discussing *Weiner v. Lenox Hill Hospital*, 88 N.Y.2d 788 (1996); *see also*, *Gunter v. Laboratory Corp. of America*, 121 S.W.3d 636 (S.Ct. 2003) (holding that when a laboratory performs an analysis to obtain a DNA profile, the practice of medicine is not involved).

<sup>17</sup> Clement and Tribe, *supra* note 2, p.12.

development of information or tools for the physician that Clement and Tribe fail to acknowledge in their paper.

*B. LDTs are Not the Practice of Medicine*

While different terminology has been used, the essential elements of the practice of medicine have historically been identified as:

*First*, in judging the nature, character and symptoms of the disease; *second*, in determining the proper remedy for the disease; *third*, in giving or prescribing the application of the remedy to the disease.<sup>18</sup>

These same elements are present in the various statutory definitions that contain words such as “diagnosis”, “treat”, and/or “prescribe” for the ailments of the human body.<sup>19</sup> Regardless of the precise definition, uniformly the practice of medicine is understood to be the process of diagnosing and treating the patient. These underlying principles have consistently been acknowledged by the FDA and courts.<sup>20</sup>

Even the definition of LDTs relied upon by Clement and Tribe, “a methodology or process—based on the laboratory’s unique knowledge of the protocols, performance characteristics, and means of analysis, by which the laboratory generates biochemical, genetic, molecular or other forms of clinical information,” does not contain the essential elements that define the practice of medicine.<sup>21</sup> The LDT is used the same way that FDA-approved assays are used to provide clinical information to a physician to inform his diagnosis and treatment regimen for the patient. Thus, another flaw in Clement and Tribe’s argument is that there is no difference for purposes of the practice of medicine between an LDT and an FDA-approved assay. They are both methods used by the laboratory to produce test results. Clement and Tribe try to distinguish the two by arguing that it is the commercial availability of the FDA-approved assay that makes it a medical device and not the practice of medicine. But whether the method is used in-house only, or is

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<sup>18</sup> *Underwood v. Scott*, 43 Kan. 714 (1890).

<sup>19</sup> For example, New York defines the practice of medicine as “diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition. (N.Y. Educ. Law §6521.); Similarly, Texas defines “practicing medicine” as the “diagnosis, treatment, or offer to treat a mental or physical disease or disorder or a physical deformity or injury by any system or method, or the attempt to effect cures of those conditions, by a person who: (A) publicly professes to be a physician or surgeon; or (B) directly or indirectly charges money or other compensation for those services.” (T.C.A., Occupations Code § 151.002[13]). Virginia defines the practice of medicine as “the prevention, diagnosis and treatment of human physical or mental ailments, conditions, diseases, pain or infirmities by any means or method.” (VA Code Ann. § 54.1-2900).

<sup>20</sup> *U.S. v. Evers*, 453 F.Supp. 1141 (Ala N.Div. 1978), *aff’d* by 5<sup>th</sup> Cir. (1981); *Linder v. U.S.*, 268 U.S. 5 (1925); *U.S. v. Regenerative Sciences, LLC*, 878 F.Supp.2d 248 (D.C. Cir. 2012); *U.S. v. Algon Chemical, Inc.*, 879 F.2d 1154 (3d Cir. 1989); *see also*, *U.S. v. Loran Medical Systems, Inc.*, 25 F.Supp.2d 1082 (C.D. Cal. 1997).

<sup>21</sup> Clement and Tribe, *supra* note 2, p.4.

commercially marketed, has no bearing on whether that testing is the practice of medicine. They both produce test results that the physician then uses in the best exercise of his or her judgment.

If all useful information and diagnostic tools used by a physician constitutes the practice of the medicine, as suggested by Clement and Tribe, then is the radiology technician who performs the x-ray on a patient practicing medicine? Is the manufacturer of the imaging device practicing medicine? Does the mother who provides a history of illness and that her child has a fever to the pediatrician, practicing medicine? Or is the child who states “his tummy hurts” and says “ouch” in fact practicing medicine? These are all useful tools for gathering the necessary information and they help with, but do not constitute, the practice of medicine. The clinical laboratory’s provision of a test result from the LDT to a physician is no more the practice of medicine than the radiology technician’s taking the x-ray and giving the image to the physician to interpret.

## **II. Clinical Laboratory Developed Testing Has Never Historically Been Considered the Practice of Medicine**

Implicit in declaring laboratory developed testing services as the practice of medicine is the notion that laboratories must be directed by physicians. However, state and federal laws are clear that laboratories can be directed by non-physicians, such as by a Ph.D. scientist.

In 1967, Congress passed the Clinical Laboratory Improvement Act of 1967, which regulated independent laboratories that engaged in interstate commerce.<sup>22</sup> Twenty years later, the Committee on Energy and Commerce conducted an investigation of clinical laboratories and whether CLIA ‘67 needed to be amended in the wake of news reports and a public outcry regarding quality concerns.<sup>23</sup> One of the concerns that the Committee identified in its report was that there were unregulated clinical laboratories, including primarily the laboratories in physician offices, and the lack of regulation by some states.<sup>24</sup> The Congressional Record notes during the debate on CLIA ‘88 that “lab tests have become an integral part of our health care system” and that reform was required to “strengthen the enforcement”, “enhance the accountability” and extend federal regulation.<sup>25</sup> Moreover, the sponsors of the bill noted the need to regulate physicians who perform laboratory tests in their offices.<sup>26</sup> After congressional hearings, CLIA

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<sup>22</sup> 81 STAT. 536, P.L. 90-174, Sec. 5, available at <http://www.gpo.gov/fdsys/pkg/STATUTE-81/pdf/STATUTE-81-Pg533.pdf> (last accessed Jan. 28, 2015).

<sup>23</sup> H.R. Rep. No. 100-899, at 10-18 (1988).

<sup>24</sup> H.R. Rep. No. 100-899, at 13-15 (1988).

<sup>25</sup> 100 CONG. REC. S15512-16 (daily ed. Oct. 11, 1988) (statement of Sen. Cohen).

<sup>26</sup> 100 CONG. REC. S15512-16 (daily ed. Oct. 11, 1988) (statement of Sen. Levin, stating “the legislation before us fills an important gap...At our hearings, sound arguments were made in favor of requiring these labs [POLs] to adhere to the same requirements as other labs. Patients should be able to expect the same level of accuracy from a lab test done by their personal physician as they do from those conducted in a hospital or large commercial lab.”)

'88 was passed.<sup>27</sup> CLIA '88 extended oversight to all clinical laboratories, including those in a physician's office, and the law was designed to improve the quality and effectiveness of proficiency testing. Additional regulations were then imposed and finalized by 1992.<sup>28</sup> CLIA '88 recognized that individuals other than physicians were capable of being laboratory directors, and that Congress was not encroaching or interfering with the practice of medicine, even when regulating physician office laboratories.

Even prior to the enactment of CLIA, it was the position of the federal government that clinical laboratories could be directed by non-physicians. In 1966 the United States Department of Justice filed suit against the College of American Pathologists ("CAP") for violating the Sherman Act, accusing CAP of price fixing, monopolizing and conspiring to eliminate persons who are not pathologists from being directors of laboratories.<sup>29</sup> The final consent judgment enjoined CAP from preventing and/or restricting non-pathologists from operating or owning a clinical laboratory.<sup>30</sup>

The same tenor and purpose of laboratory regulations can also be seen on the state level. Most states engaged to some degree in the regulation of clinical laboratories. Two states that enacted more rigorous requirements were New York and Pennsylvania. New York enacted legislation in 1964 regulating independent clinical laboratories and blood banks, declaring

The proper performance of clinical laboratory and blood banking services is a matter of vital concern, affecting the public health, safety and welfare. Clinical laboratories and blood banks provide essential public health services in aiding the health care provider by furnishing information invaluable to the diagnosis and treatment of disease. The improper performance of a laboratory procedure may induce an erroneous diagnosis or contribute to the selection of an inappropriate method of treatment, resulting in prolonged or unnecessary hospitalization, injury or even death. The protection of the people of this state requires affirmative action to insure that the performance of clinical laboratory and blood banking services meet high standards of public health care.<sup>31</sup>

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<sup>27</sup> 102 STAT. 2903, P.L. 100-578 (1988), available at <http://www.gpo.gov/fdsys/pkg/STATUTE-102/pdf/STATUTE-102-Pg2903.pdf>.

<sup>28</sup> CDC, *Chronology of CLIA Related Documents in the Federal Register & Code of Federal Regulations*, available at <http://wwwn.cdc.gov/clia/Regulatory/Chronology.aspx>.

<sup>29</sup> *Pathologists Troubles*, The A.A.B. Bulletin, Sept. 1966 at 2; see, *Opinion of the Department of Justice*, The A.A.B. Bulletin, Dec. 1969, at 2, 4.

<sup>30</sup> *Summary of Final Judgment, U.S. vs. C.A.P.*, The A.A.B Bulletin, Nov. 1969 at 4.

<sup>31</sup> N.Y. Pub. Health Law §570.

New York's law regulating clinical laboratories highlights the collaborative nature of the physician/clinical laboratory relationship, but notes the division of responsibility as well. In 1965, the Committee for Preservation of Medical Practice brought an action against the Commissioner of Health, arguing that the law passed in 1964 and its requirement that laboratory directors, even those who were pathologists, be independently certified by the State, was unconstitutional and discriminatory against physicians.<sup>32</sup> Upholding the statute in *Derman*, the court found that there was a distinction between the qualifications of a doctor to practice medicine and those qualifications necessary to "insure the proper direction of a clinical laboratory."<sup>33</sup> The court also "recognize[d] the distinction between the performance of tests in the treatment of a practitioner's own patients and the rendering of services to other practitioners in obtaining and providing information for the diagnosis, prevention, or treatment of disease or the assessment of a medical condition."<sup>34</sup> Similar to the federal position, New York found that clinical laboratories needed to be regulated, including those laboratories run by physicians, and that there was a distinction between the practice of medicine and performing clinical laboratory tests.<sup>35</sup> New York continues this distinction and now also regulates the development of LDTs.<sup>36</sup>

### Conclusion

Laboratory testing has never been, and is not now, the practice of medicine. It provides crucial information for the physician to use in the diagnosis and treatment of a patient. This is so whether the laboratory test is an FDA-approved assay or an LDT.

Even if such testing is viewed as "part and parcel" of the practice of medicine, the pre-market development of a test is not the same. It is simply the standards and processes that must be adhered to before the test is ever used in the treatment of a patient.

Clement and Tribe seek to avoid this reality by clever wordplay, but the fact that laboratory testing is an important informational tool for physicians, like so many other information tools, does not convert the development or use of that tool into the practice of medicine.

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<sup>32</sup> *Derman v. Ingraham*, 47 Misc.2d 346 (S.Ct. Ulster, 1965).

<sup>33</sup> *Id.* at 349.

<sup>34</sup> *Id.* at 350.

<sup>35</sup> Similar to New York, Pennsylvania began regulating physician office laboratories in the early 1960s. This regulatory effort was also challenged as beyond the regulatory authority of the Department of Health, but the Court ruled that it was a valid exercise of the Department's rule-making power. *See, Masland v. Bachman*, 473 Pa. 280 (1977).

<sup>36</sup> Wadsworth, *Clinical Laboratory Evaluation Program (CLEP): A Guide to Program Requirements and Services*, available at [http://www.wadsworth.org/labcert/clep/ProgramGuide/FINAL\\_JUNE\\_CLEPPROGRAMGUIDE.pdf](http://www.wadsworth.org/labcert/clep/ProgramGuide/FINAL_JUNE_CLEPPROGRAMGUIDE.pdf).