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ACLA Issues White Paper Arguing Against FDA Regulation of LDT

As *NIR* reported in November, the American Clinical Laboratory Association (ACLA) has hired some renowned legal advisors to respond to the FDA's proposed regulation of laboratory developed tests (LDTs) (See *NIR*, Nov. 25, 2014, p.1).

ACLA's legal team, former Solicitor General Paul D. Clement, now a partner with Bancroft PLLC, and Laurence H. Tribe, Professor of Constitutional Law at Harvard University, have hit the ground running and prepared a White Paper asserting that LDTs shouldn't be subject to FDA regulation. The White Paper argues FDA regulation of LDTs is not supported in the language of the Federal Food, Drug & Cosmetic Act (FDCA), the proposed regulation interferes with the practice of medicine, and FDA guidance flouts administrative law requirements for rulemaking. ACLA released the white paper January 7, the day before a two-day FDA workshop that provided a forum for public comment on the issues.

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Ebola Continues to Warrant Attention From Labs

While public interest and mainstream media coverage of Ebola may appear to be waning, the outbreak has not ended and the latest CDC reports indicate the total cases exceeds 20,000 and is still rising. The virus is also continuing to receive attention from government agencies.

Emergency Use Authorized for Unapproved Tests

The FDA announced two emergency use authorizations of in vitro diagnostic devices for detecting the Ebola virus. The two in vitro diagnostic tests authorized are the CDC Ebola Virus NP Real-time RT-PCR Assay and the CDC Ebola Virus VP40 Real Time RT-PCR Assay. Both authorizations are subject to conditions and the assays may be used only by qualified laboratories the CDC designates and with the Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument. These two assays are authorized for use for "individuals in affected areas with signs and symptoms of Ebola virus infection and/or epidemiological risk factors," according to the FDA. The assays are used to detect the virus in whole blood,

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ACLA Issues White Paper Arguing Against FDA Regulation of LDT, *from page 1*

"FDA is attempting to saddle a dynamic and innovative industry with sweeping new regulatory burdens without any statutory basis," Clement and Tribe state in the Executive Summary to their white paper. Here are the highlights of the legal arguments Clement and Tribe raise.

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>
> *— Paul D. Clement & Laurence H. Tribe, "Laboratory Testing Services, As The Practice Of Medicine, Cannot Be Regulated As Medical Devices" (1/7/2014)*

LDTs are Services Not Devices

Treating LDT services as medical devices is akin to forcing "a square peg into a round hole," Clement and Tribe assert. The white paper defines laboratory developed testing as a service: a "methodology or process—based on a laboratory's unique knowledge of the protocols, performance characteristics, and means of analysis." Indeed, throughout the paper, the authors use the phrase "laboratory-developed testing service." The FDA's guidance document, on the other hand, uses the acronym LDT for the phrase "laboratory developed test." This distinction in phrasing emphasizes just how pivotal definitions will become in this debate.

The authors explain that the LDT is part of the practice of medicine because it "generates biochemical, genetic, molecular, or other forms of clinical information about a patient specimen that is provided to the treating physician." They assert an LDT is not a product made for use by others or commercially sold but rather "a proprietary methodology that is performed only by the developing laboratory." As many have already argued, the white paper explains that such methodology often fills a void that FDA-approved, in vitro diagnostic test kits do not fill—distinguishing mutational variants, testing biomarkers and analytes for which there are no approved tests, and addressing rare diseases and conditions for which it may not be commercially feasible to develop test kits.

LDTs allow laboratories to nimbly adapt to scientific advances and patient care needs, providing a "purely informational service" utilizing "their unique knowledge of the protocols, the performance characteristics, and the means of analyzing each test, to generate clinical information about a specimen for the ultimate use of the treating physician." Thus, the authors contend this informational service is not a device subject to the Food, Drug and Cosmetic Act.

FDA Doesn't Have Authority Under the FDCA

Clement and Tribe maintain that Congress decided laboratories should be regulated by CMS under CLIA and not by the FDA under the FDCA. They claim the language in the FDCA itself expressly makes this clear and they characterize as "remarkable" the FDA's claim that the 1976 Medical Device Amendments, which added reference to in vitro reagents to the FDCA, subject all LDT services to FDA regulation.

The authors draw an analogy to radiology services, dependent on x-ray machines, to argue that LDT services are similarly a health care service that makes use of or relies upon medical devices but is not itself a medical device subject to FDA regulation. Pointing the Act's definition of devices which refers to "physical articles" and its use of the phrases "commercial distribution" and "introduction into interstate commerce," the authors emphasize that LDT services are not devices (as

"[FDA regulation of LDTs] would have a breathtaking economic impact on traditional laboratory practices, on the physicians who rely on laboratory medicine to facilitate their diagnostic and treatment decisions, and on the allocation of regulatory authority between FDA and CMS,"

— Paul D. Clement & Laurence H. Tribe, "Laboratory Testing Services, As The Practice Of Medicine, Cannot Be Regulated As Medical Devices" (1/7/2014)

explained above), remain in house at the laboratory that has developed them and aren't distributed into commerce.

Finally, the authors point to express language added in 1997 that states the Act doesn't "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient." LDT services assist the physician in medical decision-making and thus differ, they claim, from drugs or devices that "yield a particular diagnosis or treatment" when applied to a patient.

Highlighting the lack of FDA regulation of LDTs for decades, imposing premarket approval requirements now, Clement and Tribe declare "would have a breathtaking economic impact on traditional laboratory practices, on the physicians who rely on laboratory medicine to facilitate their diagnostic and treatment decisions, and on the allocation of regulatory authority between FDA and CMS." The authors argue that enactment of the 1988 CLIA amendments "would be well-nigh inexplicable" and "utterly pointless" if the FDA was intended to have oversight over LDT services. They also point to legislative history that expressed the goal of CLIA was to replace the preexisting "patchwork" of laws and standards.

FDA Guidance Violates Administrative Law

Lastly, the authors attack the FDA's release of guidance documents targeting LDT services as an effort to sidestep Administrative Procedure Act (APA) requirements for notice and comment periods for rulemaking. There is also no economic impact analysis provided in the FDA guidance document, as is required for rulemaking. Analysis of the financial impact FDA approval for laboratory developed tests is "essential" the authors claim. As discussed, such regulation impacts feasibility of developing tests to respond to rare conditions and emerging infectious diseases for which there are no marketed test kits available.

The Battle Lines are Drawn

The gauntlet has arguably been thrown down. While this white paper reiterates many arguments already asserted in opposition to LDT regulation, it does so while providing extensive references to case law, legislative history and other legal resources. At times, it reads much like a legal brief. In fact, the authors assert that the FDA's efforts to exercise regulatory authority in this area could raise constitutional issues with regard to interference with the physician-patient relationship. While not referring directly to the white paper, Jeffrey E. Shuren, MD, JD, Director, Center for Devices and Radiological Health, opened the FDA Workshop on January 8, 2015, by indicating that the FDA is listening to all feedback and the proposed guidance is indeed merely a proposal. "All aspects are open for discussion," he said, before calling on all parties to work together.

Takeaway: While not expressly threatening litigation to oppose FDA regulation, this white paper has provided a preview of potential legal arguments that might be raised against the FDA in court. G2

Source: Paul D. Clement & Laurence H. Tribe, Laboratory Testing Services, As The Practice Of Medicine, Cannot Be Regulated As Medical Devices, American Clinical Laboratory Association (2015); http://www.acla.com/wp-content/uploads/2015/01/Tribe-Clement-White-Paper-1-6-15.pdf

EBOLA Continues to Warrant Attention From Labs, *Continued from bottom of p.1*

serum, and plasma specimens. They can be used with urine specimens, "tested in conjunction with a patient-matched whole blood, serum or plasma specimen."

Additional conditions to the emergency use require that the CDC provide fact sheets for health care providers and patients about the assay, make those fact sheets available on its website and inform qualified laboratories using the tests that the use is subject to an emergency use authorization and explain the terms and conditions of the authorization. The CDC also must track and report adverse events, and record device usage and suspected false positives or false negatives, as must the laboratories that use the tests. Likewise, qualified laboratories must also provide the fact sheets to providers and patients when they report the results of the test. Laboratory staff utilizing the assays must be properly trained and use appropriate personal protective equipment. Finally, any advertising or promotion concerning these assays must clearly indicate that it is not FDA approved and authorized only for emergency use for testing for Ebola Zaire virus.

Grounds for Emergency Use

Certain conditions and threats to public health must exist to support authorizing use of unapproved products. Such emergency authorization can be granted when the HHS determines one of the following situations exists:

1. Homeland Security finds a domestic emergency or significant potential for such emergency exists relating to a "heightened risk of attack with a biological, chemical, radiological, or nuclear agent."
2. The Secretary of Defense finds a military emergency or significant potential for same, involving heightened risk of attack against military forces involving such agents.
3. The Secretary of HHS finds a public health emergency or significant potential for same, relating to such an agent, which could effect national security or US citizens living abroad.
4. Homeland Security identifies a material threat that affects national security or the health or security of US citizens abroad.

The FDA decision here is supported by a 2006 Homeland Security determination that the Ebola virus is a "material threat" that could affect national security.

Not only must there be an emergency situation, such as those described above, but the test itself must meet certain criteria. The FDA must consult with CDC, NIH and the HHS Assistant Secretary or Preparedness and Response and find that 1) an agent can cause a serious or life threatening condition, 2) scientific evidence including any data available from "adequate and well controlled clinical trials" indicate it's reasonable to believe the unapproved product could help diagnose, treat or prevent a condition caused by one of the agents discussed above and that the "known and potential benefits" outweigh the "known and potential risks" of using the product, 3) no are no other "adequate, approved and available" products, plus 4) any other criteria set by regulation.

Comment Sought on Ethical Issues

On a related note, the Presidential Commission for the Study of Bioethical Issues recently sought public comment regarding "ethical considerations and implications

of public health emergency response with a focus on the current Ebola virus disease epidemic." The Commission cited three concerns relating to the Ebola virus: 1) policies requiring the quarantine or restricted mobility of individuals' and the effect of such restrictions on public fear and anxiety or the willingness of workers to serve affected areas; 2) the ethics of using placebo-controlled trials in a public health emergency if the drug being studied "might be effective against the disease causing the emergency;" and most relevant to laboratories, 3) the ethics and standards relating to collecting and storing biospecimens in public health emergencies, and international sharing of these specimens and related data. Comments on these issues can be submitted until February 6 and will be made publicly available.

Lab Handling of Specimens Questioned

Interestingly, the same day the FDA authorization was published in the Federal Register, The Washington Post and The New York Times both reported that CDC laboratory staff might have been exposed to the virus when researchers permitted "potentially lethal specimens" from a highly secure CDC laboratory to be handled by a lesser secured CDC laboratory.

PPE Supplies for Ebola Protection

Finally, the CDC issued a document as 2014 came to a close, discussing Ebola preparedness, the status of PPE supplies in the United States and how hospitals and other health care facilities can estimate the PPE they need to be adequately prepared. That document acknowledges that given demand, some orders for PPE may be delayed or desired quantities may not be available. The CDC advised facilities to contact their state and local health departments for assistance in obtaining PPE if they are having difficulties. This document is available on the CDC website at: http://www.cdc.gov/vhf/ebola/healthcare-us/ppe/supplies.html

Takeaway: While public interest may be lessening, government concern and action with regard to Ebola is not, and the outbreak has not ended. G2

Proposed Amendment to Conditions of Participation Recognizes Same-Sex Marriages

Hospital laboratory Medicare Conditions of Participation will be amended to protect the rights of patients in same-sex marriages. A proposed rule was released responding to the US Supreme Court decision that held unconstitutional the Defense of Marriage Act (DOMA). The amendments are intended "to ensure that same-sex spouses in legally-valid marriages are recognized and afforded equal rights in Medicare and Medicaid participating facilities," the notice for the proposed rule explains.

The U.S. Supreme Court declared DOMA unconstitutional in a 2013 decision in *United States v. Windsor*, 570 U.S. 12, 133 S. Ct. 2675 (2013). The Court said DOMA violated the Fifth Amendment by stating that the word marriage should be defined to mean *only* the legal union between "one man and one woman as husband and wife" and that spouse means a person of the opposite gender. The Court explained that the federal law couldn't prohibit recognition of same sex marriages that are recognized by and legally entered into under state law. Thus, the proposed rule will amend Conditions of Participation to comply with the Court's ruling. "These revisions would promote equality and ensure the recognition of the validity of same-sex marriages when administering the patient rights and services at issue," the rule states. Under the Conditions of Participation for Hospitals, the proposal amends provisions that require a hospital inform patients and their representatives of patients' rights and give the patient the right to make informed decisions. Those provisions will state that same-sex spouses must be treated the same as opposite-sex spouses if there is a valid marriage. Provisions specifically related to hospital laboratory services would also be amended. To comply with Conditions of Participation, 42 C.F.R. 482.27 requires a hospital to have laboratory services and to screen blood and blood products for infectious disease and to notify donors and patients of findings when necessary. In particular, when notice must be given to patients determined incompetent, that notice can be given to the patient's legal representative. If a patient is competent, state may law allow a legal representative or relative to receive health information. In both cases, the amended rule will require that for notification of relatives and legal representatives (when state law defines a representative to include a spouse), same-sex spouses must receive the same treatment as opposite-sex spouses.

Similar amendments are being made to Conditions of Participation for Ambulatory Surgical Centers, Hospice, Community Mental Health Centers and Long Term Care Facilities.

Takeaway: Conditions of Participation requirements will ensure patients' rights policies treat same-sex couples in a legally recognized marriage the same as opposite-gender married couples. G2

Enforcement Trends—Labs Continue to Be a Focus

Laboratories continue to draw attention from the Department of Justice (DOJ) and the Office of Inspector General (OIG) as 2014 came to a close. In December, the DOJ announced two guilty pleas and one sentencing in cases involving clinical laboratories.

Another Biodiagnostic-Related Physician Sentencing

In a case highlighted in the OIG's December podcast, a New York pediatrician, Demetrios Gabriel, was sentenced to 37 months in prison, one year supervised release and a $75,000 fine, announced U.S. Attorney Paul J. Fishman. Gabriel had pleaded guilty to accepting bribes for referring patient blood specimens to Biodiagnostic Laboratory Services LLC (BLS), a Parsippany, N.J.-based laboratory. The U.S. Attorney's release notes that 33 people—including 22 doctors—have pleaded guilty in connection with the BLS bribery

scheme which involved millions of dollars in bribes and brought BLS over $100 million in payments from Medicare and other payers. Gabriel admitted to receiving monthly payments exceeding $4,500, including a $3,000 monthly cash fee, additional payments based on the volume of samples referred to BLS, and $1,500 paid monthly to a restaurant he owns. So far, the investigation has yielded more than $10.3 million in forfeiture, the U.S. Attorney's Office reports.

Executives Under Scrutiny As Well

It's not just physicians coming under fire but also executives. A chief financial officer for Maryland pain management clinics, Vic Wadhwa, pleaded guilty to receiving kickbacks exceeding $450,000 for referring urine specimens to a New Jersey laboratory, U.S. Attorney Rod J. Rosenstein and OIG and FBI agents announced. The lab is alleged to have paid the clinics more than $1 million in kickbacks over the course of 12 months relating to this referral arrangement. The statement announcing the plea explained that the CFO had negotiated the referral arrangement which promised the clinic half of the laboratory's profit after expenses for urine samples the clinics submitted for testing.

In another case, an owner of a New Jersey diagnostic testing facility, Vijay Patel, pleaded guilty to submitting Medicare claims for diagnostic testing services that a cardiologist had performed, according to an announcement by U.S. Attorney Paul J. Fishman. The U.S. Attorney explained the cardiologist performing the services was subject to pre-payment review and avoided such review when Patel submitted the claims as if the diagnostic testing facility had performed the services; Patel kept part of the payment received and remitted the rest to the cardiologist.

Safe Harbor and Fraud Alert Recommendations Sought

In other anti-kickback news, the OIG has issued its annual notice seeking suggestions for Special Fraud Alert topics and new anti-kickback safe harbors and modifications to existing safe harbors. Any recommendations or comments must be submitted by March 2, 2015. The opportunity for public input on these safe harbors is a response to concerns that the language of the anti-kickback law is so broad that it can capture "innocuous commercial arrangements" resulting in criminal prosecution or administrative sanctions for those involved. The Health Insurance Portability and Accountability Act of 1996 requires the OIG annually solicit these proposals. Factors the OIG considers when evaluating such proposals include access to and quality of health care services, cost to federal programs, competition among providers and patient freedom of choice, potential for overutilization of services and provision of services to underserved areas and populations.

CMS Releases New CLIA-Waived Tests, Billing Codes

CMS notified contractors of new CLIA-waived tests effective January 1, 2015. There are 25 newly waived complexity tests, the latest approved by the FDA. The tests, listed in the table below, all require the QW modifier be attached to the CPT code for recognition as a waived test. CMS's Transmittal indicates that contractors don't have to go back to "retract payment or retroactively pay claims" but must adjust claims accordingly when brought to their attention.

The following table provides a listing of the new CLIA-waived tests with their CPT Code, effective date and description.

CPT CODE	EFFECTIVE DATE	DESCRIPTION
87807QW	Mar. 18, 2014	BD Veritor System for Rapid Detection of RSV (For use with nasopharyngeal specimens) (Includes reader)
G0434QW	May 12, 2014	Native Diagnostics International, DrugSmart Dip Single/Multi-Panel Drug Screen Dip Card Tests

CPT CODE	EFFECTIVE DATE	DESCRIPTION
87807QW	May 30, 2014	Sofia RSV
G0434QW	June 9, 2014	Healgen THC One Step Marijuana Test Strip
G0434QW	June 9, 2014	Healgen THC One Step Marijuana Test Cassette
G0434QW	June 9, 2014	Healgen THC One Step Marijuana Test Cup
G0434QW	June 9, 2014	Healgen THC One Step Marijuana Test Dip Card
G0434QW	June 9, 2014	Healgen mAMP One Step Methamphetamine Test Strip
G0434QW	June 9, 2014	Healgen mAMP One Step Methamphetamine Test Cassette
G0434QW	June 9, 2014	Healgen mAMP One Step Methamphetamine Test Cup
G0434QW	June 9, 2014	Healgen mAMP One Step Methamphetamine Test Dip Card
87880QW	June 11, 2014	Poly stat Strep A Strip Test {Specimen type (Throat Swab)}
87880QW	June 25, 2014	StrepAim {Specimen type (Throat Swab)}
G0434QW	June 27, 2014	Wal-Mart Stores, Inc. ReliOn Home Drug Urine Cup Test
86308QW	July 7, 2014	Jant Pharmacal Corp. Accutest Rapid Mono Test {Whole Blood}
87880QW	July 9, 2014	Cardinal Health Strep A Dipstick – Rapid Test (Throat Swab Specimen)
G0434QW	July 18, 2014	Healgen COC One Step Cocaine Test Strip
G0434QW	July 18, 2014	Healgen COC One Step Cocaine Test Cassette
G0434QW	July 18, 2014	Healgen COC One Step Cocaine Test Cup
G0434QW	July 18, 2014	Healgen COC One Step Cocaine Test Dip Card
G0434QW	July 18, 2014	Healgen MOP One Step Morphine Test Strip
G0434QW	July 18, 2014	Healgen MOP One Step Morphine Test Cassette
G0434QW	July 18, 2014	Healgen MOP One Step Morphine Test Cup
G0434QW	July 18, 2014	Healgen MOP One Step Morphine Test Dip Card
81003QW	Aug. 8, 2014	Medline 120 Urine Analyzer

Source: CPT Codes are Copyright American Medical Association

The CMS Transmittal announcing the latest FDA approved waived tests is Transmittal 3149, Change Request 8951, Pub. 100-04, dated Dec. 12, 2014. The Transmittal and a complete list of CLIA waived devices is available on the CMS website at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3149CP.pdf.

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