April 8, 2024

The Honorable Bill Cassidy, MD
Ranking Member
Committee on Health, Education, Labor & Pensions
828 Hart Senate Office Building
Washington, DC 20510

Dear Senator Cassidy,

The Association for Diagnostics and Laboratory Medicine (ADLM) is concerned about the potential impact Food and Drug Administration (FDA) regulation of laboratory developed tests (LDTs) could have on patient care, particularly in hospitals/academic medical centers. These institutions routinely deal with critical care situations and need information promptly to diagnose and treat their patients.

ADLM recently conducted the first of several surveys to get a snapshot of the views and concerns of clinical laboratories regarding the FDA initiative. Our first inquiry focused primarily on hospitals – distinguishing between those that specialize in treating all patients (adults and children) and those that focus on pediatric care (only children).

Key Findings:

- Most hospitals have not developed contingency plans for FDA oversight of LDTs;
- Hospitals, both adult and children serving, recognize they will face difficult choices affecting patient care if the FDA extends its oversight to LDTs;
- Duplicative FDA regulation may limit patient access to testing and delay the delivery of care; and
- Hospitals may seek FDA approval for certain tests understanding it will not improve the quality of the testing they provide, but instead force them to reduce the services they offer due to the financial strain.

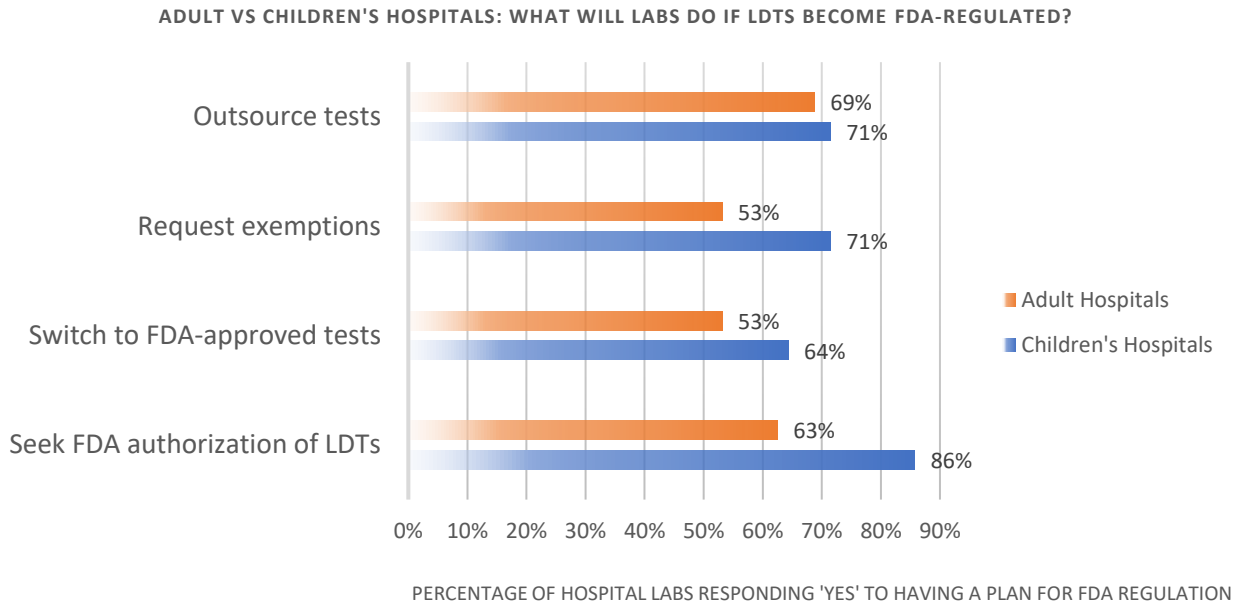
As an organization with a longstanding focus on improving pediatric care, ADLM is particularly concerned about how the FDA's proposal will adversely affect vulnerable populations and potentially undermine those hospitals dedicated to serving them. In each of the situations described, patient care suffers, as hospitals are subjected to costly, duplicative regulation that affects their ability to care for their patients.

Hospitals without Contingency Plans for FDA Oversight:
Of the 140 U.S. laboratories that responded to our survey, 87 percent stated they performed LDTs. Most facilities (59% of those primarily serving adults and 65% of those serving children)

have not, nor are they in the process of, developing a contingency plan to deal with the FDA oversight. The reasons listed include the costly and burdensome FDA oversight, which would require them to cease performing LDTs, as well as the lack of familiarity with the FDA regulatory process. Additionally, some individuals stated their institutions will make their decision later.

Hospitals With or Working on Contingency Plans for FDA Oversight:

The responses received from those hospital laboratories – both adult and children's – that have started the process of developing a contingency plan illustrate the complexity and challenges involving this issue. In many circumstances, if a hospital does not offer an LDT, the patient suffers because a disease may not be diagnosed or a disease diagnosis may be delayed thus delaying life-saving patient care. Our brief survey bears out the conflicting financial, regulatory, and patient care challenges that hospitals will face with the FDA proposal.



- **Outsourcing of tests** - Our initial results indicate that hospitals serving adults as well as those that care for children will outsource many tests (69% and 71%, respectively). This means they will no longer offer these tests themselves, relying instead on outside testing facilities, thus delaying diagnosis and treatment.

  This is particularly concerning for tests used to diagnose and monitor genetic disorders, where every minute of delay results contributes to increased brain damage for these infants and the difference between a normal or an institutionalized life.

In addition, for many therapeutic drugs such as antifungals, this means an increased length of stay in the hospital and increased costs to achieve the optimum drug doses because there is a delay in getting the drug level test results back from outside referral clinical labs.

- **Request Exemptions** - More than 70% of the children's hospitals stated they would seek an exemption from FDA oversight if permitted. The current FDA proposal nor does VALID include such an exemption.

- **Switch to FDA-approved tests** - Both hospitals and pediatric institutions stated that, in some instances, they would switch to an FDA-approved test. Generally, when a laboratory uses an LDT over an FDA-approved test it is because the LDT is either more accurate or better captures the information sought by the physician, or both. In this instance, laboratories may be switching to a test that is less helpful in diagnosing the patient.

  For example, in toxicology testing and pain management drug testing, the FDA-approved immunoassay drug screens are inadequate for determining what drugs were used and monitoring drug usage. In pediatrics especially the immunoassay drug screens do not cover the wide range of drugs that toddlers may accidentally ingest.

- **Seek FDA authorization of LDTs** - Of particular interest is the number of children's hospitals that will seek FDA authorization for some tests. Eighty-six percent of the pediatric institutions that are in the process of developing a contingency plan stated they would, for certain tests, seek FDA approval. Newborn screening follow-up testing is a category of testing that most children's hospitals may seek approval given the immediate need for the testing and the implications for the child if not performed quickly.

Having to take this route highlights the complexity of the choices children's hospitals will be forced to make as they must decide which tests to discontinue and those for which, regardless of cost, they may feel compelled to seek FDA approval—knowing that gaining agency approval will likely diminish, not improve the overall quality of care they provide.

ADLM looks forward to working with you on this issue as Congress continues to discuss federal oversight of LDTs. If you have any questions, please email Vince Stine, PhD, ADLM's Senior Director of Government and Global Affairs, at vstine@myadlm.org.

Sincerely,

Octavia M. Peck Palmer, PhD, FADLM
President, ADLM