Response to the Proposed Food and Drug Administration Regulation of Laboratory-Developed Tests: It Is Past Time for Professional Consensus

Eric Q. Konnick1*

In October 2014, the US Food and Drug Administration (FDA)2 released a long-promised draft regulatory guidance document outlining the FDA’s plan to regulate one of the most innovative areas of laboratory medicine—laboratory-developed tests (LDTs) (1). While the document and public discussion was extremely broad, the draft guidance and subsequent official public interactions often highlighted LDTs by using molecular biology techniques, next-generation sequencing, and mass spectrometry. The majority of the released comments from laboratory and public health professionals involved in patient care and public health activities opposed the draft guidance as potentially limiting patient access, increasing costs, limiting innovation, and interfering in the practice of medicine (https://www.regulations.gov, Docket ID: FDA-2011-D-0360). These concerns have been repeatedly stated in public forums, but the guidance process, unlike the comment-and-rule-making process, does not require that these specific concerns and comments be addressed or considered before release of the final regulatory guidance. Educated estimates by thoughtful and knowledgeable professionals suggest that all but the largest and well-funded commercial and academic medical centers will not be able to bear the financial and/or administrative burden that is likely required by the FDA (2). Additionally, the specific requirements lurking in the final guidance are currently unknown, and the ability of the FDA to effectively implement the proposed regulations is uncertain (3), which makes the true impact of the regulations on patient care activities even more difficult to estimate.

Pathology and laboratory medicine is a relatively small specialty in the scope of healthcare in the United States, but professionals in this field have a wide breadth of professional interests, which has led to the formation of dozens of professional societies, serving almost every conceivable niche interest in specialty. Since the release of the draft guidance, nearly every one of these professional organizations has released position statements outlining shortcomings and incorrect assumptions of the draft guidance, offering constructive suggestions or even proposing regulatory alternatives. These statements and proposals have many key ideas in common; however, rather than attempting to reach a consensus on what needs to be done to provide the

1Department of Laboratory Medicine, University of Washington Medical Center, Seattle, WA
*Address correspondence to the author at: Department of Laboratory Medicine, University of Washington Medical Center, Box 357110, 1959 NE Pacific St., Seattle, WA 98195-7110. Fax 206-598-6189; e-mail Konnick@UW.edu.
DOI: 10.1373/jalm.2016.020909
© 2016 American Association for Clinical Chemistry

2Nonstandard abbreviations: FDA, Food and Drug Administration; LDT, laboratory-developed test.
best care to our patients, there has often been
tenacious adherence to internally generated
language and concepts. This scenario has led to
a cacophony of similar, yet differing voices from
our profession, which has detracted from our
ability to have our perspectives heard and our
expertise seriously considered by regulatory
and legislative bodies. The lack of a consistent
message on key regulatory principles and concepts on which we agree has undermined our
ability to substantially influence the marketplace
of ideas that could have generated a patient-
centered update to the existing extensive regu-
latory framework.

The release of the final guidance is likely immi-
nent, with the FDA stating in multiple public fo-
rums their goal of revealing the final guidance in
2016. In the absence of legislation, laboratories
will be required to abide by the final guidance. A
legislative update to the CLIA regulations, with
input from the full spectrum of laboratories, di-
agnostic companies, patients, and medical-con-
tent experts, is in the best interests of patients
and practitioners, but the lack of a unified and
coherent message from our profession is a ma-
jor impediment to our viewpoints being consid-
ered by our legislative bodies. It is past time that
our professional societies come together to for-
mally identify our common concerns, which will
allow us to make a reasoned argument why pro-
fessionals on the frontlines of patient care
should have a say in how updated regulation of
our practice can address the perceived deficien-
cies in current regulations (4). This may be an
uncomfortable proposition for our professional
societies, because some will be asked to put
aside positions that represent an investment of
time and energy, and others will be asked to
participate in a more active way in promoting
common ideas. While the impulse for some pro-
fessional societies is to maintain the status quo,
the membership in these organizations—the
reason for their existence—can pressure their
leaders to work collaboratively in the spirit of
benefiting our patients through the innovative
and high-quality results that are provided using
LDTs. Based on public comments delivered in
response to the draft guidance, the FDA is work-
ing to finalize their guidance on the regulation of
LDTs, with an incomplete understanding of the
varied roles laboratory and pathology profes-
sionals play in personal and public health. If we
are going to fulfill our professional obligations to
our patients, it is past time to unify our message
to promote a more reasonable regulatory
approach.

Author Contributions: All authors con-
firmed they have contributed to the intellectual content of this paper and have met the following
4 requirements: (a) significant contributions to the conception and design, acquisition of data, or analysis and interpretation of data; (b) drafting or revising the article for intellectual content; (c) final approval of the published article; and (d) agreement to be accountable for
all aspects of the article thus ensuring that questions related to the accuracy or integrity of any part of the article are appropriately
investigated and resolved.

Authors’ Disclosures or Potential Conflicts of Interest: Upon manuscript submission, all authors completed the author disclosure
form. Employment or Leadership: E.Q. Konnick, University of Washington. Consultant or Advisory Role: None declared. Stock
Ownership: None declared. Honoraria: None declared. Research Funding: None declared. Expert Testimony: None de-
clared. Patents: None declared.

REFERENCES
1. Food and Drug Administration. Draft guidance for industry,
food and drug administration staff, and clinical laboratories:
Framework for regulatory oversight of laboratory
medicaldevices/deviceregulationandguidance/
guidancedocuments/ucrm416685.pdf (Accessed 18 June
2016).
2. Caliendo AM, Couturier MR, Ginocchio CC, Hanson KE,
