



American Pharmacists Association[®]

Improving medication use. Advancing patient care.

April 7, 2016

[Submitted electronically to Jeffrey.Lucas@mail.house.gov and Polly.Webster@mail.house]

Representative Larry Bucshon, M.D.
1005 Longworth House Office Building
Washington, DC 20515

Representative Diana DeGette (D-CO)
2111 Rayburn House Office Building
Washington, DC 20515

RE: Draft of the Diagnostic Accuracy and Innovation Act (DAIA)

Dear Reps. Bucshon and DeGette:

The American Pharmacists Association (“APhA”) appreciates the opportunity to provide feedback in response to the draft of the Diagnostic Accuracy and Innovation Act (DAIA) (hereinafter, “Discussion Draft”). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians’ offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA is committed to working with the Congress, the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), other health professionals and stakeholders to identify policy options to better regulate in vitro clinical tests (IVCTs), as defined in the Discussion Draft. Thus, we appreciate the opportunity to provide the perspectives of pharmacists, who are playing an active and growing role in testing, including infectious disease testing and pharmacogenomics, among others. Many pharmacies, such as those in the community setting, have obtained a certificate of waiver to expand access to Clinical Laboratory Improvement Amendment (CLIA) waived tests which connects well with pharmacists’ roles in optimizing medications and serving as an access point for monitoring and prevention services. Thus, legislation impacting lab-developed tests and other devices that may be performed by pharmacists or impact care decisions, especially those related to medications, are of great interest to APhA and our members.

APhA believes that the pharmacist's education, training and experience places them in an excellent position to advance and optimize the safe and effective use of IVCTs. APhA provides the following recommendations to improve the DAIA.

I. Pharmacist Involvement in Advisory Panels

APhA appreciates the inclusion of advisory panel to review to consider the classification of IVCTs and makes recommendations regarding the appropriate class of each test. However, APhA recommends specifically including pharmacists among the list of groups represented. Pharmacists play an important role in administering tests and making care decisions based on test results, as seen in monitoring for warfarin therapy. Recently, the FDA was made aware of performance problems associated with point of care (POC) Prothombin Time (PT)/International Normalized Ratio (INR) devices that raise patient safety concerns, including variable at-home use. Some pharmacies have set up systems where pharmacists are more involved in administering these tests to mitigate risks, monitor results, and improve care. Further, as the health care practitioner most accessible to patients, pharmacists are already playing an important role in postmarket surveillance activities which is an important component of patient safety. Therefore, including pharmacists in advisory panels will provide both medication-related expertise and information regarding real-world experiences by both practitioners and patients. While we acknowledge that "other health care professionals" should include pharmacists, the interpretation of this term in statute and regulations is varied. Consequently, to clarify and help achieve the necessary expertise on advisory panels, APhA recommends inserting "pharmacists" in provisions of the bill regarding membership.

II. Custom IVCTs

APhA highly recommends including pharmacists in the provision of the bill related to custom IVCTs which would exempt custom high-risk or moderate-risk in vitro clinical tests from some premarket requirements under certain circumstances. Some of the circumstances noted are dependent on the practitioner developing or ordering the test, specifically "physician, dentist or other healthcare professional." Like physicians and dentists, in some states, pharmacists can order and administer tests. However, as noted above, pharmacists are not routinely included in the definition of "other health care practitioner." Thus, APhA recommends specifically naming pharmacists alongside physicians and dentists to limit ambiguity. Alternatively, APhA believes our concern could also be resolved by removing references to specific practitioners and replacing such references with language that recognizes states' laws and regulation of professional scope of practice, including authority to order tests.

III. Certification of Laboratories

As of March 2016, there were over 9000 pharmacies certified to perform CLIA-waived tests which improved patient access to these tests and the related clinical services.¹ Any changes to the CLIA certification or classification process, including identification of CLIA-waived tests, has the potential to detract from these pharmacist-provided services that improve access to health care. Because the Discussion Draft clarifies that FDA approved tests eligible for a CLIA waiver are those

¹ Adams, A.J., Klepser, M.E. & Kelpser, D. (2016). An update on community pharmacies as CLIA-waived facilities, *Research in Social & Administrative Pharmacy*, 666-667.

that have been approved by FDA for home use,² APhA is concerned that the scope of tests eligible for a CLIA-waiver is overly restrictive. APhA believes that some tests approved by FDA that are not for home use could be performed in pharmacies or other CLIA-waived facilities. Given the additional degree of oversight and expertise that exists in these CLIA-waived facilities, APhA believes that the Secretary should have authority to waive a broader range of FDA approved tests for the benefit of patients and their care.

Another concern of APhA is the negative implications of modernizing CLIA policies on pharmacists and pharmacies providing tests and related services. For example, increasing waiver fees or mandating burdensome requirements could increase costs and impact the decision to offer such services. Accordingly, APhA recommends including pharmacists and pharmacies when updating and developing policies related to CLIA.

Thank you for your leadership and work on this issue. We look forward to supporting your efforts and working with you as the Discussion Draft is refined. If you have any questions please contact, myself, Alicia Kerry Mica, APhA's Senior Lobbyist, at amica@aphanet.org or 202-429-7507 and Jenna Ventresca, Associate Director for Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,



Alicia Kerry J. Mica,
Senior Lobbyist

² According to the Discussion Draft, examination and procedures are “laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that – (i) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible; or (ii) the Secretary has determined no unreasonable risk of harm to the patient if performed incorrectly.”