



American Pharmacists Association[®]
Improving medication use. Advancing patient care.

March 30, 2016

[Submitted electronically to <http://www.regulations.gov>]

Stephen Ostroff, MD
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

**RE: Patient and Medical Professional Perspectives on the Return of Genetic Test Results;
Public Workshop; Request for Comments
Docket No. FDA-2015-N-4809**

Dear Acting Commissioner Ostroff:

The American Pharmacists Association (“APhA”) appreciates the opportunity to provide feedback in response to the public workshop entitled “Patient and Medical Professional Perspectives on the Return of Genetic Test Results.” APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 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 Food & Drug Administration (“FDA”), and other health professionals and stakeholders to identify policy options that consider patient and medical professional perspectives when providing and/ or receiving results of genetic tests. We believe solutions will require the unified efforts of many diverse stakeholders, including health care professionals, patients and caregivers, community-based organizations, and federal and state governments. Thus, we appreciate the Agency’s decision to seek public comment from stakeholders, such as pharmacists, who are more and more playing an active role in genetic testing, including receiving genetic test results.

Because pharmacists play such an important role in optimizing medications as well as being an important access point for monitoring and prevention services, they are well positioned to increase the impact genetic testing and pharmacogenomics can have on patients and their health outcomes. APhA believes that the pharmacist’s education, training and experience places them in an excellent position

to advance the development and use of genetic testing and pharmacogenomics, throughout the patient care spectrum. APhA appreciates the opportunity to comment on communicating genetic test results. APhA advocates for communication policies that utilize the clinical judgement of health care professionals, including pharmacists, and would be concerned with policy based on limited/emerging evidence that supersedes clinical judgment.

I. Pharmacists' Role

APhA appreciates FDA's efforts to receive input from health care providers and patients by providing comment opportunity in writing and at the Agency's March 2, 2016 public workshop. As FDA continues to identify roles of different health care professionals with regard to care incorporating the use of genetic tests, APhA believes it is essential to include pharmacists because of their education, experience and accessibility in its policy development. Further, because pharmacists are well-positioned to use genetic data safely and effectively to improve individualized patient care, APhA requests the FDA include pharmacist representatives more formally in future meetings and workshops.

Pharmacists currently perform a wide array of services related to genetic tests, including identifying patients that are good candidates for testing; selecting appropriate tests; explaining the purpose of tests to the patient; addressing patient questions in advance of, and after testing; and upon receiving results, helping providers determine care based on the results and explaining those results to the patient. Many pharmacies already offer genetic testing to customers and pharmacists perform services that use genetic tests to influence medication decisions, such as review of drug-gene interactions and medication reconciliation. Given the amount of Americans that rely on medications on a daily basis, the pharmacist's ability to optimize medication and limit waste is becoming even more important as care shifts focus from volume to value.

Since genetic test results can play a role in different aspects of patient care, such as improving drug efficacy or avoiding adverse drug reactions, we believe it is important to consider the results alongside other pertinent health information and not restrict such information to only the health care practitioner ordering the test and the lab running the test. Pharmacists see patients regularly and are among the most accessible health care practitioners. Many patients already have an established relationship with their pharmacists and with nearly 95% of Americans living within five miles of a pharmacy, pharmacists have a unique opportunity in the case of needed monitoring and other maintenance services. Some pharmacists work with patients' other health care providers to obtain pertinent medical history before testing, as such information may influence which tests are run and affect the interpretation of the results.

Pharmacy colleges and schools have already been including genetics and pharmacogenomics courses into their curriculums. The 2016 Accreditation Council for Pharmacy Education¹ (ACPE) Standards include pharmacogenomics and, for years, pharmacy schools have been testing different models to optimize genetic education.² ACPE's expectation is that once pharmacy students complete pharmacogenomics and genetics testing education in their curriculum they will be able to determine the "genetic basis for disease and individual differences in metabolizing enzymes, transporters, and

¹ The Accreditation Council for Pharmacy Education (ACPE) sets accreditation standards and key elements for the professional program in pharmacy leading to the doctor of pharmacy degree.

² See, Adams, S.M., Anderson, K.B., Coons, J.C., Smith, R.B., Meyer, S.M., Parker, L.S., & Empey, P.E. (2016). Advancing Pharmacogenomics Education in the Core PharmD Curriculum through Student Personal Genomic Testing. *American Journal of Pharmaceutical Education*, 80(1), 3.

other biochemical impacting drug disposition and action that underpin the practice of personalized medicine.”³ Such education enables pharmacists to translate raw genetic data to clinically relevant information, which is a valuable skillset that not all health care practitioners learn.

As noted above, APhA strongly encourages any future discussions regarding genetic testing and pharmacogenomics to include the pharmacist’s perspective. Pharmacists are already receiving relevant education and playing an essential role in the integration of genetic tests and their results into patient care. By including pharmacists in subsequent discussions, the benefit of genetic testing and their impact on medications and related outcomes can be better realized.

II. Electronic Health Records

Viable methods to improve patient care using genetic test results will need to be rooted in effective communication across the patient’s care team. APhA strongly believes members of the patient’s health care team need to be able to access necessary information, including relevant genetic test results, through interoperable and integrated electronic health records. In addition, our members stress that consistency in reporting genetic test results will help prevent miscommunication or misinterpretation. As interoperable electronic health records become more commonplace and members of the care team are able to more readily access relevant information, results should be presented in an electronic health record in a clear and consistent manner, similar to lab test results.

III. Communicating Results

Any information related to genetic tests and their results should be communicated to the patient in a way that is easily understandable and provides an opportunity to have questions answered by a health care professional, such as a pharmacist. APhA recommends that clinical decision support tools be developed to help distinguish results where medical action can be taken and where it cannot. In addition, patients should also be informed that future tests or analysis may be necessary based on new and evolving research.

Our members emphasized that patients should be given information that helps place genetic test results in context. For example, the number of variants and frequency of variants in a given population may help patients understand the significance of variations. In addition, our members reiterated the importance of explaining the limitations of genetic testing to patients and the public.

APhA believes that effective communication of results to patients and other members of the health care team will be crucial to integrating genetic information into patient care. As described above, pharmacists are already playing a leadership role in using pharmacogenomic information to optimize patient care. Patient communication and education is an important part of medication-related services. Consequently, as more information is learned about ideal ways to communicate results, it will be necessary to incorporate what is learned.

IV. Coverage of Services

APhA promotes pharmacists as health care providers in the provision of genetic testing and the collection, use, interpretation and application of pharmacogenomic data. It is important that payers

³ Accreditation Council for Pharmacy Education, “Standards 2016”, released February 2, 2015, available at: <https://www.acpe-accredit.org/pdf/Standards2016FINAL.pdf>, last accessed March 15, 2016.

recognize the time needed to appropriately perform services related to genetic test and their results. Reimbursement for providing these tests is limited and most payers' coverage of genetic tests does not account for the interpretation and communication of results, especially when provided by pharmacists. Failure to incentivize health care practitioners will be a significant barrier to effective clinical integration of genetic tests into patient care and the impact these tests could have on patients' health outcomes and the health care system generally. Thus, APhA recommends for the appropriate integration and optimization of genetic testing into patient care that pharmacists be included as a health care provider able to perform these tests and adequate reimbursement accompany any requirement to communicate results with patients.

V. Research

In line with panelists at the March 2 meeting, we agree that more research regarding genetic test results is needed. As the use of genetic tests is becoming more common, APhA encourages research related to genetic tests, including post-market surveillance, clinical research and research derived from genetic databases, such as the National Institute of Health's Genetic Testing Registry and PrecisionFDA. We believe that coordinating private and public efforts will help limit redundancies and improve efficiency.

Thank you for your leadership and work on this issue. We look forward to supporting your efforts and working with FDA as it addresses genetic test results and other, personalized/precision medicine efforts. If you have any questions please contact, Jenna Ventresca, Associate Director for Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,

A handwritten signature in black ink that reads "Thomas E. Menighan". The signature is written in a cursive, flowing style.

Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO