



ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
6120 Executive Boulevard, Suite 700, Rockville, Maryland, 20852
Tel: 301-634-7987 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

AMP Expresses Support for Citizen Petition from the Coalition to Preserve Access to Pharmacogenomics Information

AMP recommends remedies to address consequences of recent FDA actions and improve patient care

ROCKVILLE, Md. – May 4, 2020 – The Association for Molecular Pathology (AMP), the premier global, molecular diagnostic professional society, today submitted a [formal response in support of the Citizen Petition](#) from Hyman, Phelps & McNamara, P.C. on behalf of the Coalition to Preserve Access to Pharmacogenomics (PGx) Information. The response builds on AMP’s [PGx Best Practices Statement](#) and includes a series of recommendations that will rectify recent FDA actions, which have suppressed important patient safety information.

Clinical PGx testing services provide vital medical information that can aid healthcare providers with treatment selections for their patients. These tests are offered by highly qualified, board-certified molecular pathology professionals and are currently held to the same standards as all other laboratory developed testing procedures (LDPs). All supporting clinical validity evidence must be documented before the test is offered to patients. Recently, FDA took suppressive actions that limited the inclusion of clinical interpretation information in PGx test reports. These actions disregarded all of the qualifications of molecular professionals and the well-established clinical evidence for PGx testing. In its response in support of the Citizen Petition, AMP concluded that these actions were unlawful, infringed on the practice of medicine and threatened patient safety.

“AMP is deeply concerned with the numerous examples of FDA overstepping its authority and employing haphazard approaches for regulating LDPs. In the past year, FDA has jeopardized patient safety with these suppressive actions for PGx tests and initially prevented qualified molecular professionals from developing, validating and performing assays to detect SARS-CoV-2 in patients at the onset of the COVID-19 pandemic,” said Jordan Laser, MD, Medical Director of Long Island Jewish Medical Center – Pathology and Laboratory Medicine, and Chair of AMP Professional Relations Committee. “AMP’s recommendations are based on our collective expertise in this rapidly developing field and reflect our ongoing commitment to improving professional practice and patient care.”

The response to the Citizen’s Petition is another example of AMP’s continuing work to engage key stakeholders as part of its efforts to improve clinical practice for pharmacogenomic tests. During the past year, AMP published a [PGx Best Practices Statement](#) and is also publishing a series of evidence-based expert consensus opinion recommendations for frequently used pharmacogenomic genotyping assays.

To read AMP’s full response to the Citizen Petition on behalf of the Coalition to Preserve Access to PGx Information, please visit https://www.amp.org/AMP_Response_to_PGx_Citizen_Petition

To read AMP’s full position statement on pharmacogenomic testing, please visit <https://www.amp.org/PGxBestPracticesStatement>.

ABOUT AMP

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP’s 2,500+ members practice various disciplines of molecular

diagnostics, including bioinformatics, infectious diseases, inherited conditions, and oncology. Our members are pathologists, clinical laboratory directors, basic and translational scientists, technologists, and trainees that practice in a variety of settings, including academic and community medical centers, government, and industry. Through the efforts of its Board of Directors, Committees, Working Groups, and Members, AMP is the primary resource for expertise, education, and collaboration in one of the fastest growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high quality, appropriate testing. For more information, visit www.amp.org and follow AMP on Twitter: [@AMPath](https://twitter.com/AMPath).

MEDIA CONTACT:

Andrew Noble

anoble@amp.org

415-722-2129

###