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By Electronic Submission

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

RE: Docket No. FDA-2020-P-0152, Citizen Petition of the Coalition to Preserve Access to Pharmacogenomics Information

To Whom It Concerns:

Washington Legal Foundation (WLF) submits this comment in support of the Citizen Petition of the Coalition to Preserve Access to Pharmacogenomics (PGx) Information.

Founded in 1977, WLF is a public-interest law firm and policy center with supporters nationwide. WLF often appears before federal courts and administrative agencies to promote free enterprise, individual liberty, limited government, and the rule of law. To that end, WLF routinely defends commercial speech rights by appearing as an *amicus curiae* in state and federal courts in important First Amendment cases.[1]

WLF has also litigated in favor of First Amendment limits on the Food and Drug Administration's (FDA) authority to restrict manufacturer speech.[2] As a result of that litigation, the FDA is subject to a permanent injunction curtailing the agency's authority to bar manufacturers from sharing peer-reviewed medical texts and journal articles about off-label uses of their FDA-approved products.

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[1] *See, e.g.*, *Sorrell v. IMS Health, Inc.*, 564 U.S. 552 (2011); *Merck & Co. v. U.S. Dep't of Health & Human Servs.*, __ F.3d __ (D.C. Cir. June 16, 2020); *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012).

[2] *See Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

As the U.S. Supreme Court has recognized, the need to ensure the free flow of truthful information "has great relevance in the fields of medicine and public health, where information can save lives."[3] Understanding gene-drug interactions allows a physician to make better informed prescribing decisions, which should lead to better health outcomes and lower healthcare costs. The Coalition's petition thus raises legitimate questions about the FDA's ongoing campaign to "suppress communications by clinical laboratories and software providers about the role of PGx in the metabolism of, and response to, specific drugs."[4]

The FDA's suppression campaign not only threatens to undermine the public health, it also runs afoul of the Constitution. By prohibiting clinical labs and software providers from sharing gene-drug testing data with physicians, the FDA directly infringes on truthful, non-misleading speech. If challenged in federal court, the FDA would need to show that it has a compelling governmental interest in suppressing that speech. The FDA cannot possibly meet that burden.

A. Dissemination of PGx data is constitutionally protected scientific speech.

"Scientific and academic speech reside at the core of the First Amendment."[5] A laboratory's ability to convey accurate PGx test results is essential to scientific inquiry. Medical-research scientists and healthcare providers increasingly rely on PGx testing to better understand how a patient's genetic makeup influences the effectiveness of a given medical therapy.[6] Such tests typically rely on algorithms, bottomed on extensive medical and scientific literature, that interpret genotype data to yield phenotypes that predict likely gene-drug interactions. Both the interpretive and predictive outputs of these tests are conclusions, based on scientific judgment and expertise, delivered to physicians and other healthcare providers in a written report.

Just as a newspaper does not lose its First Amendment protection because it is sold for profit,[7] neither do *The Lancet* or *The New England Journal of Medicine*. Nor does the fact that patients, or their insurers, pay for a PGx test result somehow

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[3] *IMS Health, Inc.*, 564 U.S. at 566.

[4] Pet. at 1.

[5] *Friedman*, 13 F. Supp. 2d at 62.

[6] John Stanley Mattick, *How Precision Medicine Is Helping to Change the Future of Healthcare*, The Conversation (Feb. 2, 2018) <https://tinyurl.com/yatsq8l6>.

[7] *New York Times v. Sullivan*, 376 U.S. 254, 266 (1964).

alter its nature as purely scientific speech. Such "speech does not retain its commercial character when it is inextricably intertwined with otherwise fully protected speech"; it is "fully protected expression."[8] So even if PGx tests may be viewed as partly commercial, the scientific component of the speech at issue is entitled to full constitutional protection.

B. Suppressing the dissemination of PGx data constitutes an impermissible content- and viewpoint-based restriction.

The FDA's attempt to prohibit the sharing of PGx test results is a content-based restriction on fully protected speech. Although the federal government has enthusiastically supported the development and dissemination of PGx data through programs operated by the National Institutes of Health (NIH) and the Centers for Disease Control (CDC), the FDA has taken the view that most PGx tests are unlawful medical devices. Last year, for example, the FDA issued a warning letter to the Inova Genomics Laboratory (Inova) of Falls Church, Virginia.[9] Inova had been marketing PGx testing services under the MediMap® brand, including services for newborns and services related to opioids. The FDA claimed that these testing services constituted unlawful medical devices and threatened an enforcement action, "without further notice," including "seizure, injunction, and civil money penalties."[10] Faced with the FDA's threats, Inova ended its genetic testing services.

A "regulation of speech is content based if a law applies to particular speech because of the topic discussed or the idea or message expressed."[11] Here, the FDA is targeting the dissemination of PGx data because that data identifies a relationship between genetic variations and drug effect. The FDA also speculates that doctors, if they have access to accurate PGx test results for their patients, "may make" prescribing decisions that the agency considers "inappropriate."[12] Because the FDA is silencing speech that conflicts with the agency's view on the clinical utility of PGx data, the FDA's warning also constitutes quintessential viewpoint discrimination. The FDA is restricting speech "because of disagreement with the message it conveys."[13]

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[8] *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 782 & 796 (1988).

[9] FDA, Warning Letter to Inova Genomics Laboratory (Apr. 4, 2019) <https://tinyurl.com/yaksbf2a>.

[10] *Id.*

[11] *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015).

[12] FDA, Warning Letter to Inova Genomics Laboratory (Apr. 4, 2019) <https://tinyurl.com/yaksbf2a>.

[13] *IMS Health, Inc.*, 564 U.S. at 566.

At bottom, the FDA's objection to PGx testing appears to be that gene-drug interactions are "not described in the FDA-approved labeling for these drugs."[14] But the First Amendment protects "off-label" speech.[15] And the FDA has recognized, for decades, that a label cannot possibly contain all clinically relevant information about a drug.[16] Because "prescription drug labeling is static compared with clinical [research]," incorporating the latest findings on "the interplay between various genetic and non-genetic factors" in an FDA-approved label is simply not feasible.[17] In other words, drug labeling "cannot be both authoritative and avant-garde."[18]

True, if no legitimate scientific basis existed to claim a relationship between a genetic variation and a given drug's interaction, then the FDA could ban such speech as false or misleading. But the FDA cannot make that claim; the agency now includes pharmacogenetic data on the labels of roughly 300 prescription drugs.[19] And an overwhelming scientific consensus supports the use of PGx testing when deciding on drug therapies. As the NIH explains on its website, for example, pharmacogenomics can help "predict whether a medication will be effective for a particular person and to help prevent adverse drug reactions."[20] That is why the CDC can insist, for example, that "[t]he breakdown of the antidepressant drug amitriptyline is influenced by two genes called CYP2D2 and CYP2C19."[21] Simply put, the view that genetic variations can predict the effectiveness of certain drugs enjoys broad scientific support.

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[14] FDA, Warning Letter to Inova Genomics Laboratory (Apr. 4, 2019) <https://tinyurl.com/yaksbf2a>.

[15] *See United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015).

[16] *See, e.g.*, 40 Fed. Reg. 15392, 15394 (Apr. 7, 1975) ("The Commissioner clearly recognizes that the labeling of a marketed drug does not always contain all the most current information available to physicians relating to the proper use of the drug in good medical practice. Advances in medical knowledge and practice inevitably precede labeling revision by the manufacture and formal labeling approval by the Food and Drug Administration.").

[17] Katarzyna Drozda, FDA, *Pharmacogenetic Labeling of FDA-Approved Drugs: A Regulatory Retrospective*, 3 J. Am. Coll. Cardiology 545, 548 (2018).

[18] Robert Temple, *Legal implications of the Package Insert*, 58 Med. Clinics N. Am. 1151, 1155 (1974).

[19] FDA, Table of Pharmacogenetic Biomarkers in Drug Labeling <https://tinyurl.com/yd9g5d8x>.

[20] Nat'l Inst. of Health, *What Is Pharmacogenomics?* <https://tinyurl.com/yd8x2cog>.

[21] Ctrs. For Disease Control & Prevention, *Pharmacogenomics: What Does It Mean for Your Health?* < https://tinyurl.com/y9dz5nyr>.

C. The FDA's suppression of PGx data cannot survive strict scrutiny under the First Amendment.

Ordinarily, "it is all but dispositive to conclude that a law is content based and, in practice, viewpoint discriminatory."[22] As an "egregious form of content discrimination," viewpoint discrimination "is presumed to be unconstitutional."[23] Any restriction on the sharing of PGx data is thus presumptively unconstitutional unless the FDA can show that it is both "necessary to serve a compelling state interest" and "narrowly drawn to achieve that end."[24] The FDA cannot make that showing here, particularly since labs provide PGx test results directly to doctors and other health care providers who must exercise their independent judgment in deciding which drugs to prescribe to their patients.

The government may not anoint itself the arbiter of scientific truth in an area subject to reasonable scientific debate. The FDA offers *no* evidence of patient harm to justify its speculation that PGx test results may cause "inappropriate" medical outcomes. Just as it may not consider "all scientific claims" about the safety and effectiveness of prescription drugs "presumptively untruthful or misleading," the FDA may not ban a lab's speech about a given patient's likely gene-drug interactions simply because physicians "may make" prescribing decisions that the agency considers "inappropriate."[25]

Nor is the FDA the arbiter of appropriateness. Federal law does not authorize the FDA "to regulate or interfere with the practice of medicine."[26] And courts have rejected the FDA's attempts to shield physicians from important scientific information. After all, "it is the physician's role to consider multiple factors, including a drug's FDA approval status, to determine the best course of action for her patient."[27] Doctors have a right to rely not only on the information in a drug's label, but on all "other adequate scientific data available."[28] The FDA has no legitimate—much less compelling—interest in suppressing that data. Patients whose genetic makeup reveals that a specific drug will cause an adverse reaction are directly harmed by the FDA's actions.

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[22] *IMS Health*, 564 U.S. at 567.

[23] *Rosenberger v. Rectors and Visitors of the Univ. of Va.*, 515 U.S. 819, 828-29 (1995).

[24] *Town of Gilbert*, 576 U.S. at 180-81.

[25] FDA, Warning Letter to Inova Genomics Laboratory (Apr. 4, 2019) <https://tinyurl.com/yaksbf2a>.

[26] 37 Fed. Reg. 16503, 16504 (Aug. 15, 1972).

[27] *Caronia*, 703 F.3d at 167.

[28] 37 Fed. Reg. 16503, 16504 (Aug. 15, 1972).

Nor can the FDA show that suppressing the dissemination of PGx data is no more extensive than necessary to advance its interest in arresting the "potential" for patient harm. The FDA has not explained, for example, why it cannot adequately address its concerns by requiring that PGx test reports disclose that the FDA does not believe that the relationship between certain gene variations and prescription drugs has been established, and that the FDA has neither evaluated nor approved the claims in the report. This would be a less restrictive means of addressing the FDA's concerns than suppressing the dissemination of truthful scientific speech.

In short, the FDA seeks to suppress truthful PGx test results based solely on a public-policy disagreement. That is precisely the evil that the First Amendment's bar on content- and viewpoint-based discrimination prevents.

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The FDA should grant the Citizen Petition of the Coalition to Preserve Access to PGx Information. Under the First Amendment, the FDA's fear that a physician might make an "inappropriate" prescribing decision if she has access to accurate PGx test results cannot justify suppressing that information. PGx test results, which include patient-specific PGx information intended solely for use by physicians treating their patients, constitute core scientific speech entitled to full First Amendment protection. The FDA cannot supply the requisite governmental interest in suppressing such speech. And even if it could, it has chosen the most restrictive means available to accomplish its aims. The FDA should stop inserting itself between doctors and their patients and abandon its campaign to suppress the dissemination of PGx data.

Sincerely,

/s/ Cory L. Andrews

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