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To: The Honorable Delores G. Kelley
Chair, Finance Committee

From: The Office of the Attorney General's Health Education and Advocacy Unit

Re: Senate Bill 706 (Health Occupations – Pharmacists – Laboratory Tests): Letter of Concern

The Office of the Attorney General's Health Education and Advocacy Unit (HEAU) has serious concerns about Senate Bill 706. None of the bill's proposed changes to current law are necessary for the diagnosis and treatment of Covid-19 or other medical conditions during the ongoing pandemic. Accordingly, consideration of the bill should be postponed until after the pandemic ends and in-depth study and analysis of its foreseeable consequences can be completed. We foresee little, if any, benefit for patients and serious risks of financial and medical harm if this bill becomes law because the bill contains no patient protections from the medical and financial risks of the scheme that is proposed. Private insurance is unlikely to cover the costs of laboratory tests ordered and administered by pharmacists and patients are entitled to full disclosure regarding the risk of noncoverage, and that some of the laboratory tests may be covered if ordered by physicians or other authorized prescribers.

The bill does not limit the laboratory tests that pharmacists would order and administer to laboratory tests approved or authorized by the U.S. Food and Drug Administration (FDA). To the contrary, the permitted laboratory tests would be those used for "health awareness [meaning] screening for medical conditions [but] **does not include medical screening for a definitive diagnosis**." (emphasis added)(p. 3, l. 15-20) This definition is inconsistent with the Preamble's statement that "[c]ancer and other disease screenings have substantially been reduced and there is a concern that there will be an aftershock of other **disease diagnoses** and mortalities following the Covid-19 pandemic". (emphasis added)(p. 2, l. 4-6) This bill's internal contradictions raise serious

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doubts that the proposed changes would facilitate diagnosis and treatment of cancer or other diseases, including Covid-19.

Though it may appear that this bill would merely authorize pharmacists, in addition to physicians and other authorized prescribers, to order medical laboratory tests and that pharmacists would, like physicians and other authorized prescribers, do so subject to the medical laboratory regulatory scheme in Title 17 of the Health-General Article, the bill does not make clear that pharmacists would remain subject to Title 17 as they certainly would and should.

Instead, the bill would expand the Pharmacy Practice Act by allowing pharmacists to order and administer "laboratory tests in accordance with regulations adopted under § 12-513," (p. 3, l. 10-11) which is a new section in the Pharmacy Practice Act. This new section in the Health Occupations Article makes no express reference to the current regulatory scheme in Title 17 of the Health General Article. The newly-created Health Occupations Article section defines the laboratory tests that pharmacists would be allowed to order and administer in broader terms than those permitted under Title 17, among other differences between the two schemes.

The bill contains no express reference to the regulatory oversight by the Office of Health Care Quality (OHCQ) in the Department of Health that would and should apply to laboratory tests ordered and administered by pharmacists. A threshold question is whether the Board of Pharmacy has or may attempt to assert authority over laboratory testing. It should be clear that the bill would not create a new laboratory testing scheme for pharmacists separate from the medical laboratory regulatory scheme in Title 17 of the Health-General Article and that OHCQ retains undivided regulatory oversight.

We are unable to discern any unmet patient needs in Maryland for pharmacist-ordered lab tests, given the broad authority to order lab tests that pharmacists currently enjoy under § 12-6A-07 of the Health Occupations Article. Pharmacists acting in collaborative practice agreements with physicians or other authorized prescribers are authorized to order and interpret preventive service lab tests, for example, cholesterol screening. The bill also fails to account for the fact that while physicians and other medical providers are reimbursed under Medicare Part B and private insurance for providing necessary health care services, pharmacists' services are not reimbursed in this fashion, placing patients at unnecessary financial risk.

The broad scope of the testing authorized by this bill could create business benefits at the expense of patients. Because "screening for medical conditions" is not defined, and because the bill does not limit scope of testing to FDA authorized or approved testing, we foresee the possibility that elimination of the physician order requirement could result in recreational and other genetic testing by use of products not approved by the FDA, thereby placing patient health and privacy at unjustifiable risk.

The bill also raises federal preemption questions regarding potential conflicts with the FDA's pre-approval regulatory scheme requiring clinical trials and human subject research protections- principally informed consent- pursuant to the Federal Policy for the Protection of Human Subjects ('Common Rule'), and related restrictions imposed by the Federal Trade Commission (FTC) on the marketing of FDA regulated products. Maryland law provides patients the minimum protections of the Common Rule and enhances those protections in Title 13, Subtitle 20 of the Health-General Article, and provides protections like those enforced on the federal level by the FTC through the Consumer Protection Act and related caselaw.

We urge the General Assembly to take a cautious approach regarding the potentially disruptive effect this bill could have on the current regulatory protections for patients under federal and state law. We also direct your attention to the VALID Act of 2020 which would have amended the Federal Food, Drug, and Cosmetic Act to update the regulation of laboratory tests, but was not acted upon, presumably due to the need for a series of federal Covid-19 relief bills. https://www.congress.gov/bill/116th-congress/senate-bill/3404/text

Some of the serious concerns we have for Marylanders can be illustrated by an example based on public information about the OneTest marketed by 20/20 Gene Systems, Inc. (20/20). The company's website states: "OneTest™ is a multi-cancer screening test that harnesses the power of [artificial intelligence, also known as] AI with a broad panel of tumor markers and personal clinical factors to help identify risk of more than 6 common types of cancer. OneTest is available in the US through our CLIA lab[.]" https://2020gene.com/

We think most people would agree that worries about developing or having cancer are prevalent and that unreliable lab test results – false positives or false negatives - about cancer risks or diagnoses threaten to harm patients physically, emotionally and financially. Nevertheless, the company admits in its FAQs that "**the results of [its] algorithms, which were derived mainly from an overseas population, should be used with caution**." (emphasis added). The full question and answer are set forth below (emphasis added):

> **"Is this product FDA approved?**
>
> OneTest is classified as a Laboratory Developed Test (LDT) since the test is run in the lab of the test developer. Except in very rare circumstances LDTs are not currently regulated by the U.S. Food & Drug Administration (FDA) but is instead regulated by the Center for Medicare & Medicaid Services (CMS) and the Maryland Department of Health under the Clinical Laboratory Improvement Amendments (CLIA). In general, CLIA approval

is directed at laboratory procedures and the technical performance and analytical validity of the test (i.e. whether the test delivers consistent results) rather than the impact of the test on disease outcomes. **When the test volume begins to exceed the capacity of our CLIA lab we expect to then seek FDA approval so that the tests can be run in other labs. Real-world outcome data (i.e. the numbers of true cancers detected early with the aid of this test vs. false alarms) from a statistically significant number of Americans (e.g. 50,000) will be used in support of this regulatory approval application. We therefore seek the assistance of the consumers of this test and their healthcare providers to assist us in collecting reliable outcome data. Until then, the results of the algorithms, which were derived mainly from an overseas population, should be used with caution."**

https://onetestforcancer.com/faqs/

The company's plan to have users pay for its tests—presumably based on expectations of reliable results- and to use the results to improve reliability in order to obtain FDA approval, is revealed in filings relating to equity crowdfunding efforts that are required by the U.S. Securities and Exchange Commission (SEC): "Retail (walk-in) clinics such as urgent care centers and pharmacy chains present the best opportunities to provide convenient "one-stop shopping" for OneTest" and would provide access to "healthy adults between the ages of 45 to 75" to generate data for the FDA, and to generate profits. The company describes a "low cost/high profit model" based on "very low-cost reagent kits" and says "[t]his means that our partner labs have a strong motivation to offer our tests to their medical providers."

https://www.sec.gov/Archives/edgar/data/1139685/000121390019027270/f1a2019a3_2020genesystems.htm#a_002

We are concerned that patients would not have pre-purchase access to impartial advice from physicians about OneTest and other products like it if this bill becomes law. 20/20 stated in its SEC filing: "We have no immediate plans for a pure direct-to-consumer model that avoids physicians entirely" and that its commercial success would depend on "acceptance in the medical community." We are concerned that the abandonment of the physician order requirement in this bill is based on rejection by medical providers of OneTest because test results include "false alarms" that harm patients physically, emotionally and financially, and require expensive follow up to rule out false positives. Our concern is not limited to OneTest because similar products by other businesses would be allowed under the bill. Thank you for considering our concerns.

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