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February 18, 2021

To: The Honorable Shane E. Pendergrass
Chair, Health and Government Operations Committee

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

Re: House Bill 810 (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 House Bill 810 which warrant, we believe, in-depth study and analysis which the circumstances of this session simply will not accommodate. Accordingly, consideration of the bill should be postponed until after in-depth study and analysis of its consequences have been completed.

Though it may appear that this bill would only 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. 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," a new section to the Health Occupations Article that would broadly define the lab tests that pharmacists would be allowed to order and administer, without reference to Title 17 or express regulatory oversight. The Office of Health Care Quality in the Department of Health has regulatory oversight of medical laboratories under Title 17 and we believe the same oversight, at a minimum, would be required to provide some patient protections from the medical and financial risks of this proposed scheme. It should be clear 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.

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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 creates discernible business benefits at the expense of patients. 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, and would provide unregulated businesses unrestricted access to identifiable genetic information for commercial uses, plus revenues they might not otherwise obtain legally.

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/

The company further states: "OneTest can help aid in the early detection of many other cancer types including those of the lung, liver, pancreas, and more." Five steps are outlined for the purchase and use of OneTest: (1) Buy the test, (2) Consult your doctor, (3) Get a blood test, (4) Our lab analyzes your sample, and (5) Result sent to you and your doctor. https://onetestforcancer.com/product/onetest/

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.

We trust the General Assembly appreciates the patient risks and healthcare system costs involved in allowing businesses to market medical laboratory tests without physician orders using the approach described in 20/20's SEC filing (emphasis added):

> "[O]ur unique technical approach involves the following three elements: **(i) obtain "real-world" data from tens of thousands of apparently healthy individuals (i.e. no apparent signs of symptoms of cancer)** who are screened for cancer using blood tests that are routine in certain parts of the world (e.g. East Asia), **(ii) use this data to build machine learning algorithms that improve the accuracy of those tests by integrating clinical factors (age, gender, etc.)**, and (iii) **introduce those tests and algorithms** worldwide even in parts of the world where this testing approach is less common (e.g. North America) **while examining variability across patient populations.** As of the date of this offering circular, are unaware of any other companies that have adopted this approach.

We are also concerned that the bill would disrupt current law that has protected consumers from physical, financial and privacy/security risks posed by DTC medical and genetic testing businesses. For example, Maryland's regulatory scheme enabled state regulators to prevent Ravens DNA Day and a mass invasion of genetic privacy in September 2017:

> The promotion would have allowed participants to learn about their genetic makeup by swabbing the inside of their cheek, dropping the sample into a stadium bin and registering with the company online. Orig3n was offering — for free — a test of four genes, including the ACTN3 gene, which the firm said can yield information on whether a person "is likely to have enhanced performance in power and sprint activities or is considered normal." […] But the promotion drew criticism over the mass collection of DNA samples raising privacy concerns.

http://www.baltimoresun.com/business/bs-bz-ravens-dna-rescheduled-20170917-story.html

Genetics professionals had raised privacy concerns about the DNA test giveaway, and warned the results could be of dubious value (emphasis added):

> In this instance, the four tests being offered by ORIG3N have very low predictive value for any individual since there are many factors that contribute to the likelihood of developing a problem. For example, a DNA test that tells someone they are at a modestly lower risk of vitamin D deficiency compared to other individuals does not replace the need for consideration of many other factors, including measurement of vitamin D levels (which, if low, require supplementation). Conversely, some testing may cause a false alarm regarding perceived high risk, when in reality the actual risk of a particular disease is still incredibly low. […] There is still much to learn about the human genome and the interpretation of genetic testing. This uncertainty is of special note when the results have a potential impact on health. For these reasons, DTC genetic testing interpreted without knowledge of family history and co-existing medical and environmental variables can be confusing, difficult to understand and inaccurate.[…]
> **Consumers should also have knowledge of where their DNA sample is being sent and how it will be used, even if it is a free test**."

http://www.baltimoresun.com/news/opinion/readersrespond/bs-ed-rr-ravens-20170920-story.html

Businesses are making a lot of money selling genetic information from samples solicited directly from consumers under circumstances that provide little or no clue about the value of what consumers are giving up, and the price that they and their family members may pay in the future. Businesses may claim they "deidentify" data, but researchers have shown that they can identify the people who provided the samples, as well as their genetic relatives.

Consumers require protection now more than ever because an increasing number of businesses are soliciting genetic samples directly from consumers and sharing or selling their genetic information, risking the genetic privacy of the consumer and their family members with whom they share identifying genetic information. The potential harms include being denied employment, life and long-term care insurance and loans.

For these and other reasons, we urge caution regarding this bill.

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