

# **Lab Testing at Pharmacies Bill.pdf**

Uploaded by: Cohen, Jonathan

Position: FAV

Maryland General Assembly  
Bill Nos. [SB 0706](#) & [HB 0810](#)

*Ordering & Administering  
Certain Laboratory Tests  
by Pharmacists*

February 2021



# Outline



- **What are clinical lab tests and why expand their access? Why now?**
- **Who can order clinical lab tests today? What types of tests can Md. pharmacists currently order?**
- **What role are pharmacies playing in the pandemic response?**
- **Key provisions of SB 0706 & HB 0810**
- **Safeguards and Patient Protections**
- **Who is supporting this legislation?**



# Comparing Lab Tests to Rapid Tests

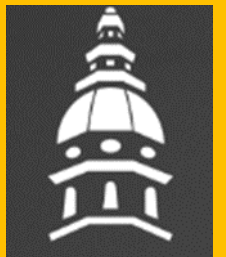
	Laboratory Tests	Rapid Tests
<i>Specimen Collection Location</i>	Clinic or Pharmacy	Clinic or Pharmacy
<i>Analysis Location</i>	Clinical Laboratory	Clinic or Pharmacy
<i>Accuracy / Sophistication</i>	High / High	Moderate / Low
<i>Time for Results</i>	~1 to 2 days	~10 minutes
<i>Regulation</i>	CLIA (CMS & States)	FDA
<i>No. of Marketed Test</i>	~100,000	~1,000
<i>Examples (Pandemic Related)</i>	Covid-19 Virus (PCR) Testing	Covid-19 Antibody & Antigen Testing



# Who Can Order Lab Tests in Maryland Today?

[Code of Maryland Regulations 10.10.06](#)

- Doctor of medicine, osteopathy, podiatric medicine, or dentistry (tests not limited to medical specialty)
- Nurse midwife
- Nurse practitioner or physician's assistant
- Chiropractor (blood or urine)
- Employer (job-related test for alcohol or controlled substances)
- **Pharmacist, but only for tests that qualify for a letter of exception under [COMAR 10.10.03.02B](#) and for glucose, A1c, lipids (including total cholesterol, HDL, LDL, and triglycerides), AST, and ALT (expanded in Spring 2020 to include Covid-19 tests)**



# Pharmacies Help Meet the Urgent Demand for Covid-19 Testing

GOVERNOR HOGAN ANNOUNCES  
**BROADENED CRITERIA  
FOR TESTING, DRAMATIC  
EXPANSION OF TESTING  
AVAILABILITY STATEWIDE**

- » Authorizes and encourages licensed pharmacists to order and administer COVID-19 tests
- » Appointment-free testing in Maryland begins Thursday and Friday at select sites; two new VEIP sites opening in Prince George's County
- » Marylanders can now get tested even if asymptomatic
- » Maryland has now tested 3.5% of state's population, far exceeding goals established by federal health officials



HHS Assistant Secretary for Health Brett P. Giroir, M.D. ("Coronavirus Testing Czar") issued the following statement on 4/8/20:

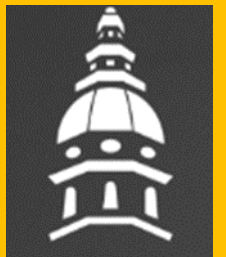
*"In an effort to expand testing capabilities, we are authorizing licensed pharmacists to order and administer COVID-19 tests to their patients. The accessibility and distribution of retail and independent community-based pharmacies make pharmacists the first point of contact with a healthcare professional for many Americans."*



# Why Expand Lab Testing at Pharmacies? Why now?



- Consumer demand for testing at pharmacies made clear throughout the pandemic
- Pharmacist deemed a trusted and know source for healthcare information by Marylanders
- Substantial innovation in laboratory developed tests occurred as a result of Covid-19
- An array of “long-haul” ailments predicted after coronavirus infections likely requiring novel tests and testing approaches
- Many routine screenings were missed during the pandemic creating need to catch-up to avoid late-stage diagnoses



# Key Provisions of SB 0706 & HB 0810

*[Click Link to Read Bill](#)*

- Pharmacists, at their option, can order and administer certain health screening tests
- Pharmacy technicians help patient collect specimens such as capillary blood, saliva, etc.
- Specimens sent to CLIA laboratory for analysis
- Results reported to pharmacy and patient
- Abnormal results forwarded to patient's primary care provider
- Geared mainly to self-pay tests (unless 3<sup>rd</sup> party payer expressly authorizes pharmacy orders)

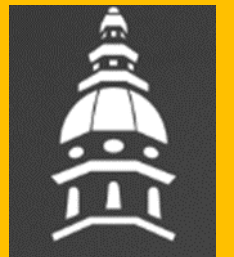




# Safeguards & Patient Protections



- Limited to health screening tests (not definitive diagnostics)
- Out of range test results to be reported to patient's PCP or medical specialist
- Limited to bodily specimens that can be safely collected at a pharmacy
- Three-year pilot with sunset provision pending Board of Pharmacy review and report

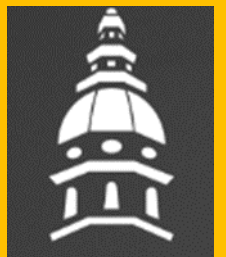
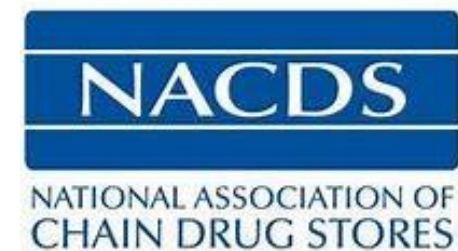


# Organizations Supporting this Legislation

As of 2/9/21



MARYLAND ASSOCIATION  
OF CHAIN DRUG STORES



# Contact for More Information

**Robert J. Garagiola**

Compass Government Relations Partners

**Phone** 443-343-7143 **Mobile** 301-801-9678

**Web** [www.CompassAdvocacy.com](http://www.CompassAdvocacy.com)

**Email** [RGaragiola@CompassAdvocacy.com](mailto:RGaragiola@CompassAdvocacy.com)

48 Maryland Ave. Suite 400, Annapolis, MD 21401



# **Feldman\_SB706\_Cancer Screening Tests and Cancer Di**

Uploaded by: Feldman, Brian

Position: FAV

# Letters

## RESEARCH LETTER

### Cancer Screening Tests and Cancer Diagnoses During the COVID-19 Pandemic

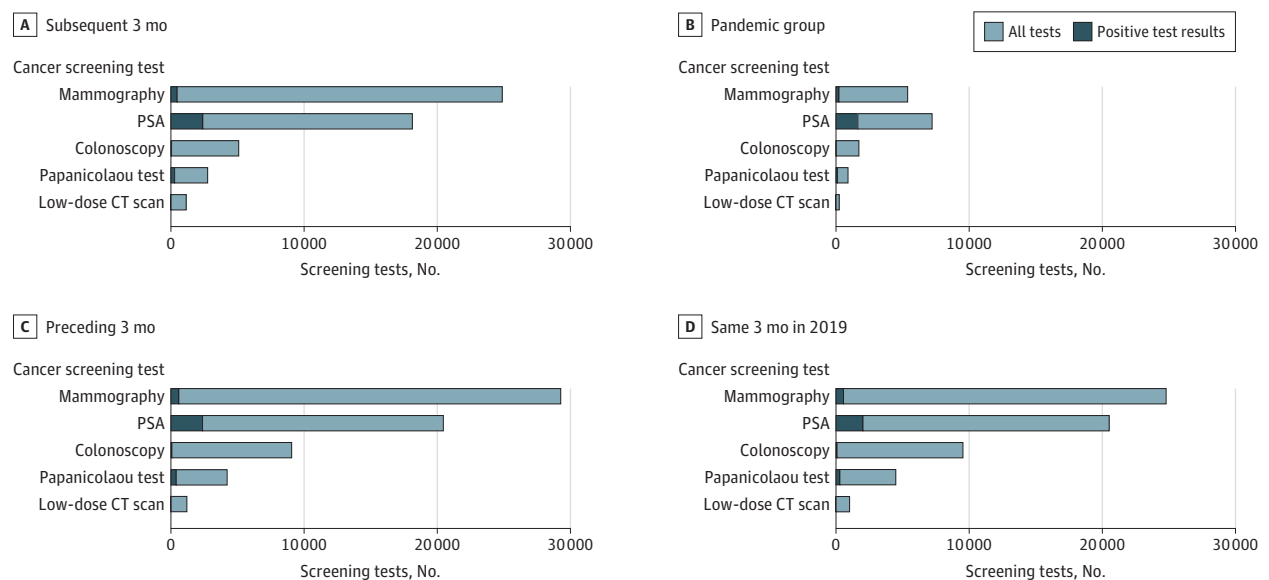
Oncology patient care may be disrupted secondary to coronavirus disease 2019 (COVID-19) through delays in diagnostic investigations and surgical procedures, as well as delayed cancer diagnoses because of reduced cancer screening. This study assesses the number of patients undergoing cancer screening tests and of ensuing cancer diagnoses during the COVID-19 pandemic in the largest health care system in the northeastern United States, Massachusetts General Brigham.

**Methods** | This study comprised four 3-month periods. One period, during the first peak of the pandemic in the New England area of the United States (from March 2 to June 2, 2020),<sup>1</sup> was compared with 3 control periods before and after the main study period (the preceding 3 months from December 1, 2019, to March 2, 2020; the same 3 months in the preceding year from March 2 to June 2, 2019; and the 3 months after the main study period from June 3 to September 3, 2020). The percentage decrease in screening tests and in diagnoses during the pandemic period compared with each of the control periods was computed as percentage decrease =  $(N_{\text{pandemic}} - N_{\text{control}}) / N_{\text{control}}$ . The 95% CIs were computed using the Clopper-

Pearson method using the DescTools package in R. All analyses were performed using R, version 3.6.1 (R Foundation for Statistical Computing) (eMethods in the Supplement). Ethical approval for the study was provided by Brigham and Women's Hospital prior to commencement of data analysis, including a waiver of the requirement for individual patient consent given the retrospective and noninterventional nature of the research.

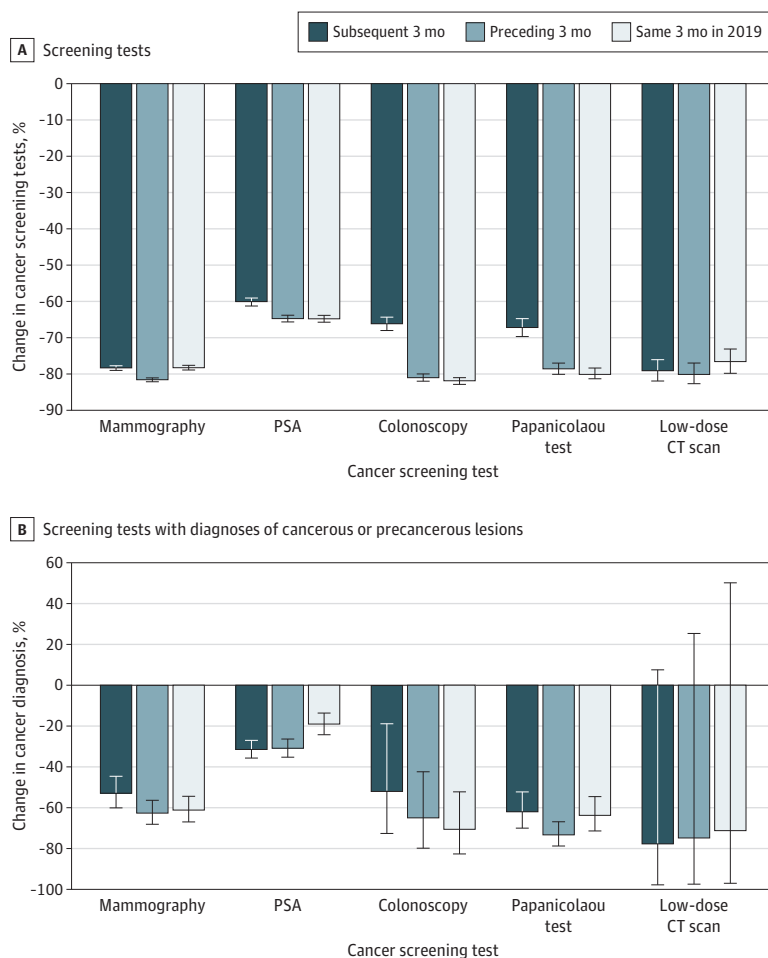
**Results** | A total of 192 060 patients underwent screening during the 4 screening periods. The overall mean (SD) age was 59.6 (12.2) years, 58.6% of all patients were female, and 80.1% were non-Hispanic White. Overall, 15 453 patients (with 1985 ensuing diagnoses) had undergone 1 of the 5 cancer screening examinations (low-dose computed tomography, Papanicolaou test, colonoscopy, prostate-specific antigen screening, or mammography) during the 3-month pandemic study period, compared with 51 944 patients (3190 diagnoses) during the subsequent 3 months, 64 269 patients (3423 diagnoses) in the preceding 3 months, and 60 344 patients (2961 diagnoses) during the same 3 months of the preceding year (2019). The decrease in screening tests was accompanied by decreases in ensuing diagnoses and was found across the 5 screening tests (Figure 1). The percentage of positivity of screening tests appeared to be higher during the primary pandemic period compared with the 3 control periods for mammographies (4.1% vs 1.9%-2.3%), prostate-specific antigen screenings (22.7% vs

Figure 1. Changes in the Numbers of Cancer Screening Tests and Ensuing Diagnoses



Changes in the numbers of cancer screening tests and ensuing diagnoses by cancer screening test and screening period during the primary pandemic study period compared with 3 control periods (subsequent 3 months, preceding 3 months, and same 3 months in the preceding year). CT indicates computed tomography; PSA, prostate-specific antigen.

Figure 2. Percentage Decreases in the Numbers of Screening Tests and Ensuing Diagnoses



Percentage decreases during the primary pandemic study period compared with 3 control periods (subsequent 3 months, preceding 3 months, and same 3 months in the preceding year) in the number of screening tests (A) and in the number of screening tests leading to diagnoses of cancerous or precancerous lesions (B). Error bars indicate 95% CIs. CT indicates computed tomography; PSA, prostate-specific antigen.

9.9%-13.2%), colonoscopies (1.3% vs 0.7%-0.9%), and Papanicolaou tests (11.6% vs 6.5%-10.0%), but not for low-dose computed tomography scans (0.8% vs 0.7%-0.8%). The percentage decreases in screening were pronounced across all screening tests, compared with all 3 control periods, and ranged from -60% to -82% (Figure 2A). The percentage decreases in diagnoses resulting from the cancer screening tests, compared with all 3 control periods, were also pronounced (-19% to -78%; Figure 2B). Assuming the same number of patients (64 269) would have otherwise been screened during the pandemic period as in the previous 3 months, approximately 1438 cancerous and precancerous lesion diagnoses (1985 vs 3423 diagnoses) were “missed” during the primary pandemic period.

**Discussion** | This study reports a significant decrease in the number of patients undergoing screening tests for cancer and in the number of ensuing diagnoses of cancerous and precancerous lesions during the COVID-19 pandemic in 1 health care system in the Northeastern United States. We found that, from June to September 2020, there was a significant recovery in the number of screening tests and ensuing diagnoses, to almost prepandemic levels. Moreover, we report that the num-

ber of potential “missed” diagnoses during the primary pandemic period were likely lower than would have been expected because the percentage of screening tests leading to a diagnosis of a cancerous or precancerous lesion was higher during the primary pandemic period, which may reflect the prioritization of high-risk patients for cancer screening during the pandemic. The limitations of this study include the incomplete capture of the population of Massachusetts and not accounting for patients who may have transitioned their screening procedures closer to home during the pandemic to a clinician not captured in the network.

Ziad Bakouny, MD, MSc  
 Marco Paciotti, MD  
 Andrew L. Schmidt, MD  
 Stuart R. Lipsitz, ScD  
 Toni K. Choueiri, MD  
 Quoc-Dien Trinh, MD

**Author Affiliations:** Lank Center for Genitourinary Oncology, Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, Massachusetts (Bakouny, Schmidt, Choueiri); Division of Urological Surgery, Brigham and Women's Hospital, Boston, Massachusetts (Paciotti, Trinh); Center for Surgery and Public Health, Brigham and Women's Hospital, Boston, Massachusetts

(Paciotti, Lipsitz, Trinh); Department of Urology, Humanitas Clinical and Research Center IRCCS, Rozzano, Italy (Paciotti).

**Accepted for Publication:** November 3, 2020.

**Published Online:** January 14, 2021. doi:[10.1001/jamaoncol.2020.7600](https://doi.org/10.1001/jamaoncol.2020.7600)

**Corresponding Authors:** Toni K. Choueiri, MD, Department of Medical Oncology, Dana-Farber Cancer Institute, 450 Brookline Ave, Boston, MA, 02215 ([toni\\_choueiri@dfci.harvard.edu](mailto:toni_choueiri@dfci.harvard.edu)); Quoc-Dien Trinh, MD, Center for Surgery and Public Health, Brigham and Women's Hospital, 75 Francis St, Boston, MA ([qtrinh@bwh.harvard.edu](mailto:qtrinh@bwh.harvard.edu)).

**Author Contributions:** Drs Bakouny and Paciotti had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Drs Bakouny, Paciotti and Schmidt are co-first authors. Drs Choueiri and Trinh are co-senior authors.

*Concept and design:* Bakouny, Schmidt, Lipsitz, Choueiri, Trinh.

*Acquisition, analysis, or interpretation of data:* All authors.

*Drafting of the manuscript:* Bakouny, Paciotti, Schmidt, Lipsitz.

*Critical revision of the manuscript for important intellectual content:* Bakouny, Schmidt, Lipsitz, Choueiri, Trinh.

*Statistical analysis:* Bakouny, Paciotti, Schmidt, Lipsitz.

*Obtained funding:* Choueiri.

*Administrative, technical, or material support:* Schmidt, Choueiri.

*Supervision:* Choueiri, Trinh.

**Conflict of Interest Disclosures:** Dr Bakouny reported receiving grants from Genentech/IMCore and nonfinancial support from Bristol Myers Squibb outside the submitted work. Dr Schmidt reported receiving nonfinancial support from Astellas and Pfizer outside the submitted work. Dr Choueiri reported receiving nonfinancial support from the COVID-19 and Cancer Consortium during the conduct of the study and personal fees from Pfizer, exelixis, Bristol Myers Squibb, Merck, Roche/Genentech, and Novartis related to kidney cancer for clinical trials, to being on advisory boards, to consultancy, and to manuscript support outside the submitted work. Dr Trinh reported receiving personal fees from Astellas, Bayer, and Janssen and grants from Intuitive Surgical outside the submitted work. No other disclosures were reported.

**Funding/Support:** Dr Trinh is supported by a Health Services Research pilot test grant from the Defense Health Agency and an unrestricted educational grant from the Vattikuti Urology Institute.

**Role of the Funder/Sponsor:** The funding sources had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

1. Mass.gov. Archive of COVID-19 cases in Massachusetts. Accessed October 25, 2020. <https://www.mass.gov/info-details/archive-of-covid-19-cases-in-massachusetts>

# **Feldman\_SB706\_Delay in Cancer Screening and Diagno**

Uploaded by: Feldman, Brian

Position: FAV



# Delay in Cancer Screening and Diagnosis During the COVID-19 Pandemic: What Is the Cost?

Julie M. Vose, MD, MBA  
Chief, Hematology/Oncology  
Neuman M. and Mildred E. Harris Professor  
University of Nebraska Medical Center  
Omaha, NE

**D**uring the height of the coronavirus disease 2019 (COVID-19) pandemic, many health care facilities needed to focus on screening for and treating patients with known or suspected COVID-19. This resulted in the diversion of health care workers and resources. As a result, standard cancer screening such as breast cancer screenings dropped by 89.2% and colorectal cancer screenings dropped by 84.5% through May 2020.<sup>1</sup> These pandemic control efforts translated into a significant decline in the number of new cancer diagnoses, resulting in a decrease of 65.2% incidence of new cancer diagnoses in April 2020.<sup>1</sup> In evaluating specific types of cancer diagnosis, patients with a new diagnosis of melanoma dropped 67.1% in April 2020 compared with 2019 and a diagnosis of a new lung cancer which dropped 46.8% over the same time.<sup>1</sup> This study and others have demonstrated an alarming decrease in the diagnosis of new cancers which will potentially increase the number of patients with later-stage cancers leading to decreased survival for these patients.<sup>2,3</sup> Using National Health Service (NHS) data on cancer diagnosis and hospital administrative datasets, the investigators' modeling study evaluated estimated changes in future death rates. Across different scenarios as compared with prepan-

demographic figures, the investigators estimated a 7.9% to 9.5% increase in deaths from breast cancer up to 5 years from diagnosis.<sup>3</sup> In addition, a 15.5% to 16.6% increase in colorectal cancer deaths and a 4.8% to 5.3% increase in lung cancer deaths were estimated.<sup>3</sup> In addition to health care facilities decreasing routine screening and nonurgent surgeries to increase capacity for patients with COVID-19 complications, patients themselves have in some cases expressed concern about visiting the health care facilities to do routine cancer screenings for fear of COVID-19 exposure. However with current strict measures in place at all health care facilities, this would be a very low risk procedure for the patient.

Prior to the COVID-19 pandemic, the US cancer statistics had continued to improve over the last few decades including a 25% drop in cancer mortality over the past 25 years.<sup>4</sup> However, with less cancer screening comes the potential for malignancies to be diagnosed at a later stage. This could translate into worse outcomes when patients are diagnosed later in the course of the disease making treatment more difficult and the cancer less able to be cured. We do need to encourage patients to continue their standard cancer screenings during these difficult times, so that the progress in cancer diagnosis, treatment,

and survival continues to improve over the next decades to come. As our nation slowly and safely opens up again, cancer screening and diagnosis needs to continue to play an important part in our standard healthcare measures. Without going back to pre-COVID screening numbers, our cancer diagnosis and mortality rates could revert to numbers seen many years ago without the benefit of our current technological advancements. Those of us in the oncology community should join forces with the primary care physicians and health care systems to enhance opportunities for cancer screening to reverse this concerning trend. ■

## REFERENCES

1. London JW, Fazio-Eynullayeva E, Palchuk MB, et al: Effects of the COVID-19 pandemic on cancer-related patient encounters. *JCO Clinical Cancer Inform*. 2020;4: 657-665. doi: 10.1200/CCI.20.0006
2. Epic Health Research Network: Preventive cancer screenings during COVID-19 pandemic. May 1, 2020. Accessed August 20, 2020. <https://www.ehm.org/wp-content/uploads/Preventive-Cancer-Screenings-during-COVID-19-Pandemic.pdf>
3. Maringe C, Spicer J, Morris M, et al: The impact of the COVID-19 pandemic on cancer deaths due to delays in diagnosis in England, UK: a national, population-based, modelling study. *Lancet Oncol*. 2020;21(8):1023-1034. doi:10.1016/S1470-2045(20)30388-0
4. Siegel RL, Miller KD, Jemal A: Cancer statistics, 2019. *CA Cancer J Clin*. 2019;69(1):7-34. doi:10.3322/caac.21551

# **Feldman\_SB706\_Slide Deck Lab Testing at Pharmacies**

Uploaded by: Feldman, Brian

Position: FAV

Maryland General Assembly  
Bill Nos. [SB 0706](#) & [HB 0810](#)

*Ordering & Administering  
Certain Laboratory Tests  
by Pharmacists*

February 2021



# Outline



- **What are clinical lab tests and why expand their access? Why now?**
- **Who can order clinical lab tests today? What types of tests can Md. pharmacists currently order?**
- **What role are pharmacies playing in the pandemic response?**
- **Key provisions of SB 0706 & HB 0810**
- **Safeguards and Patient Protections**
- **Who is supporting this legislation?**



# Comparing Lab Tests to Rapid Tests

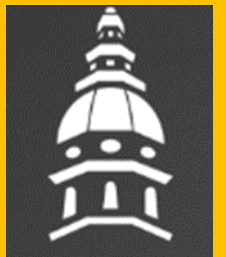
	Laboratory Tests	Rapid Tests
<i>Specimen Collection Location</i>	Clinic or Pharmacy	Clinic or Pharmacy
<i>Analysis Location</i>	Clinical Laboratory	Clinic or Pharmacy
<i>Accuracy / Sophistication</i>	High / High	Moderate / Low
<i>Time for Results</i>	~1 to 2 days	~10 minutes
<i>Regulation</i>	CLIA (CMS & States)	FDA
<i>No. of Marketed Test</i>	~100,000	~1,000
<i>Examples (Pandemic Related)</i>	Covid-19 Virus (PCR) Testing	Covid-19 Antibody & Antigen Testing



# Who Can Order Lab Tests in Maryland Today?

[Code of Maryland Regulations 10.10.06](#)

- Doctor of medicine, osteopathy, podiatric medicine, or dentistry (tests not limited to medical specialty)
- Nurse midwife
- Nurse practitioner or physician's assistant
- Chiropractor (blood or urine)
- Employer (job-related test for alcohol or controlled substances)
- **Pharmacist, but only for tests that qualify for a letter of exception under [COMAR 10.10.03.02B](#) and for glucose, A1c, lipids (including total cholesterol, HDL, LDL, and triglycerides), AST, and ALT (expanded in Spring 2020 to include Covid-19 tests)**



# Pharmacies Help Meet the Urgent Demand for Covid-19 Testing

GOVERNOR HOGAN ANNOUNCES  
**BROADENED CRITERIA  
FOR TESTING, DRAMATIC  
EXPANSION OF TESTING  
AVAILABILITY STATEWIDE**

- » Authorizes and encourages licensed pharmacists to order and administer COVID-19 tests
- » Appointment-free testing in Maryland begins Thursday and Friday at select sites; two new VEIP sites opening in Prince George's County
- » Marylanders can now get tested even if asymptomatic
- » Maryland has now tested 3.5% of state's population, far exceeding goals established by federal health officials



HHS Assistant Secretary for Health Brett P. Giroir, M.D. ("Coronavirus Testing Czar") issued the following statement on 4/8/20:

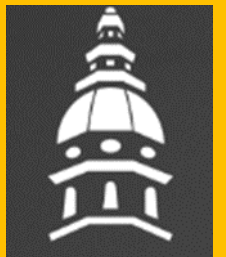
*"In an effort to expand testing capabilities, we are authorizing licensed pharmacists to order and administer COVID-19 tests to their patients. The accessibility and distribution of retail and independent community-based pharmacies make pharmacists the first point of contact with a healthcare professional for many Americans."*



# Why Expand Lab Testing at Pharmacies? Why now?



- Consumer demand for testing at pharmacies made clear throughout the pandemic
- Pharmacist deemed a trusted and know source for healthcare information by Marylanders
- Substantial innovation in laboratory developed tests occurred as a result of Covid-19
- An array of “long-haul” ailments predicted after coronavirus infections likely requiring novel tests and testing approaches
- Many routine screenings were missed during the pandemic creating need to catch-up to avoid late-stage diagnoses





# Key Provisions of SB 0706 & HB 0810

*[Click Link to Read Bill](#)*

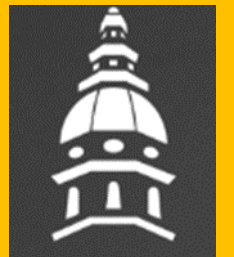
- Pharmacists, at their option, can order and administer certain health screening tests
- Pharmacy technicians help patient collect specimens such as capillary blood, saliva, etc.
- Specimens sent to CLIA laboratory for analysis
- Results reported to pharmacy and patient
- Abnormal results forwarded to patient's primary care provider
- Geared mainly to self-pay tests (unless 3<sup>rd</sup> party payer expressly authorizes pharmacy orders)



# Safeguards & Patient Protections



- Limited to health screening tests (not definitive diagnostics)
- Out of range test results to be reported to patient's PCP or medical specialist
- Limited to bodily specimens that can be safely collected at a pharmacy
- Three-year pilot with sunset provision pending Board of Pharmacy review and report

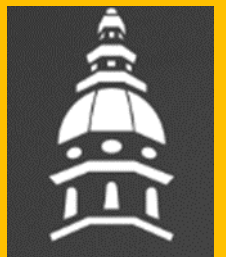
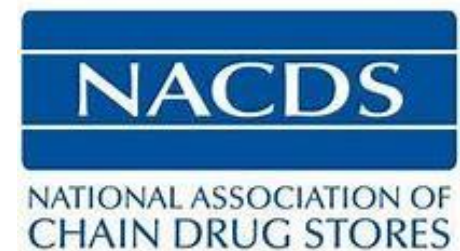


# Organizations Supporting this Legislation

As of 2/9/21



MARYLAND ASSOCIATION  
OF CHAIN DRUG STORES



# Contact for More Information

**Robert J. Garagiola**

Compass Government Relations Partners

**Phone** 443-343-7143 **Mobile** 301-801-9678

**Web** [www.CompassAdvocacy.com](http://www.CompassAdvocacy.com)

**Email** [RGaragiola@CompassAdvocacy.com](mailto:RGaragiola@CompassAdvocacy.com)

48 Maryland Ave. Suite 400, Annapolis, MD 21401



# **Feldman\_SB706\_US Cancer Diagnoses Fell by 50 Perce**

Uploaded by: Feldman, Brian

Position: FAV

## U.S. Cancer Diagnoses Fell by 50% in 2020 Amid the Pandemic, says NCI Director Sharpless

<https://www.managedhealthcareexecutive.com/view/u-s-cancer-diagnoses-fell-by-50-in-2020-amid-the-pandemic-says-nci-director-sharpless>

February 19, 2021

[Peter Wehrwein](#)

*NCI Director Norman Sharpless discussed deferred care, missed screening and his future at the institute in an interview with Managed Healthcare Executive.*

The number of new cancer diagnoses in the U.S. plummeted by 50% last year during the months after the onset of the COVID-19 pandemic, Norman Sharpless, M.D., director of the National Cancer Institute, said in an interview yesterday with *Managed Healthcare Executive*.

Sharpless said the steep drop-off occurred because of delayed care and decreased screening and that there is no reason that it reflects a true dip in cancer incidence. He noted that the decrease was similar for cancers detected through screening and those that are diagnosed clinically, often after people have symptoms.

“That delayed care that decreased diagnosis — we do believe will translate into excess mortality over the next decade,” said Sharpless, adding, though, that more effective treatment for late-stage cancers may delay any rise in cancer mortality. In the shorter term, Sharpless foresees many more patients getting diagnosed with later-stage cancers.

“Instead of being diagnosed, now, when they have symptoms, it’ll be six months or a year from now, when their symptoms become worse. So that will lead to diagnosis at a later stage and upstaging and presumably cancers that are difficult to treat and less likely to be cured. So that’s really the worry of this delay in detection,” said Sharpless in a wide-ranging interview with *MHE* Senior Editor Peter Wehrwein and Karen Appold, a regular contributor to the publication.

Sharpless said it was surprising how well telehealth had worked for some cancer patients but that it has limitations: “There’s still a lot of things you can’t really do by telehealth and there are patients who don’t have access to telehealth. We’ve seen evidence in certain underserved populations that their ability to see a doctor virtually is not as good.” Those limitations and people’s reluctance to go to the doctor to get evaluated when they have symptoms that might be related to cancer means “they are just sort of living with things that normally would have brought them to medical attention sooner,” said Sharpless.

Sharpless also said that more than 500,000 cancer screenings were “missed” in the U.S. in 2020. In response to a question, Sharpless said the decrease will present researchers an opportunity to study low-value cancer screening: “It is definitely true that screening finds both aggressive malignancies that you want to interdict on and treat, but it also finds indolent cancers that wouldn’t be clinically significant and just lead to overdiagnosis and overtreatment. That’s been a big problem with prostate cancer, that’s been a problem with breast cancer.”

“But to be clear,” he added, “we're seeing delayed diagnoses of cancers like pancreatic cancer and there's no really good version of that.”

Sharpless has been NCI director since 2017, and he said in the interview with *MHE* that he has told Biden administration officials he wants to continue in the job. He said the new administration is “clearly very interested in science” and mentioned that First Lady Jill Biden visited the institute virtually on World Cancer Day on Feb. 4. Sharpless said he worked “only modestly” with Biden on the Cancer Moonshot when Biden was vice president and he was the director of Lineberger Comprehensive Cancer Center at the University of North Carolina.

About the NCI post, Sharpless said, “Well, I'm here now. I think in this role one always serves at the pleasure of the president. And that's the great thing and the not-so-great thing about being a federal employee.” The new administration has asked him to stay over and lead the NCI through this transition, said Sharpless, who described the NCI directorship as “really one of the greatest jobs in government.” Here are some of the other topics Sharpless discussed during the interview:

- **Vaccination.** People with cancer should be vaccinated against COVID-19. “Even when you adjust for other comorbidities and age, cancer is a risk factor for a bad outcome,” Sharpless said. He said it appears that patients with hematologic malignancies may do worse than patients with solid tumors.
  - **Adjustment by caregivers.** “I have been really impressed by the way certain groups of caregivers have sort of Macgyvered this situation. They figured out ways to proceed with care, with testing, and isolating patients and having shifts of caregivers and using telehealth.”
  - **Delays in lung cancer screening.** Clinics catching up on missed screening are finding more patients with nodules and patients with nodules seem to have more advanced cancers, according to Sharpless: “That’s sort of the first sign in our statistics that the upstaging you would rationally predict is actually occurring.”
  - **Delays in clinical trials.** Trials with experimental therapies with “curative intent” were slowed down a bit, he said. Others that involved screening or subtle changes to the standard of care were “sharply disrupted.”
-

**2021 ACNM SB 706 Senate Side.pdf**

Uploaded by: Chitalia, Suhani

Position: UNF





**Committee:** Senate Education, Health, and Environmental Affairs Committee  
**Bill Number:** Senate Bill 706  
**Title:** Health Occupations – Pharmacy – Tests  
**Hearing Date:** March 2, 2021  
**Position:** Oppose

---

The Maryland Affiliate of the American College of Nurse Midwives (ACNM) opposes *Senate Bill 706 – Health Occupations – Pharmacy Tests*. This bill authorizes pharmacists to administer health awareness tests under protocols approved by the Board of Pharmacy.

While ACNM appreciates the sponsors intent to broaden access to certain health care tests, we are concerned about several unintended consequences from the bill language, specifically the safety and privacy of patients. The language, as written, encompasses any test that does not lead a definitive diagnosis. Many laboratory tests do not result in definitive diagnosis, and therefore, allow pharmacists the authority to order a broad range of tests, raising a number of patient safety concerns. For example, this bill could authorize pharmacists to order STI testing in urine. While an STI screening can be considered a “health awareness test”, there are a number of complexities and severe health concerns associated with these infections. STI’s can require immediate treatment, and even minor delay can pose risks to the patient. Because of the necessity for a quick diagnosis, these tests should be ordered and interpreted by health care providers who can diagnose, provide treatment, and refer to any appropriate specialists, such as family health centers, primary care providers, or women’s health centers, for follow-up.

ACNM is also concerned of the potential care fragmentation that may take place as a result of this bill. Health care tests, including laboratory tests are a critical part of a patient’s medical diagnosis and history. It is important for a provider to provide follow-up care based on test results. Following a test given by a pharmacist, a patient may not follow-up with their primary care provider. While the bill requires a referral from the pharmacist to the primary care provider, the bill does not provide for coordination of care. Further, the bill does not address

what happens when a patient does not have a primary care provider. This inefficiency may create risk to the patient because of gaps in care.

Thank you for your consideration of our testimony. We are committed to working with the sponsor and other stakeholders on the issues raised by this bill; but, due to the serious nature of our concerns, we ask for an unfavorable report at this time. If we can provide any further information, please contact Suhani Chitalia at [schitalia@policypartners.net](mailto:schitalia@policypartners.net) or (240)-506-9325.

**2021 MNA SB 706 Senate Side.pdf**

Uploaded by: Crain, Elaine

Position: UNF



## Oppose

### Senate Bill 706 – Health Occupations – Pharmacy - Tests

Senate Education, Health, and Environmental Affairs Committee

March 2, 2021

The Maryland Nurses Association opposes *Senate Bill 706 – Health Occupations – Pharmacy Tests*. The bill authorizes pharmacists to administer health awareness tests under protocols approved by the Board of Pharmacy.

MNA appreciates the sponsors intent to broaden access to certain health care tests. MNA's opposition is based on several unintended consequences from the bill language:

- **Consumer Safety:** The bill would authorize pharmacists to administer health awareness tests. The bill language provides several examples, i.e. metabolites, but the language would encompass any test that does not lead to a definitive diagnosis. Many laboratory tests do not result in a definitive diagnosis; and therefore we read this bill as authorizing pharmacists to order a broad range of tests; and thus raising a number of safety consumers. For example, this bill could authorize pharmacists to order leukocyte testing in urine. The presence of leucocytes can indicate several health conditions from urinary tract infections to bladder cancer. Any of these conditions require immediate treatment; and even minor delays pose risks to the patient. Therefore, we believe that tests should be ordered and interpreted by health care providers who can diagnose, provide treatment, and refer to any appropriate specialists for follow-up.
- **Genetic Testing:** The bill authorizes pharmacists to order genetic tests and then refer to a primary care provider if the results are not within the normal range. MNA notes that determining what is normal is complicated, and may be outside the scope of a pharmacist's education. For example, if someone gets a test for a genetic marker for ovarian cancer, the results must be interpreted in context of the patient's and family medical history, rather than just the test results themselves.
- **Creating Fragmentation in the Health Care System:** We believe that health care tests, including laboratory tests should be ordered by the practitioner who can also provide follow-up care. While the bill requires a referral from the pharmacist to the primary care provider, the bill does not provide for coordination of care; and the bill does not address what happens when a patient does not have a primary care provider. This means that many patients may be left to navigating multiple providers. This is inefficient; and in some circumstances, it could create risk to the patient because of gaps in care.

Thank you for your consideration of this testimony. We are committed to working with the sponsor and other stakeholders on the issue raised by this bill; but due to the serious nature of our concerns, we ask for an unfavorable report at this time. If we can provide any additional information, please contact Robyn Elliott at [relliott@policypartners.net](mailto:relliott@policypartners.net) or (443) 926-3443.

Maryland Nurses Association  
6 Park Center Court, Suite 212  
Owings Mills, MD 21117  
410-944-5800  
Web Site: [www.marylandrn.org](http://www.marylandrn.org)

**NPAM Letter to Oppose HB810.pdf**

Uploaded by: Lang, Beverly

Position: UNF



*“Advocating for NPs since 1992”*

February 24, 2021

Re: **HB 810/SB 0706 Health Occupations – Pharmacists – Laboratory Tests OPPOSED**

On behalf of the Nurse Practitioner Association of Maryland, Inc., (NPAM) the only professional association advocating solely for the over 7,100 certified Nurse Practitioners (NPs) licensed in Maryland, and the over 800 active members of NPAM, we are respectfully requesting you **OPPOSE HB 1810/SB 0706 Health Occupations – Pharmacists – Laboratory Tests.**

This bill would alter the definition of “practice pharmacy” to include the ordering and administering of laboratory tests for the purposes of early detection of disease, screening, and health awareness.

We are concerned that when patients are screened for early detection of disease, there is no follow-up with the Primary Care Provider (PCP). Typically, these types of laboratory tests are ordered at regular intervals during regular and routine appointments with the PCP, and are ordered based on the results of a thorough history and physical assessment obtained at each office visit and thoughtful analyses of the patient’s co-morbidities. Following the tests, the PCP reviews and analyzes the laboratory report, and bases suggested treatment on those results, in concert with the wishes of the patient.

Simply obtaining laboratory tests without examining a patient will lead to overutilization of healthcare resources, excess costs to the healthcare system, and, potentially, excess costs to the patient. Further, this practice would fragment the healthcare system. Additionally, interpretation of the laboratory results would be done by the Pharmacist without the knowledge of the patient’s past medical history and co-morbidities.

NPAM is hopeful you will **OPPOSE HB 810/SB 0706 Health Occupations – Pharmacists – Laboratory Tests.** Feel free to contact Beverly Lang, Executive Director, NPAM if you require additional information.

Kindest Regards,  
**Beverly Lang MScN, RN, ANP-BC, FAANP**  
Executive Director,  
Nurse Practitioner Association of Maryland Inc.  
443-367-0277 (Office)  
Fax: 410-772-7915  
NPAMexdir@npedu.com

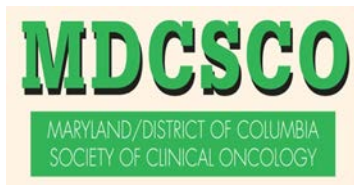
The Nurse Practitioner Association of Maryland, Inc.  
5372 Iron Pen Place Columbia, MD 21044  
Office: 443-367-0277 Fax: 410-772-7915  
[www.npamonline.org](http://www.npamonline.org) [NPAM@npedu.com](mailto:NPAM@npedu.com)

**SB0706\_UNF\_MedChi, MDCSCO, MACHC, MDACOG, MDAAP -**

Uploaded by: Wise, Steve

Position: UNF





MID-ATLANTIC  
ASSOCIATION OF  
COMMUNITY HEALTH  
CENTERS  
*Serving Maryland and  
Delaware*



TO: The Honorable Paul G. Pinsky, Chair  
Members, Senate Education, Health, and Environmental Affairs Committee  
The Honorable Brian Feldman

FROM: J. Steven Wise  
Pamela Metz Kasemeyer  
Danna L. Kauffman

DATE: March 2, 2021

RE: **OPPOSE** – Senate Bill 706 – *Health Occupations - Pharmacists - Laboratory Tests*

---

On behalf of the Maryland State Medical Society, the Maryland Chapter of the American Academy of Pediatrics, the Maryland Section of the American College of Obstetricians and Gynecologists, the Mid-Atlantic Association of Community Health Centers, and the Maryland/District of Columbia Society of Clinical Oncology, we submit this letter of opposition for Senate Bill 706.

Senate Bill 706 would require the Board of Pharmacy to adopt regulations authorizing any pharmacist to order and administer laboratory tests without any prescription from an authorized prescriber. The pharmacists would be broadly authorized to order tests related to “health awareness, including screening and early disease detection.”

The above organizations are very concerned about tests being ordered by pharmacists without basic information about the patient having first been obtained and considered by an appropriately trained provider. Normally, a patient will be asked by a provider for their patient history and an examination of the patient would occur. Based on that information, the provider will order needed tests to determine whether a patient suffers from a disease or may be at risk for a disease. This process helps ensure that only relevant and needed lab tests are pursued and avoids unnecessary lab tests and added health care costs for the patient. Senate Bill 706 removes this initial interaction between the patient and their primary care provider, and instead allows a pharmacist to order tests without requiring any apparent basis for doing so. A physician who orders lab tests with no basis is subject to discipline for overutilizing health care services and failing to adhere to the appropriate standard of care. See Md. Code Ann., Health Occ. §14-404(a).

In addition, the bill requires the pharmacist to provide test results to the patient’s primary care provider. This is a recognition that primary care providers have an important role in such testing. Our view is that this role should continue to be at the front of the testing process, not the end, since the provider may determine that the test is not needed to begin with. Furthermore, if the pharmacist is not the right person to be interpreting the results and recommending any necessary treatment, as the bill clearly recognizes, then we would suggest that the pharmacist is also not the appropriate person to be ordering the test in the first place.

For these reasons, the above organizations strongly oppose Senate Bill 706.

**For more information call:**

Pamela Metz Kasemeyer  
J. Steven Wise  
Danna L. Kauffman  
410-244-7000

**SB0706 Pharm Labs\_INF\_OAG HEAU.pdf**

Uploaded by: O'Connor, Patricia

Position: INFO

**BRIAN E. FROSH**  
*Attorney General*

**WILLIAM D. GRUHN**  
*Chief*  
Consumer Protection Division

**ELIZABETH F. HARRIS**  
*Chief Deputy Attorney General*

**CAROLYN QUATTROCKI**  
*Deputy Attorney General*

Writer's Direct Fax No.  
(410) 576-6571

Writer's Direct Email:  
pocannon@oag.state.md.us



**STATE OF MARYLAND**  
**OFFICE OF THE ATTORNEY GENERAL**  
**CONSUMER PROTECTION DIVISION**

Writer's Direct Dial No.  
(410) 576-6515

March 2, 2021

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

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](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.

cc: Sponsor