

SCHWARTZ, METZ & WISE, P.A.

ATTORNEYS

20 WEST STREET
ANNAPOLIS, MARYLAND 21401

TEL: 410-244-7000

FAX: 410-269-5443

TO: The Honorable Peter A. Hammen, Chair
Members, House Health & Government Operations Committee
The Honorable Neil Parrott

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

DATE: March 7, 2016

RE: **OPPOSE** – House Bill 1392 – *Medical Laboratories – Direct-to-Consumer Genetic Testing*

On behalf of MedChi, the Maryland State Medical Society (MedChi), the American Congress of Obstetricians and Gynecologists, Maryland Section (MDACOG), and the Maryland Chapter of the American Academy of Pediatrics (MDAAP), we oppose House Bill 1392.

House Bill 1392 would remove the current ban on medical laboratories advertising or soliciting business directly from patients. It would allow a certified Clinical Laboratory Improvement Amendments (CLIA) laboratory to perform genetic testing for an adult but would require that the laboratory advise consumers to talk with their provider or genetic counselor about the result of the test and explain that it may have an effect on the adults' ability to obtain life or long-term care insurance. It essentially authorizes "Direct to Consumer" genetic testing which is purported to increase consumer awareness of, and access to, testing.

The issues related to Direct to Consumer testing (DTC) can be complex and do not lend themselves to a simple "pro" or "con" response given the wide range of tests offered by DTC companies. To that end, in 2013, the Department of Health and Mental Hygiene published an issue paper on DTC testing that was included in a request for public comment. It provided a good review and raised a number of concerns regarding DTC testing that echoed the concerns of the above named organizations. These concerns include, but are not limited to:

1. Different risk predictions for the same individuals have been made depending on the methodology used by various labs.
2. Advertisements can be misleading and seem to promote false benefits of the testing.
3. There is a lack of regulatory oversight of the companies that develop and market the tests.
4. Patient privacy issues are present given that HIPPA protections do not apply and there are no requirements that assure protection of consumer information.

5. Testing for certain genes, such as BRCA and other high risk tests that have clinical significance, could lead to false reassurance for normal results or significant medical management decisions without the input of medical providers.
6. Testing in prenatal settings is of concern.

While initially raised in 2014, the above delineated concerns remain current concerns. The named organizations continue to have concerns with the validity of this testing. The results on risks of different diseases varies across tests performed by various laboratories. In short, the tests may produce false positives or false negatives, leading patients to wrongly conclude that they are not at risk or that they are at risk for certain conditions and diseases. And with some tests, a proper family history, if available, can be equally, if not more, predictive. In addition, the above named organizations are opposed to the use of DTC in prenatal settings such as those for sex selection, paternity and ancestry testing as well as for the evaluation of third parties. House Bill 1392 does not prohibit testing in prenatal settings.

The physician community remains concerned about the uncertainty of the test results and the impact they may have upon a patient's decision-making; the lack of involvement and guidance by a licensed health care provider prior to testing; and the failure to prohibit testing in prenatal settings where they are often used for sex selection, paternity and ancestry testing. These concerns are sufficient to request an unfavorable report on House Bill 1392.

For more information call:

Pamela Metz Kasemeyer

J. Steven Wise

Danna L. Kauffman

(410) 244-7000