ARUP LABORATORIES

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RE: Maryland Senate Bill 78 – "Protect Our Prostate Act" (MD SB78)

Dear Senator Ellis and members of the Maryland Senate,

I am providing this letter to express my concern that certain aspects of MD SB78 may not be logistically feasible for many clinical laboratories and could actually have unanticipated negative impacts on patient care. I request that you please consider making edits to the bill prior to advancing MD SB78 for further discussion.

As a brief introduction, I serve as Chief Medical Officer and Senior Director of Government Affairs at ARUP Laboratories, a non-profit enterprise of the University of Utah Department of Pathology. ARUP is the nation's largest non-profit clinical reference laboratory, with hospital customers in all 50 states, including Maryland. I am providing this letter in my government affairs capacity at ARUP Laboratories and as a practicing clinical pathologist with expertise in diagnostic testing modalities, including the screening for prostate specific antigen (PSA). My New York State Certificate of Qualification includes Clinical Chemistry testing, which includes the measurement of soluble tumor markers such as PSA.

I have three primary concerns with the proposed legislation, as currently drafted.

1. LOT NUMBER REPORTING REQUIREMENT

My first concern regards the requirement to report "lot number" (i.e., the lot of reagent material used for a particular test) to providers:

> *(4) "DOCUMENT AND DISCLOSE TO THE ORDERING PROVIDER THE TEST METHODOLOGY, MANUFACTURER, AND LOT NUMBER OF THE TESTING ASSAY USED"*

Clinical and Operational Concerns

A clinical laboratory information system (LIS), the computer system used to transmit laboratory data, is not typically configured for the reporting of reagent lot numbers. Reporting of lot numbers to providers is not a federal requirement under CLIA (the Clinical Laboratory Improvement Amendments of 1988) – the federal law that governs clinical laboratory testing across the country – and while documentation of lot

numbers in use are maintained and recorded in most laboratory settings, this is typically only contained within new lot validation paperwork and is not stored in conjunction with patient clinical results.

Reporting of PSA lot numbers to providers with results conceivably could only be conducted using one of two mechanisms: 1) as part of interpretive comments, or 2) as unique data elements typically used for laboratory results. **There are significant problems with using either mechanism for PSA reagent lot number reporting**.

First, interpretive comments for PSA test results are typically hard coded within the LIS and cannot be quickly and easily updated every time a new lot validation is completed and prior to the reagent being put into use (e.g., every few weeks to months, often with short notice based on reagent availability/delivery from manufacturers). For example, reagent changes may occur overnight or during weekends when IT resources may be limited or unavailable.

Second, and more clinically concerning to me as a laboratory director, **reporting lot numbers as discrete data elements could lead to significant patient harm, as clinicians may inadvertently mistake a lot number with an actual PSA result!** Such a "false positive" interpretation by a provider (easy to do, since discrete data elements are often charted in electronic health records in a manner that could easily make them appear to be test results), could erroneously lead to an unnecessary prostate biopsy. I believe this is counter to the intended goal of the legislation.

Fortunately, reporting lot numbers is generally *NOT* considered necessary for clinical laboratory reporting, as assay calibration already adjusts for lot-to-lot variability automatically. If an assay is appropriately calibrated to an international standard (e.g., WHO), the reagent lot used is generally of no clinical benefit to a provider. Reporting of lot numbers for calibrated PSA assays would therefore introduce patient risk with no actual patient benefit.

2. REQUIREMENT FOR FDA APPROVAL

I have additional concerns regarding the unintended impact of another requirement:

> *"(1) USE TESTING ASSAYS THAT HAVE BEEN APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION"*

Clinical and Operational Concerns

First, it is likely that most commercial PSA assays have FDA *clearance* through the 510k pathway, not FDA *approval* through the FDA premarket authorization (PMA pathway). The PMA pathway of FDA approval is typically only required of new, high-risk tests for which a predicate device is not already on the market. PSA assays, however, are well researched and well understood, with many predicate devices already available to compare to. At minimum, I would suggest editing the language to specific "HAVE BEEN CLEARED OR APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION" to remove this limitation.

Second, while most PSA tests are *already* FDA-cleared, there may be other innovative types of prostate cancer screening tests that may *include* PSA measurement, but in conjunction with other markers, algorithms, or calculations that have not necessarily been reviewed in their entirety by the FDA. These types of tests are considered to be laboratory developed tests (LDTs), and they are permissible federally under CLIA. I am concerned that, as written, the act may prohibit access to any such current or future innovative LDTs containing PSA to patients in the state of Maryland.

3. REQUIREMENT FOR WORLD HEALTH ORGANIZATION ASSAY CALIBRATION

I have one final comment regarding the calibration requirement:

> *"(2) IMPLEMENT CALIBRATION OF PROSTATE–SPECIFIC ANTIGEN TEST ASSAYS USING WORLD HEALTH ORGANIZATION INTERNATIONAL STANDARDS OR ANOTHER NATIONALLY RECOGNIZED REFERENCE STANDARD;"*

Clinical and Operational Concerns

Requiring World Health Organization assay calibration (e.g., versus traditional Hybritech calibration) would require revalidations for many PSA and PSA-containing assays in clinical laboratories. Adoption of new calibrations takes time, resources, and frequently "patient re-baselining" to ensure that any switch in calibration is not misinterpreted by clinicians as a change in disease state. Additionally, clinicians need to be educated in new interpretive cutoff values that vary based on calibration of the assay used in their institution. While I am in favor of WHO / international standard calibrations, if this bill is advanced clinical laboratories will need sufficient time prior to enforcement to ensure that revalidation activities (and corresponding educational efforts to inform clinicians about changes in patient results due to new calibrations) are completed in a thorough and appropriate manner. I would suggest that a delayed enactment date (i.e., 12 months) would be sufficient time to complete such activities.

CONCLUSIONS

Given the above concerns, I oppose the bill as written and ask that the Senate remove the requirement for reporting lot number and remove the limitation regarding FDA approval from the proposed legislation. Additionally, I request that a delay in enforcement date be added for the reasons outlined above.

Thank you for your consideration, and please let me know if I can provide any additional information.

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