ARIZONA SOCIETY OF PATHOLOGISTS

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February 8, 2021

(Via email sbolick@azleg.gov)

Representative Shawnna Bolick
Arizona House of Representatives
1700 West Washington. Room 302
Phoenix, AZ 85007

Re: Oppose House Bill 2812

Representative Bolick:

The Arizona Society of Pathologists (ASP), representing pathologists who practice in Arizona at hospitals, independent clinical laboratories, academic medical centers and cancer treatment facilities, is writing to request House Bill (HB) 2812 not move forward in the legislative process. As physicians with both ethical and legal obligations to our patients, we are respectfully making this request in order to protect our patients from the unintended adverse medical consequences of this legislation, which we will explain in detail below.

The retention of patient specimens cannot be waived or attenuated under state law. The retained use of patient specimens is fundamental to providing accurate diagnosis and care of the patient. Recognizing this fact, federal law, the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C § 263a) ("CLIA"), and federal regulations (42 CFR § 493.1105) contemplate and stipulate periods, for as long as ten years, to retain certain tissue specimens. Federal law in this area preempts and supersedes any state law that is not as stringent as federal law.

In addition, national clinical laboratory accrediting bodies, such as the College of American Pathologists (CAP) (see attached) have certain specimen retention requirements that exceed standards established under federal law. The purpose of national regulations and accrediting body standards in this area is to ensure the optimal, high quality medical diagnosis and treatment for the patient. It is also to ensure an evidentiary record should the accuracy of an initial diagnosis be subject to litigation.

One of the important clinical reasons to retain tissue specimens is to not only provide a medical record of what was examined, but also to allow for secondary or retrospective review of a patent specimen should advances in medical or diagnostic science enhance the initial diagnosis, prognosis, or treatment of a patient. As I am sure you are aware, breakthrough therapies in medical science are providing new insights each year, especially in cancer diagnosis and treatment.

Patient's lives are being saved because by retaining specimens we have the ability to identify genetic biomarkers that were previously not identified nor considered significant or even identifiable at the time a specimen was taken. Furthermore, the progression of a disease in a patient, as evidenced by the chronology of a specimen, constitutes an important part of the clinical record in the care of a patient and cannot be replicated if patient specimens are destroyed. We cannot ethically undertake actions that would jeopardize the health or safety of our patients.

In sum, for all these many legal, scientific and clinical reasons, we strongly urge that this legislation not be considered. Thank you for considering this information.

Sincerely,

Richard N. Eisen

Richard Eisen, MD, FCAP
President

cc: Jon Amores, Arizona State Medical Association
Barry R. Ziman, College of American Pathologists