



October 21, 2014

Howard A. Zucker, MD, JD  
Commissioner of Health  
State of New York, Department of Health  
Corning Tower Empire State Plaza  
Albany, New York 12237

Dear Commissioner Zucker:

I am writing in response to your correspondence of May 6, 2014, in which you communicated that the New York Department of Health declined the request of the College of American Pathologists (CAP) and the New York State Society of Pathologists (NYSSPATH) to rescind a state regulation (10 NYCRR § 34-2.11(b)(1)(v)) that prohibits pathologist-patient conferral on the interpretation of laboratory/pathology test results. However, in that same correspondence you requested information on "models for this interdisciplinary approach to health care that involve pathologists."

In response to your request, and in reiteration of our initial request for rescission of the regulation referenced above, I am submitting several documents for your review. These documents underscore and validate the grossly improper application of the regulation in restriction of the pathologist scope of medical practice in counseling patients on the meaning or interpretation of tests results. Moreover, the Department of Health's posture that this prohibition be maintained is especially questionable given recent implementation of federal regulations that have invalidated New York's restriction on clinical laboratory provision of test results to patients upon their request.

As stated in our initial correspondence of February 11, 2014: "this regulation in New York, that denies patient consultation with their diagnosing pathologist, appears to be unique among the states, as we know of no other regulation or law in the nation that establishes such a fundamental and substantial legal impediment to physician pathologists in their practice of medicine as it relates to patient conferral."

Moreover, of related concern, regarding how patients are counseled on test results, 2008 published literature on reporting of molecular genetic tests to patients found in an October 2005 survey of OBGYN physician practices in New York City that "secretaries" in 86% of cases "communicate results" to patients and in 59% of cases "review results" with patients.<sup>1</sup>

In conspicuous contrast to these findings, the College strongly believes that pathologists, as physicians, are, without question, medically trained and have requisite knowledge to advise their patients on the meaning or interpretation of pathology and laboratory tests. As was extensively documented in our prior correspondence, pathologists in New York are legally and ethically obligated to ensure their patients receive the information they need to understand their tests results.

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<sup>1</sup> Lubin, et al, Ordering Molecular Genetic Tests and Reporting Results: Practices in Laboratory and Clinical Settings, Journal of Molecular Diagnostics, Vol 10, No5, September 2008, page 464.

## College of American Pathologists

The attached documents validate both the compelling medical benefit and clinical need for pathologist-patient conferrals. Also attached herein, we have included a "**Medical Consensus Statement**" of over **108 physicians in New York from 40 hospitals, laboratories, and medical academic institutions**, located throughout the state. Please note these 108 New York physicians have affixed their signature to this document to make clear their strong personal conviction and support for the clinical position enunciated in the document.

In addition, we are enclosing the following articles:

- Fiscella, J. Introducing Patients to Their Pathology Reports, CAP Today, January 2014.
- Epstein, JI. Letter to the Editor, The FAQ Initiative Explaining Pathology Reports to Patients. Modern Pathology (2010) 23, 1298-1300
- Gutmann, EJ. Pathologists and Patients: Can We Talk? Mod Pathol.2003 16(5):515-518
- Strobel, T. The Surgical Pathology Report as an Educational Tool for Cancer Patients, Annals of Clinical & Laboratory Science, Vol. 32, No.4, 2002

Because of the fundamental challenge this regulation poses to the appropriate practice of pathology medicine in New York, we are requesting a meeting to review our concerns should the Department maintain the position in support of the prohibition, as communicated to us in May 2014. We look forward to hearing from you. Thank you for your courtesies and consideration of these materials.

Sincerely,



Gene Herbek, MD, FCAP  
President

cc: Michael P. Ryan, Director, Division of Laboratory Quality, NYS Health Dept  
Rana Samuel, MD, President, New York State Society of Pathologists  
Barry R. Ziman, CAP Director, Legislation and Political Action