

New York State Bar Association

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Ronald F. Kennedy, *Director • Department of Governmental Relations • (FAX) 518/487-5579*

April 3, 2018

Stephanie Schulman, Ph.D., Director CLEP
New York State Department of Health
Wadsworth Center
P.O. Box 509, Empire State Plaza
Albany, NY 12201-0509

Re: Proposed Rule by the NYSBA Health Law Section

Dear Dr. Schulman,

The enclosed proposal, approved by the Association's Executive Committee on January 25, 2018, was developed by the Association's Health Law Section (the "Section"). More specifically, it was developed by the Section's Committee on Medical Research and Biotechnology chaired by Sam Servello and Alex Brownstein.

The New York State Department of Health ("DOH") is respectfully urged to consider promulgating the enclosed proposed rule.

The proposed rule would revise: *10 NYCRR 58.1.8: Results of tests to be reported only to physicians or other authorized persons*. This proposal would revise New York State regulations to allow research laboratories to disclose research findings that arise in an Institutional Review Board (IRB) approved study, and that may be clinically significant, to the health care provider designated by the study subject.

In preparing this proposal, input was invited from the members of our Section who are knowledgeable about issues which may arise upon its implementation. Concerns have been raised regarding a health care providers' ability to interpret research results and how information would flow between researchers, physicians and laboratories. Although treating providers are responsible for ordering tests for their patients, a Medical Doctor-Pathologist may be better trained to assess whether research data warrants clinical testing and whether an appropriate test is available. The development of guidance for stakeholders has been suggested by a number of our Section members. We believe these and other issues can be addressed while the DOH is processing its consideration of this proposal.

We welcome any questions you have as you consider this proposal.

Sincerely,

Ronald F. Kennedy

Enclosure: 1

CC: Mike Ryan, Ph.D., Director, Division of Laboratory Quality Certification
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