



National Institutes of Health  
National Heart, Lung, and  
Blood Institute  
Bethesda, Maryland 20892

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Ms. Danielle Brian  
Executive Director  
Ned Feder, M.D.  
Staff Scientist  
Project on Government Oversight  
1100 G Street, N.W.  
Washington, D.C. 20005

Dear Ms. Brian and Dr. Feder:

Please accept my apology for the delay in responding to your letter suggesting a study of the use of statins to prevent influenza deaths. We are aware of retrospective, observational studies as well as basic mechanistic research in cells and animals suggesting the potential importance of statins in treating lung injury. The Acute Respiratory Distress Syndrome Clinical Trials Network (ARDSnet), a clinical research network supported by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH), has recently begun (April 2010) a randomized controlled treatment trial of statins for patients with established infection-related acute lung injury. This clinical trial will study a subset of the target population of that planned for "STIP: Statin Trial for Influenza Patients" that you noted in your letter. The ARDSnet trial will answer the specific question whether statins are efficacious in treating infection-related acute lung injury. The ARDSnet protocol has already obtained all necessary peer and safety reviews and approvals, and is ready to start.

As the ARDSnet trial and STIP are different studies addressing related questions, they could ultimately be complementary. However, to bring STIP up to scale, it would have required creation of a large new infrastructure, and it would need to undergo a review similar to ARDSnet to ensure patient safety and scientific validity. This would have likely substantially delayed the trial. In addition, the speed with which STIP could have been conducted depended on the rate of hospital admissions for flu-like illness. These points made it difficult to have implemented STIP in a timely manner. It may be of interest to note that the first version of the ARDSnet study submitted for peer review included the broad entry criteria very similar if not identical to those of the STIP trial. The reviewers thought that specifying the entry criteria to infection-related acute lung injury increased the likelihood of demonstrating statin benefit, if present. Taken together, NIH believes that the study being performed by the ARDSnet is an appropriate first step.

In addition, the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention, and the Food and Drug Administration have worked closely with the NHLBI ARDSnet to conduct a surveillance study that will inform the critical care community about the nature, time course, and incidence of the flu in critically ill hospitalized patients. ARDSnet is uniquely suited to conduct a high quality study of this nature and took advantage of their established partnership with a pediatric critical care network, Pediatric Acute Lung Injury Sepsis Investigators (PALISI) to implement this study. Complete detailed information was obtained on approximately 1600 adult and pediatric patients in approximately 90 intensive care

Page 2 – Ms. Danielle Brian and Ned Feder, M.D.

units across the United States. This information may be key in understanding the characteristics of the disease and to accurately estimate clinical resource utilization and needs. Also, these data will be crucial in helping clinicians optimize care for H1N1-associated critical illness. This study is recently completed and initial results were presented at the American Thoracic Society meeting and will be submitted for publication.

We believe the research efforts described above take advantage of the strengths of the organizations that are in place to facilitate rapid implementation of important projects related to an H1N1 pandemic.

Please let me know if you have additional questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan B. Shurin". The signature is fluid and cursive, with a large initial "S" and "B".

Susan B. Shurin, M.D.  
Acting Director