

July 10, 2000

Chairman Joe Skeen  
House Subcommittee on Agriculture  
2362 Rayburn House Office Building  
Washington, D.C. 20515-6016

**RE: Proposed Amendments No. 67 and 68 to H.R. 4461, the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2001**

Dear Chairman Skeen:

I am writing on behalf of the Infectious Diseases Society of America (IDSA) to urge you and your Subcommittee to reject Amendments No. 67 and 68 to H.R. 4461, the "Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2001." IDSA is a medical society representing more than 5,500 physicians and scientists devoted to patient care, education, research, and community health planning in the area of infectious diseases. As such, we are extremely concerned about the safety and effectiveness of the vaccines given to our nation's children and adults as well as the manner in which the federal government oversees our nation's vaccine infrastructure.

The two amendments offered by Representative Dan Burton state that the relevant HHS agencies, including the Food and Drug Administration, which have oversight of certain federal vaccine related advisory committees, not use any of the monies appropriated under H.R. 4461 to fund such committees, if that agency grants a waiver on applicable conflicts of interest rules pursuant to the Federal Advisory Committee Act (FACA).

From his actions it is obvious that Representative Burton has concerns about whether these advisory committees are being operated well within the restraints of FACA. IDSA supports the FACA's intent that decisions made by federal advisory committees be made with public involvement in the process, that such decisions be free of unscrupulous bias and that any apparent conflicts of interest be brought to light. IDSA also supports Congress and Chairman Burton's oversight into the Federal Advisory Committee process to ensure consistency with FACA. However, we are concerned about the "fix" being proposed, because it is not at all obvious that anything is broken in the current process.

In order to assure that conflicts of interest do not adversely impact on committee decision-making, each of the relevant agencies has the ability under FACA to restrict members from voting on matters where the appearance of a conflict would have the effect of undermining what's best for the nation. In allowing agencies to waive FACA rules in certain instances, Congress recognized that these agencies also occasionally will need some flexibility to permit informed scientific debate to take place even when the appearance of a conflict has been disclosed. Mr. Burton's amendments will undermine Congress' chosen process.

Taken to their logical conclusion, these amendments will either dismantle the federal government's vaccine related expert advisory committees by stopping their funding or will fill the slots that this amendment will make vacant with people who may be less familiar with the many and diverse aspects of the science of immunization.

The federal government's vaccine advisory committees, as currently constituted, have consistently recruited the country's top immunization scientists for their advise an a wide range of immunization policies -- from vaccine licensure to recommendations on immunization schedules and doses. Appointment to these committees has been based on a consistent track record of excellence and expertise in a wide range of fields relevant to vaccine research: microbiology, molecular biology, immunology, clinical research, epidemiology and statistics, to name only a few.

The federal government, and more importantly, the nation's citizenry, have been well served by recruiting the best scientists in the country. These committees have overseen the control and near elimination of the majority of vaccine preventable diseases of children. The impact that vaccines have made on the health and well-being of the public is without question the greatest triumph in public health in the past century. At a time when investments in understanding the molecular basis of modern medicine--in particular genetics and immunology--now allow for a new generation of tools to treat and prevent an expanded range of diseases, we will need even greater scientific, clinical and methodological expertise on our federal committees, not less.

Let us not forget that these outside expert committees serve to inform, not make, federal vaccine policy. Without their input and the public-private collaboration that they represent, there would be even greater power afforded to the government's own policy makers with less input from others.

Sincerely,

Catherine M. Wilfert, M.D.  
President