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February 26, 2010

Committee on Public Health  
State of Connecticut General Assembly  
Legislative Office Building, Room 3000  
Hartford, CT 06106

Dear Members:

I am writing this letter on behalf of the Connecticut Rheumatology Association, which represents approximately 50 of the academic and clinical rheumatologists in our state. The letter expresses our concern regarding Senate Bill No. 270, "An Act Concerning the Establishment of a Regional Policy on the Prohibition of Certain Gifts from Pharmaceutical and Medical Device Manufacturing Companies to Health Care Providers."

I have some concerns about the expansion of restrictions from the agreed upon PhRMA guidelines that have been adhered to on a national level by almost all pharmaceutical companies and physicians. There are certain specific details in this bill that I would like to point out that I think are inappropriate restrictions.

I do feel that there is no data to support that reduction of these biopharmaceutical industry interactions with physicians is a cost-saving measure.

The exemption of payments for clinical trials reported to [clinicaltrials.gov](http://clinicaltrials.gov) does not exempt preclinical and phase I research, which are not reported to the website. Cooperative research with companies for clinical trials would be impacted because many providers would not want to be submitted to the scrutiny that accompanies disclosure of information, especially when labeled as a gift. Clinical research is not a gift, and payments for clinical researchers for services rendered such as a physician's office visits to establish patients that are currently paid for by either commercial or Medicare or Medicaid-type insurance plans. Similarly to services rendered for physician care, clinical research studies require a great deal of expenditures, both the space and staff personnel. The implication that revenues generated by performance of clinical research trials represents a PhRMA gift is erroneous and misleading and would lead to both diminished participation on behalf of patients and physicians in research trials.

SB 270 allows only modest meals in the provider's office. This goes beyond the PhRMA code on interactions with healthcare providers because meals in non-marketing settings provided by pharmaceutical companies are not allowed; example: Training sessions, no dinner presentations, and no research meetings or job interviews over a meal.

Many academic presentations are on new therapies, both from the viewpoint of efficacy and safety data, and are presented to physicians outside of the office and not necessarily in a CME meeting. I think this is not a cost-effective measure and would only serve to not enable physicians to learn about new therapies that might be helpful to their patient. Personally, I have learned many things about new therapies from PhRMA-sponsored presentations performed by licensed physicians or other providers. Some of these have occurred at lunchtime in the office, and some of these have occurred over a dinner outside the office where the time availability is greater than a short office presentation. This prohibition is inappropriate and implies that our prescribing habits are totally influenced by the size of the meal that we are given.

This bill could prevent companies from providing research grants to physicians. Conducting an investigator-sponsored clinical trial would arguably not constitute consideration for a research grant and thus the grant would be unlawful. This could prevent physicians in Connecticut from conducting small clinical initial studies that improve medical care and practice for patients.

The disclosure and publication requirement would make Connecticut a less than desirable place to host clinical trials and other consultant-driven research as affiliated practitioners may not be comfortable having their names and compensation published on the state's web site for other interactions with pharmaceutical companies. This could decrease the number of clinical trials available to patients in Connecticut. Patients who participate in clinical trials gain access to new therapies and for many patients that are underinsured or do not have insurance, it provides access to medical care.

Of major concern to myself and my colleagues is the fact that there is a national PhRMA guideline that has been adhered to both by physicians and by the PhRMA industry that prohibits many of the things you point out in this proposed bill. I am not sure what the motivation is to expand this guideline beyond what was approved by both the AMA and PhRMA industry that I think has been sufficient to eliminate gifts of substance. I fear that the further restrictions will have untoward consequences that will affect physician education, dissemination of information to physicians regarding new therapies, and lastly, the impact on clinical research studies as pointed out previously in this letter.

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Thank you for your consideration.

Very truly yours,

A handwritten signature in black ink, appearing to read "K. Miller". The signature is fluid and cursive, with a large loop at the end.

Kenneth A. Miller, M.D.  
Vice President  
Connecticut Rheumatology Association

KAM:rgy