299

TESTIMONY OF DR. JOHN BOOSS
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Good Morning Sen. Crisco, Rep. Fontana and members of the Insurance and Real Estate Committee. My name is Dr. John Booss and I reside in Bethany Connecticut. In 2005 I retired as the National Director of Neurology for the Department of Veteran's Affairs. I remain on the staff of the VA Medical Center in West Haven in an unpaid capacity and am Professor Emeritus at the School of Medicine at Yale University. I am on the Legislative Affairs Committee of the American Academy of Neurology, the Government Relations Committee of the CT Chapter of the National Multiple Sclerosis Society, serve as a volunteer Neurologist at the Hill Health Center in New Haven and also serve as a volunteer Neurologist at the Nathan Smith Clinic [for persons with HIV] at the Yale New Haven Hospital.

I want to offer my support for S. B. No. 299 AN ACT EXPANDING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS

I have been involved in numerous clinical trials throughout my career, and I understand that patients need to be sure that their participation in a clinical trial will not threaten the health insurance coverage that they have without participation in the trial.

The need to find new and better treatment options for many devastating and chronic illnesses seems an obvious one, and it is clear that clinical trials are an important part of this process. Coordinating third party payer coverage for routine patient care costs in clinical trials is a sensible step. This issue determines which diseases will be the subjects of clinical trials and the willingness of patients to enter clinical trials (by alleviating fear that they will be left with costs that they would not have to pay in standard treatment). While this coverage would be good policy for all clinical trials, it is crucial in clinical trials for less common diseases because if insurers deny coverage for these costs in that setting, no sponsor will undertake the research. There is evidence that routine patient care costs for clinical trial patients is roughly equivalent to routine patient care costs for patients in standard treatment.[1]

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[1]Bennet *et al.*, *Evaluating the Financial Impact of Clinical Trials in Oncology: Results from a Pilot Study From the Association of American Cancer Institutes/Northwestern University Clinical Trials Costs and Charges Project*, 18 J. OF CLINICAL ONCOLOGY 15, 2805-10 (2000).
[1]*Id.*

The insurance companies are not being asked to pay for other than standard of care services -- they are not being asked to pay for any of the costs of the clinical trials themselves. The precedent has been set and widely accepted in clinical trials to treat cancer.

As the rules stand now, only pharmaceutical companies can afford the costs (with the exception of very few government sponsored trials). Pharmaceutical companies are not going to bear these costs unless there will be enough sales of the drug after approval to make it worthwhile. One cause of high study costs is the need to find research funding for activities that would normally be standard of care. If third party payers sustained their responsibility for those aspects of the study that were within standard of care, then funds could be raised for more research to pay for new medicines, or procedures required only by the study protocol.

The position that cancer trials have obtained has greatly facilitated research in those diseases. Very common diseases are also generally adequately covered. But many diseases are relatively uncommon and not of interest to the large pharmaceutical companies. Patients with these diseases would benefit tremendously if the same rules that exist in many states for cancer applied to all serious diseases. Some states have in fact required coverage beyond cancer to all serious or life-threatening diseases. Now we in Connecticut should expand on the work that oncology advocates have done and move this coverage beyond cancer.

Much research needs to be done and much of it will be physician initiated research; patients with uncommon diseases (that are not the subject of sufficient research because discovering treatment will not produce sufficient profits for the drug companies) should also benefit from sustained insurance coverage of routine patient care costs. The wording of the legislation should be careful not to shift costs that are rightfully borne by the trial sponsor to others. Having said this, it would be useful to allow for well controlled and supervised studies on drugs used off label in so-called orphan diseases

Federal action on this issue would be most desirable; a national standard would provide one consistent definition of the terms such as routine patient care and prevent the need to wage the same battle in all 50 states. Medicare in fact does in fact cover routine medical care costs in all types of trials,

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[1]Bruce H. Firemen, et al., *Cost of Care for Patients in Cancer Clinical Trials*, 92 J. THE NAT'L CANCER INST. 7, (2000.).

[1]Wagner, et al., *Incremental Costs of Enrolling Cancer Patients in Clinical Trials: A Population Based Study*, 91 JNCI 10, 847-53 (1999).

[1]Goldman et. al, *Incremental Treatment Costs in National Cancer Institute-Sponsored Clinical Trials*, 289 J. OF THE AM. MED. ASSOC. 22, 2970-77 (June 11, 2003). Note that the date used in this study was compiled before Medicare began paying routine patient care costs in clinical trials.

not just those for victims of cancer. This issue would have been addressed in an exemplary manner in the patients' bill of rights legislation[2], but Congress never acted on that bill. It may be that unless this issue is addressed in a separate bill in Congress, a state by state initiative is the only immediate option.

Sustained coverage is sensible, just, and would create good public policy. It is important that patient protection remain the top priority in Connecticut in what could be an increased number of trials. It is important that all the citizens of Connecticut have access to clinical trials relevant to their disease, that they not be denied access because of the fear that their insurance coverage will be abrogated.

Thank you for this opportunity to express my views as a citizen of Connecticut. I have spent my career working with patients with illnesses that would benefit from the advances from clinical trials. I urge you to pass legislation that will encourage clinical trials in all types of illnesses by assuring responsible insurance coverage of standard medical costs.

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[2] S. 1012 Sec. 119 (109th Congress); H.R. 2259 Sec. 119; and H.R. 2650 Sec. 119