



Quality is Our Bottom Line

**Insurance Committee Public Hearing
Thursday, February 3, 2011**

**Connecticut Association of Health Plans
Testimony in opposition to**

SB 21 AAC Health Insurance Coverage for Routine Patient Care Costs for Clinical Trial Patients

The Connecticut Association of Health Plans is very proud of the work we've done previously with the American Cancer Society and leading Connecticut oncologists to cooperatively develop a model on coverage for the routine costs of cancer clinical trials. That bill took 12 months to craft, for a single area of care where all parties agreed that coverage for routine care expenses was the right thing to do, and that patient safety and sound medical research protocols were paramount to providing meaningful health benefits for members' health care dollars. The most encouraging thing about the process surrounding the cancer clinical trials bill was that there was no argument about the fundamental principle of the bill: patient safety and sound medical research protocols.

The present bill seeks to expand coverage for research trials to the arena of "disabling, progressive or life threatening" illnesses. This is a challenging area to define. Thousands of clinical trials exist on almost any medical illness ranging from near sightedness to cholesterol management. (ClinicalTrials.gov) The issue of whether a condition is "disabling, progressive or life threatening" would be difficult or impossible to determine. Any disease an individual has could meet this definition. "Life threatening" could mean that an individual's cholesterol level might some day lead to a heart attack. Clinical trial coverage could very well be opened up to every medical condition. Trying to determine which trials meet a given set of criteria for a given patient for an infinite number of diseases would be an impossible medical task.

To demonstrate the complexity of this issue, please note that this bill deviates from the cancer clinical trials law in that it limits cancer trials for the prevention of cancer to Phase III trials approved by one of the listed expert entities that are conducted at multiple institutions – but there is no such limit for trials for prevention of any other illness. We question why other diseases would have preventive trials covered when cancer would not. This would mean that for all conditions other than cancer, insurers would have to cover even Phase I and Phase II trials for prevention, even though Phase I trials study the safety of an intervention (i.e., to determine whether it is lethal), and Phase II trials which are not yet proven therapies. This would be enormously costly.

Productive clinical research on disease treatment is a laudable goal for society to support, but the question of how to pay for it is much more difficult. We need to ask what the responsibility of insurers should be for subsidizing medical research? Many of the thousands of trials conducted by NIH and other bodies are well-researched; however, many others are neither well-established nor subjected to rigorous scientific protocols. Forcing insurers to cover expenses for the latter would clearly be a mistake, but even requiring coverage for the former begs the question: "Why is health insurance paying for research?" Privately purchased health insurance is paid for by employers, employees and individuals who are having a hard time shouldering the cost of their coverage in an environment where premium increases are escalating. Adding to this financial burden the cost of care for a broad range of unproven treatments would add to the health care affordability crisis, pricing health insurance out of reach for more people. Cost is always a difficult issue, and it's an unfortunate thing, but a policy that covered everything imaginable would only be affordable to a very few. We believe that private employers, employees and individuals should not be required to fund medical research with their premium dollars.

One additional matter to consider with respect to this proposal is the cost it imposes in the context of the Patient Protection and Affordable Care Act of 2010 (PPACA). PPACA covers only trials for cancer and other life-threatening diseases. To be eligible, trials must be funded or approved by NIH, CDC, AHCRO, CMS, DOD/VA cooperative group, or an NIH-qualified research entity - or it can be a drug trial being reviewed by the FDA or that is exempt from such FDA review. Additional conditions require that any study be subject to certain peer-review systems and assure an unbiased review of the highest scientific standards. Any clinical trial coverage in excess of these standards will be ineligible for federal subsidy and therefore any additional costs will be borne by Connecticut taxpayers alone.

We respectfully request that you oppose SB 21. Thank you for your consideration.