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Good morning, Sen. Crisco, Rep. Fontana and members of the Insurance and Real Estate Committee. My name is Dina Berlyn. Some of you might recognize me at the LOB as State Senate Majority Leader Martin Looney's Counsel and Executive Aide, which I am, but I am not here in that role. I am a patient with multiple sclerosis. I am here to testify on two healthcare policy issues of deep personal interest to me: coverage of routine patient care costs in clinical trials and the burden of proof in appeals from benefit denials. Both SB 260, AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS and SB 258, AN ACT CONCERNING APPEALS OF HEALTH INSURANCE BENEFITS DENIALS would make our healthcare coverage more rational and compassionate for patients.

I have researched, written, and been published on coverage of routine patient care in clinical trials, and I want to share with you my discoveries about this matter -- particularly the irrational nature of the for-cancer-only provision in our statutes.

In 2001, the Connecticut General Assembly passed PA 01-171 AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR CANCER CLINICAL TRIALS, HEARING AIDS FOR CHILDREN AGE TWELVE AND YOUNGER, PAP SMEAR TESTS, COLORECTAL CANCER SCREENING AND MAMMOGRAMS, PSYCHOTROPIC DRUG AVAILABILITY AND MEDICAID COVERAGE FOR MAMMOGRAMS[1]. The bill started with a more conventional title: AN ACT CONCERNING HEALTH INSURANCE COVERAGE DURING CLINICAL TRIALS. This legislation had laudable goals – to require insurers to sustain their responsibility to patients who participate in clinical trials by covering standard of care treatment

[1] In 2007 PA 07-67 made some changes regarding required coverage for out of network costs in cancer clinical trials

for clinical trial patients. Unfortunately, this bill in its final form required coverage for cancer clinical trials only. Many insurers already covered these expenses for cancer due to the high visibility and influence of cancer care and the use of NIH cooperative groups. While this coverage would be good policy for all clinical trials, it is crucial in clinical trials for rare diseases because if insurers deny coverage for these costs in that setting, no sponsor will undertake the research. Note that there is evidence that routine patient care costs for clinical trial patients are essentially the same as routine patient care costs for patients in standard treatment[2]. In fact it is my belief that for many patients with diseases such as multiple sclerosis that have high standard treatment costs, the routine patient cost of clinical trial patients would likely be lower. In MS, for example, the cost of the approved drugs is quite high -- I take Betaseron which costs my insurer over $3000 per month. Were I in a clinical trial, the trial sponsor would cover the cost of the investigational drug and I would cease taking Betaseron. It is unlikely that my routine patient care costs would increase by $3000 per month.

The denial by insurers of routine care costs that they would be obligated to pay absent a clinical trial by claiming that the costs are ancillary to the trial can be devastating to medical progress. President Clinton changed Medicare Policy so that Medicare covers routine care costs for clinical trials. Federal action would be most desirable, and if the Patients' Bill of Rights had passed in Congress, none of this would be necessary. However, absent congressional action, Connecticut should pass this legislation. I strongly urge you to require that insurers sustain their responsibility to patients who enter clinical trials.

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[2] 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).

[2] *Id.*

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

Most unfortunately, last year I experienced first hand the appeals process for healthcare coverage denials. At the beginning of the process it was unclear that the denial was coming from the pharmacy benefits manager; Caremark would not give straight answers. Once it became clear that my doctor had renewed the prescription appropriately and the problem was a denial by Caremark, I began the appeal process. I lost at the first two rounds of internal appeal; there is not much of an opportunity to present your case in these rounds especially since the insurer does not disclose their records in your case to you. I made repeated requests to Caremark for their record in my case. I have not received the record to this day. I did receive a fax which started at page 50 and purported to be the record but in fact it was a copy of the appeal form from the department of Insurance (which I already had). Once the internal rounds were done, I filed an external appeal with the state Department of Insurance. I spent over 20 hours researching and writing this document. I included journal articles supporting the use of Provigil for fatigue in MS (it is the most common symptom in the disease). I pointed out that this drug has been extraordinarily effective in my case and I noted that Caremark made a number of claims that were not backed up by evidence.

Once the Department of Insurance receives an appeal, it sends the appeal out to their external reviewer and to the insurer. When Caremark received my letter they chose to cover the prescription rather than go through the appeal. I believe that they feared that if they lost this appeal that they would not be able to deny others with a prescription for the same drug. When a healthcare provider prescribes a drug for a specific condition which has been effective for a patient and for which there is evidence of effectiveness, an insurer should not be allowed to substitute its judgment for that of the skilled providers. In addition, a patient should not be forced to forego a needed prescription during the course of the appeal; this can create an undue hardship on these patients. This bill contains reforms which would assist patients in receiving the care they require.

I realize that the oral chemotherapy issue was heard last week and I had not intended to testify but I would like to make a couple of comments. The argument made by the insurers that this is a quality control issue is specious because these biologic drugs are currently in use. The only question is the manner of reimbursement. I would like to encourage the committee to expand the scope of the oral chemotherapy bill to include conditions other than cancer. There are a number of medical conditions (e.g. Multiple Sclerosis, Rheumatoid Arthritis, Crohn's Disease, etc.) which can now be treated with biologics that can be administered P.O. (by mouth) rather than I.V. (intravenous). It does not make a lot of sense that the P.O. drugs often carry an unaffordable co-pay.

I am most appreciative of your efforts on these issues of extraordinary importance.