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Good morning, Sen. Crisco, Rep. Megna 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 S.B. No. 21 AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS and S.B. No. 18 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

MAMMOGRAMS¹. 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 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 treatment². 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 Tysabri now but have taken Betaseron in the past. Both drugs cost 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 the approved therapy. 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

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

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.*

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

to medical progress. President Clinton changed Medicare Policy so that Medicare covers routine care costs for clinical trials. In the Affordable Care Act Congress requires coverage of routine patient care costs *but* only in trials for cancer or other life-threatening diseases. The definition for 'life-threatening' is extraordinarily narrow and thus will not include the majority of chronic and disabling diseases. I do hope that Congress will act to make the language in the Affordable Care Act consistent the rational and enlightened policy developed by the Centers for Medicare & Medicaid Services. However, since the prospects for Congressional action are unclear, Connecticut should pass this legislation. I strongly urge you to require that insurers sustain their responsibility to patients who enter clinical trials.

In addition, I applaud the inclusion of section 15 which would expand the off-label use of drugs beyond the use of such drugs for cancer. There are many drugs which, although they have been shown to be effective for diseases other than the one for which they were originally approved to treat, are technically not approved for these other diseases. This is the situation I encountered that led to my experience with the system for appeal of a healthcare denial. Doctors, not insurers should engage in the practice of medicine.

Most unfortunately, I have experienced first hand the appeals process for healthcare coverage denials. This experience is why I believe that S.B. No. 18, AN ACT CONCERNING APPEALS OF HEALTH INSURANCE BENEFITS DENIALS, is needed. At the beginning of the process in my case 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 records in my case but NEVER received them. 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 am most appreciative of your efforts on these issues of extraordinary importance to Connecticut's citizens.