



**Testimony of
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**Committee on Public Services and Consumer Affairs
Bill 17-0469
“Clinical Trials Insurance Coverage Act of 2007”**

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Children's National Medical Center (Children's National) is pleased to offer testimony in support of Bill 17-0469, the “Clinical Trials Insurance Coverage Act of 2007.” Clinical trials are a cornerstone of pediatric oncology – the rule as opposed to the exception - and over the past four decades, childhood cancer mortality in the United States has declined dramatically. The dramatic successes in improving outcomes achieved in pediatric oncology demonstrate the fruits of investing in coverage for clinical trial care.

Children's National Medical Center is a 283 bed not-for-profit academic medical center that has provided hope to sick children and their families throughout the Washington metropolitan region for more than 135 years. Children's mission is to improve health outcomes for children regionally, nationally and internationally, be a leader in creating innovative solutions to pediatric healthcare problems and excel in care, advocacy, research and education to meet the unique needs of children, adolescents and their families.

Serving as an advocate for all children, Children's National is the largest non-governmental provider of pediatric care in the District of Columbia. Through public-private partnerships with several District government agencies, Children's National manages health care for the District's children in foster care, employs all school nurses in the District of Columbia Public School system, and has dramatically improved immunization compliance among the District's pre-school and school-age children.

Cancer Research & Treatment at Children's National

Children's National is not only a national but an international leader in childhood cancer research, treatment, education, and advocacy. Each year, the Division of Oncology treats approximately 225 children as new cancer patients. Regardless of insurance status, patients receive comprehensive, state-of-the-art care and have access to the technical and clinical excellence that gives them their best opportunity for survival.

Through participation in more than 100 clinical trials, Children's National strives not only to cure cancer, but to minimize the side effects of treatment. Faculty at Children's National serve as study chairs for several national and international clinical trials in acute leukemia, brain tumors, renal tumors, bone tumors, and other solid tumors. In addition, Children's National is the only center in the region and one of only a handful in the country with access

to the Children's Oncology Group's Phase I trials and the Pediatric Brain Tumor Consortium protocols.

Clinical Trials and Improved Pediatric Cancer Survival Rates

Pediatric cancer is the leading cause of death by disease in children. Cancer is the sixth most common chronic disease of childhood. Only asthma, congenital anomalies, epilepsy, cystic fibrosis, and diabetes are more common. An estimated 12,400 children will be diagnosed with cancer and more than 2,300 will die from it this year. The role of clinical trials in improving pediatric cancer outcomes, however, can not be overstated.

A report released in December 2007 by the Centers for Disease Control and Prevention finds that the cancer death rate for children in the United States has declined sharply – down 20 percent from 1990-2004. Across all pediatric cancers, the overall rate of survival stands at 70 percent. This tremendous improvement in survival rates is due in part to the vast number of children enrolled in closely monitored clinical research trials, which in turn has significantly helped to define optimal treatments.

For children with cancer, enrollment in a clinical trial is the standard of care, and more than 70% of children with cancer participate. That compares to only about 3% of adult cancer patients who are enrolled in clinical trials. Studies show that 20% of adult cancer patients are eligible for clinical trials but don't enroll, largely out of fear that their insurer would no longer pay for the costs of their routine care. In the last 20 years, general acceptance of clinical trials as a standard of care for pediatric oncology patients has paved the way for enrollment and led to dramatically improved outcomes. In one study, it was shown that survival for children on a clinical trial was 35% better than for those with the same type of cancer not treated on a clinical trial.

Insurance Coverage and Pediatric Clinical Trials

Usually when a patient enrolls in a clinical trial, the cost of tests, procedures, drugs, extra doctor visits and any research directly related to the study itself is covered by the group sponsoring the clinical trial. The sponsoring organization does not, however, cover the routine patient care services associated with the clinical trial. Routine patient care costs are services for the care that is required because the patient has cancer, for example, physician visits, x-rays, and blood work. These routine services do not include the cost of the drug or any research-related costs. It is care that the patient needs regardless of whether or not the patient receives standard therapy or participates in a clinical trial. This also represents care for which the patient continues to pay premiums.

It is generally Children's National's experience that pediatric patients with either private or public health insurance do not encounter significant coverage barriers for routine patient care costs associated with clinical trials. This is not, however, always the case. For example, the insurance carrier for a Children's leukemia patient refused to cover her clinical trial care because she was enrolled in a study evaluating the timing of standard chemotherapy. Despite appeals by the patient's clinical care team and clinical social worker, as well as the hospital's resource management team, the insurance carrier refused to accede and those services were not covered.

Again, by and large children with cancer do not face as many barriers to insurance coverage for the basic patient care costs associated with clinical trials as do their adult counterparts. The “Clinical Trials Insurance Coverage Act” would, however, go a long way toward ensuring no child in the District of Columbia will face such an additional hardship while battling cancer and will take a significant step toward improving coverage for adults with cancer.

Conclusion

Children’s National Medical Center applauds Councilmembers Cheh and Catania, and Chairman Grey, for championing this important legislation. No cancer patient – adult or pediatric - should have to forego the most innovative care available to them because they cannot pay out of pocket for care in a clinical trial.

Max Coppes, MD, PhD, MBA, is Executive Director of the Center for Cancer and Blood Disorders at Children’s National Medical Center in Washington, DC. Dr. Coppes specializes in treatment of solid tumors, specifically renal tumors, and is the author of numerous studies and publications.