

**Statement on behalf of the
Pennsylvania Society of Oncology and Hematology
Before the
House of Representatives Insurance Committee
Regarding House Bill 1778
Off-label Coverage
March 27, 2002**

Good morning. My name is Dr. Mary Simmonds, spokesperson for the Pennsylvania Society of Oncology and Hematology (PSOH) on the off-label use of prescription drugs. PSOH is the state association that represents physicians and health care professionals devoted to the improvement of oncologic and hematologic care of patients. I am a practicing cancer physician in the Harrisburg area, and president-elect of the National American Cancer Society.

The Pennsylvania Society of Oncology and Hematology supports House Bill 1778, which would provide coverage for off-label drug use. We believe it is a narrowly drawn and balanced proposal that provides off-label coverage to patients whom are most in need of care – those with life-threatening, chronic, and disabling conditions.

Off-label prescribing occurs when a physician prescribes a drug for a purpose other than that approved by the U.S. Food and Drug Administration (FDA). It is a routine and necessary part of the practice of medicine, especially in regard to special needs populations.

The FDA approval process for drugs costs millions of dollars and requires an average of more than five years to complete. Due to the expense involved, pharmaceutical companies often limit the number of drug indications for which they seek initial approval. This does not mean, however, that a drug could not be beneficial in treating other conditions. Frequently, once a drug is available to the public, subsequent research and studies often yield new, innovative and clinically sound uses.

The National Cancer Institute, in response to questions in 1989 Senate Appropriations hearings, noted that “the history of cancer drug development in our country shows that the most beneficial uses for new agents are generally discovered in the post-marketing phase, that is, after a drug has been approved by the FDA for marketing of the labeled indication.”

An interesting example is the drug, Taxol. It was initially approved in 1992 for the treatment of ovarian cancer. At the time of approval, clinical trials were already underway to test the effectiveness of this same drug for the treatment of metastatic breast cancer. Fortunately, the results were very good. Later, the pharmaceutical company went back to the FDA for approval. The data showed excellent results and approval was granted.

With such promise, clinical trials were then initiated for the treatment of Stage II node and breast cancer. Preliminary results showed fewer cancer recurrences. The company sought and was granted approval for a third indication for the drug Taxol. Interestingly enough, follow-up results indicate there may not be an advantage to adding Taxol to the treatment at this stage of disease. The indications still stand today. Bear in mind that four doses of Taxol more than doubles the cost of the treatment and adds toxicity.

In the meantime, results of clinical trials on using Taxol in other forms of cancer have been reported at national scientific meetings and in peer-reviewed journals. There is sound scientific evidence to use Taxol in the treatment of lung cancer, bladder cancer, non-Hodgkin's lymphoma, and prostate cancer. The point is that FDA indications are not the only and not necessarily the most reliable.

The American Society of Clinical Oncology's policy on coverage of unlabeled drug indications states, "Many of the off-label uses are for a combination of drugs used as a therapy." The FDA does not routinely approve combinations of drugs as therapy.

Prescribing drugs for an off-label use is a routine part of the practice of oncology, and is frequently the most effective form of treatment for our most severely ill patients. In fact, nearly 80 percent of cancer drugs are technically prescribed off-label. Off-label use of approved drugs is considered rational and accepted medical practice by the FDA when it is medically appropriate. It is medically appropriate when it is listed in the drug compendia and supported by clinical research that appears in peer-reviewed medical literature. However, despite widespread use and acceptance, some health plans routinely deny coverage for medically appropriate off-label prescriptions.

HB 1778 will not increase costs. There is no data that indicates appropriate off-label drug use results in increased costs to health plans or the health care system. Insurance Department officials in New York and Michigan, states that have enacted off-label legislation, estimate that their off-label laws have had little or no deleterious impact on health care costs. Additionally, the Congressional Budget Office believes that off-label prescribing does not increase costs in the Medicare program. In fact, off-label drug uses often provide more effective treatment at lower overall cost.

Required coverage of off-label uses of drugs is not new. More than 30 states have enacted some form of coverage of off-label drug use. Texas and California adopted off-label legislation to protect special needs populations from insurer denials. Other states, including Alabama, Georgia, Indiana, Maryland, Missouri, New Jersey, North Dakota, and Tennessee have enacted more liberal laws guaranteeing all persons coverage for off-label uses of FDA-approved drugs prescribed by physicians. Additionally, Medicare covers off-label uses of FDA-approved oncology drugs for its beneficiaries when supported by peer-reviewed clinical literature. In fact, Pennsylvania's Medicare Part B Carrier, HGSAdministrators, believing that Medicare beneficiaries with cancer should not be hassled by delays in approval of covered drugs, worked with the Pennsylvania Society of Oncology and Hematology to streamline the procedure for obtaining Medicare coverage for off-label usage of FDA approved cancer chemotherapeutic agents.

Cancer is a devastating disease. It is important that our patients have access to promising new uses of existing therapies. HB 1778 would assure that access. We ask the members of the Insurance Committee to support this legislation.

Thank you for your time and attention. I will be happy to respond to any questions from members of the committee.