



## Oncology Nursing Society

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January 27, 2016

Senator Bryan W. Simonaire

James Senate Office Building, Room 320

11 Bladen St., Annapolis, MD 21401

Dear Senator Simonaire,

ONS is a professional organization of over 38,000 registered nurses and other health care providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. ONS members are a diverse group of professionals who represent a variety of roles, practice settings, and subspecialty practice areas. Oncology nurses are leaders in the health care arena, committed to continuous learning and leading the transformation of cancer treatment by advocating for high-quality care for people with cancer.

ONS commends the effort to support patients with cancer who otherwise may lack access to life-sustaining treatment, and welcomes the opportunity to provide support and feedback.

### **Cancer as a Life-Limiting Illness**

Cancer is a cohort of diseases for which uncontrolled growth of abnormal cells is a shared characteristic. Uncontrolled spread of cancer ultimately results in death. Cancer can be caused by external factors, such as exposure to carcinogens in the environment, infectious organisms, or dietary choices; it may also be caused by genetic mutations, immune conditions, or hormonal factors.

Although there is no single origin for a cancer diagnosis, metastases, or spread of cancer, is the leading cause of cancer death. The five-year survival rate for all cancers has improved throughout this century; these data are reflective of early diagnosis and improved treatment options for some cancers. Despite these improvements, cancer continues to claim lives.

### **Expanded Access to Investigational Products**

Participation in clinical trials is the standardized and regulated process that generates much needed data that may result in FDA approval of investigational drugs and products. Benefits of such trials can range from extension of life to disease stabilization and/or enhanced symptom management. Thus, ONS supports unencumbered access to participation in clinical trials for comprehensive cancer care delivery. ONS also strongly advocates that racial, financial and cultural disparities in terms of access to clinical trials be eliminated. Expanded access (also called compassionate use) or single-patient access of investigational products outside of a clinical trial provides opportunity for patients who may not otherwise have access to these products.

However, there are patients who are ineligible to participate in trials, may be unable to locate or travel to clinical trial sites, or may have disease for which no clinical trials are currently available. Although compassionate use protocols provide investigational access, processing time to gain approval for compassionate use may exceed life expectancy for some patients.



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ONS believes that provision of treatment that may prove to be life-sustaining is a fundamental human right, and that people with cancer who have exhausted existing treatment options, and who may not otherwise have access to investigational products through clinical trials, should have access to investigational products following a well-informed discussion with their healthcare provider regarding the risks and benefits. Patients with advanced cancer, who have no other treatment options, have a cancer for which there is reason to expect that the investigational product may provide benefit, and who have provided an informed consent should have access to otherwise inaccessible treatment options.

### Protection of Providers

ONS applauds the protections afforded to healthcare providers as outlined in the bill, to include freedom to recommend treatment options that are in alignment with the goals, needs, and values of the patient. ONS strongly encourages development of contractual relationships between patients and investigational drug manufacturers to limit patient and estate liabilities, and encourages revision of the bill to state that provisions under this bill must include such contractual agreements.

I appreciated the opportunity to discuss this legislation and other important healthcare concerns in person with you this past November, and wish you great success with this legislation. If you should need further information from ONS, please contact ONS' Health Policy Director, Alec Stone, at 412-859-6041 or [astone@ons.org](mailto:astone@ons.org).

Sincerely,

Mary Ellen McFadden, RN, MA, OCN<sup>®</sup>

Past President and Current Board Member,  
ONS Baltimore Chapter