



May 18, 2015

The Honorable Fred Upton  
House Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Frank Pallone, Jr.  
United States House of Representatives  
237 Cannon House Office Building  
Washington, DC 20515

The Honorable Joseph R. Pitts  
United States House of Representatives  
420 Cannon House Office Building  
Washington, DC 20515

The Honorable Gene Green  
United States House of Representatives  
2470 Rayburn House Office Building  
Washington, DC 20515

The Honorable Diana DeGette  
United States House of Representatives  
2368 Rayburn House Office Building  
Washington, DC 20515

**RE: Expanded Access, Sections 2082 and 2083 of the 21<sup>st</sup> Century Cures Act**

Dear Chairman Upton, Ranking Member Pallone, Health Subcommittee Chairman Pitts, Health Subcommittee Ranking Member Green, and Representative DeGette:

On behalf of the Oncology Nursing Society (ONS), I write to thank you for the inclusion of Sections 2082 (Expanded Access Policy) and 2083 (Finalizing Draft Guidance on Expanded Access) in the *21<sup>st</sup> Century Cures Act*.

These provisions would place transparency requirements on certain drug companies regarding their expanded access to programs for patients to access drugs before they are approved, and would create an expanded access task force to provide recommendations to Congress for further reforms of the program. Sections 2082 and 2083 would provide clarity to patients, caregivers, and healthcare providers surrounding the opportunity to obtain medications, when appropriate, in the pre-approval process. With the acceleration of precision medicine in oncology, many health care patients and providers are seeking the ability to initiate treatment with novel agents when currently available therapies do not work for them and they cannot get into clinical trials. As such, ensuring there is a consistent and clear method to explore further treatment options is a priority for ONS and the patients we treat.

As you know, cancer is the cause of nearly 1 out of every 4 deaths in the United States. Over one and a half million new cancer cases are diagnosed each year, with 1,600 cancer related deaths each day. Oncology nurses are the health professionals involved in the administration and monitoring of chemotherapy and managing the associated side effects cancer patients may experience. Every day, oncology nurses see the pain and suffering caused by cancer and understand the physical, emotional, and financial challenges that people with cancer face throughout their diagnosis and treatment.

ONS is a professional organization of over 35,000 registered nurses and other health care providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. The growing demand for cancer care, from prevention to palliative care, requires oncology nurses to play a pivotal and increasingly important role in delivery high quality, safe, effective and efficient health care to people affected by, or at risk for, cancer.

Thank you again for the inclusion of Sections 2082 and 2083 in the *21<sup>st</sup> Century Cures Act*. We stand ready to work with you and your staff to reduce and prevent suffering from cancer, and are committed to maximizing the potential that nurses, the largest group of health care professionals, have in reducing the incidence of cancer. We would be happy to discuss ways in which ONS may be of assistance in this endeavor, and would encourage you to contact Alec Stone, MA, MPA, ONS Director of Health Policy, at [astone@ons.org](mailto:astone@ons.org).

Sincerely,

A handwritten signature in cursive script that reads "Dr. Margaret Barton-Burke". The signature is written in black ink and is positioned above the printed name.

Margaret Barton-Burke, PhD, RN, FAAN  
President, Oncology Nursing Society