



THE INTERNATIONAL MYELOMA FOUNDATION, THE MDS FOUNDATION AND A COALITION OF PATIENT ADVOCACY ORGANIZATIONS CALL FOR UPDATED RULES FOR REIMBURSEMENT, ACCESS AND APPROVALS FOR NEW AND EXISTING CANCER TREATMENTS

--Patient "Statement of Principles" to be Unveiled at the Global ASCO Cancer Meeting in Orlando, Florida--

--Principles Emphasize Equal Insurance Coverage, Prevention Research, Continued Innovation, Early Approvals, and Expanded Access to Experimental Drugs--

Orlando, FL, May 29, 2009 – A coalition of cancer patient advocacy organizations led by the International Myeloma Foundation (IMF) and the MDS Foundation (MDSF), today announced plans to unveil a patient "Statement of Principles" at the Annual Meeting of the American Society for Clinical Oncology (ASCO) in Orlando, Florida. The principles, issued on behalf of patients and caregivers, state:

- Prevention is the key to reducing the burden of cancer
- Continuing innovation is critical to early diagnosis and better treatment
- Equality of access to care is imperative
- Early approval of new treatments for deadly cancers is essential
- Patients who have exhausted approved therapies need simplified access to experimental agents whenever possible

"The application of these principles is especially important to patients diagnosed with any of the eight lethal cancers, those that have five-year survival rates of less than 50 percent," said Susie Novis, president and co-founder of the IMF. "These cancers, including multiple myeloma, will cause nearly half the 560,000* cancer deaths projected in America this year. This is one of the key reasons we must assure that all patients have access to well-trained specialists and that we continue to develop newer, better treatments until there is a cure."

"When patients are diagnosed with cancer, their concern should be managing their disease, not reimbursement for their treatments," said Kathy Heptinstall, BSN, RN, operating director and co-founder of the Myelodysplastic Syndromes Foundation. "Oral drugs should have the same coverage as hospital-based procedures; research and innovation must be encouraged and supported; and for fatal diseases, the criteria for drug approvals should emphasize expedited approval and ready access to them."

The patient advocacy organizations supporting these principles believe they can make initial progress working to resolve the critical disparity in insurance coverage. Medicare and many private insurance programs require higher deductibles and co-payments for oral drugs than for intravenous drugs and hospital-based procedures. Because private insurance is regulated at the state level, Oregon, Indiana and now Iowa have laws requiring equal coverage for oral and intravenous drugs, with similar laws pending in several additional states and federal legislation introduced in Congress.

Former NFL linebacker Elijah Alexander, a myeloma patient and founder of the Tackle Myeloma Foundation, says this insurance inequity must end: “This unequal coverage is unreasonable and unfair. I just take a pill at home, I feel good and I’m again active in my work and with my family. As patients we should be able to take advantage of the best care, and not be limited to what our insurance will cover.”

The Statement of Principles is in keeping with sessions at the ASCO conference that go beyond clinical trial data to discuss the impact of financial issues on access to, compliance with, and reimbursement for cancer therapies. The Principles and supporting petitions will be located in booth 2806, at the MDS Foundation booth 2813, and the IMF booth 2904 in the ASCO exhibit hall. The materials can also be found on the websites of the IMF (www.myeloma.org) and the MDSF (www.mds-foundation.org).

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About the Cancer Patient Statement of Principles

THE CANCER PATIENT STATEMENT OF PRINCIPLES: Prevention, Innovation, Access, and Early Approvals

PRINCIPLE 1: Prevention is the key to reducing the burden of cancer. We must support every reasonable attempt to encourage studies of cause and prevention to reduce the number of new cancer cases.

- A study in the *Journal of Clinical Oncology* projects that the number of new cancer cases diagnosed each year will jump 45 percent in the next 20 years.
- In multiple myeloma an even greater increase (57%) is projected, and we are already seeing increasing diagnoses in patients under age 65 including patients in their thirties, in what was once a “rare disease of the elderly.”

PRINCIPLE 2: Continuing innovation is critical to the early diagnosis and the more effective and safer treatment of the vast majority of patients with cancer

- We are in full support of the tenets of the 21st Century Cancer ALERT Act and other federal initiatives that support and encourage research.
- We believe in the importance of new and better tests to ensure the early diagnosis of all clinically significant forms of cancer.
- We believe a deep, diverse pipeline of new and better treatments will lead to better outcomes and a better quality of life for all patients.
- We believe in full funding of legislation that promotes and encourages drug and biomarker research and development intended to bring new options for patients in need.

PRINCIPLE 3: Equality of access (and equality of insurance coverage) should be available to all patients for all approved cancer treatments.

- Every cancer patient should have access to the treatments recommended by their physicians.
- Patients should not suffer from *cost discrimination* based on the type of therapy provided or the mechanism of delivery
- Oral drugs should have the same coverage as intravenous drugs, surgery, radiation, transplantation, etc.
- The Medicare donut hole is an arbitrary and unfair burden on our most vulnerable citizens.

PRINCIPLE 4: National policies and procedures for early approval of new treatments for cancer and other deadly diseases need to be reformed and streamlined.

- In the interests of patients with disorders with a five-year survival rate of less than 50 percent, the emphasis should be on proof of effectiveness and early availability, with full disclosure of risk for adverse effects.
- A more efficient mechanism is needed for early approval of off-label uses of already approved medications, possibly based on registry data, actual clinical practice, peer-reviewed studies and NCCN guidelines without the expense and delay of complex and time-consuming clinical trials.

PRINCIPLE 5: An efficient and effective mechanism is needed to permit access to unapproved and experimental therapies for patients who have exhausted other available possibilities.

- In the United Kingdom, in 2008, the Department of Health gave approval to a network of 19 hospital units where terminally ill cancer patients can volunteer to participate in trials of experimental cancer therapies that may be years away from approval.
- It should be easy, not difficult, for patients who have run out of other options to gain access to investigational drugs whenever possible – with appropriate clinical input.

About the eight lethal cancers

Eight forms of cancer, of which multiple myeloma is one, are projected to cause 49% of the 562,340* cancer deaths projected in 2009. For each of these forms of cancer, at least half of the patients diagnosed will die from their cancer within five years. Those cancers are:

Type of cancer	Deaths projected in 2009	New diagnoses projected in 2009	5-year survival rate
Brain cancer	12,920	22,070	35%
Pancreatic cancer	35,240	42,470	5%
Esophageal cancer	14,350	16,470	16%
Liver cancer	18,160	22,620	10%
Lung cancer	159,390	219,440	15%
Multiple myeloma	10,580	20,580	34%
Ovarian cancer	14,600	21,550	45%
Stomach cancer	10,620	21,130	24%

***Source:** Cancer Facts & Figures 2009, American Cancer Society, Atlanta. 2009