

NPAF National Patient Advocate Foundation

The Patient's Voice | since 1996

EXECUTIVE BOARD

Nancy Davenport-Ennis

CEO, President
Patient Advocate Foundation

Edward G. Connette, Esquire

Board President
Essex Richards, PA

Christian Downs, MHA, JD

Board Vice President
Executive Director
Association of Community Cancer Centers

Leah Arnett, RN, BSN, MHCA

Board Secretary
Nursing Director
University Health Services

University of Texas at Austin

John L. Murphy

Board Financial Officer
Saugenay Capital, LLC

Bruce Avery, MD

Hematology-Oncology Knoxville

Alan J. Balch, Ph.D.

Vice President
Preventive Health Partnership

Rene Cabral-Daniels, JD, MPH

Vice President of Grant Programs
Williamsburg Community Health Foundation

Richard D. Carter, Esquire

Carter & Lay
Patient Advocate Foundation

Dennis A. Gastineau, MD

Director, Human Cell Therapy Laboratory
Divisions of Transfusion Medicine & Hematology
Mayo Clinic

Venus Ginés, MA

Founder & CEO
Dia de la Mujer Latina, Inc.

The Honorable Phil Hamilton

Virginia House of Delegates

Pearl Moore, RN, MN, FAAN

CEO (Ret.)
Oncology Nursing Society

Roy Ramthun

President
HSA Consulting Services

Sheldon Weinhaus, Esquire

Weinhaus & Potashnick

SCIENTIFIC BOARD

Lori Williams, PhD, DSN[®], RN, AOCN

Chair, PAF Scientific Board of Directors
University of Texas

MD Anderson Cancer Center

David Brizel, MD

Professor
Duke University Health System

Radiation Oncology Department

Robert M. Rifkin, MD, FACP

Director, Cellular Therapeutics
Rocky Mountain Blood & Marrow Transplant Program

Rocky Mountain Cancer Centers

F. Marc Stewart, MD

Professor of Medicine, University of Washington
Fred Hutchinson Cancer Research Center

Richard L. Theriault, DO, MBA

Professor of Medicine
MD Anderson Cancer Center

HONORARY BOARD

The Honorable Mary T. Christian

Virginia House of Delegates (Ret.)

The Honorable Patrick Dougherty

Missouri State Senate (Ret.)

Paula Trahan-Rieger, RN, MSN, ACON, FAAN

Chief Executive Officer
Oncology Nursing Society

Leo Sands

Executive VP & Chief Administrative Officer
US Oncology

Doris Simonson

August 31, 2010

Food and Drug Administration

Division of Dockets Management (HFA-305)

5630 Fishers Lane, rm. 1061

Rockville, MD 20852

Re: Docket Nos. FDA-2010-N-0284 and FDA-2009-D-0461 - Risk Evaluation and Mitigation Strategies

Dear Sir or Madam:

National Patient Advocate Foundation (NPAF) is a non-profit organization dedicated to improving access to healthcare services through both federal and state policy reform. Our mission is to be the voice for millions of patients who have sought care after a diagnosis of a chronic, debilitating or life-threatening illness. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive direct, sustained services from Patient Advocate Foundation (PAF), which provides professional case management assistance to patients. In 2009, PAF resolved 55,384 patient cases and received four million additional inquiries from patients in all 50 states.

On behalf of the patients served by PAF, NPAF is pleased to submit comments to the Food and Drug Administration (FDA) on the issues and challenges associated with the development and implementation of risk evaluation and mitigation strategies (REMS) for drugs and biological products. NPAF acknowledges that REMS are instrumental in enhancing patient safety and patient/prescriber education relative to innovative medications and therapies. Many patients, especially those diagnosed with chronic, debilitating or life-threatening diseases rely on access to these therapies for their very lives. NPAF acknowledges that the REMS process allows patients access to potentially life-saving medications that would otherwise be unavailable.

Medication Guide Language

Patients in the midst of a health crisis are generally not apt to thoroughly read a medication guide. Family members, friends or caretakers may step in and take over that responsibility. Each of these persons may have a different level of education or the ability/inability to grasp technical issues that would interfere with his/her ability to impart needed information to the patient. Irrespective of who assumes that responsibility, it is important that the language of medication guides be such that the average, non-medically oriented person be able to understand the essence of what is intended to be imparted. We recognize that this can be a great challenge especially in light of the sensitivity of the issues that need to be addressed. We would ask that the FDA make this issue a priority.

In June, 1998 President Clinton issued a memorandum to all executive departments and agencies on plan language in government. He cited the need for government documents to have a logical organization, be easy-to-read and use common, every day words except where it is necessary to use technical terms. We recognize that adherence to these principles when the subject matter deals with science can be difficult. Fashioning language that meets the intent of a medication guide, while at the same time being able to say what needs to be said, is challenging. We urge FDA to continue to explore

ways to make medication guides become a more useful tool for users. We suggest that the medication guides be written at a sixth grade reading level.

Medication guides cite a medication's adverse effects. This can influence a patient's decision as to whether he/she should begin a course of therapy on that medication. In many cases the only in-depth information available to a patient is the medication guide. Physicians, in some cases, will thoroughly explain the advantages and disadvantages of the proposed medication. However, this is not always the case given the constraints on their time. Patients will leave their physician's office, the hospital outpatient department, etc. with only the medication guide in hand. What was said during the discussion with a physician or physician extender about whether or not to start on a drug regimen probably will be "left in the office". One way to counter this would be for medication guides to be written in a way so that there can be an introductory statement about why the medication generally would be prescribed. This at least would provide the patient with a tangible written piece of information to which he/she can refer. This statement would be clear that all patients are different and that medications may not be appropriate for all patients even those with a similar diagnosis.

Balancing Information and Safety

NPAF recognizes that medication guides serve an important safety function. Yet, we are mindful that any internal or externally imposed administrative requirement will require a regulated entity to expend capital, primarily in the form of staff resources, to adequately meet those requirements. We urge the FDA to, as much as possible, reduce the record keeping effort that will cause providers to divert resources from patient care responsibilities.

REMS Standardization

NPAF believes that the REMS process would benefit by FDA providing a "template" that manufacturers could follow when developing a REMS for a drug. This would provide a guide for the manufacturer and could enable the end user to become more familiar with REMS in general. Currently, not all REMS are structured similarly because each REMS is developed by the drug's manufacturer. As more drugs require REMS going forward, the number of distinctly different REMS will increase. Providers, prescribers and patients will all benefit from a more standardized REMS system that reduces administrative burden and improves communication. A more standardized REMS format would enhance clarity and allow critically important information to be succinctly summarized so that doctors and patients can better understand the risks and benefits of a given therapy. NPAF also believes that patients, as well as patient advocates, can offer valuable insight into the REMS standardization process by reviewing a proposed REMS format.

NPAF sincerely appreciates the opportunity to share its views on this matter. If we can be of assistance to FDA please do not hesitate to contact us.

Respectfully submitted,



Nancy Davenport-Ennis
President and Chief Executive Officer

CC:
Steve Miller
Executive Vice President of Regulatory Affairs