

National Organization for Rare Disorders, Inc.®



out of the darkness
into the light

NATIONAL MEMBER ORGANIZATIONS

Alagille Syndrome Alliance
Alpha 1 Association
Alpha 1 Foundation
American Brain Tumor Association
American Laryngeal Papilloma Foundation
American Porphyria Foundation
American Syringomyelia Alliance Project
Aplastic Anemia & MDS International Foundation, Inc.
Association for Glycogen Storage Disease
Association of Gastrointestinal Motility Disorders, Inc. (AGMD)
Batten Disease Support & Research Association
Benign Essential Blepharospasm Research Foundation
Charcot-Mane Tooth Association
Chromosome 18 Registry Research Society
Cleft Palate Foundation
Cornelia De Lange Syndrome Foundation
Cystinosis Foundation, Inc.
DEBRA of America
Dysautonomia Foundation, Inc.
Dystonia Medical Research Foundation
Ehlers Danlos National Foundation
Epilepsy Foundation
Families of Spinal Muscular Atrophy Foundation for Ichthyosis and Related Skin Types
Genetic Alliance
Guillain Barre Syndrome Foundation International
Hemochromatosis Foundation
Hereditary Colon Cancer Association
Hereditary Disease Foundation
HHT Foundation International, Inc.
Histocytosis Association of America
Huntington's Disease Society of America
Immune Deficiency Foundation
International FOP Association, Inc.
International Joseph Diseases Foundation, Inc.
International Rett Syndrome Association
Interstitial Cystitis Association
Lowe Syndrome Association, Inc.
Mastocytosis Society, Inc.
Mucopolidosis Type IV Foundation, Inc.
Myasthenia Gravis Foundation of America, Inc.
Myeloproliferative Disease Research Center
Myositis Association of America, Inc.
Narcolepsy Network, Inc.
National Adrenal Disease Foundation
National Alopecia Areata Foundation
National Ataxia Foundation
National Foundation for Ectodermal Dysplasias
National Hemophilia Foundation
National Marfan Foundation
National MPS Society, Inc.
National Multiple Sclerosis Society
National Neurofibromatosis Foundation
National PKU News
National Spasmodic Torticollis Association
National Tay Sachs & Allied Diseases Association
National Urea Cycle Disorders Foundation
Neurofibromatosis, Inc.
Osteogenesis Imperfecta Foundation
Parkinson's Disease Association, Inc.
Platelet Disorder Support Association
Prader Willi Syndrome Association, USA
Pulmonary Hypertension Association
PXE International, Inc.
Reflex Sympathetic Dystrophy Syndrome Association
Scleroderma Foundation
Sickle Cell Disease Association of America
Stevens Johnson Syndrome Foundation
Sturge-Weber Foundation
The Erythromelalgia Association
The Oxalosis and Hyperoxaluria Foundation
The Paget Foundation
Tourette Syndrome Association
Trigeminal Neuralgia Association
United Leukodystrophy Foundation
United Mitochondrial Disease Foundation
VHL Family Alliance
Wegener's Granulomatosis Association
Williams Syndrome Association
Wilson's Disease Association

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June 27, 2003

Dockets Management Branch (HFA-305)

Docket No. 03N-0168

Food & Drug Administration

5630 Fishers Lane

Room 1061

Rockville, MD 20852

**Re: Docket Number 03N-0168
Current Status of Useful
Prescription Drug Information
For Consumers**

Dear Sir or Madam:

In response to the *Federal Register* notice and request for comments about useful prescription drug information for consumers, we would suggest that after more than 30 years, it is time for FDA to stop tinkering around the edges of this matter and to enforce a regulated prescription drug information system that is unbiased and understandable to consumers.

We remember when Senator Ted Kennedy proposed "Patient Package Inserts" in the 1970's, and we remember the repeal of rules in the 1980's based on industry "promises" that they would "voluntarily" disseminate this information. We also recall the "medication guides" program of the 1990's, and yet we are still waiting for understandable consumer information to consistently reach American consumers. Meanwhile, people continue to be harmed by drug interactions, overdoses, and "underdoses" for lack of adequate information.

In the 1970's and 80's, pharmaceutical manufacturers and professional medical societies objected to consumer RX information because they felt patients would be frightened by lists of side effects, and therefore not take medicines. But by the 1990's, they could no longer make this claim because the *Physicians Desk Reference* (PDR) has been on the bestseller list too long, and the Internet has proven that consumers aggressively seek understandable information about medicines that their doctors and pharmacists don't provide to patients. Moreover,

Associate Member Organizations

Acid Maltase Deficiency Association (AMDA)
American Autoimmune Related Disease Association
American Behcet's Disease Association
American Self-Help Group Clearinghouse
Amyotrophic Lateral Sclerosis (ALS) of Greater Philadelphia Chapter
Association for People with the Van Lohuizen Syndrome (CMIC)
A T Children's Project
The CDG Family Network Foundation

Canadian Organization for Rare Disorders (CORD)
Children's PKU Network
Chromosome Deletion Outreach Inc.
Chronic Granulomatous Disease Association
CLIMB
Consortium of Multiple Sclerosis Centers
Contact A Family
Cushing Support & Research Foundation Inc.
EURORDIS
Family Caregiver Alliance

Family Support Network of North Carolina
Freeman Sheldon Parent Support Group
Hydrocephalus Association
Incontinentia Pigmenti International Foundation
K-T Support Group
Late Onset Tay-Sachs Foundation
Les Turner ALS Foundation Ltd
Mercy Medical Airlift
National Lymphedema Network Inc.
National Niemann-Pick Disease Foundation

National Spasmodic Dysphonia Association
Organic Academia Association
Osteoporosis and Related Bone Diseases National Resource Center
Parent to Parent New Zealand Inc.
Rare & Expensive Disease Management Program (REM)
Recurrent Respiratory Papillomatosis Foundation
Restless Legs Syndrome Foundation
Sarcoïd Networking Association

Shwachman Diamond Syndrome International Society for Progressive Supranuclear Palsy Inc.
Sotos Syndrome Support Association
Takayasu's Arteritis Association

Associations are joining continuously For newest listing please contact the NORD office

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Dedicated to Helping People with Orphan Diseases

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numerous studies have proven that hundreds of millions of dollars are wasted annually and thousands of lives are lost to drug side effects and interactions, causing devastating problems with huge costs to the health care system.

Obviously, consumers want and need to be educated about the treatments they take, potential side effects, timing or avoidance of foods and sunlight, interactions with other medicines, etc. We believe the cost of not providing consumer information for prescription drugs is higher than the cost of providing it.

In answer to your questions:

- 1) What steps is the private sector taking to improve the usefulness of written drug information?

Answer: Not much. Prescription drug information is generally available from mail order pharmacies and many chain drug stores, but many independent pharmacies distribute no information at all. Additionally, if you get the same RX drug from different drug stores, each provides different information about the same drug. There is no consistency, and important information can be missing.

- 2) What barriers exist and what plans exist to reach the goal?

Answer: This is a question for the pharmaceutical and pharmacy industries, and we would like to know the answers. We would like to see every information sheet in a standardized format, written in understandable language by an unbiased author.

- 3) What should FDA's role be in assuring full implementation of the Action Plan?

Answer: FDA should standardize the format of the information sheets and if all pharmacies do not comply by a certain date, they should be compelled to distribute the sheets with every prescription after that date. For example, the format should include (among others) pregnancy and pediatric warnings, take with meals or on an empty stomach, avoidance of sunlight, drug interactions, side effects, etc.

- 4) Other initiatives FDA should consider:

Answer: When consumers want understandable information about drugs, they can find certain books that are explanatory and concise. For example, the American Hospital Formulary Service issues a multiple volume set, and one of the books is written specifically for patients. Pharmacies will not have enough space to stock pamphlets, and if they do, they will be out-of-date quickly. Therefore, patient information pages should be printed by computers when the pharmacist labels the prescription. This is the best way to solve the problem, but FDA should review and approve the written information.

The FDA's mission is to protect and enhance the public's health. But after 30 years of reviewing this matter, the agency's inaction should be an embarrassment to the government. The paralysis has obviously been caused by the lobbying of industries and medical societies who object to information that the public wants and needs. It's time for the FDA to put its foot down and require understandable and unbiased information with every prescription drug. If pharmacies don't comply by a certain date, they should be fined and

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the money should go for the medical care of patients who suffered avoidable illness and injury because they were not adequately informed about side effects and interactions of their prescription drugs.

Very truly yours,

A handwritten signature in black ink, appearing to read "Abbey S. Meyers". The signature is written in a cursive, flowing style.

Abbey S. Meyers
President

ASM:aa

Cc: Diane Dorman, NORD Vice President for Public Policy