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50 Years of Nationwide Service

Statement before
House Committee on Commerce
Subcommittee on Health and Environment

United States House of Representatives

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Hearing on PDUFA and FDA Reform

by **Martha Keys**
Senior Public Policy Advisor

for the

National Multiple Sclerosis Society

Mr. Chairman and Members of the Subcommittee, I am pleased to have the opportunity of speaking to you today. I am Martha Keys, and I am here representing the National Multiple Sclerosis Society and the third of a million Americans with KS and their families. We believe that the issues we are speaking about are of vital importance to our members and indeed to all those present and future who have serious medical conditions.

We ask you, the Congress, to act now without further delay to continue the progress and prepare the FDA for the challenges and opportunities of the 21st Century. The time is ripe for action, the need is clear and compelling, and there is wide bipartisan agreement this year on what should be done.

The interests of our members in this outcome is clear. MS is a progressive, degenerative disease of the central nervous system, unpredictable in its course, devastating in its impact, striking young women and men usually between the ages of 20 and 40 just when they are beginning their careers and families. It does not significantly shorten the life span and it cannot be prevented with life-style changes. Thus our hope to end the devastating effects of this cruel disease rests in the discovery of new therapies to control, treat and eventually halt its progression.

Within the last three years, three new drugs have been approved -- the first ever that affect the basic course of the disease and slov its progression. The many therapies previously available to MS patients merely controlled some of the symptoms, which include spasticity, tremor, abnormal fatigue, bladder and bowel dysfunction and visual and

mobility impairment.

MS patients, along with patients with AIDS, cancer, Alzheimer's, lupus, diabetes and all other serious diseases, desperately need the FDA to be as efficient as possible so that important new therapies and hoped-for cures can be made available as quickly as possible. Make no mistake about it; in drug development and approval, time is of the essence and the difference to the individual is quality of life, if not life itself.

The National MS Society strongly supports reauthorization of PDUFA for five more years. The record-setting results of 1996 in approving 139 drugs and biological products with 53 of these being brand new molecular entities, speak volumes about the success of this venture jointly developed by Congress, FDA and industry in 1992. These additional funds which have hired up to 600 new reviewers enabled FDA to cut review times almost in half -- to 15.5 months for drugs for which user fees were paid in 1996. One of these new drugs was a treatment for MS.

Just as the 1992 law was for five years, a reauthorized PDUFA must be for five years. A one-year renewal will not suffice. Congress made a long-term commitment when it initiated the program -- and it should keep that commitment to FDA and to patients all across the country. The agency will not be able to retain and attract the best and brightest reviewers if Congress reauthorizes the program on a piecemeal basis and momentum would dissipate. Moreover, some important improvements proposed for a renewed user-fee law, such as a paperless, electronic information system, require an extended period of time to

implement.

Obviously for the new user fee law to take effect, Congress must provide full funding for FDA -- i.e., funding at least equal to that amount appropriated for the current fiscal year, adjusted for inflation. Otherwise, if baseline appropriations are not maintained, the user fees would just replace regular funding. In that case the net effect of the user fees would be to allow the government to reduce the annual deficit -- not to improve the drug development and review process for the benefit of patients.

The National MS Society also believes that the need to reauthorize PDUFA for five more years presents an excellent opportunity to enact related improvements in FDA's structure and practices. Last year there was considerable discussion in Congress and around the country about FDA reform. While commending FDA for its many internal improvements, we believe this is an excellent time to enact some additional reform measures on which there now is bipartisan agreement and agreement among many groups, including patients, Congress, FDA and industry. These moderate, commonsense and substantive provisions would enable the agency to become more efficient and productive while maintaining the highest safety and efficacy standards and they should be codified into law. We believe such changes would give FDA the authority and procedures to meet the challenges ahead in this time of exciting and speedy advances in medicine and science.

We would hope that these changes will include provisions to allow dissemination of peer-reviewed, up-to-date medical and scientific information to health providers on off-label uses. With all kinds of

information swirling around patients through the public media, on the Internet and by word-of-mouth, we believe patients interests are well served by this dissemination to their physicians who can help them assess its relevance for them. Likewise, we believe that prohibiting such peer-reviewed information from being disseminated is harmful to the interests of patients and their families. People with MS struggle daily to cope with an unpredictable disease that they will have for the rest of their lives and ravenously seek new information that may he of help. Many have been helped by using drugs apart from their primary effect, such as anti-viral drugs Amantadine and Pemoline used to fight the abnormal fatigue and some anti-depressant drugs used to assist in bladder control.

Our position is that to the extent that bipartisan agreement exists on these provisions, Congress should take the opportunity of enacting them as part of the reauthorization of PDUFA. This would be a landmark achievement -- for Congress, FDA, and most of all for Americans with MS and many other diseases whose lives indeed depend on quick approval of safe and effective new therapies.

Thank you.

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MARTHA KEYS

Martha Keys was elected in 1974 to the U.S. House of Representatives and served until 1979. She was a member of the Ways and Means Committee and its Subcommittees on Health and Public Assistance and also served on a Select Welfare Reform Committee in the 95th Congress. She was active in initiating successful legislation in areas of health public assistance, reducing work disincentives to the disabled, Social Security and tax law.

In 1979, she became Special Advisor to the Secretary of HEW and later that year Assistant Secretary of Education. She has directed foundation supported programs in the education area and has been a visiting professor of public policy on more than a dozen campuses. She developed and directed a national policy center, The Center for a New Democracy, in the mid-1980's and later was a partner in a group of public policy advisors.

Currently, Martha Keys is the Senior Public Policy Advisor to the National MS Society, after having served as the Vice President for Public Affairs since 1990. She was appointed to a five-year term as member of the Advisory Committee for Social Security in 1995. In 1996, Hs. Keys also began serving a three-year term with the National Institute of Neurological Disorders and Stroke Council of the National Institutes of Health.

ADDENDUM

In accordance with Rule XI, clause 2(g)(4) of the Rules of the House, and Rule 4(b)(2) of the Committee, the federal grants received by the National Rultiple Sclerosis Society for fiscal years 1995-1997 are as follows:

	1997	1996	1995
US National and Community Service-Americorps	$117,709	$668,591	5341,526
US Department of Education Project Alliance		3,000	132,157
US Department of Health and Human Services-NIH	25,000	25,000	25,000
TOTAL	$142,709	$696,591	$498,683