

Correspondence

Approval by the Food and Drug Administration of polymerized ragweed extract for treatment of ragweed-sensitive individuals

To the Editor:

The Allergy Section of Northwestern University has developed a new treatment for ragweed hay fever that is a significant advance in allergy injection therapy. This treatment is called *polymerized ragweed*. The license application has been before the Food and Drug Administration (FDA), Office of Biologics, for more than 4 years and is still awaiting approval.

Research on polymerized allergens has been conducted for the last 14 years by the Northwestern University Allergy Section and funded significantly by peer reviewed grants from National Institutes of Health. All data have been published extensively in critically reviewed journals.¹⁻¹¹

Polymerized ragweed is a major therapeutic advance that is safe and effective and may sharply reduce costs for millions of patients in the United States. The published data on the treatment are supported by all the leaders in academic allergy whom we have contacted to date.

Additionally, the FDA External Advisory Panel on Review of Allergenic Extracts has recommended licensing based on the safety and efficacy of polymerized ragweed. Most recently, our double-blind, placebo-controlled study of polymerized grass immunotherapy of identical design to the double-blind ragweed study was awarded the Lowell Memorial Prize. "The article chosen fulfills all the criteria for a well-controlled study of immunotherapy."¹²

Allergenic Products Branch of FDA has reopened the questions of safety and efficacy. Analyses by two groups at Northwestern and by another group at Key have independently confirmed the original conclusions, that the product is safe and effective.

No personal financial return will come to me or any member of the Allergy Section of Northwestern University from the therapy. All royalties that would come to me will be donated to allergy research and training at Northwestern University; Northwestern University uses its share of the royalties for general support of research.

Polymerized ragweed is a significant improvement in allergy injection therapy that we believe allergists will use to treat many more patients than can be treated now. We believe it should be licensed for use as soon as possible.

We call on the readers of this JOURNAL to correct this problem by writing their Senators and Representatives and asking them to review the status of the polymerized ragweed license application, reference number 80-305.

It is customary to address your Congressmen and Senators as follows:

The Honorable _____
U.S. Senator
Senate Office Building
Washington, DC 20510.

U.S. Capitol switchboard (202) 224-3121.

The Honorable _____
U.S. Representative
House of Representatives
Office of Building
Washington, DC 20515.

*Roy Patterson, M.D., Chairman
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