Reimbursement

The FDA compensates patient representatives for time spent participating in the meeting and covers related travel expenses (such as food and lodging).

Training

If selected, the FDA staff offers training and support to Patient Representatives about policies, procedures, and regulation. Training includes:

- FDA 101 teleconference
- Monthly webinars
- Annual FDA Patient Representative workshops for first-year representatives
- Other one-on-one support as needed

How to Apply

Anyone may nominate—or self–nominate—a candidate to serve as a Patient Representative on FDA Advisory Committees. All nominations must include a resume or curriculum vitae.

Please mail, fax or email nomination to:

FDA Patient Representative Program
Office of Special Health Issues
Building 32, Room 5361
Silver Spring, MD 20993
Phone: (301) 796–8460
Fax: (301) 847–8623

The Office of Special Health Issues works with patients and their advocates to encourage and support their active participation in formulating of the FDA's regulatory policy. The staff is familiar with the concerns confronting patients and families dealing with a life-threatening illness.

www.fda.gov/oshi

Office of Special Health Issues
Food and Drug Administration

FDA Patient Representative Program

FDA Patient Representative Program

The FDA Patient Representative Program gives patients a role in reviewing and approving new drugs, biologics and medical devices.

In 1991, the first patient representative served on the Antiviral Drug Advisory Committee for HIV. The patient represenative was included in the advisory committee because patients' groups advocated for a larger role in the development and regulation of medical products.

Ten years later, the FDA created the Patient Consultant Program, which offered patients the chance to take part in the FDA's decision-making process at meetings of the FDA and product developers.

Since then, the FDA combined the two programs into a single FDA Patient Representative Program. Now, patient representatives can take part in various FDA-sponsored activities.

Patient Representative Responsibilities

A Patient Representative's responsibilities includes providing a patient's point of view during the process, asking questions, and offering comments. To do this, Patient Representatives participate in Advisory Commitee meetings or medical products (such as drugs, devices or biologics) development meetings. Sometimes, they participate in both.

Advisory Committees

Advisory Committees provide expert advice to the FDA to help FDA officials make sound decisions about new drugs, biologics, medical devices and other public health matters. Scientific experts, such as doctors, statisicians, consumser and industry represenatives sit on FDA Advisory Committees, in addition to patient representatives. Advisory Committees are open to members of the public and media.

Medical Product Development Meetings

Medical product development meetings are confidential discussions between FDA officials and a medical product product developer. Usually held in telephone conference calls, these meeting ensure the FDA and the developer hear the patients' perspective throughout the development process.

FDA Patient Representative Criteria

To be considered for the program, an applicant must be a legal U.S. resident at least 18 years of age and have:

- Personal experience with the disease either as a patient, or primary caregiver such as a family member or friend.
- Ability to be objective while representing the concerns of other patients
- Willingness to communicate their views
- Knowledge about treatment options for the disease and research in that area
- No financial or ethical conflicts of interests for self or close family member