UNDERSTANDING DRUG WARNING LABELS

One of the most persistent concerns among people with psoriasis and psoriatic arthritis is coping with the side effects of prescription drugs. The specific benefits and side effects of each medication approved by the U.S. Food and Drug Administration (FDA) are spelled out in detailed "prescribing information"—those folded pieces of paper with the tiny words found in the medication's package. But for many people, just understanding the labels, particularly the long lists of possible side effects, can be a frustrating task.

The message boards on *www.psoriasis.org*, the National Psoriasis Foundation's Web site, are strewn with concerns over the side effects of medications. Many Members express frustration at not being able to understand the warning labels, and many seek the perspective of someone who's used the drug. Others have said the warning label simply doesn't say all it should.

"The brief bullet-point lists of side effects given to customers at the pharmacy counter are too broad and ambiguous," says Lynne, a psoriatic arthritis sufferer from Cape Cod who has visited the message boards in search of other patients' perspectives. "The informational leaflets provided by pharmaceutical companies are written for doctors and pharmacists and are much too scientific for the average person to understand."

Enbrel and Remicade are among the most fretted-over drugs, based on messages. Enbrel was first approved in 1998 for the treatment of rheumatoid arthritis; in 2002 it received approval for the treatment of psoriatic arthritis. Remicade was first approved for Crohn's disease and for rheumatoid arthritis in 1999; it is being tested for the treatment of psoriasis and psoriatic arthritis. Enbrel is under review at the FDA for the treatment of psoriasis.

Both Enbrel's and Remicade's success rates created a stir when first introduced. They are effective medications that, for some patients, can quickly and significantly reduce pain and swollen joints, as well as improve the ability to perform daily activities. And, like Amevive and Raptiva, two other biologics new on the market for psoriasis treatment, the side effects at first were perceived to be minor: upset stomachs, chills, fever, headaches, etc.

Over time, though, reports of tuberculosis, sepsis, heart disorders and other major health concerns materialized in association with Remicade and Enbrel—perhaps an unforeseen result of prolonged usage. The reports were rare and existed chiefly among patients who had dormant or pre-existing conditions. The warning labels were updated, but that in turn created a separate problem. The fear that "it could happen to me" is discouraging some people from using Enbrel and Remicade.

Many physicians are familiar with this dilemma and cite examples of patients who have discontinued using a particular drug because they've misunderstood the label or been scared off by a possible side effect. Craig Leonardi, M.D., an associate clinical professor of dermatology at St. Louis University School of Medicine and a member of the Psoriasis Foundation Medical Board, explains: "They're very complicated, very hard to understand, and the listing of side effects can be frightening. They can take the most simple drug and make it seem very scary."

Steven Feldman, M.D., Ph.D., also a member of the Foundation's Medical Board, voices similar criticism. "They're certainly not the Holy Grail for patient information," he says, stating that labels are not only frequently misunderstood but can even contradict a doctor's recommended treatment.

How to document accurately a medication's side effects, which vary so greatly, is a growing difficulty, especially when considering that many newer medications—including those for the treatment of psoriasis and psoriatic arthritis—may have long-term effects that aren't immediately noticeable. Each person's system controls his or her reaction to a medication in a different way, so side effects also vary among different users. But the FDA requires the warning label to inform of all potential danger to all users, not just those who are particularly susceptible.

In such matters, the FDA has enormous authority over the pharmaceutical industry. It decides not only what is approved, but also which drugs may even be tested—and when they are, it exhaustively oversees every detail. This power began with 1938's Federal Food, Drug and Cosmetic Act, which first required review and approval of all new medications by the FDA. In 1962, the thalidomide tragedy prompted the Kefauver-Harris Drug Amendments, which dramatically remodeled and intensified the review process. Now, it takes an average of 10 years for a drug to travel from the lab to the consumer, even if the drug has already enjoyed widespread approval in Europe or Canada. Some criticize this delay; others feel it's not long enough.

Right or wrong, the FDA is often forced to choose between speedily issuing a medication that's believed to be helpful, and waiting a certain amount of time before all the medication's side effects can be determined. Should the FDA wait decades for all the potential long-term side effects of Enbrel to become known, or authorize its use now so that those willing to risk unknown side effects can get the prompt relief it offers?

"I am willing to try anything that may be of help to me," writes Scott Bell, an Atlanta resident who has psoriatic arthritis. "I do not see how some people refuse to take meds that can help them. They must not be in as near the pain that I am."

Bell's perspective is in contrast to those who prefer to spend hours, months or even years carefully researching a new medication before trying it. Their general feeling is that a revision of the warning labels would eliminate a lot of frustration.

Until that happens, the best solution is to educate yourself fully about any medication you wish to use. Never hesitate to ask your physician. "The patient should not take action about something they've read on the label without calling the doctor to put it into context," says Dr. Leonardi.

Dr. Feldman cites the Psoriasis Foundation's brochures as the most accessible and understandable source of information. In addition, many medical Web sites have message boards dedicated to such discussion, and most pharmaceutical companies' home pages also answer these questions in relatively plain language. And remember: warning labels are there to educate, not to discourage you from getting what may be the best treatment available.

—Nathan Denny, freelance writer, Portland, Ore.