FDA Address, Lotronex

I am here today to speak in favor of allowing reintroduction of Lotronex to the market in our country. My reason for appearing is that my wife Virginia has lived with Irritable Bowel Syndrome for about twenty five years. When this medication was prescribed for Virginia, she got immediate relief from the symptoms of the disease. When the medication was pulled from the market, the reversing of its effect was just as immediate.

The labeling for this product says the product is indicated for "the treatment of irritable bowel syndrome (IBS) in women whose predominant bowel symptom is diarrhea." That is a perfect description of the problem Virginia has had over these twenty five years.

I want to create the image of why reintroduction of Lotronex is significant enough to Virginia and me for us to finance the cost of a trip from Louisiana to Washington just to have our time here today. As IBS develops and becomes more severe, the patient finds themselves with a much more limited life. The symptoms come on with very little warning. Therefore, the normal activities of life represent new problems. Virginia and I are fortunate in that I earn an adequate income so that she does not have to work outside the home daily. When she did work, getting to work and performing her responsibilities were made much more difficult by the unpredictability of IBS. It has also been common for us to change plans at the last minute or to have to leave activities because of this unpredictability. There is no need to get more graphic with the description, but be assured that there are often days at a time when Virginia does not leave home because the symptoms cannot be controlled.

For people who have not lived with IBS, it is difficult to understand the nature of the limits the disease creates. The patient develops a fear of leaving the home. The distance to the nearest bathroom becomes a major concern. We have made numerous accommodations in our effort to live with IBS. For example, we drive a large vehicle because we need room for the portable toilet in the back. I have developed the practice of going to many functions alone because Virginia is uncomfortable in committing to a specific timetable. Time with our grandchildren cannot be planned because cancellations are common. Simple shopping trips can become extended while waiting outside the public restrooms for Virginia. So, as you can see, the disease affects the family as significantly as it does the patient.

At present, there is no cure for IBS. The disease is very complex and not all the causes are known, so the potential for a real cure is very remote. Therefore, patients such as Virginia are just looking for something that will relieve symptoms. The cost of this disease over twenty five years has been huge. Fortunately, we have had good health insurance during this time. But when Virginia was taking Lotronex, she was able to reduce other medications. Therefore, while Lotronex was not available long enough to truly determine the financial effect, it is my belief that it would have helped reduce Virginia's health care cost over time.

We recognize there are risks involved with taking this drug. I have always worked under the assumption that all medicines, as foreign substances to the body, are poisons. We simply hope that the doctors know the right dose of the poison. Therefore, Lotronex will present risks as well. The question of importance to us is, Do the potential benefits outweigh the potential risks? Because of the experience we have with Lotronex, we have no doubt that the benefits do outweigh the risks.

The role of the FDA is to provide protections to the community in general against medications that may produce more risks than the benefits it provides. We appreciate the serious nature of the duty you have. However, having lived with this disease for twenty five years, desire for relief can create a sense of desperation. And then to have a drug available for a short time that provides relief and then to have the drug removed from the market only increases the desperation. If the FDA believes Lotronex should not be available for general distribution, at least make it available to those who have documented improvement while taking the drug. This would also allow for a population of patients from which to glean additional information about its affects in the real world.

Much information about Lotronex and the controversy surrounding its removal from the market is available on the internet. It is interesting to note that the links that are found by the search engines include the Lotronex Action Group and a variety of attorney firms. The Lotronex Action Group is, of course, actively lobbying for reintroduction of Lotronex. A telling indicator of the seriousness of this problem in the community is the fact that the Lotronex Action Group web site is registering over 30,000 hits. The attorney firms are actively seeking patients for a class action law suit. For the record, Virginia nor I have any relationship to either of these groups. But this does point out the dilemma. There is no doubt that if Lotronex is reintroduced, there will be law suits that Glaxo will have to defend. However, we believe the drug to be safe and effective for the problem Virginia has and would therefore be willing to sign liability releases to again have the drug available.

We thank you for this opportunity to address this group today. We trust that your studied approach to evaluation of Lotronex will allow for again making this drug available for Virginia and patients like her.

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