

To: Professor Sansom and members of his committee.

With respect, may I offer the following observations for your consideration?

This anecdote adds to my experience of Warfarin use since 1963, it having been first used in the area of anticoagulation, I believe, in the 1950's..

The date is relevant in this respect. I believe that around 50-60 years ago the requirements for marketing approval in information from clinical trials was very much less than now. The broad pre-marketing studies done now were unlikely to have been done then.

My experience is that one area, that of associated psychological disorder, could have been neglected. Specifically, I believe that if feelings of depression were present in patients under study, the symptoms would have been inevitably attributed to the patient's medical disorder, be it atrial fibrillation or stroke or any other disorder requiring anticoagulant therapy. Thus, my suggestion is that the possibility of depression resulting from the medication, warfarin, would have been overlooked.

My anecdote is as follows: a patient was taking warfarin for atrial fibrillation (AF) in order to avoid stroke. Her AF was more or less controlled. But her depression was significant, attributed by the patient to the warfarin. The feelings were sufficiently severe for her to seek to discontinue warfarin. She underwent ablation as treatment for her AF. It was partly successful. She now had sinus rhythm with atrial ectopics, along with persisting depression from, she believed, the warfarin. The warfarin was eventually ceased with immediate improvement in the mood disorder. However, within a few months she suffered other problems which, along with atrial dysfunction, led to a stroke.

Had she been still taking warfarin, the stroke would probably not have happened.

The patient was felt by her medical advisers to need a return to anticoagulant therapy. In view of her difficulty attributed to warfarin, she was commenced on Pradaxa. Her health since commencing Pradaxa has been good. There has been no recurrence of the depression associated with warfarin. Her recovery from the stroke is proceeding slowly.

I could add details of a case of deep vein thrombosis in a young man who also suffered adverse psychological effects when on warfarin.

I respectfully suggest that the possibility of adverse effects from warfarin that may have been overlooked - such as depression - should be considered in your deliberations. Perhaps a new study investigating psychological disorders in patients taking anticoagulants should be undertaken.

As a further consideration, please imagine the suffering this patient and her family have undergone, and the cost to her and to the community of the stroke. I have no doubt that those costs very far outweigh the cost of the Pradaxa which would probably have prevented the stroke, in a patient who could not tolerate warfarin.

I request that, in view of the significant costs associated with the listing of Pradaxa, you consider at least recommending approval for Pradaxa for patients who cannot tolerate warfarin.

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