southwest technologies inc.
treating the world well

5434 '98 JUL 31 A11 :05

July 25, 1998

Dockets Management Branch (HFA-305)
FDA
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Dear Sir:

Although this may be a little late for the official response period, I just was made aware of the comment period with the July issue of MM & M and I wanted to express my opinion on the "dissemination by manufacturers of unapproved-use information".

The restriction of the sharing of information on the use of products for "unapproved use" is a disservice to the potential patients and highly unfair to the companies" scientific staff, because it is only by sharing information, whether for approved use or unapproved use, by scientists can the field of science be advanced. Many of these scientists are employed by companies. It is these company scientists that are in the position to accumulate, assemble and evaluate the reports and only by sharing , discussing , and critically evaluating them can they determine if such reports validate and justify the expenditure of $100's of thousands of dollars to prove the validity of such uses.

Continued interference of FDA into the inhibition of communications of the scientific society will greatly inhibit the advancement of the development of many uses of already proven safe drugs and devices.

For example, we have not promoted the use of our products for the reversal of hypertrophic and keloid scars because it requires more than $50,000 for the controlled studies needed. However, a physician did finally published a summary of some of his results that he has accumulated over the last 6 years. It is too bad that we have been restricted in sharing the information. We have reports from at least 50 different institutions that use the product routinely for this application with exceptional success. Our product costs about 1/5 the cost of another commonly used product. The saving to the industry and government could be highly significant, because of the relatively inexpensive product, but many major reconstructive surgeries could be prevented..

In fact, we know and have known for more than 10 years that the use of our product as a dressing will prevent such scar formation, but again have been inhibited from disseminating this information because it is not an approved use. Many re-constructive surgeries could have been and could be prevented if we could market our products for all of the uses that have been found for them. These uses could have saved the tax payers and the insurance companies millions of dollars and can continue to do so, but it will not happen if the information can not be shared.

The costs for the required clinical studies for all the different applications would be well more that $25 million dollars. Much beyond the budget of our company with only a $3million gross annual income.

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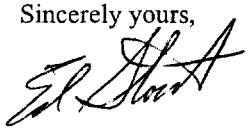
In addition, we are harassed by the FDA about every two years about our claim for being bacteriostatic and fungistatic and have to spend weeks of valuable time and effort to re-educate and re-establish our basic proven claim. This is unfair and highly inappropriate action by the FDA.

If FDA staff would be more reasonable in their position during discussions and communications with companies, the whole health care industry and the monetary savings to the community would be far better off. This doesn't mean that FDA should just let everyone do whatever they want, but that FDA needs to be open-minded when entering discussions and have a cooperative attitude.

We are all limited by our experience and training. To think that we are infallible is to be stupid. To be unable to admit to making mistakes is to be a failure. To be unbending and intolerant is to inhibit progress. To inhibit the dissemination of information is to inhibit the advancement of science.

Sincerely yours,



Ed Stout

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