ALDARA / Imiquimod

ClinicalTrials.gov identifier: NCT00799110

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PLEASE ALLOW ME TO INTRODUCE MYSELF. My name is Richard Beasley and I have a special reason for contacting you, which I will explain right after sharing with you a relevant segment of my background.

I have a multi-expertise engineering background which has allowed me opportunities to work on a variety of scientific and experimental projects throughout my forty year career. I hold numerous U. S. patents. During the late 1970s and early 1980s, I worked on experimental artificial mechanical heart projects that were associated with the team of Dr. Denton Cooley and Dr. Michael DeBakey, located in Houston, Texas. During that period of research, it was mandatory I learn a great deal about human physiology, with a special emphasis on the immune system, coupled with research involving implant rejections and impregnated materials that limit such rejections. There is no need for me to expand any further on my background but I do want to share with you the fact I am not a medical doctor nor am I a member of the medical community. However, I do have the expertise and knowledge to interpret clinical data, which involves negative chemical influences and stresses that ***Imiquimod*** imposes on the immune system by way of its very dangerous and unpredictable drug mechanism.

Imiquimod, or IQ, is one of the most dangerous small molecule chemicals to be approved by FDA for human use. As stated and recorded by Dr. Herbert Slade in Federal Depositions, IQ is not specific in what it can identify for destruction through apoptosis. It might identify cancer cells, it might identify a virus, or bacteria, or any number of other types of cells. So, IQ is not selective in that manner. It can even turn on an immune response directed at the sinus membranes and lead to sinusitis or other respiratory drug-induced conditions. From that standpoint, IQ is not controllable in practice. *(Slade was Director of 3M's International and National Pharmaceuticals division until the forced sale of that division during the last decade)*

Dr. Jim Lee, Director of Adverse Event Reporting and FDA Relations during this same time period, stated that IQ was found to be unacceptably aggressive at altering the immune response toward destruction of mucous membrane tissue. So aggressive that warnings were placed on the product sheet for Aldara.

Dr. Alain Rohan, working under the direction of Lee in AER, stated that IQ molecules would indeed enter circulation much quicker and more transparently when applied to open wounds or breaks in the skin.

3M, at Dr. Slade's direction, included this statement in the documentation submitted to the FDA for approval of Aldara. "Should IQ somehow find its way into blood circulation, in would most likely result in catastrophic consequences for the patient"

The FDA ran their own independent lab analysis on drugs and chemicals which alter the delicate balance between the relationship of Th_1 & Th_2 groups of cytokines. The FDA concluded that the unnatural shifting of cytokine relationship between these two groups of cytokines is responsible for the manifestation of some of the most dreadful autoimmune diseases known to mankind.

However, this very unwanted and dangerous drug mechanism the FDA found to be so devastating in their studies, 3M finds as a most desirable design parameter for IQ drug mechanism in Aldara. In fact, 3M readily states that it is this very FDA dreaded Th_1 & Th_2 alteration they so heavily rely upon for Aldara's success in today's marketplace.

You should all take a moment and determine which of these two entities got it right, because one of them is grossly wrong and has been irresponsible or should I say "responsible" for allowing IQ to reach the market under a veil of falsehoods.

Aldara was rammed through the FDA Fast Track Approval process in the late 1990s, and now there is an unjustified race taking place to find new and more broadly-accepted uses for Aldara/IQ. In a sense, that is an acceptable process of post approval-developmental progressions for an approved drug. But when I see studies and really human experimentations being conducted on the scale you are suggesting in your trials, I must object in the strongest of terms. Either you and your colleagues are operating in total denial of all the massive first & second generation clinical study results performed on this drug or you truly are operating with the assumption 3M has given you enough "selective" and "sanitized" data that you have gained a false sense of security that you are safely conducting your trials on humans. You and your colleagues should all take a breath and read the attached "Abstract on Aldara", see who is quoting the data, then reconsider just how far you should go in your attempt to expand the market for Aldara to include some of these bazaar uses such as breast cancer or cervical cancer.

Since being injured, permanently, from my own use of Aldara in 2000, I have focused like a laser on researching this drug, even to the point of collecting thousands of complaints from other users of Aldara, who likewise have been severely injured by their use of the drug. The pattern of injury is overwhelmingly suggestive that Aldara is in fact very dangerous, costing users both

their health and high medical costs as they concentrate their efforts on regaining whatever possible minute portions of the once excellent health they enjoyed prior to using Aldara.

In the face of so much negative data and the fact that 3M and the FDA both know how dangerous Aldara can be, I ask that you reconsider the continuation of your trials and experimentations, at least until you have had the opportunity to completely understand the drug you are investigating in your research. I know you are thinking you have all the pertinent information you need to professionally and safely conduct studies but I would like to challenge that position by saying that for every positive technical attribute you might list for Aldara, I can list two that are negative. The safety profile for Aldara is flawed and based upon irrelevant subjects and in no way represents the true and accurate results and findings from 3M research.

I trust that after thoroughly reviewing the" Abstract on Aldara" you will find the need to further investigate this drug and its pharmacological mechanism of drug actions on the innate immune system; more especially when the IQ molecule is allowed to be released into circulation as you are suggesting will be done in your experimentations.

Thank you for your time and professional consideration of these matters,

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NOTE: The information and comments in this document are my own personal opinions and commentary. Although based upon what I believe to be true and accurate statements from others who are very knowledgeable experts within the medical and pharmaceutical industry, the reader should not rely upon any of this information as a basis for conducting or altering research or likewise any other type of studies. It is intended that the collective data within this document become a catalyst for the reader conducting his or her own investigations into the subject matter contained herein.