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My name is Kent S. Carson, M.D. I am a physician with Board Certification in dermatology. I am a clinical associate professor of dermatology at Stanford University Medical Center, Stanford, California, and have had extensive clinical experience with the disease of scabies caused by the mite sarcoptes scabiei, for several decades.

I am opposed to the experimentation previously performed and proposed for the future by Larry G. Arlian of the Department of Biological Sciences, Wright State University, Dayton, Ohio, on the subject of immunology of scabies and the proposed development of a scabies vaccine.

I do not feel that any information useful to humans will derive from this research. Sarcoptes scabiei is a mite with many species variance that have undergone evolution and adaptation to a particular host over course of time. Over 40 animal hosts and over 17 families of mites exist. These are all different physiologically and immunologically. Arlian has and intends to continue to utilize a dog variety of scabies mite, sarcoptes scabiei var. canis, in his studies. Any immunologic or physiologic information obtained from the use of such a species of scabies would be inappropiate to extrapolate to humans. All the concepts Arlian proposes to study have been previously discussed in the literature and evaluated in humans. For Arlian to introduce facts into the literature based on a purely animal species of scabies that is unable to even infect humans long term, would not add to our understanding of this disease, but cloud it.

The best studies in this area would utilize sera from humans infected with the human variety of scabies, obtained by a physician while curing the patient of the disease. Unfortunately, Arlian is not a physician, and as a researcher accustomed to working with animals, is limited in the scope to which he can study this disease. As far as a development of a vaccine, scabies affects a very small percentage of the population in the United States, and its incidence is decreasing over the recent decades. Population affected is highly variable and is not spread evenly throughout the United States, but exists in pockets or clusters. Scabies has essentially no mortality associated with it and is easily curable with existing therapies. The cost and potential side effects of a vaccine makes it an illogical consideration considering the ease of current therapy of scabies. Constant inbreeding between strains of scabies mites undoubtedly occurs, therefore the immunity of the organism

would be constantly changing, and wouldn't be amenable to the development of a vaccine.

Even if we had a vaccine, who would be vaccinated? The disease is not uniform through the United States. Nursing home patient's and individuals who are immunosuppressed by various diseases can develop scabies occasionally in mini-epidemics. Yet, this population is least likely to be able to mount an active immune response to a vaccine since it is the absence of an effective immune response that enabled the scabies to become chronic in these patients, initially. Scabies doesn't initiate de novo in such a population of patients, it is brought into the nursing home, as an example, by an infected worker. They, in turn, were infected by a sexual contact, or by their child or some other family contact, who in turn has their own contact outside of the family. Where would the vaccination program begin or end in such an open ended population? All this is ~~mute~~ moot since we have safe and effective therapies for scabies. The solution to scabies is education of patients and physicians and proper utilization of currently existing therapies in an epidemiologic, appropriate manner.

Even in Third World Countries, studies have shown that the answer to scabies is education and treatment with therapeutic methods that already exist.

The suffering of the animals used "to maintain a colony" of scabies organisms is considerable. The itching is intense and constant, and over time the functioning of the animals internal organs is adversely affected potentially leading to the death of the animal amid a great deal of suffering. Two previous studies by Arlian and coworkers has addressed this. Under the guise of scientific advancement, the authors allowed rabbits to chronically be infested by scabies after which they were killed, and the degeneration of their organ systems described in detail. All of the findings were common sense extrapolations of already existing knowledge. The papers served no purpose other than to propagate funding obtainable by these researchers at the expense of the taxpayers and their animal subjects.

The conclusions of Arlian's papers admits that the studies were done in rabbits, utilizing a species of scabies that doesn't normally parasitize rabbits as its natural host, thereby bringing into question all of the papers conclusions by the authors own admission. To produce such spurious conclusions; the suffering of animals and the expenditure of taxpayers money is unjustified.

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Mr. Cantor:

I recently completed my residency training in dermatology and am currently engaged in private practice and basic research. Prior to attending medical school, I completed a Ph.D. in biology at the City University of New York. My work involved the study of skin kinetics in lizards and snakes. For the last fourteen years I have been involved in basic skin rsearch. As a resident in dermatology, I have been working on a newly developed human skin culture model which, I believe, will have a major impact on the way we do research.

I have recently been asked to review a grant proposal to study the effects of S. scabiei var. canis on blood indexes in rabbits and dogs. Over the past four years, I have treated dozens of patients with S. scabiei infections. Upon reading the papers sent to me, and a copy of the grant proposal itself, I have serious misgivings about some of the proposed experiments.

To begin with, I do believe that the animals will experience a great deal of suffering as a result of the induced infestations. Of the dozens of patients that I have treated for scabies, a vast majority of them complain of intense, unremittant pruritus. I believe that the animals used in this study will experience the same degree of suffering. I also feel that this suffering is completely unecessary given the potential usefulness of the proposed experiments. These experiments, like many other animal models, are often completely unreliable when extrapolated back to the human condition. In fact, in one of his papers, the author states that "not all parasitized rabbits were affected in the same way." Given this degree of unreliability, within the experimental group of animals, I believe that it is highly unlikely that any of the data collected from the proposed studies will have any bearing on the future treatment of humans.

While it is interesting to consider hematological and biochemical changes induced in humans infected by S. scabiei, I believe that attempting to establish an animal model will prove to be a waste of valuable government funding. I do agree, however, with the section of the proposal regarding blood tests on infected human subjects. Firstly, there are enough sujects to be studied and, secondly, the proposed tests will pose no threat to the patient's health or comfort. I believe that the data collected from these studies will prove to be much more reliable than any data collected from animal models. Also, the author states that as of the time that the grant proposal was written, there were no *in vitro* means of raising S. scabiei. However, in the last year, my laboratory has been working to perfect a novel human skin culture in cooperation with Advanced Tissue Sciences (La Jolla, California). I believe that this culture system may prove useful to the investigator in terms of raising S. scabiei *in vitro*

A a physician, my primary concern is the welfare of my patients. While I do believe that S. scabiei infections continiue to be a dermatologic problem among human populations, I strongly disagree with the notion that the proposed experimental animal models will be of any major benefit in treating or preventing this disease. I feel that the author should concentrate on studying changes in blood indexes of infected humans rather than relying on data collected from unreliable animal models.

If I can be of any further assistance, please do not hesitate to contact me.

Sincerely,

Paul C. Contard, Ph.D., M.D.
Department of
Dermatology