A new bioassay method, termed the "maximization test," is described and its application to the testing of a number of well-known substances is recorded. [The S2(2) indicated that this paper has been cited in over 320 publications since 1966.]

My suspicion was confirmed on several occasions, the most spectacular relating to the incorporation in toiletries of tetrachlorosalicylanilide, a bacteriostat and a potent contact and photocontact sensitizer. The manufacturer averred that five Draize tests had been conducted (1,000 subjects) by testing laboratories with no instances of sensitization. A conscientious test on 20 subjects would have revealed the allergenic capacity of this malevolent chemical that caused havoc in England.

Being a constitutional iconoclast, I set about to find out whether the Draize test could identify topical agents that dermatologists had come to recognize as significant allergens, including neomycin, benzoic acid, nitrofurans, ammoniated mercury, penicillin, substituted hydroquinones, and others. The result was unequivocal: the test lacked sensitivity and could not pick up familiar troublemakers. The Draize test could not stand up to testing.

My next task was to develop a procedure that could reliably identify contact allergens on a small number of volunteers. I took advantage of the fact that damaged skin is more easily sensitized. I pretreated the test sites with an anionic surfactant, sodium lauryl sulfate; this provoked an inflammatory response and also made the skin highly permeable to the test materials. I was able to show that even mild allergens could be reliably identified by 5- to 48-hour exposures on a panel of 25 subjects. I and others have modified the procedure but the basics remain. The popular of the test rests on its feasibility and reliability.

The moral of this story is that regulatory procedures issuing from government institutions are not to be exempt from one of the holiest structures of the scientific enterprise, namely, repeatability by other persons.

How could an insensitive method be so widely accepted? My dark answer is because of its insensitivity. A negative result is reassuring. It spells safety and is comforting to the manufacturer. Silence is tranquilizing. The maximization test, by contrast, is a vexation. It often results in one or more of the test subjects becoming sensitized. This is a troublesome result because one must then undertake an analysis of risk. The data have to be passed through the human mind and judgments have to be made. The maximization test only measures sensitizing potential and does not tell what percentage of people will become sensitized under actual use conditions. The maximization test is by no means a darling among producers of topical skin care products. Some would prefer not to know.