Accepted Manuscript

The Ocular Surface
A JOURNAL OF REVIEW, LIVING LABORATORY SCIENCE, CLINICAL SCIENCE, AND CLINICAL PRACTICE

Generally Regarded As Safe

Gary D. Novack, PHD

PII: S1542-0124(16)30227-0

DOI: 10.1016/j.jtos.2016.11.002

Reference: JTOS 208

To appear in: *Ocular Surface*

Please cite this article as: Novack GD, Generally Regarded As Safe, *Ocular Surface* (2016), doi: 10.1016/j.jtos.2016.11.002.

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

ACCEPTED MANUSCRIPT

SECTION: Pipeline, Gary D. Novack, PhD, Section Editor

TITLE: Generally Regarded As Safe

BYLINE: GARY D. NOVACK, PHD

FOOTNOTES

From PharmaLogic Development Inc., San Rafael CA and Departments of Pharmacology and Ophthalmology, University of California, Davis.

Disclosure: Gary D. Novack PhD consults with numerous pharmaceutical firms.

The general use of antibiotics and vaccines in the 1950s decreased the risk of death from many illnesses. However, this decreased risk of illness from bacterial and viral diseases was accompanied by a growing concern about toxicity from the increased use of chemicals in foods and food processing, including the potential to cause cancer. This concern was reflected in the 1958 Food Additives Amendment (Public Law 85-529) to the U.S. Federal Food, Drug and Cosmetic Act (**FFDCA**) of 1938. The basic thrust of this amendment was to require that before a substance could be used in food, its manufacturer must demonstrate the safety of the substance to the FDA, after which the FDA would establish a regulation defining the conditions under which the substance could be safely used.[1] Under the new law, qualified experts could judge substances as being "Generally Regarded As Safe" (**GRAS**) and thus not subject to this regulatory review (decreasing regulation). Then, a clause developed by the late Representative James Delaney (D-NY) stated that if a substance caused cancer in animals or humans, it could not be used as a food additive. Even a trace of such a substance detected in food would result in its prohibition. Rep. Delaney had lost a family member to cancer, and this may have been a factor in his proposing this regulation.

As a pharmacologist and toxicologist, I was taught the aphorism of Paracelsus from the 1500s that "…all things are poison and nothing is without poison; only the dose makes a thing not a poison." The Delaney clause fails to consider this perspective, assuming instead that even the littlest amount of a carcinogen is carcinogenic. While the benefit/risk consideration for a therapeutic agent might justify a risk of carcinogenesis, this is not likely to apply to food additives. Thus, in the 1950s, in public policy the perception was that there was no such thing as a "no-effect" dose. At that time, chemical analysis was performed using techniques such as liquid chromatography with sensitivity in parts per thousand (mg/g) and parts per million (µg/g).

Download English Version:

https://daneshyari.com/en/article/8591337

Download Persian Version:

https://daneshyari.com/article/8591337

Daneshyari.com