INTERNATIONAL MEDICAL TRIBUNE

641 LEXINGTON AVENUE
NEW YORK, N.Y. 10022
PHONE: (212) 421-4000

MEDICAL TRIBUNE
and Medical News
HOSPITAL TRIBUNE
New York, N. Y., U.S.A.

MEDICAL NEWS-TRIBUNE
Great Britain
London, England

MEDICAL TRIBUNE
International Edition
Africa
London, England

MEDICAL TRIBUNE
International Edition
Scandinavia
London, England

MEDICAL TRIBUNE
Internationale Wochenzeitung-
Ausgabe für Deutschland
Wiesbaden, West Germany

TRIBUNE MEDICALE
Paris, France

MEDICAL TRIBUNE
Internationale Wochenzeitung-
Ausgabe für die Schweiz
Baden, Switzerland

MEDICAL TRIBUNE
Internationale Wochenzeitung-
Ausgabe für Österreich
Vienna, Austria

Japan International
MEDICAL TRIBUNE
Tokyo, Japan

ARTHUR M. SACKLER, M.D.
International Publisher

A Sackler

April 16, 1979

Dr. Joshua Lederberg
Rockefeller University
1230 York Avenue
New York, N. Y. 10021

Dear Joshua:

I am becoming more and more convinced of the urgency and critical importance of your thoughts and desire to do something to lodge the concept of comparative toxicology. I know you are probably very busy but would appreciate your letting me know when you have written for the grant we had discussed. I have been out "beating the drums" for your idea and find I get very receptive responses. I have the clear-cut reaction that yours is "an idea whose time has come."

// discussed on phone

In respect to comparative toxicology, I think you would be interested in the following.

In my work on Medical Tribune, I have become concerned not only with the double standards, but with the lack of consistency in application of existing standards, and the absence of clear criteria as to what much of our toxicologic findings signify.

I was astonished to discover that the intermediates and end-products of the fluoridination and chlorination of drinking water have not been studied with the same technology and criteria as used to determine carcinogenicity, teratogenicity and mutagenicity of essential prescription therapeutic agents. The rigid criteria applied to new, potentially life-saving medications (whose research and entry into medical therapeutics have thereby been delayed or excluded or terminated) have not been applied to drinking water.

In 1975, I first interviewed Dr. Theodore Cooper, then Assistant Secretary for Health, and raised the question as to whether the tests which FDA required for INDs and NDAs had been applied to drinking water to which the fetus is exposed from conception and the individual through his entire life. Dr. Cooper indicated surprise and promised to investigate. Subsequently, he checked with Dr. Schneiderman of the National Cancer Institute and other relevant government agencies and unofficially informed me that he could locate no such information.

It now seems that I may have finally been able to confirm that the tests and criteria used to approve clinical pharmacologic investigations on new therapeutic agents have not been applied to drinking water.

The following question was posed to the current Commissioner of the FDA:

"Have the standard procedures used in respect to prescription drugs been applied to determine mutagenicity, carcinogenicity and teratogenicity of fluorides and/or chlorine, fluoridated water and/or chlorinated water and the substances found in water as a result of fluoridation and chlorination? "

After my interview with the Commissioner on June 24, 1977, and my letter of September 29, 1977,* I finally received the following response:

"The answer is no."
From his letter of December 22, 1978.**

In effect, at this point I believe two issues arise:

1. Why the failure to apply basic tests and criteria to drinking water, the commonest substance known to man and used without restriction in the United States when such tests have been used to delay or refuse permission for clinical research, to stop research, or remove from testing important therapeutic agents?

2. Of equal importance, why, despite my information from Dr. Cooper, did it subsequently take one and one-half years to obtain from FDA a direct, unequivocal reply, and then with qualifications and explanations?

* See Appendix I
** See Appendix II

I am enclosing, as background, some off-the-record material and other sections not published from my interview with Dr. Donald Kennedy (see Appendix III). Published sections were in Medical Tribune, Oct. 5, 12, 1977.

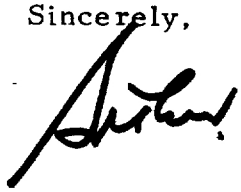
After receipt of the statement from Dr. Kennedy that "The answer is no", I was contacted by the Commissioner's office and asked for a personal discussion of the matter. Following a meeting with a member of this agency, I was informed that I would receive another communication from the FDA. When this communication is received, I will pass it on to you.

I am sending this material to you and to a few other scientists whom I hold in high regard. I would appreciate your reactions to the significance of the situation as it exists and to the problems posed in respect to

(1) realistic, balanced, regulatory processes for new drug research, therapeutics, food and water; and

(2) the imperative that responsible questions relating to these be forthrightly and promptly addressed.

Sincerely,



k