DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

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Arthur M. Sackler, M.D.
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Dear Dr. Sackler:

I can give you a simple and direct answer to the question in your letter of September 29. The answer is no; standard procedures used to assess the mutagenicity, carcinogenicity, and teratogenicity of prescription drugs have not been applied by FDA to fluorides, to chlorine, to drinking water treated with these chemicals, or to most substances found in water as a result of such treatment. That answer, while correct, is seriously misleading, in part because the question itself is subject to misinterpretation. Let me try to explain without, I hope, getting into a welter of bureaucratic or scientific technicalities.

In the first place, chlorination of water supplies has been around for a long time, a good deal longer than the Food, Drug, and Cosmetic Act. Toxic effects have not been demonstrated. On the other hand, the public health benefits of chlorination have proven little short of miraculous. Fluoridation, of course, has a shorter history, but its demonstrated role in preventing dental caries is such that the Public Health Service not only allows communities to add fluorides to community water supplies, but strongly encourages them to do so. The FDA does have a specific policy with respect to the use of fluorine compounds in drinking water. It appears in 21 CFR 170.45.

The answer to your question does not, however, rest solely on tradition or legal precedent. There is, in fact, what I believe to be a rational scientific basis for the view that testing requirements are appropriate and necessary in the evaluation of prescription drugs are not per force applicable to chemicals used to treat community water supplies. In the one instance (treatment of drinking water) we are talking about preventive health measures that reach and benefit tens of millions of people throughout their entire lifetimes, most of whom are in good health most of the time. The health significance of exposure to environmental factors is gauged through large and often lengthy epidemiological studies, which may lead to the kind of laboratory research designed to elucidate the cause of an adverse health effect.

In testing drugs to establish their safety and effectiveness, and specifically to discover their potential for causing cancer, genetic changes, birth defects, etc., we face a substantially different situation. Here we are talking about substances that are prescribed by physicians for a circumscribed, if often large, population. In the case of new drugs, these substances will most often be materials that are not commonly present in the environment, that do not have a lengthy record of use without toxic effects, that may in fact be quite harmful if improperly used, and that for the most part will be given to individuals whose health is believed to be compromised by acute or chronic illness or by injury. In those circumstances, common sense demands, and the Agency's regulations require, that the fullest possible spectrum of knowledge about potential harm be gathered before a drug is approved, information that may in fact result in a decision not to approve a drug for marketing if its risks are found clearly to outweigh its benefits.

Thus, there are both procedural and scientific reasons for answering your question in the negative. I hope that this, together with my earlier letter of July 31, not only answers but also clarifies the question you raised.

Sincerely yours,

Donald Kennedy
Commissioner of Food and Drugs