April 8, 1981

Dr. Lederberg:

Here's a copy of the paragraphs I put together after our lunch yesterday. If you have any objections to the way I construed your remarks, please give me a call by the end of the week. Again, thanks for taking time to speak with us. Your comments make a very valuable addition to our regulatory coverage.

Sincerely yours,

Mike Hartung

Michael Hartung
Associate Editor
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 1. | Dearth of good data threatens rational regulation. Laboratory studies that simulate the effect of toxic substances on humans are raw material for nearly every health standard that is written, yet a leading scientist finds the research woefully inadequate. "I am dismayed about the very nearly total irrelevance of most of the toxicological testing that goes on these days," says Dr. Joshua Lederberg, president of Rockefeller University, N.Y.C., and Nobel laureate. "Testing protocols for carcinogens do not even reflect what we know about the mechanism of cancer initiation and promotion," he told PT. In his view, it is imperative that universities, industry and government agencies develop new research methods and disciplines to generate better scientific data which can direct the course of future rule-making. Recent court decisions have stressed the need for government regulators to base their regulations on demonstrated hazards and remedies. OSHA, for example, has seen its benzene and lead standards remedied for further evidence of their provisions. But good data is often simply not available, says Lederberg, and with government research funds shrinking, the task more often falls on universities and industry to do basic research on health hazards. "Industry, in particular, has a vanishing opportunity to keep its credibility a responsible seg-
ment of society," Lederberg remarks, "and academic disciplines haven't been flexible enough to respond to increasingly complex toxicological threats."

Under Lederberg's leadership, Rockefeller University is setting up a comparative toxicology lab to investigate body mechanisms of carcinogenesis and neurotoxicology. Researchers will reportedly rely more heavily on monitoring human reaction to toxic chemical exposure by testing the body's response to accidental exposures. Only the Massachusetts Institute of Technology, Cambridge, Mass., is embarked on a similar program, says Lederberg, and useful data may be at least five years away. Despite the Reagan administration's call for cooperation with industry in rule-making, Lederberg believes public opinion will more and more demand stringent regulatory steps be taken to control toxic chemical production and disposal, perhaps needlessly stifling innovation and business growth. "

"We'd research an industrial chemical accident with the same rigor that investigators use in an airplane crash. Accidents can tell us a lot about the limits of human tolerance," says Lederberg.