# THE LAST WORD/

by Daphne Kamely

## ON THE RELEASE OF GENETICALLY ALTERED VIRUSES

Can genetically altered viruses be safely released into the environment? This question has concerned scientists and policy-makers for some time. The task of weighing the benefits against the risks is formidable. Further, there is little information from which to predict the potential hazards that modified viruses may pose. Nevertheless, with the current strong research interest in genetically altered viruses, this issue must be resolved. Using genetic engineering techniques, scientists are beginning to exploit certain properties of viruses to study diseases and their possible prevention at the molecular level, and to understand gene regulation and gene expression in eukaryotic cells. As cloning vehicles, genetically altered viruses provide an important tool in the development of new vaccines, therapeutic agents, chemicals, and pesticides.

In order to assess potential hazards, it is important to characterize the survival, spread, infectivity, and pathogenicity of modified viruses, and to predict their transport and fate in the open environment. The few scattered examples of risk models for viruses cannot possibly constitute a risk assessment program. Yet both industry and the regulatory agencies are in imminent need of a full-scale risk assessment program in anticipation of new commercial applications for modified viruses. Clearly, we must develop better testing and evaluation methods, monitoring techniques, and assessment procedures.

Insight regarding the release of modified viruses into the environment can be gained from experience with genetically altered bacteria, on which most commercial application has focused to date. Because risks associated with genetically altered bacteria are better understood than those of viruses, it should be much less difficult to approve the environmental release of modified bacteria than that of viruses. Based, however, on the difficulties in obtaining approval to release the first batch of genetically engineered bacteria, approval for viruses will not be easy. Despite extensive greenhouse experiments and considerable data on the survivability of the bacterium, its host range, and its competitiveness with other bacteria, the release into the environment of genetically modified organisms has raised substantive public concerns and has triggered several lawsuits against the federal government.

If a bacterial field test has raised so much controversy, what can be said of the environmental release of genetically altered viruses? Obviously, there is no such thing as zero risk. Like bacteria, viruses exist practically everywhere: in humans, animals, and the environment. Unlike other microorganisms, however, viruses are incapable of reproducing themselves except through the cells of other organisms. By their nature, therefore, viruses infect other organisms—and are often pathogenic. The properties that are responsible for environmental transmission and persistence of viruses are poorly understood. And most information available concerns naturally occurring viruses and viruses altered through conventional techniques, as in the development and production of vaccines.

In order to address the issue of genetically altered viruses in the environment, EPA (in cooperation with the American Association for the Advancement of Science, AAAS) sponsored a conference in April of 1985 at the Banbury Center of Cold Spring Harbor, New York. In May, a symposium addressing Environmental Aspects of Genetically Altered Viruses was presented at the 1985 AAAS Annual Meeting in Los Angeles. (The full proceedings of the Banbury Conference were published in a Banbury book in January 1986.)

Some surprising information was presented on the stability of viruses over time and distance in the environment. For example, a gastroenteric virus has been reported to survive in water over a period of several months and remained infectious when collected and put back into culture. Similarly, viruses which were detected 60 miles downstream retained their full virulence. Although viruses are known to become pathogenic, scientists seemed to agree that genetic manipulation of viruses would probably weaken the viral strains, and that nature puts a selective pressure against the development of virulent strains. Interestingly, experimental results have shown that the more one modifies a virus, the more attenuated it is in the host and the weaker it becomes in the environment.

I believe that the benefits to be derived from genetically engineered viruses outweigh the risks. At the same time, we ought to keep in mind that the effects of genetic alteration are unpredictable. In fact, it was shown at the Banbury meeting that a single gene alteration can result in tremendous malignancy and virulence. Yet the few examples cited cannot be generalized to predict whether a release is safe or not. Initially, each release will have to be evaluated on a case-by-case basis. As more commercial applications of research on viruses become available, a risk assessment program to explore viral action in the environment should replace the case-by-case approach.

As Albert H. Teich, head of AAAS's office of public sector programs, wrote in his summary of the Banbury conference, "Many key decisions on regulation of genetically altered viruses are likely to be made by policy-makers with relatively limited knowledge of the scientific nature of viruses. Following experiences like Three Mile Island, decision-makers and members of the public seem increasingly unwilling to accept technical experts' assurances that a technology is safe." The scientific community must act with the utmost care and responsibility in providing a solid scientific basis for policy and regulatory decisions. This approach will help to safeguard public health and the environment while assuring that beneficial applications of genetically altered viruses are exploited to their full extent.

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