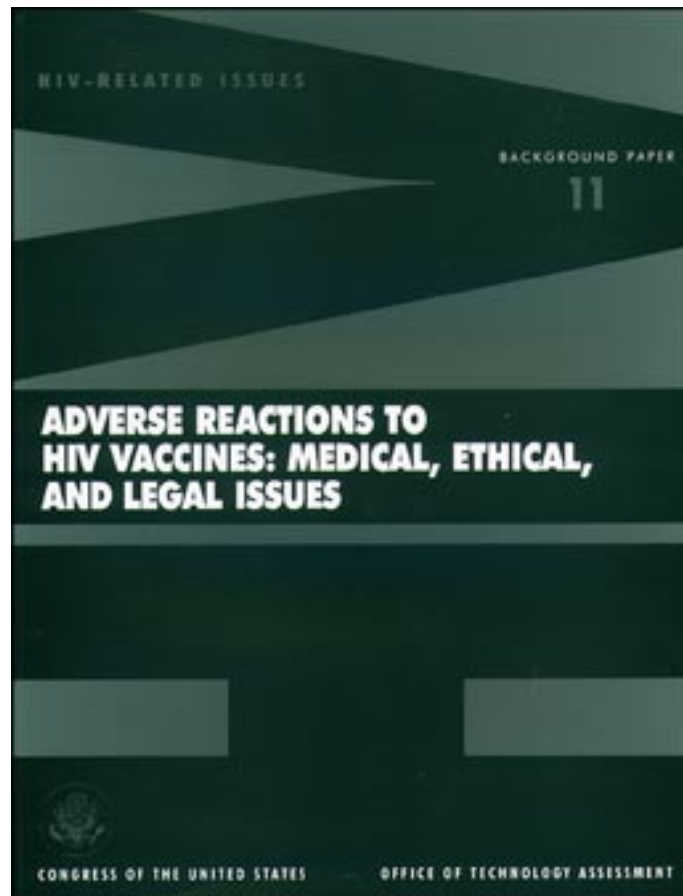


*Adverse Reactions to HIV Vaccines:  
Medical, Ethical, and Legal Issues*

September 1995

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# Foreword

**A**IDS researchers are investigating new vaccines that would prevent infection with HIV and reduce the spread of AIDS. Some have argued that product liability concerns have discouraged investment in HIV vaccine research and development. The purpose of this OTA background paper is to describe the current state of development of HIV vaccines, and to discuss what is known about adverse reactions that may occur. The background paper provides an overview of ethical issues that arise in the conduct of HIV vaccine trials. The report also discusses alternatives to the current product liability system to encourage the development of HIV vaccines and to fairly compensate those who are harmed as a result of adverse reactions to the vaccine.

This background paper was prepared in response to a request from the Subcommittee on Health of the House Ways and Means Committee. It is eleventh in OTA's series of studies on HIV-related issues. The preceding papers in this series were:

Do Insects Transmit AIDS? (9/87),  
AIDS and Health Insurance: An OTA Survey (2/88),  
How Effective is AIDS Education? (6/88),  
The Impact of AIDS on the Kaiser Permanente Medical Care Program (Northern California Region) (7/88),  
How Has Federal Research on AIDS/HIV Disease Contributed to Other Fields? (4/90),  
The Effectiveness of Drug Abuse Treatment: Implications for Controlling AIDS/HIV Infection (9/90),  
HIV in the Health Care Workplace (11/91),  
The CDC's Case Definition of AIDS: Implications of the Proposed Revisions (8/92),  
Difficult-to-reuse Needles for the Prevention of HIV Infection Among Injecting Drug Abusers (10/92), and  
External Review of the Federal Centers for Disease Control and Prevention's HIV Prevention Programs (9/94).

Other OTA reports addressing AIDS-related issues include:

Blood Policy and Technology (1/85),  
Review of the Public Health Service's Response to AIDS  
(technical memorandum, 1/85),  
The Cost of AIDS and Other HIV Infections: Review of the Estimates  
(staff paper, 5/87),  
Medical Testing and Health Insurance (8/88),  
Adolescent Health (11/91), and  
The Continuing Challenge of Tuberculosis (9/93).



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**Note:** OTA appreciates and is grateful for the valuable assistance and thoughtful critiques provided by the participants in OTA's workshop on April 6, 1994. The workshop participants do not, however, necessarily approve, disapprove, or endorse this background paper. OTA assumes full responsibility for the background paper and the accuracy of its contents.