

ANNEX E

**JOINT NUCLEAR,
CHEMICAL, AND BIOLOGICAL, DEFENSE
PROGRAM
FUNDING SUMMARY
AND
STATEMENT REGARDING CHEMICAL AND
BIOLOGICAL DEFENSE PROGRAMS
INVOLVING HUMAN SUBJECTS**

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INTRODUCTION

Section 1511 of Title 50 of the U.S. Code (50 USC 1511) required the Secretary of Defense to submit an annual report to Congress setting forth amounts spent during the preceding year for research, development, test, and evaluation (RDT&E) of all lethal and nonlethal chemical and biological agents, including a full explanation of each expenditure. In addition, the Secretary of Defense was directed to provide a full accounting of all experiments and studies conducted by DoD in the preceding year, whether directly or under contract, which involve the use of human subjects for the testing of chemical or biological agents.

This reporting requirement was repealed by the FY96 National Defense Authorization Act (Public Law 104-201, Section 1061). Because of public and Congressional concerns regarding this information, a funding summary is provided in Section I of this annex. Information on the use of human subjects involving chemical or biological agents is provided in Section II of this Annex.

**SECTION I:
JOINT NBC DEFENSE PROGRAM FUNDING SUMMARY**

In accordance with 50 USC 1522, *Department of Defense Chemical and Biological Defense Program*, RDT&E for all DoD chemical and biological defense programs (with the exception of those conducted by the Defense Advanced Research Projects Agency, DARPA) are consolidated into six defense-wide program element (PE) funding lines. Detailed funding information previously contained in this annex is provided annually to Congress in the Joint Service Chemical and Biological Defense Program, President's Budget Submit, Descriptive Summaries of Research, Development, Test and Evaluation, and in the Department of Defense Extract found in the Budget of the United States. These budget submissions provide a detailed account of prior year accomplishments and planned activities for the budget request period. Table E-1 provides a summary of appropriated and requested funding from FY96–FY99. FY96 was the first year in which all Service and Defense Agency CB defense programs were consolidated into defense-wide funding lines. Prior to FY96, funding was included in several separate Service and Defense Agency funding lines. Also, during FY96 approximately \$30 million was transferred to the CB Defense Program procurement line from Army operations and maintenance accounts for biodefense vaccine acquisition. Much of the growth in the program between FY96 and FY97 resulted from the transfer of funds between existing accounts rather than real growth in the overall CB Defense Program.

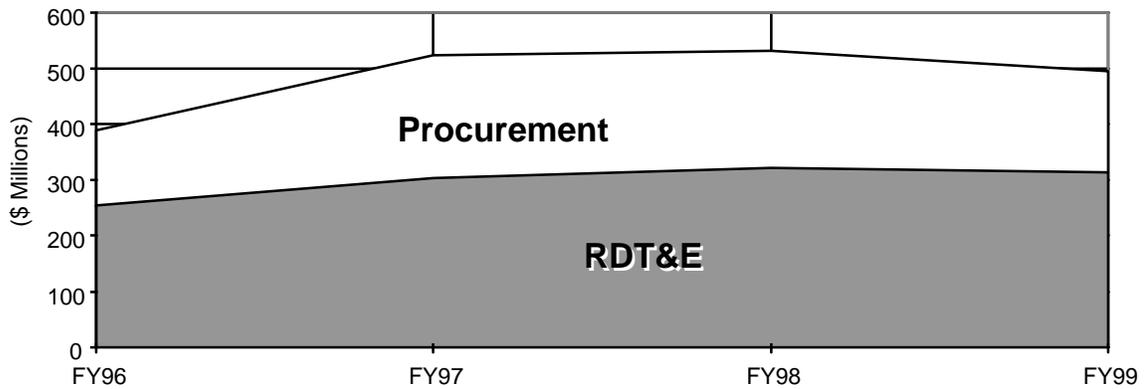


Figure E-1. Chemical and Biological Defense Program Funding

Table E-1. Chemical and Biological Defense Program Funding Summary

Program Element (PE)	(\$millions)			
	FY96*	FY97*	FY98**	FY99**
0601384BP - Basic Research	26.528	29.325	25.190	26.018
0602384BP - Applied Research	68.565	67.852	60.023	58.360
0603384BP - Advanced Development	34.219	43.092	41.223	40.581
0603884BP - Demonstration/Validation	29.946	48.492	55.145	61.910
0604884BP - Engineering & Manufacturing Development	87.326	97.476	120.535	108.006
0605884BP - Management Support	7.007	16.365	18.730	17.677
RDT&E Subtotal	253.491	302.602	320.846	312.552
Procurement	135.286	220.399	210.010	183.004
CB Defense Program Total	388.777	523.001	530.856	495.556

* Appropriation

** President's Budget Request

**SECTION II:
STATEMENT REGARDING CHEMICAL AND BIOLOGICAL DEFENSE
PROGRAMS INVOLVING HUMAN SUBJECTS**

50 USC 1511 previously required the Secretary of Defense to provide “a full accounting of all experiments and studies conducted by the Department of Defense in the preceding year, whether directly or under contract, which involve the use of human subjects for the testing of chemical or biological agents.” In addition, 50 USC 1520 requires prior notification of at least 30 days to Congress and others before any such tests are conducted. (See Section III of this annex for the complete text of 50 USC 1511 and 50 USC 1520.)

Table E-2 provides a summary of prior and planned tests conducted by the Department of Defense, both directly or under contract, which involve the use of human subjects for the testing of chemical or biological agents. In summary, there has been no such testing since 1969 with biological agents, since 1975 for chemical agents, and no testing is planned.

**Table E-2. Summary of Experiments and Studies with Human Subjects
Involving the Use of Chemical or Biological Agents**

November 25, 1969	– Human biological agent testing ended
July 28, 1975	– Human chemical agent testing ended
Since 1969/1975	– No activities with human subjects involving exposure to biological agents (since 1969) nor chemical agents (since 1975) have occurred since testing ended

The Department is in full compliance with the requirements of all laws regarding the use of human subjects involving chemical or biological agents. DoD is involved in no experimentation or any other efforts which involve the exposure of human subjects to chemical or biological agents.

As part of the DoD Chemical and Biological Defense Program, DoD requires the use of small quantities of chemical and biological agents in the research, development, test and evaluation (RDT&E) of detection, protection, and decontamination equipment and systems. Chemical agents are also used in small quantities in training U.S. forces to operate in protective equipment and to operate detection and decontamination systems in a chemical or biological environment. However, no RDT&E nor training involves the exposure of human subjects to chemical or biological agents.

Medical chemical and biological defense programs involve the use of human subjects in controlled clinical trials to test and evaluate the safety, immunogenicity, and other effects of medical products (drugs, vaccines, therapies, *etc.*) to protect against chemical and biological agents. The use of human subjects in these trials involves volunteers who have provided informed consent. All use of human subjects in these trials is in full compliance with the

“Common Rule,” Federal Policy for the Protection of Human Subjects, Food and Drug Administration (FDA) regulations, Federal Acquisition Regulations (FAR), DoD Directives and Instructions, and *all* other applicable laws, regulations, issuances, and requirements. No medical chemical or biological defense programs involving human subjects involves the exposure of these subjects to chemical or biological agents.

While DoD conducted tests involving the exposure of human subjects to chemical and biological agents in the past, all such tests and programs have been halted and disbanded. The United States formally renounced the “use of lethal biological agents and weapons, and all other methods of biological warfare” in National Security Decision 35, November 25, 1969. Human testing with lethal biological warfare agents was never done and testing with incapacitating biological warfare agents was ceased in 1969. The last human testing of chemical warfare agents occurred on July 25, 1975. Acting Secretary of Army Norman Augustine suspended testing of chemical compounds on human volunteers on July 28, 1975.

Tests involving the exposure of human subjects to chemical agents began in the 1940s and continued following World War II through the Cold War until the early 1970s. Such testing has been documented and reported to Congress. See for example, Department of Army, Inspector General Report, DAIG-IN 21-75, *Use of Volunteers in Chemical Agent Research*, March 1976. In addition, there was extensive Congressional testimony on this subject during 1975 and 1976. DoD has not conducted any experimentation since that time involving the exposure of human subjects to chemical warfare agents.

**SECTION III:
TEXT OF PUBLIC LAWS REGARDING USE OF HUMAN SUBJECTS IN TESTS
INVOLVING CHEMICAL OR BIOLOGICAL AGENTS**

50 USC 1511 Reports to Congress

Repealed by Public. Law 104-106, title X, Sec. 1061(k), Feb. 10, 1996, 110 Stat. 443

The Secretary of Defense shall submit an annual report to Congress on or before January 31 setting forth the amounts spent during the preceding year for research, development, test, and evaluation of all lethal and nonlethal chemical and biological agents. The Secretary shall include in each report a full explanation of each expenditure, including the purpose and the necessity therefor. The report shall include a full accounting of all experiments and studies conducted by the Department of Defense in the preceding year, whether directly or under contract, which involve the use of human subjects for the testing of chemical or biological agents.

50 USC 1520. Use of human subjects for testing of chemical or biological agents by Department of Defense; accounting to Congressional committees with respect to experiments and studies; notification of local civilian officials

(a) Not later than thirty days after final approval within the Department of Defense of plans for any experiment or study to be conducted by the Department of Defense, whether directly or under contract, involving the use of human subjects for the testing of chemical or biological agents, the Secretary of Defense shall supply the Committees on Armed Services of the Senate and House of Representatives with a full accounting of such plans for such experiment or study, and such experiment or study may then be conducted only after the expiration of the thirty-day period beginning on the date such accounting is received by such committees.

(b)(1) The Secretary of Defense may not conduct any test or experiment involving the use of any chemical or biological agent on civilian populations unless local civilian officials in the area in which the test or experiment is to be conducted are notified in advance of such test or experiment, and such test or experiment may then be conducted only after the expiration of the thirty-day period beginning on the date of such notification.

(2) Paragraph (1) shall apply to tests and experiments conducted by Department of Defense personnel and tests and experiments conducted on behalf of the Department of Defense by contractors.

(Pub. L. 95-79, title VIII, Sec. 808, July 30, 1977, 91 Stat. 334; Pub. L. 97-375, title II, Sec. 203(a)(1), Dec. 21, 1982, 96 Stat. 1822.)