

104TH CONGRESS
2D SESSION

H. R. 4257

To amend the Public Health Service Act to provide a one-stop shopping information service for individuals with serious or life-threatening diseases.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 27, 1996

Mr. LAZIO of New York introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Public Health Service Act to provide a one-stop shopping information service for individuals with serious or life-threatening diseases.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. INFORMATION PROGRAM ON DRUGS FOR SERI-**
4 **OUS OR LIFE-THREATENING DISEASES.**

5 Section 402 of the Public Health Service Act (42
6 U.S.C. 282) is amended—

7 (1) by redesignating subsections (j) and (k) as
8 subsections (k) and (l), respectively; and

9 (2) by inserting after subsection (i), the follow-
10 ing new subsection:

1 “(j)(1) The Secretary, acting through the Director of
2 the National Institutes of Health, shall establish, main-
3 tain, and operate a program with respect to information
4 on research, treatment, detection, and prevention activities
5 relating to serious or life-threatening diseases and condi-
6 tions. The program shall, with respect to the agencies of
7 the Department of Health and Human Services, be inte-
8 grated and coordinated, and, to the extent practicable, co-
9 ordinated with other data banks containing similar infor-
10 mation.

11 “(2)(A) After consultation with the Commissioner of
12 Food and Drugs, the directors of the appropriate agencies
13 of the National Institutes of Health (including the Na-
14 tional Library of Medicine), and the Director of the Cen-
15 ters for Disease Control and Prevention, the Secretary
16 shall, in carrying out paragraph (1), establish a data bank
17 of information on clinical trials and treatments (including
18 drugs, biologicals, devices, and other therapies) with re-
19 spect to serious or life-threatening diseases and conditions.

20 “(B) In carrying out subparagraph (A), the Secretary
21 shall collect, catalog, store and disseminate the informa-
22 tion described in such subparagraph. The Secretary shall
23 disseminate such information through information sys-
24 tems, which shall include toll-free telephone communica-
25 tions, available to individuals with serious or life-threaten-

1 ing diseases and conditions, to other members of the pub-
2 lic, to health care providers, and to researchers.

3 “(3) The Data Bank shall include the following:

4 “(A) A registry of clinical trials (whether Fed-
5 erally or privately funded) of experimental treat-
6 ments (including drugs, biologicals, devices, and
7 other therapies) for serious or life-threatening dis-
8 eases and conditions under regulations promulgated
9 pursuant to sections 505 and 515 of the Federal
10 Food, Drug, and Cosmetic Act that provides a de-
11 scription of the purpose of each experimental drug
12 protocol, either with the consent of the protocol
13 sponsor, or when a trial to test efficacy begins. In-
14 formation provided shall include eligibility criteria, a
15 description of the location of trial sites, and a point
16 of contact for those wanting to enroll in the trial,
17 and shall be in a form that can be readily under-
18 stood by members of the public. Such information
19 must be forwarded to the Data Bank by the sponsor
20 of the trial not later than 21 days after approval by
21 the Food and Drug Administration.

22 “(B) Information pertaining to experimental
23 treatments for serious or life-threatening diseases
24 and conditions that may be available—

1 “(i) under a treatment investigational new
2 drug application that has been submitted to the
3 Food and Drug Administration pursuant to
4 part 312 of title 21, Code of Federal Regula-
5 tions;

6 “(ii) as a Group C cancer drug; or

7 “(iii) under an exemption for devices for
8 investigational use pursuant to part 812 of title
9 21, Code of Federal Regulations.

10 The Data Bank shall also include information per-
11 taining to the results of clinical trials of such treat-
12 ments, with the consent of the sponsor, including in-
13 formation concerning potential toxicities or adverse
14 effects associated with the use or administration of
15 such experimental treatment.

16 “(4) For the purpose of carrying out this subsection
17 there are authorized to be appropriated such sums as may
18 be necessary.”.

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