

114TH CONGRESS  
1ST SESSION

# H. R. 3284

To amend the Public Health Service Act to provide for the establishment of a mesothelioma patient registry, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 29, 2015

Mr. KATKO (for himself, Ms. SCHAKOWSKY, Mr. COLLINS of New York, Mr. KING of New York, Mr. KENNEDY, Ms. MCCOLLUM, and Mr. LANCE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Public Health Service Act to provide for the establishment of a mesothelioma patient registry, and for other purposes.

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. SHORT TITLE.**

4 This Act may be cited as the “Mary Jo Lawyer Spano  
5 Mesothelioma Patient Registry Act of 2015”.

1 **SEC. 2. PATIENT REGISTRY FOR MESOTHELIOMA DATA**  
2 **COLLECTION AND RESEARCH.**

3 Title III of the Public Health Service Act is amended  
4 by inserting after section 399V–5 of such Act (42 U.S.C.  
5 280g–16) the following:

6 **“SEC. 399V–6. PATIENT REGISTRY FOR MESOTHELIOMA**  
7 **DATA COLLECTION AND RESEARCH.**

8 “(a) IN GENERAL.—The Secretary, acting through  
9 the Administrator of the Agency for Toxic Substances and  
10 Disease Registry, shall develop a patient registry to collect  
11 data on mesothelioma, including information with respect  
12 to the incidence and prevalence of the disease in the  
13 United States.

14 “(b) USES.—The Secretary shall use the registry  
15 under subsection (a)—

16 “(1) to enhance and expand infrastructure and  
17 activities for tracking the epidemiology of mesothe-  
18 lioma patients;

19 “(2) to collect, consolidate, and report on health  
20 information on patients who have been diagnosed  
21 with mesothelioma, including with respect to—

22 “(A) treatment outcomes, including patient  
23 longevity; and

24 “(B) the number of patients receiving  
25 treatment for mesothelioma disaggregated by  
26 hospital;

1           “(3) to better describe the incidence and preva-  
2           lence of mesothelioma in the United States;

3           “(4) to facilitate further research on mesothe-  
4           lioma;

5           “(5) to examine factors, such as environmental  
6           and occupational factors, that may be associated  
7           with mesothelioma;

8           “(6) to better outline key demographic factors  
9           (such as age, race or ethnicity, gender, and family  
10          history) associated with mesothelioma; and

11          “(7) to make the information in such registry,  
12          other than individually identifiable information,  
13          available to the public to facilitate and enhance re-  
14          search on, and prevention and treatment of, meso-  
15          thelioma.

16          “(c) CONTENT.—In carrying out this section, the  
17          Secretary—

18                 “(1) shall provide for the collection and storage  
19                 of information on the incidence and prevalence of  
20                 mesothelioma in the United States;

21                 “(2) when scientifically possible, shall provide  
22                 for the collection and storage of other available in-  
23                 formation on mesothelioma, such as information con-  
24                 cerning—

1           “(A) demographics and other information  
2 associated or possibly associated with mesothe-  
3 lioma, such as age, race, ethnicity, sex, geo-  
4 graphic location, and family history;

5           “(B) risk factors associated or possibly as-  
6 sociated with mesothelioma, including genetic  
7 and environmental risk factors; and

8           “(C) diagnosis and progression markers;  
9 and

10          “(3) may provide for the collection and storage  
11 of information relevant to analysis on mesothelioma,  
12 such as information concerning—

13           “(A) the epidemiology of the disease;

14           “(B) the natural history of the disease;

15           “(C) the prevention of the disease;

16           “(D) the detection, management, and  
17 treatment approaches for the disease; and

18           “(E) the development of outcomes meas-  
19 ures.

20          “(d) CONSULTATION.—In carrying out this section,  
21 the Secretary shall consult with individuals with appro-  
22 priate expertise, including non-Federal mesothelioma ex-  
23 perts including—

24           “(1) epidemiologists with experience in disease  
25 surveillance or registries;

1           “(2) representatives of national voluntary asso-  
2           ciations that focus on mesothelioma or have dem-  
3           onstrated experience in research, care, or patient  
4           service for mesothelioma;

5           “(3) health information technology experts or  
6           other information management specialists;

7           “(4) clinicians with expertise in mesothelioma;  
8           and

9           “(5) research scientists with experience con-  
10          ducting translational research or utilizing surveil-  
11          lance systems for scientific research purposes.

12          “(e) COORDINATION WITH OTHER FEDERAL AGEN-  
13          CIES.—The Secretary shall make information in and anal-  
14          ysis derived from the registry under this section available,  
15          as appropriate, to Federal departments and agencies, such  
16          as the National Institutes of Health, the Food and Drug  
17          Administration, the Centers for Medicare & Medicaid  
18          Services, the Agency for Healthcare Research and Quality,  
19          the Department of Veterans Affairs, and the Department  
20          of Defense.

21          “(f) PUBLIC ACCESS.—Subject to subsection (g), the  
22          Secretary shall make information in, and analysis derived  
23          from, the registry under this section available, as appro-  
24          priate, to the public, including researchers.

1       “(g) PRIVACY.—The Secretary shall ensure that pri-  
2 vacy and security protections applicable to the registry  
3 under this section are at least as stringent as the privacy  
4 and security protections under HIPAA privacy and secu-  
5 rity law (as defined in section 3009).

6       “(h) REPORTS TO CONGRESS.—

7           “(1) INITIAL REPORT.—Not later than 18  
8 months after the date of enactment of the Mary Jo  
9 Lawyer Spano Mesothelioma Patient Registry Act of  
10 2015, the Secretary shall submit to the Congress a  
11 report that—

12                   “(A) shall outline—

13                           “(i) the findings in the mesothelioma  
14 patient registry under subsection (a);

15                           “(ii) future plans for expansion or re-  
16 vision of such registry; and

17                           “(iii) the scope of such registry; and

18                   “(B) may include a description of the ac-  
19 tivities undertaken by the Secretary to establish  
20 partnerships with research and patient advocacy  
21 communities to expand such registry.

22           “(2) SUBSEQUENT REPORT.—Not later than 4  
23 years after the date of enactment of the Mary Jo  
24 Lawyer Spano Mesothelioma Patient Registry Act of  
25 2015, the Secretary shall submit a report to the

1 Congress concerning the implementation of this sec-  
2 tion. Such report should include information on—

3 “(A) the development and maintenance of  
4 the mesothelioma patient registry under sub-  
5 section (a);

6 “(B) the type of information collected and  
7 stored in the registry;

8 “(C) the use and availability of such infor-  
9 mation, including guidelines for such use; and

10 “(D) the use and coordination of databases  
11 that collect or maintain information on meso-  
12 thelioma.”.

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