

105TH CONGRESS  
2D SESSION

# H. R. 3234

To require peer review of scientific data used in support of Federal regulations, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 12, 1998

Mr. POMBO (for himself, Mr. LEWIS of California, Mr. McKEON, Mr. SESSIONS, Mr. STUMP, Mr. DOOLITTLE, and Mr. COBURN) introduced the following bill; which was referred to the Committee on Government Reform and Oversight, and in addition to the Committee on Science, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To require peer review of scientific data used in support of Federal regulations, 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 “Science Integrity Act”.

5 **SEC. 2. PEER REVIEW REQUIREMENT.**

6 (a) IN GENERAL.—Not later than January 1, 1999,  
7 the head of each Federal department or agency which  
8 issues or may issue regulations supported by scientific

1 data shall issue regulations under this section establishing  
2 procedures to ensure that the acquisition, interpretation,  
3 incorporation, and application of all such scientific data  
4 is subject to peer review by at least 2 but not more than  
5 5 individuals from the list created pursuant to subsection  
6 (b).

7 (b) LIST OF PEER REVIEWERS.—The head of each  
8 Federal department or agency which issues or may issue  
9 regulations supported by scientific data shall create, using  
10 the Federal Register, scientific and commercial journals,  
11 the National Academy of Sciences, and other similar re-  
12 sources, a list of individuals who are qualified and willing  
13 to perform peer review functions for the department or  
14 agency. Such list shall include only individuals who—

15 (1) by virtue of advanced education, training, or  
16 avocational, academic, commercial, research, or  
17 other experience, are competent to review the appro-  
18 priateness of any scientific methodology supporting  
19 regulations that the department or agency may  
20 issue, the validity of any conclusions drawn from the  
21 supporting data, and the competency of the research  
22 or preparation of the scientific data; and

23 (2) are not otherwise employed by or under con-  
24 tract with the department or agency.

1       (c) SELECTION OF PEER REVIEWERS.—The head of  
2 each department or agency shall select individuals from  
3 the list created pursuant to subsection (b) to peer review  
4 each proposed regulation of the department or agency that  
5 is supported by scientific data. No individual shall be se-  
6 lected who—

7           (1) has actively participated in advocating or  
8 opposing the issuance of the proposed regulation;

9           (2) has a direct financial interest in the pro-  
10 posed regulation; or

11          (3) is employed by or related to any person hav-  
12 ing a direct financial interest in the proposed regula-  
13 tion.

14       (d) PROVISION OF SCIENTIFIC DATA TO PEER RE-  
15 VIEWERS.—Peer reviewers selected under subsection (c)  
16 shall be provided with all scientific data used in support  
17 of the proposed regulation, and any other related data re-  
18 quested by the peer reviewer that is reasonably available  
19 to the department or agency.

20       (e) EXPENSES.—Peer reviewers selected under sub-  
21 section (c) shall be reimbursed by the department or agen-  
22 cy for expenses directly incurred in performing the peer  
23 review, but shall not otherwise be compensated for per-  
24 forming the peer review.

1       (f) AVAILABILITY FOR PUBLIC COMMENT.—Upon re-  
2 ceipt of all peer review reports for a proposed regulation,  
3 the head of a department or agency shall publish in the  
4 Federal Register a notice of the availability of those re-  
5 ports, and the scientific data reviewed therein, for public  
6 comment. The department or agency shall make such re-  
7 ports and scientific data readily available upon request  
8 and shall receive public comment thereon for a period of  
9 60 days after the publication of notice in the Federal Reg-  
10 ister.

11       (g) REVIEW BY OFFICE OF REGULATIONS INTEG-  
12 RITY.—Within 30 days after the completion of a public  
13 comment period described in subsection (f), the head of  
14 a department or agency shall transmit to the Office of  
15 Regulations Integrity established under section 3—

- 16           (1) each peer review report;  
17           (2) all scientific data used in support of the  
18       proposed regulation or requested by a peer reviewer;  
19           (3) the response of the head of the department  
20       or agency to points of disagreement, if any, among  
21       the peer reviewers; and  
22           (4) all public comments received.

23 The proposed regulation may not be issued in final form  
24 until 30 days after the transmittal under this subsection.  
25 Any recommendations of the Office of Regulations Integ-

1 rity in response to a transmittal under this subsection  
2 shall be provided to the department or agency, the Presi-  
3 dent, and the Congress.

4 (h) FINAL ISSUANCE.—The publication of a final reg-  
5 ulation peer reviewed under this section shall include a  
6 summary of the related peer review reports and any points  
7 of disagreement among the peer reviewers, and the re-  
8 sponse of the head of the department or agency to the  
9 peer review reports.

10 (i) EMERGENCY EXCEPTION.—Regulations issued  
11 under subsection (a) shall include provisions that permit  
12 the issuance of regulations supported by scientific data in  
13 emergency circumstances without peer review, on the con-  
14 dition that peer review be completed within 90 days after  
15 such issuance.

16 **SEC. 3. OFFICE OF REGULATIONS INTEGRITY.**

17 (a) ESTABLISHMENT.—There is established an Office  
18 of Regulations Integrity (in this section referred to as the  
19 “Office”).

20 (b) DUTIES.—The duties of the Office shall be—

21 (1) to review regulations issued by each depart-  
22 ment or agency under section 2(a), and if the Office  
23 determines that such regulations do not represent  
24 the expert opinions of a majority of the scientists  
25 who will be carrying out peer reviews under section

1       2, or that such regulations are inadequate or inap-  
2       propriate in any respect, to notify the department or  
3       agency, the President, and the Congress;

4           (2) to transmit to the President and the Con-  
5       gress an annual report on the performance of each  
6       department or agency in complying with its regula-  
7       tions issued under section 2(a); and

8           (3) to review regulations issued by a depart-  
9       ment or agency with supporting scientific data, if  
10      the Office has reason to believe the regulations were  
11      issued, or the scientific data was acquired, inter-  
12      preted, incorporated, or applied, in a manner signifi-  
13      cantly inconsistent with the regulations issued by the  
14      department or agency under section 2(a), and if the  
15      Office finds the issuance, acquisition, interpretation,  
16      incorporation, or application to be inconsistent with  
17      the regulations issued by the department or agency  
18      under section 2(a), to notify the department or  
19      agency, the President, and the Congress.

20      (c) ACCESS TO INFORMATION.—The Office shall be  
21      provided access by a department or agency to information  
22      required for carrying out a review under subsection (b).

23      (d) DIRECTOR.—

24           (1) APPOINTMENT.—The Office shall have a  
25      Director, who shall be appointed by the President,

1 subject to confirmation by the Senate, for a term of  
2 1 year.

3 (2) QUALIFICATIONS.—The Director shall be a  
4 person with a scientific background, in good stand-  
5 ing in the scientific community.

6 (3) BASIC PAY.—The Director shall be paid at  
7 a rate not to exceed the rate of basic pay for level  
8 III of the Executive Schedule, under section 5314 of  
9 title 5, United States Code.

10 (e) STAFF.—The professional staff of the Office shall  
11 be persons with scientific backgrounds, in good standing  
12 in the scientific community.

13 (f) ADMINISTRATIVE SUPPORT.—The Office of Man-  
14 agement and Budget shall provide such administrative  
15 support as the Office established under this section re-  
16 quires, but the Director of the Office of Management and  
17 Budget shall have no responsibilities with respect to carry-  
18 ing out the duties of the Office under this section.

19 **SEC. 4. DEFINITION OF PEER REVIEW.**

20 For purposes of this Act, the term “peer review”  
21 means identifying technical or scientific deficiencies of a  
22 proposal, assessing whether the methodology and analysis  
23 supporting a proposal conform to the standards of the aca-

- 1 demic and scientific community, and determining whether
- 2 a proposal is supported by sufficient credible evidence.

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