

110TH CONGRESS
1ST SESSION

H. R. 1165

To amend the Federal Food, Drug, and Cosmetic Act to establish additional authorities to ensure the safe and effective use of drugs, to establish whistleblower protections for certain individuals, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 16, 2007

Mr. MARKEY introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish additional authorities to ensure the safe and effective use of drugs, to establish whistleblower protections for certain individuals, and for other purposes.

1 reports released by the Food and Drug Administra-
2 tion, the National Institutes of Health, the Agency
3 for Healthcare Research and Quality, or another rel-
4 evant agency, actions or reports by regulatory agen-
5 cies in foreign countries, or studies published in sci-
6 entific or academic journals), that the labeling of the
7 drug be modified to include specific wording re-
8 quired by the Secretary to ensure the safe and effec-
9 tive use of the drug.”.

10 (e) **RULE OF CONSTRUCTION REGARDING CERTAIN**
11 **PEDIATRIC STUDIES.**—The amendments made by this
12 section establish authorities in addition to, and not in lieu
13 of—

14 (1) the program under section 505A of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 355a); and

17 (2) authorities under section 505B of such Act
18 (21 U.S.C. 355b).

19 **SEC. 3. WHISTLEBLOWER PROTECTIONS.**

20 (a) **PROHIBITION.**—It shall be unlawful for any per-
21 son to discharge, demote, suspend, reprimand, investigate,
22 or take or fail to take any other personnel action that in
23 any manner discriminates against any covered individual,
24 or in any other manner discriminate against any covered
25 individual (including by a denial, suspension, or revocation

1 of a security clearance or by any other security access de-
2 termination, or by denial of award of a Federal contract
3 or subcontract), or to threaten or recommend the dis-
4 charge, demotion, suspension, reprimand, investigation,
5 other personnel action (or rejection of such action) that
6 in any manner discriminates against any covered indi-
7 vidual, or other manner of discrimination if such action,
8 discrimination, or recommendation is due, in whole or in
9 part, to any lawful act done, perceived to have been done,
10 or intended to be done by the covered individual—

11 (1) to provide information, cause information to
12 be provided, or otherwise assist in an investigation
13 or proceeding regarding any conduct which the cov-
14 ered individual reasonably believes constitutes evi-
15 dence of a violation of any law, rule, or regulation,
16 a substantial and specific threat to public health or
17 safety, an abuse of authority, fraud, waste, or mis-
18 management of public funds, censorship, distortion,
19 or suppression of scientific information, research, or
20 analysis, or the willful disclosure of false, mis-
21 leading, or incomplete scientific information, if the
22 information or assistance is provided to or the inves-
23 tigation or proceeding is conducted by—

24 (A) a Federal, State, or local regulatory or
25 law enforcement agency (including an office of

1 Inspector General under the Inspector General
2 Act of 1978);

3 (B) any Member of Congress, any com-
4 mittee of Congress, or the Government Ac-
5 countability Office;

6 (C) any person with supervisory or mana-
7 gerial authority over the covered individual (or
8 any other person who has the authority to in-
9 vestigate, discover, or terminate misconduct); or

10 (D) a potential witness to or other person
11 affected by or aware of the conduct described in
12 this section who has the authority to inves-
13 tigate, discover, or terminate misconduct;

14 (2) to file, cause to be filed, testify, participate
15 in, or otherwise assist in a proceeding or action filed
16 or about to be filed relating to an alleged violation
17 of any law, rule, or regulation; or

18 (3) to refuse to violate or assist in the violation
19 of any law, rule, or regulation.

20 (b) ENFORCEMENT ACTION.—

21 (1) IN GENERAL.—A covered individual who al-
22 leges discharge or other discrimination by any per-
23 son in violation of subsection (a) may seek relief
24 under paragraph (3) by—

1 (A) filing a complaint with the Secretary of
2 Labor; or

3 (B) if the Secretary has not issued a final
4 decision within 180 days after the filing of the
5 complaint and there is no showing that such
6 delay is due to the bad faith of the claimant,
7 bringing an action at law or equity for de novo
8 review in the appropriate district court of the
9 United States, which shall have jurisdiction
10 over such an action without regard to the
11 amount in controversy.

12 (2) PROCEDURE.—

13 (A) IN GENERAL.—An action under para-
14 graph (1)(A) shall be governed under the rules
15 and procedures set forth in section 42121(b) of
16 title 49, United States Code.

17 (B) EXCEPTION.—Notification made under
18 section 42121(b)(1) of title 49, United States
19 Code, shall be made—

20 (i) to the person named in the com-
21 plaint; and

22 (ii) to the person's employer.

23 (C) BURDENS OF PROOF.—An action
24 brought under paragraph (1)(B) shall be gov-
25 erned by the legal burdens of proof set forth in

1 section 42121(b) of title 49, United States
2 Code.

3 (D) STATUTE OF LIMITATIONS.—An action
4 under paragraph (1) shall be commenced not
5 later than 6 years after the date on which the
6 violation occurs.

7 (3) REMEDIES.—

8 (A) IN GENERAL.—A covered individual
9 prevailing in any action under this subsection
10 shall be entitled to all relief appropriate to
11 make the covered individual whole.

12 (B) DAMAGES.—Relief for any action
13 under this subsection shall include—

14 (i) reinstatement with the same se-
15 niority status and employment grade or
16 pay level (or the equivalent) that the cov-
17 ered individual would have had, but for the
18 discrimination;

19 (ii) compensatory damages, including
20 the amount of any back pay, with interest;

21 (iii) compensation for any special
22 damages sustained as a result of the dis-
23 crimination, including litigation costs, ex-
24 pert witness fees, and reasonable attorney
25 fees; and

1 (iv) punitive damages in an amount
2 not to exceed the greater of 3 times the
3 amount of any monetary damages awarded
4 under this section (apart from this para-
5 graph) or \$5,000,000.

6 (c) CRIMINAL PENALTIES.—

7 (1) IN GENERAL.—Any person who violates
8 subsection (a) shall be fined under title 18 of the
9 United States Code, imprisoned not more than 10
10 years, or both.

11 (2) REPORTING REQUIREMENTS.—The Attor-
12 ney General of the United States shall (based on
13 such periodic reports and other information from the
14 Department of Labor as the Attorney General may
15 require) submit to the Congress an annual report on
16 the enforcement of paragraph (1). Each such report
17 shall—

18 (A) identify each case in which formal
19 charges under paragraph (1) were brought;

20 (B) describe the status or disposition of
21 each such case; and

22 (C) in any action under subsection (b) in
23 which the covered individual was the prevailing
24 party or the substantially prevailing party, indi-
25 cate whether or not any formal charges under

1 paragraph (1) have been brought and, if not,
2 the reasons therefor.

3 (d) RIGHTS RETAINED BY COVERED INDIVIDUAL.—
4 Nothing in this section shall be deemed to diminish the
5 rights, privileges, or remedies of any covered individual
6 under any Federal or State law, or under any collective
7 bargaining agreement. The rights and remedies in this
8 section may not be waived by any agreement, policy, form,
9 or condition of employment.

10 (e) NOTIFICATION.—The provisions of this section
11 shall be prominently posted in any place of employment
12 to which this section applies.

13 (f) DEFINITIONS.—For purposes of this section:

14 (1) The term “covered individual” means an
15 employee or a contractor or subcontractor of the
16 Food and Drug Administration.

17 (2) The term “lawful” means not specifically
18 prohibited by law.

19 **SEC. 4. RIGHT TO PUBLISH.**

20 Subchapter E of chapter V of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is
22 amended by adding at the end the following section:

23 **“SEC. 565. RIGHT TO PUBLISH.**

24 “Officers and employees of the Food and Drug Ad-
25 ministration, and individuals sponsored by such Adminis-