

111TH CONGRESS  
2D SESSION

# S. 3690

To provide for additional quality control of drugs.

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IN THE SENATE OF THE UNITED STATES

AUGUST 3, 2010

Mr. BENNET introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To provide for additional quality control of drugs.

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 “Drug Safety and Ac-  
5 countability Act of 2010”.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

8 (1) Recent manufacturing quality problems re-  
9 sulting in drug recalls and warnings from the Food  
10 and Drug Administration have exposed gaps in qual-  
11 ity systems to ensure drugs in the United States are  
12 safe and free from contamination.

1           (2) Adherence to quality standards is the most  
2           effective way to ensure drug quality and integrity. It  
3           is impossible to test every pharmaceutical item that  
4           is produced.

5           (3) More than 1,300,000 over-the-counter chil-  
6           dren’s medicines were recalled in 2010 for quality  
7           issues that presented possible risk to patient health,  
8           and the quality standards at many other over-the-  
9           counter manufacturers are unknown.

10          (4) Up to 149 Americans died in 2007 and  
11          2008 after taking heparin, a blood thinner, contami-  
12          nated during the manufacturing process in China.

13          (5) Up to 80 percent of the active ingredients  
14          in drugs used in the United States are made over-  
15          seas, many in countries where regulatory oversight  
16          does not meet the standards of the United States.

17 **SEC. 3. QUALITY CONTROL OF DRUGS.**

18          (a) ADULTERATION.—Section 501 of the Federal  
19          Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amend-  
20          ed by adding at the end the following:

21                 “(j) If it is a drug that was manufactured, prepared,  
22          propagated, compounded, or processed by an establish-  
23          ment that is, or was at the time of such manufacture,  
24          preparation, propagation, compounding, or processing, in  
25          violation of subsection (q) or (r) of section 510.”.

1 (b) ADDITIONAL REQUIREMENTS OF PRODUCERS OF  
2 DRUGS.—Section 510 of the Federal Food, Drug, and  
3 Cosmetic Act (21 U.S.C. 360) is amended by adding at  
4 the end the following:

5 “(q) QUALITY MANAGEMENT PLANS.—

6 “(1) SCOPE.—Each person required to register  
7 under subsection (b), (c), (d), or (i), with respect to  
8 the manufacture, preparation, propagation, com-  
9 pounding, or processing of a drug shall have in ef-  
10 fect and implement a quality management plan to  
11 ensure the quality and safety of—

12 “(A) each such drug, including when such  
13 drug is prepared, propagated, compounded, or  
14 processed by another person;

15 “(B) each active and inactive ingredient of  
16 such drug, including when such ingredient is  
17 prepared, propagated, compounded, processed,  
18 or held by another person; and

19 “(C) materials used in the manufacture of  
20 the active ingredient, based on a risk assess-  
21 ment that gives additional consideration to ma-  
22 terials extracted or derived from plants, mi-  
23 crobes, animal tissue, or other biological  
24 sources.

25 “(2) PROVISIONS.—

1           “(A) IN GENERAL.—Each quality manage-  
2           ment plan required under paragraph (1) shall—  
3           “(i) address risk assessment, risk con-  
4           trol, risk communication, and risk review;  
5           “(ii) provide for an assessment, prior  
6           to contracting with a person to supply in-  
7           gredients or to undertake any aspect of the  
8           manufacturing of a drug, of the suitability  
9           and competence of such person to carry  
10          out such activity, using audits, material  
11          evaluations, or qualification, as appro-  
12          priate;  
13          “(iii) define responsibilities and com-  
14          munication processes for manufacturing,  
15          quality control, and quality assurance ac-  
16          tivities of any person described in clause  
17          (ii);  
18          “(iv) provide for the monitoring and  
19          review through periodic on-site audits of  
20          the facility conditions, controls, and prac-  
21          tices of any person described in clause (ii)  
22          and ensure the implementation of appro-  
23          priate measures to improve such condi-  
24          tions, controls, and practices;

1           “(v) provide for the monitoring of in-  
2           coming materials to ensure that such ma-  
3           terials are from a person who meets the re-  
4           quirements under clauses (ii) through (iv);

5           “(vi) provide for implementation of ef-  
6           fective systems, including appropriate spec-  
7           ifications and test methods and verification  
8           of the identity, quality, strength, and pu-  
9           rity of drug ingredients, to detect any haz-  
10          ard that has been, or is reasonably likely  
11          to be, present in or on the drug during  
12          production, manufacturing, processing,  
13          packing, holding, or transporting; and

14          “(vii) provide for adequate assessment  
15          of materials used in the manufacture of  
16          the active ingredient.

17          “(B) ADDITIONAL PROVISIONS.—If the  
18          Secretary determines that provisions in addition  
19          to those described in subparagraph (A) would  
20          be appropriate to include in quality risk man-  
21          agement plans for the protection of the public  
22          health, including provisions for the prevention  
23          of intentional adulteration of a drug or class of  
24          drugs, the Secretary may by regulation require

1           that such provisions be included in quality risk  
2           management plans.

3           “(3) REVIEW AND UPDATING.—Each person re-  
4           quired to implement a quality management plan  
5           under this subsection shall periodically review such  
6           plan and update such plan as necessary.

7           “(4) APPLICATION OF SPECIFICATIONS OR TEST  
8           METHODS BY ORDER OF THE SECRETARY.—If the  
9           Secretary finds that there is a significant threat to  
10          public health, the Secretary may order an establish-  
11          ment—

12                   “(A) to promptly revise its quality risk  
13                   management plan to include new or modified  
14                   specifications or test methods for a drug; and

15                   “(B) to promptly implement such specifica-  
16                   tions or test methods.

17          “(5) INSPECTION OF QUALITY MANAGEMENT  
18          PLAN.—The Secretary shall, in the course of an in-  
19          spection under section 704 of an establishment sub-  
20          ject to this subsection or upon request by the Sec-  
21          retary, conduct a review of the quality management  
22          plan of the establishment.

23          “(r) DOCUMENTATION OF SUPPLY CHAIN.—Each  
24          person required to register under subsection (b), (c), (d),  
25          or (i), with respect to the manufacture, preparation, prop-

1 agation, compounding, or processing of a drug shall pro-  
2 vide, at the request of the Secretary, documentation of the  
3 names, addresses, phone numbers, and Global Positioning  
4 System coordinates of each producer, manufacturer, dis-  
5 tributor, and shipper involved in the production of a drug  
6 or the production or transport of the active ingredients  
7 of a drug, and, where the assessment of materials de-  
8 scribed in subsection (q)(2)(A)(vii) is required, each pro-  
9 ducer, manufacturer, distributor, and shipper involved in  
10 the production or transport of such materials. Such docu-  
11 mentation shall show that the drug and the ingredients  
12 of the drug were manufactured, prepared, propagated,  
13 compounded, processed, and handled in a manner ensur-  
14 ing the identity, safety, quality, purity, and strength of  
15 such drug.

16       “(s) TRACKING SYSTEMS.—Not later than 1 year  
17 after the date of enactment of the Drug Safety and Ac-  
18 countability Act of 2010, the Secretary shall develop and  
19 maintain information systems to track and assess every  
20 establishment that is involved in the manufacturing, prep-  
21 aration, propagation, compounding, or processing of a  
22 drug or active ingredient of a drug. The Secretary shall  
23 ensure the interoperability of all databases relevant to the  
24 tracking and assessment of such establishments and in-  
25 clude in each such database the D–U–N–S number of each

1 such establishment required under subsection (b) to pro-  
2 vide a D–U–N–S number.

3 “(t) OVER-THE-COUNTER DRUGS.—In determining,  
4 for purposes of inspection, the risk associated with a per-  
5 son required to register under this section, the Secretary  
6 shall not consider whether the drugs manufactured, pre-  
7 pared, propagated, compounded, or processed by such per-  
8 son are drugs described in section 503(b).”.

9 (c) UNIQUE REGISTRATION NUMBERS.—Section 510  
10 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
11 360) is amended—

12 (1) in subsection (b)—

13 (A) in paragraph (1), by striking “and all  
14 such establishments” and inserting “all such es-  
15 tablishments, and the D–U–N–S number of  
16 each such establishment”; and

17 (B) in paragraph (2), by striking “and all  
18 such establishments” and inserting “all such es-  
19 tablishments, and the D–U–N–S number of  
20 each such establishment”;

21 (2) in subsection (c), by striking “such estab-  
22 lishment” and inserting “such establishment, and  
23 the D–U–N–S number of such establishment”;

1           (3) in subsection (d), by inserting “, and the  
2           D–U–N–S number of such establishment” after “de-  
3           vices”; and

4           (4) in subsection (i)(1)(A), by inserting “the  
5           D–U–N–S number of each such establishment,”  
6           after “place of business of the establishment,”.

7           (d) FACTORY INSPECTION.—Section 704(a)(1) of the  
8           Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
9           374(a)(1)) is amended, in the first sentence, by inserting  
10          “in the United States or for import into the United  
11          States,” after “to enter, at reasonable times, any factory,  
12          warehouse, or establishment in which food, drugs, devices,  
13          tobacco products, or cosmetics are manufactured, proc-  
14          essed, packed, or held,”.

15          (e) MUTUAL RECOGNITION AGREEMENT PROGRESS  
16          REPORT.—The Secretary of Health and Human Services  
17          shall, not later than 1 year after the date of enactment  
18          of this Act, issue a report that describes the progress on  
19          implementing cooperative arrangements and mutual rec-  
20          ognition agreements relating to the regulation of drugs  
21          and good manufacturing practices entered into under sec-  
22          tion 510(i)(3) or section 803 of the Federal Food, Drug,  
23          and Cosmetic Act (21 U.S.C. 360(i)(3), 383).

24          (f) MANDATORY RECALL AUTHORITY FOR DRUGS.—

1           (1) IN GENERAL.—Chapter V of the Federal  
2           Food, Drug, and Cosmetic Act (21 U.S.C. 351 et  
3           seq.) is amended by inserting after section 506C the  
4           following:

5           **“SEC. 507. MANDATORY RECALL AUTHORITY FOR DRUGS.**

6           “(a) ORDER TO CEASE DISTRIBUTION; NOTIFICA-  
7           TION; PROCESS.—

8                   “(1) ORDER TO CEASE DISTRIBUTION; NOTIFI-  
9                   CATION.—If the Secretary finds that there is a rea-  
10                   sonable probability that a drug intended for human  
11                   use would cause serious, adverse health conse-  
12                   quences or death, the Secretary shall issue an order  
13                   requiring the appropriate person (including the man-  
14                   ufacturers, importers, distributors, or retailers of the  
15                   drug)—

16                           “(A) to immediately cease distribution of  
17                           such drug; and

18                           “(B) to immediately notify health profes-  
19                           sionals and hospitals and other health care fa-  
20                           cilities of the order and to instruct such profes-  
21                           sionals and facilities to cease use of such drug.

22                   “(2) PROCESS.—The order under paragraph  
23                   (1) shall provide the person subject to the order with  
24                   an opportunity for an informal hearing, to be held  
25                   not later than 10 days after the date of the issuance

1 of the order, on the actions required by the order  
2 and on whether the order should be amended to re-  
3 quire a recall of such drug. If, after providing an op-  
4 portunity for such a hearing, the Secretary deter-  
5 mines that inadequate grounds exist to support the  
6 actions required by the order, the Secretary shall va-  
7 cate the order.

8 “(b) ORDER TO RECALL.—

9 “(1) IN GENERAL.—If, after providing an op-  
10 portunity for an informal hearing under subsection  
11 (a), the Secretary determines that the order should  
12 be amended to include a recall of the drug with re-  
13 spect to which the order was issued, the Secretary  
14 shall, except as provided in paragraph (2), amend  
15 the order to require a recall. The Secretary shall  
16 specify a timetable in which the drug recall will  
17 occur and shall require periodic reports to the Sec-  
18 retary describing the progress of the recall.

19 “(2) AMENDED ORDER.—An amended order  
20 under paragraph (1)—

21 “(A) shall—

22 “(i) not include recall of a drug from  
23 individuals; and

24 “(ii) not include recall of a drug from  
25 hospitals and other health care facilities if

1           the Secretary determines that the risk of  
2           recalling such drug from the facilities pre-  
3           sents a greater health risk than the health  
4           risk of not recalling the drug from use;  
5           and

6           “(B) shall provide for notice to individuals  
7           subject to the risks associated with the use of  
8           such drug.

9           “(3) ASSISTANCE.—In providing the notice re-  
10          quired by paragraph (2), the Secretary may use the  
11          assistance of health professionals who prescribed or  
12          used such a drug for individuals. If a significant  
13          number of such individuals cannot be identified, the  
14          Secretary shall notify such individuals pursuant to  
15          section 705(b).”.

16          (2) REGULATIONS.—Until the date that the  
17          Secretary of Health and Human Services issues a  
18          final regulation to implement section 507 of the  
19          Federal Food, Drug, and Cosmetic Act (as added by  
20          paragraph (1)), the regulations on medical device re-  
21          call authority in part 810 of title 21, Code of Fed-  
22          eral Regulations, shall apply to any recall of a drug  
23          under such section 507.

1           (3) PROHIBITED ACTS.—Section 301 of the  
2       Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3       331) is amended by adding at the end the following:

4       “(uu) The failure to comply with an order issued  
5       under section 507.”.

6       (g) SUBPOENA AUTHORITY.—Section 702 of the  
7       Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372)  
8       is amended by adding at the end the following:

9       “(f)(1) The Secretary may conduct investigations as  
10      the Secretary deems necessary—

11           “(A) to carry out the authority of the Secretary  
12           under this Act or section 351 of the Public Health  
13           Service Act; or

14           “(B) to determine whether any person has en-  
15           gaged or is about to engage in any act that con-  
16           stitutes or will constitute a violation of this Act or  
17           such section 351.

18       “(2) For the purpose of any investigation conducted  
19      under paragraph (1), the Secretary may administer oaths  
20      and affirmations, subpoena witnesses, compel the attend-  
21      ance of such witnesses, take evidence, and require the pro-  
22      duction of any books, papers, documents, or other mate-  
23      rials that are relevant to the investigation.

24       “(3)(A) In case of contumacy or refusal to obey a  
25      subpoena issued under paragraph (2), the district court

1 of the United States for the judicial district in which such  
2 investigation or proceeding is conducted, or in which the  
3 subpoenaed person resides or conducts business, may issue  
4 an order requiring such person to appear before the Sec-  
5 retary, testify, or produce books, papers, documents, or  
6 other materials that are relevant to the investigation. All  
7 process in any such case may be served in the judicial dis-  
8 trict in which such person resides or may be found.

9 “(B) Any failure to obey an order issued under sub-  
10 paragraph (A) may be punished by the court as contempt  
11 of court.”.

12 (h) CIVIL PENALTIES.—

13 (1) IN GENERAL.—Section 303(f) of the Fed-  
14 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
15 333(f)) is amended—

16 (A) in paragraph (4), by striking “or 505-  
17 1” each place it appears and inserting “505-1,  
18 or 505A”;

19 (B) by adding at the end the following:

20 “(10)(A)(i) Any manufacturer, distributor, im-  
21 porter, broker, or filer that violates a requirement of  
22 this Act that relates to drugs for human use (except  
23 a requirement referred to in paragraph (4) or sub-  
24 section (g)) shall be liable to the United States for  
25 a civil penalty not to exceed \$100,000 per violation.

1           “(ii) Each day during which a violation con-  
2           tinues shall be considered a separate violation under  
3           clause (i).

4           “(B)(i) Any manufacturer, distributor, im-  
5           porter, broker, or filer that knowingly reports or en-  
6           ters false or misleading data on documents related  
7           to the importation of a drug shall be liable to the  
8           United States for a civil penalty not to exceed  
9           \$150,000.

10           “(ii) Each act of reporting or entering false  
11           data shall be considered a separate violation under  
12           clause (i).”; and

13           (C) in paragraph (5) by striking “, or (9)”  
14           each place it appears and inserting “(9), or  
15           (10)”.

16           (2) APPLICABILITY.—Section 303(f)(10) of the  
17           Federal Food, Drug, and Cosmetic Act, as added by  
18           paragraph (1), shall apply to violations described in  
19           such section that occur after the date of enactment  
20           of this Act.

21           (i) EXCHANGE OF INFORMATION.—

22           (1) IN GENERAL.—Section 708 of the Federal  
23           Food, Drug, and Cosmetic Act (21 U.S.C. 379) is  
24           amended—

1 (A) by striking “The Secretary” and in-  
2 serting “(a) The Secretary”; and

3 (B) by adding at the end the following:

4 “(b)(1)(A) The Secretary may provide to any Federal  
5 agency acting within the scope of its jurisdiction any infor-  
6 mation relating to drugs that is exempt from disclosure  
7 pursuant to subsection (a) of section 552 of title 5, United  
8 States Code, by reason of subsection (b)(4) of such sec-  
9 tion, or that is referred to in section 301(j).

10 “(B) Any such information provided to another Fed-  
11 eral agency shall not be disclosed by such agency except  
12 in any action or proceeding under the laws of the United  
13 States to which the receiving agency or the United States  
14 is a party.

15 “(2)(A) In carrying out this Act, the Secretary may  
16 provide to a State or local government agency any infor-  
17 mation relating to drugs that is exempt from disclosure  
18 pursuant to section 552(a) of title 5, United States Code,  
19 by reason of subsection (b)(4) of such section, or that is  
20 referred to in section 301(j).

21 “(B) Any such information provided to a State or  
22 local government agency shall not be disclosed by such  
23 agency.

24 “(3) In carrying out this Act, the Secretary may pro-  
25 vide to any person any information relating to drugs that

1 is exempt from disclosure pursuant to section 552(a) of  
2 title 5, United States Code, by reason of subsection (b)(4)  
3 of such section, if the Secretary determines that providing  
4 the information to the person is appropriate under the cir-  
5 cumstances and the recipient provides adequate assur-  
6 ances to the Secretary that the recipient will preserve the  
7 confidentiality of the information.

8       “(4) In carrying out this Act, the Secretary may pro-  
9 vide any information relating to drugs that is exempt from  
10 disclosure pursuant to section 552(a) of title 5, United  
11 States Code, by reason of subsection (b)(4) of such sec-  
12 tion, or that is referred to in section 301(j)—

13               “(A) to any foreign government agency; or

14               “(B) any international organization established  
15 by law, treaty, or other governmental action and  
16 having responsibility—

17                       “(i) to facilitate global or regional harmo-  
18 nization of standards and requirements in an  
19 area of responsibility of the Food and Drug Ad-  
20 ministration; or

21                       “(ii) to promote and coordinate public  
22 health efforts,

23 if the agency or organization provides adequate as-  
24 surances to the Secretary that the agency or organi-

1 zation will preserve the confidentiality of the infor-  
2 mation.

3 “(c) Except where specifically prohibited by statute,  
4 the Secretary may disclose to the public any information  
5 relating to drugs that is exempt from disclosure pursuant  
6 to section 552(a) of title 5, United States Code, by reason  
7 of subsection (b)(4) of such section, if the Secretary deter-  
8 mines that such disclosure is necessary to protect the pub-  
9 lic health.

10 “(d) Except as provided in subsection (e), the Sec-  
11 retary shall not be required to disclose under section 552  
12 of title 5, United States Code, or any other provision of  
13 law any information relating to drugs obtained from a  
14 Federal, State, or local government agency, or from a for-  
15 eign government agency, or from an international organi-  
16 zation described in subsection (b)(4), if the agency or or-  
17 ganization has requested that the information be kept con-  
18 fidential, or has precluded such disclosure under other use  
19 limitations, as a condition of providing the information.

20 “(e) Nothing in subsection (d) authorizes the Sec-  
21 retary to withhold information from the Congress or pre-  
22 vents the Secretary from complying with an order of a  
23 court of the United States.

1 “(f) This section shall not affect the authority of the  
2 Secretary to provide or disclose information under any  
3 other provision of law.”.

4 (2) CONFORMING AMENDMENT.—Section 301(j)  
5 (21 U.S.C. 331(j)) is amended by striking “or to the  
6 courts when relevant in any judicial proceeding  
7 under this Act,” and inserting “to the courts when  
8 relevant in any judicial proceeding under this Act, or  
9 as specified in section 708,”.

10 (j) WHISTLEBLOWER PROTECTION.—Chapter X of  
11 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391  
12 et seq.) is amended by adding at the end the following:

13 **“SEC. 1012. PROTECTIONS FOR EMPLOYEES WHO REFUSE**  
14 **TO VIOLATE, OR WHO DISCLOSE VIOLATIONS**  
15 **OF, THIS ACT OR SECTION 351 OF THE PUB-**  
16 **LIC HEALTH SERVICE ACT.**

17 “(a) IN GENERAL.—

18 “(1) PROTECTIONS FOR EMPLOYEES.—No per-  
19 son that submits, or is required to submit to the  
20 Secretary a submission described in paragraph (2),  
21 or any officer, employee, contractor, subcontractor,  
22 or agent of such a person, may discharge, demote,  
23 suspend, threaten, harass, or in any other manner  
24 discriminate against an employee in the terms and  
25 conditions of employment because of any lawful act

1 done by the employee, including within the ordinary  
2 course of the job duties of such employee—

3 “(A) to provide information, cause infor-  
4 mation to be provided, or otherwise assist in  
5 any investigation regarding any conduct which  
6 the employee reasonably believes constitutes a  
7 violation of any section of this Act or the Public  
8 Health Service Act described under paragraph  
9 (2), any other provision of Federal law relating  
10 to the safety or effectiveness of a drug, biologi-  
11 cal product, or device, or any provision of Fed-  
12 eral law prohibiting fraud against the Food and  
13 Drug Administration, if the information or as-  
14 sistance is provided to, or an investigation  
15 stemming from the provided information is con-  
16 ducted by—

17 “(i) a Federal regulatory or law en-  
18 forcement agency;

19 “(ii) any Member of Congress or any  
20 committee of Congress; or

21 “(iii) a person with supervisory au-  
22 thority over the employee (or such other  
23 person working for the employer who has  
24 the authority to investigate, discover, or  
25 terminate the misconduct);

1           “(B) to file, cause to be filed, testify, par-  
2           ticipate in, or otherwise assist in a proceeding  
3           filed or about to be filed (with any knowledge  
4           of the employer) relating to an alleged violation  
5           of any section of this Act or the Public Health  
6           Service Act described under paragraph (2), any  
7           other provision of Federal law relating to the  
8           safety or effectiveness of a drug, biological  
9           product, or device, or any provision of Federal  
10          law prohibiting fraud against the Food and  
11          Drug Administration; or

12           “(C) to refuse to violate or assist in the  
13          violation of any section of this Act or the Public  
14          Health Service Act listed described paragraph  
15          (2), any other provision of Federal law relating  
16          to the safety or effectiveness of a drug, biologi-  
17          cal product, or device, or any provision of Fed-  
18          eral law prohibiting fraud against the Food and  
19          Drug Administration.

20          “(2) SUBMISSION.—A submission described in  
21          this paragraph is—

22                 “(A) a new drug application under section  
23                 505(b);

24                 “(B) an abbreviated new drug application  
25                 under section 505(j);

1           “(C) a biologics license application under  
2 section 351 of the Public Health Service Act;

3           “(D) an application for an investigational  
4 new drug exemption under section 505(i);

5           “(E) a new animal drug application under  
6 section 512(b);

7           “(F) an abbreviated new animal drug ap-  
8 plication under section 512(b);

9           “(G) an application under section 571;

10          “(H) a request under section 572;

11          “(I) an application or report for premarket  
12 approval under section 515;

13          “(J) an application for an investigational  
14 device exemption under section 520(g);

15          “(K) a report under section 510(k);

16          “(L) an application for a humanitarian de-  
17 vice exemption under section 520(m);

18          “(M) an amendment, supplement, or other  
19 submission with respect to any such application  
20 or report described in subparagraphs (A)  
21 through (L); or

22          “(N) a record or report related to an ad-  
23 verse event, a postapproval study, a post-  
24 approval clinical trial, a report, or postmarket

1 surveillance under section 505(k), 505(o), 519,  
2 522, or 760.

3 “(b) ENFORCEMENT ACTION.—

4 “(1) IN GENERAL.—An employee who alleges  
5 discharge, or other discrimination in violation of  
6 subsection (a), may seek relief in accordance with  
7 the provisions of subsection (c), by—

8 “(A) filing a complaint with the Secretary  
9 of Labor; or

10 “(B) if the Secretary of Labor has not  
11 issued a final decision within 210 days of the  
12 filing of the complaint and there is no showing  
13 that such delay is due to the bad faith of the  
14 claimant, bringing an action at law or equity  
15 for de novo review in the appropriate district  
16 court of the United States, which shall have ju-  
17 risdiction over such an action without regard to  
18 the amount in controversy.

19 “(2) PROCEDURE.—

20 “(A) IN GENERAL.—Any action under  
21 paragraph (1) shall be governed under the rules  
22 and procedures set forth in section 42121(b) of  
23 title 49, United States Code.

24 “(B) EXCEPTION.—Notification in an ac-  
25 tion under paragraph (1) shall be made in ac-

1 cordance with section 42121(b)(1) of title 49,  
2 United States Code, except that such notifica-  
3 tion shall be made to the person named in the  
4 complaint and to the employer.

5 “(C) BURDENS OF PROOF.—An action  
6 brought under paragraph (1)(B) shall be gov-  
7 erned by the legal burdens of proof set forth in  
8 section 42121(b) of title 49, United States  
9 Code.

10 “(D) STATUTE OF LIMITATIONS.—An ac-  
11 tion under paragraph (1) shall be commenced  
12 not later than 180 days after the date on which  
13 the violation occurs.

14 “(c) REMEDIES.—

15 “(1) IN GENERAL.—An employee prevailing in  
16 any action under subsection (b)(1) shall be entitled  
17 to all relief necessary to make the employee whole.

18 “(2) COMPENSATORY DAMAGES.—Relief in an  
19 action under subsection (b) shall include—

20 “(A) reinstatement with the same seniority  
21 status that the employee would have had, but  
22 for the discrimination;

23 “(B) the amount of backpay owed to the  
24 employee, with interest; and

1           “(C) compensation for any special damages  
2           sustained as a result of the discrimination, in-  
3           cluding litigation costs, expert witness fees, and  
4           reasonable attorney fees.

5           “(d) RIGHTS RETAINED BY EMPLOYEE.—Nothing in  
6 this section shall be deemed to diminish the rights, privi-  
7 leges, or remedies of any employee under any Federal or  
8 State law or under any collective bargaining agreement.  
9 The rights and remedies in this section may not be waived  
10 by any agreement, policy, form, or condition of employ-  
11 ment.”.

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