

105TH CONGRESS  
1ST SESSION

# H. R. 1094

To amend the Federal Food, Drug, and Cosmetic Act to make improvements  
in the regulation of drugs.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 18, 1997

Mr. FOX of Pennsylvania introduced the following bill; which was referred to  
the Committee on Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to  
make improvements in the regulation 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 AND REFERENCE.**

4       (A) **SHORT TITLE.**—This Act may be cited as the  
5       “Life Extending and Life Saving Drug Act”.

6       (b) **REFERENCE.**—Whenever in this Act an amend-  
7       ment or repeal is expressed in terms of an amendment  
8       to, or repeal of, a section or other provision, the reference  
9       shall be considered to be made to a section or other provi-  
10      sion of the Federal Food, Drug, and Cosmetic Act.

1 **SEC. 2. MISSION OF THE FOOD AND DRUG ADMINISTRA-**  
2 **TION.**

3 Section 903 (21 U.S.C. 393) is amended by adding  
4 at the end the following:

5 “(d) The mission of the Food and Drug Administra-  
6 tion (with respect to drugs, biological products, and de-  
7 vices) is to promote and protect the health of the American  
8 people. This mission should be achieved by—

9 “(1) facilitating the timely availability of safe  
10 and effective products that benefit the American  
11 public,

12 “(2) encouraging the efficient development of  
13 new products in the United States,

14 “(3) taking prompt and appropriate action  
15 where postmarketing surveillance demonstrates that  
16 products present a health risk to the American pub-  
17 lic,

18 “(4) ensuring that human drugs and biological  
19 products are tested and manufactured consistent  
20 with the goal of harmonization of international  
21 standards,

22 “(5) facilitating the flow of information to edu-  
23 cate health professionals and the American public,  
24 and

25 “(6) enforcing the applicable statutes and regu-  
26 lations in a timely, fair, and decisive manner.

1 **SEC. 3. LIMITING THE REQUIREMENT FOR INVESTIGA-**  
2 **TIONS USING PRODUCTS MANUFACTURED AT**  
3 **A FULL-SCALE TESTING FACILITY; GUIDE-**  
4 **LINES; HARMONIZATION.**

5 (a) **FACILITIES.**—Section 505 (21 U.S.C. 355) is  
6 amended—

7 (1) in subsection (b)(1), by inserting after the  
8 second sentence the following: “The investigations  
9 referred to in clause (A) shall be required to be per-  
10 formed using products manufactured at a full-scale  
11 commercial facility only if the Secretary finds, after  
12 providing opportunity for an informal hearing, that  
13 investigations using products manufactured at such  
14 a facility are necessary to assure the safety and effi-  
15 cacy of the drug being investigated or, in the case  
16 of a biological product subject to section 351 of the  
17 Public Health Service Act, to assure that the re-  
18 quirements applicable under such section are met.”;  
19 and

20 (2) in clause (1) of subsection (d), by inserting  
21 after “to subsection (b),” the following: “were not  
22 performed at a full-scale commercial facility as re-  
23 quired under subsection (b)(1) or”.

24 (b) **GUIDELINES.**—The Secretary, acting through the  
25 Commissioner of Food and Drugs and after consultation  
26 with the Institute of Medicine, shall develop guidelines for

1 the clinical testing required by subsections (b) and (i) of  
2 section 505 of the Federal Food, Drug, and Cosmetic Act  
3 (21 U.S.C. 355).

4 (c) HARMONIZATION.—The Secretary shall take such  
5 action as may be appropriate to harmonize the require-  
6 ments of the Federal Food, Drug, and Cosmetic Act for  
7 pre-clinical and clinical investigations with the require-  
8 ments of similar laws in foreign countries through the  
9 International Conference on Harmonization.

#### 10 **SEC. 4. REGULATION OF BIOLOGICAL PRODUCTS.**

11 Section 351(a) of the Public Health Service Act (42  
12 U.S.C. 262(a)) is amended by inserting “(1)(A)” after  
13 “(a)” and by striking “any virus” and all that appears  
14 thereafter and inserting in lieu thereof the following: “a  
15 biological product to which this section applies unless—

16 “(i) such biological product has been propa-  
17 gated, manufactured, or prepared in accordance with  
18 good manufacturing practices;

19 “(ii) such biological product is the subject of an  
20 approved product license or complies with a stand-  
21 ard established by the Secretary; and

22 “(iii) each package of such biological product is  
23 plainly marked with the proper name of the biologi-  
24 cal product contained therein, the name, address,  
25 and establishment number of the manufacturer, and

1 the date beyond which the contents cannot be ex-  
2 pected to yield their specific results.

3 “(B) The Secretary shall by regulation specify which  
4 biological products shall be required to have a product li-  
5 cense or shall be subject to standards established under  
6 subparagraph (A)(ii), except that tissue, blood and blood  
7 components and derivatives (other than blood test kits)  
8 shall be subject to standards under paragraph (4).

9 “(2)(A) The Secretary shall establish, by regulation,  
10 requirements for product license applications. The Sec-  
11 retary shall approve a product license application upon a  
12 demonstration that there exists reasonable assurance that  
13 the biological product which is the subject of the applica-  
14 tion is safe and effective.

15 “(B)(i) The Secretary shall establish, by regulation,  
16 standards for biological products subject to such stand-  
17 ards under paragraph (1)(B), except that tissue, blood,  
18 and blood components or derivatives (other than blood test  
19 kits) shall be subject to standards established under para-  
20 graph (4). Standards shall, as appropriate, reasonably as-  
21 sure the safety, purity, and potency of the biological prod-  
22 uct or class of biological products subject to such stand-  
23 ard.

24 “(3)(A) A product license approved by the Secretary  
25 under paragraph (2)(A) and regulations established by the

1 Secretary under paragraph (2)(B) may require that lots  
2 or batches of a biological product be released only after  
3 certification that such lots or batches have the characteris-  
4 ties of safety, purity, and potency which the biological  
5 product purports or is represented to possess.

6 “(B)(i) A product license shall specify whether certifi-  
7 cation under subparagraph (A) will be by the manufac-  
8 turer of the biological product, by the Secretary, or by a  
9 certified individual or independent laboratory under sec-  
10 tion 906 of the Federal Food, Drug, and Cosmetic Act.

11 “(ii) Certification of lots or batches by the Secretary  
12 or independent laboratory shall be required only for a pe-  
13 riod of not more than 6 months, which period will not be  
14 extended unless the Secretary determines in writing that  
15 continuing such certification is required to assure the safe-  
16 ty and efficacy of the biological product.”.

17 “(iii) The Secretary may at any time, upon petition  
18 by the manufacturer or upon the Secretary’s own initia-  
19 tive, terminate any requirement for certification.

20 “(4)(A) The Secretary shall by regulation establish  
21 standards for tissue, blood, and blood components or blood  
22 derivatives (other than blood test kits). Such standards  
23 shall assure the safety and integrity of the tissue, blood,  
24 and blood components or derivatives (other than blood test  
25 kits). The Secretary shall solicit the submission of one or

1 more proposed standards, applicable to tissue, blood, and  
2 blood components or derivatives (other than blood test  
3 kits) and approved by the Secretary as appropriate for  
4 purposes of this section, from professional and scientific  
5 organizations. The Secretary shall publish such standards  
6 as a notice of proposed rulemaking in accordance with  
7 paragraph (2)(B)(ii).

8       “(B) The Secretary shall use professional and sci-  
9 entific organizations and accrediting bodies used to assure  
10 compliance with the standards of such organizations to as-  
11 sist in the implementation of subparagraph (A) and to as-  
12 sure that tissue, blood, and blood components or deriva-  
13 tives (other than blood test kits) are processed in accord-  
14 ance with good manufacturing practices established by the  
15 Secretary under paragraph (6).

16       “(5) For purposes of this subsection, the term ‘tissue’  
17 means a collection of human cells which are similar or the  
18 intercellular substances surrounding them, or both,  
19 which—

20               “(A) are intended for administration to a  
21 human being for the diagnosis, cure, mitigation,  
22 treatment, or prevention of any disease or condition;

23               “(B) are procured, processed, stored, or distrib-  
24 uted by methods to prevent the transmission of in-

1 fectious disease and to preserve or enhance clinical  
2 usefulness;

3 “(C) may be processed to remove some of its  
4 constituents but have not been modified chemically;

5 “(D) may be combined with substances such as  
6 excipients, fillers, or carriers that are not devices or  
7 pharmacologically active;

8 “(E) if subjected to expansion, manipulation, or  
9 other processing (which may include modification of  
10 physical form or structure) before being trans-  
11 planted or implanted, are not thereby substantially  
12 altered in their inherent structural or functional  
13 characteristics; and

14 “(F) achieve their principal intended purposes  
15 through structural or functional support and not  
16 systematic action;

17 but such term does not include vascularized human or-  
18 gans.”.

19 **SEC. 5. GOOD MANUFACTURING PRACTICES.**

20 Section 501 (21 U.S.C. 351(a)) is amended—

21 (1) by inserting “(A)” after “(a)(1)” and redesi-  
22 gnating “(2)(A)” as “(B)(i)”, “(B)” as “(ii)” both  
23 times it appears, “(3)” as “(C)”, “(4)” as “(D)”,  
24 “(5)” as “(E)”, “(6)” as “(F)”, and “(A)” as “(i)”  
25 the second time it appears; and

1           (2) by inserting the following at the end of sub-  
2           section (a):

3           “(B) The Secretary shall by regulation establish good  
4           manufacturing practices applicable to drugs subject to sec-  
5           tion 505 of this Act and biological products (other than  
6           blood) subject to section 351 of the Public Health Service  
7           Act as follows:

8           “(i) One set of regulations shall apply only to  
9           drugs and biological products which cannot be char-  
10          acterized adequately by physical or chemical meth-  
11          ods.

12          “(ii) A second set of regulations shall apply  
13          only to drugs and biological products which can be  
14          characterized adequately by physical or chemical  
15          methods.

16          “(C) Regulations established under subparagraph  
17          (B) shall establish requirements for submissions to the  
18          Secretary of changes in manufacturing practices by the  
19          applicant or holder. Such regulations shall provide as fol-  
20          lows:

21          “(i) In the case of drugs and biological products  
22          which can adequately be characterized by physical or  
23          chemical methods, approval of manufacturing  
24          changes shall be required prior to implementation of  
25          such changes only if such manufacturing changes

1 are specified in regulations as substantially affecting  
2 the safety or efficacy of such drugs and biological  
3 products.

4 “(ii) In the case of drugs and biological prod-  
5 ucts which cannot be characterized adequately by  
6 physical or chemical methods, approval of such man-  
7 ufacturing changes before implementation shall be  
8 required—

9 “(I) in the case of a drug or a biological  
10 product which is required under section  
11 351(a)(1)(B) of the Public Health Service Act  
12 to have a product license, only if such manufac-  
13 turing changes are specified in regulations as  
14 substantially affecting the safety and efficacy of  
15 such drug or biological product; or

16 “(II) in the case of a biological product  
17 which is subject to standards as determined  
18 under section 351(a)(1)(B) of the Public  
19 Health Service Act, only if such manufacturing  
20 changes are specified in the regulations as sub-  
21 stantially affecting the safety, purity, potency  
22 (or, in the case of tissue, safety, and integrity)  
23 of such biological products.

24 “(iii) Such regulations shall specify the types of  
25 manufacturing changes that must be submitted in

1 writing to the Secretary (but not required to be ap-  
2 proved prior to implementation). A request to make  
3 such changes must be submitted by the applicant or  
4 holder at least 30 days prior to implementation of  
5 such changes. Such request shall be deemed ap-  
6 proved on the 31st day after submission unless on  
7 or before such day the Secretary disapproves such  
8 request and notifies the applicant or holder in writ-  
9 ing of such disapproval. Such notification shall in-  
10 clude a complete statement of the reasons for dis-  
11 approval and a statement of modifications to the re-  
12 quest which, if made by the applicant or holder, will  
13 allow approval of the request.

14 “(iv) A description of manufacturing changes  
15 not covered by clauses (i) or (iii) shall be submitted  
16 by the applicant or holder to the Secretary on an an-  
17 nual basis.

18 “(D)(i) The Secretary shall, after notice and oppor-  
19 tunity for public comment pursuant to section 553 of title  
20 5, United States Code, establish not later than December  
21 31, 1998, regulations to be used in determining whether  
22 a drug or a biological product can adequately be character-  
23 ized by physical or chemical methods.

24 “(ii) If the applicant disagrees with a determination  
25 by the Secretary that the drug or biological product which

1 is the subject of an application cannot be adequately char-  
2 acterized by physical or chemical methods, such applicant  
3 may contest such determination by requesting an informal  
4 hearing.

5 “(E) For purposes of subparagraphs (B) through  
6 (D)—

7 “(i) the term ‘changes in manufacturing prac-  
8 tices’ means—

9 “(I) changes in manufacturing procedures  
10 generally applicable throughout the facility,  
11 such as changes in recordkeeping procedures,  
12 validation processes, methods of training of per-  
13 sonnel, and methods of qualification of equip-  
14 ment;

15 “(II) changes in equipment; and

16 “(III) changes in manufacturing proce-  
17 dures of specific applicability to a biological  
18 product;

19 “(ii) the term ‘holder’ means a person whose  
20 drug application submitted under section 505 or  
21 product license application submitted under section  
22 351 of the Public Health Service Act has been ap-  
23 proved; and

24 “(iii) the term ‘applicant’ means a person  
25 whose application described under clause (ii) has

1       been submitted to, but not approved by, the Sec-  
2       retary.”.

3       **SEC. 6. NEW DRUG APPROVAL STANDARD.**

4       The last sentence of section 505(d) (21 U.S.C.  
5       355(d)) is amended to read as follows: “As used in this  
6       subsection and subsection (e), the term ‘substantial evi-  
7       dence’ means evidence consisting of scientifically sound  
8       data, including data from one well-controlled clinical inves-  
9       tigation and confirmatory evidence (obtained either before  
10      or after such investigation) on the basis of which experts  
11      qualified by scientific training and experience to evaluate  
12      the effectiveness of the drug involved could fairly and re-  
13      sponsibly conclude, taking into account the entire knowl-  
14      edge base on the drug’s effectiveness and safety, inter-  
15      preted as a whole, that the drug will have the effect it  
16      purports or is represented to have under the conditions  
17      of use prescribed, recommended, or suggested in the label-  
18      ing or proposed labeling of the drug.”.

19      **SEC. 7. EXPEDITED REVIEW OF NEW DRUGS.**

20      Section 505 (21 U.S.C. 355), as amended by section  
21      6, is amended by adding at the end the following:

22      “(o)(1) Any person who could submit or has submit-  
23      ted an application for a new drug pursuant to subsection  
24      (b)(1), other than an application described in subsection

1 (b)(2), may submit an application for approval pursuant  
2 to this subsection.

3 “(2) Any person may submit to the Secretary an ap-  
4 plication (including a supplemental application for a new  
5 indication) for approval of a new drug, including approval  
6 of a switch of a new drug from prescription to non-  
7 prescription status, at any dose and for any indication  
8 based upon an evaluation by a domestic nongovernmental  
9 organization under clause (C) following licensing or ap-  
10 proval of such new drug after the date of enactment of  
11 the Life Extending and Life Saving Drug Act by any of  
12 the following third party organizations:

13 “(A) The European Medicines Evaluation  
14 Agency or any successor organization.

15 “(B) The United Kingdom Medicines Control  
16 Agency or any successor organization.

17 “(C) Any competent governmental or non-  
18 governmental organization established to evaluate  
19 the safety and effectiveness of drugs which meets  
20 any general criteria that the Secretary may by regu-  
21 lation establish.

22 “(3) The application shall consist of the following ma-  
23 terials:

24 “(A) The complete dossier or other submission  
25 made to a third party organization described in

1 paragraph (2) (in this paragraph referred to as ‘the  
2 third party organization’), including any amend-  
3 ments or additions.

4 “(B) All correspondence, memoranda of meet-  
5 ings and telephone discussions, and similar docu-  
6 ments reflecting communications between the appli-  
7 cant and the third party organization or persons  
8 working with the third party organization prepared  
9 or received by the applicant relating to the new  
10 drug.

11 “(C) All analyses and other documents pre-  
12 pared by or for the third party organization relating  
13 to any aspect of the new drug that the third party  
14 organization provides to the applicant upon request  
15 and a letter authorizing the Secretary to obtain any  
16 other such document directly from the third party.

17 “(D) A summary of adverse event information  
18 obtained as the result of any marketing outside the  
19 United States.

20 “(E) A copy of the labeling approved by the  
21 third party organization and proposed United States  
22 labeling that is consistent with the Secretary’s gen-  
23 erally applicable labeling requirements.

24 “(F) An adequate summary of the documents  
25 that constitute the application.

1       “(4) Within 7 days after receipt of the application,  
2 the Secretary shall send the summary to each member of  
3 a scientific review group established pursuant to section  
4 904. Within 60 days after receipt of the application by  
5 the Secretary, the scientific review group shall meet to  
6 consider the application and to make its conclusions and  
7 recommendations to the Secretary.

8       “(5) Within 180 days after receipt of the submission  
9 by the Secretary (or if an application under subsection  
10 (b)(1) was submitted before the submission under this  
11 subsection, then within 180 days of receipt of the applica-  
12 tion under subsection (b)(1) or 90 days of the receipt of  
13 the submission under this subsection, whichever is later),  
14 the Secretary, taking into account any conclusions and  
15 recommendations of the scientific review group, shall ei-  
16 ther (A) approve the application, (B) disapprove the appli-  
17 cation if the Secretary demonstrates, based on the infor-  
18 mation in the submission (and, if an application has been  
19 filed under subsection (b)(1), on the information in such  
20 application) that the drug is unsafe or ineffective, and (C)  
21 if the application is disapproved, publish a notice of the  
22 decision in the Federal Register. If the Secretary does not  
23 publish a notice of disapproval in the Federal Register  
24 within such 180 days, the conclusions and recommenda-  
25 tions of the scientific review group regarding the applica-

1 tion shall be deemed to be the decision of the Secretary  
2 and the Secretary shall implement them immediately. If  
3 the Secretary does not publish a notice of disapproval in  
4 the Federal Register within 90 days and no scientific  
5 group has made conclusions or recommendations within  
6 that period regarding the application, the application shall  
7 be deemed to be approved and the Secretary shall imme-  
8 diately approve the application. The failure of the Sec-  
9 retary to take any such action shall constitute final agency  
10 action for purposes of judicial review. The Secretary may  
11 at any time take action to revoke the approval of an appli-  
12 cation approved pursuant to this paragraph on the ground  
13 specified in clause (B) using the procedures established  
14 in subsections (e) through (h) of this section.

15 “(6) The Secretary shall continue to pursue inter-  
16 national harmonization of drug regulation among nations  
17 both through (A) adoption of uniform technical require-  
18 ments and a registration dossier and (B) mutual recogni-  
19 tion of marketing approval.”.

20 **SEC. 8. CLINICAL RESEARCH.**

21 Section 505(i) (21 U.S.C. 355(i)) is amended by add-  
22 ing at the end the following: “A clinical study of a new  
23 drug may begin after the Secretary has received from the  
24 sponsor a notification containing information about the  
25 drug and the clinical study. Such notification shall be re-

1 quired to contain only summaries of basic information,  
2 certified by the applicant to be accurate, needed to assess  
3 the safety of the clinical study and shall not be required  
4 to contain detailed information on chemistry, manufactur-  
5 ing, or controls or primary data tabulations or case report  
6 forms or tabulations from animal or human studies. At  
7 any time the director of the office within which the appli-  
8 cation is being reviewed may issue to the sponsor in writ-  
9 ing a clinical hold prohibiting the sponsor from conducting  
10 the investigation and specifying the basis for the clinical  
11 hold. The director of such office may issue a clinical hold  
12 only upon a demonstration, based on specific information  
13 available to the Secretary, that the drug represents an un-  
14 reasonable risk to the safety of the persons who are the  
15 subject of the clinical study, taking into account the condi-  
16 tion for which the drug is to be investigated and the health  
17 status of the subjects involved. Any response from the  
18 sponsor to the director of such office requesting that the  
19 clinical hold be removed shall receive a decision, in writing  
20 and specifying the reasons therefor, within 15 days or the  
21 clinical hold shall be deemed to be withdrawn. The director  
22 may not delegate the authority to issue a clinical hold.

1 **SEC. 9. CONTENT AND REVIEW OF NEW DRUG APPLICA-**  
2 **TION.**

3 (a) SECTION 505(b)(1) APPLICATION.—Section  
4 505(b) (21 U.S.C. 355) is amended by adding at the end  
5 the following:

6 “(4)(A) An application submitted under paragraph  
7 (1) shall include reports of studies on safety and effective-  
8 ness certified by the applicant to be accurate summaries  
9 which are supported by summary tables of the relevant  
10 data. Such an application shall not be required to include  
11 the primary data tabulations or case report forms or tab-  
12 ulations. In extraordinary circumstances, the director of  
13 the office of the Food and Drug Administration respon-  
14 sible for review of the drug for which the application is  
15 submitted may request, in writing and specifying the rea-  
16 sons for the request, the submission of primary data tab-  
17 ulations. The director may not delegate the authority to  
18 make such a request.

19 “(B) In reviewing an application submitted under  
20 paragraph (1), the Secretary, after obtaining agreement  
21 of the applicant, shall contract with outside organizations  
22 or individuals with expertise in relevant disciplines for the  
23 review of all or parts of such application.

24 “(C) The Secretary shall establish standards for the  
25 review of applications submitted under paragraph (1) re-  
26 lating to promptness, technical excellence, lack of bias and

1 conflict of interest, and a knowledge of regulatory and sci-  
2 entific standards which apply equally to outside reviewers  
3 and to employees of the Secretary who review such appli-  
4 cations. The Secretary shall conduct and maintain records  
5 of training programs for outside reviewers and employees  
6 of the Secretary who review such applications to assure  
7 their compliance with good review practices and good re-  
8 view standards and shall monitor their compliance with  
9 such practices and standards, the requirements of section  
10 708, and the statutory time limits for action.

11       “(D) Advice provided to a sponsor or applicant at its  
12 request by a responsible Food and Drug Administration  
13 employee regarding appropriate testing of a new drug  
14 shall not be changed after such testing begins except with  
15 the written agreement of the sponsor or applicant or by  
16 a decision in writing after an informal hearing by the di-  
17 rector of the office in which the drug is reviewed. The di-  
18 rector may not delegate the authority to require such a  
19 change.

20       “(E) The written decisions of the center for drugs  
21 and the center for biologics of the Food and Drug Admin-  
22 istration on all aspects of matters relating to a new drug  
23 or biologic shall be binding upon, and may not directly  
24 or indirectly be changed by, the field personnel or the of-  
25 fices of compliance in the centers.

1           “(F) No action by the center for drugs or the center  
2 for biologics on any matter relating to a new drug or bio-  
3 logic may at any time or under any circumstance be de-  
4 layed because of the unavailability of information or action  
5 by the field personnel or because of issues relating to the  
6 integrity of data, except on the basis of evidence presented  
7 to the applicant, followed by an informal hearing, that  
8 data in that particular application are false.”.

9           (b) SUMMARIES.—Section 505(b)(1)(A) (21 U.S.C.  
10 355(b)(1)(A)) is amended by inserting “(including de-  
11 tailed summaries)” after “full reports and investigations”.

12 **SEC. 10. REVIEW BY INDEPENDENT TESTING ORGANIZA-**  
13 **TIONS.**

14           (a) PRIVATIZATION.—Chapter IX is amended by add-  
15 ing after section 905 (21 U.S.C. 395) the following:

16           “PRIVATIZATION OF APPROVAL FUNCTIONS

17           “SEC. 906. (a) The Secretary, acting through the  
18 Commissioner of Food and Drugs, may establish and im-  
19 plement a program under which the Commissioner will  
20 contract, in whole or in significant part, with individuals  
21 and laboratories certified under subsection (b) to conduct,  
22 under such conditions as the Secretary may specify to as-  
23 sure unbiased scientifically valid results, the following ac-  
24 tivities and responsibilities of the Food and Drug Adminis-  
25 tration in connection with the approval of drugs and de-  
26 vices under sections 505 and 515 and with reviewing noti-

1 fications required under section 510(k) and making writ-  
2 ten recommendations of initial classification under section  
3 513(f)(1) of devices:

4           “(1) Toxicology reviews to determine if applica-  
5 ble requirements are being met.

6           “(2) Chemistry reviews to determine if applica-  
7 ble requirements are being met.

8           “(3) Statistical analysis to determine if applica-  
9 ble requirements are being met.

10           “(4) Preapproval manufacturing practice in-  
11 spections to determine if applicable requirements are  
12 being met.

13           “(5) Clinical reviews to determine if applicable  
14 requirements are being met.

15           “(6) Any other function of the Food and Drug  
16 Administration relating to the review and approval  
17 of drugs or devices that the Secretary determines  
18 can be adequately performed under contract with  
19 qualified individuals and laboratories.

20           “(b) The Secretary, acting through the Commissioner  
21 of Food and Drugs, shall certify individuals and labora-  
22 tories as qualified to carry out the functions described in  
23 paragraphs (1) through (6) of subsection (a) under a con-  
24 tract with the Commissioner of Food and Drugs.

1           “(c) The Secretary shall provide that drugs and de-  
2 vices which are subject to review under subsection (a) shall  
3 be approved under sections 505 and 515 if the review de-  
4 termines that the drugs and devices meet all applicable  
5 approval requirements.

6           “(d)(1) Information otherwise protected from dislo-  
7 sure to the public under section 301(j) or 520(e) may be  
8 disclosed to—

9                   “(A) contractors certified under subsection (b),  
10           and

11                   “(B) employees of such contractors,  
12 if, in the opinion of the Secretary, such disclosure is nec-  
13 essary for the satisfactory performance by the contractor  
14 of work under a contract under subsection (a).

15           “(2) The Secretary shall, in writing, require as a con-  
16 dition to the disclosure of information under paragraph  
17 (1) that the person receiving such information take such  
18 security precautions respecting the information as the Sec-  
19 retary shall by regulation prescribe. Disclosure by such  
20 person of such information to a person not authorized to  
21 receive it shall constitute a violation of section 301(j) and  
22 of section 1905 of title 18, United States Code.

23           “(e) The review of an application for approval of a  
24 new drug or device under this Act or a biological product  
25 under section 351 of the Public Health Service Act shall

1 not include the review of the environmental impact of such  
2 drug, device, or biological product under the Environ-  
3 mental Quality Improvement Act of 1970 (42 U.S.C. 4371  
4 et seq.).”.

5 (b) REPORT.—Not later than the expiration of one  
6 year from the date of the enactment of this Act, the Sec-  
7 retary of Health and Human Services shall report to the  
8 Congress on—

9 (1) the use the Secretary has made under sec-  
10 tion 906 of the Federal Food, Drug, and Cosmetic  
11 Act of the authority to contract for individuals and  
12 laboratories to perform duties of the Food and Drug  
13 Administration, and

14 (2) any difficulties encountered in contracting  
15 under such section 906.

16 **SEC. 11. RESEARCH ACTIVITIES.**

17 (a) ACTIVITIES.—Chapter IX, as amended by section  
18 10, is amended by adding after section 906 the following:

19 “RESEARCH ACTIVITIES

20 “SEC. 907. Research activities of the Food and Drug  
21 Administration relating to drugs, devices, and biological  
22 products, which are authorized under section  
23 903(b)(2)(D) and section 352 of the Public Health Service  
24 Act, shall directly relate to the review and approval of  
25 drugs, devices, and biological products. In conducting such  
26 research activities, the Food and Drug Administration

1 may collaborate with the National Institutes of Health,  
2 academic health centers, and other scientific institutions  
3 and the drug and device industry.”.

4 (b) PURPOSE.—Section 903 (21 U.S.C. 393), as  
5 amended by section 2, is amended by adding at the end  
6 the following:

7 “(e) Any research conducted by or for the Food and  
8 Drug Administration shall be solely related directly to (1)  
9 the regulatory mission or (2) professional staff develop-  
10 ment related to that mission and shall be limited to the  
11 minimum necessary to achieve such purposes.”.

12 **SEC. 12. POLICY AND PERFORMANCE REVIEW.**

13 Section 903 (21 U.S.C. 393), as amended by section  
14 11(b), is amended by adding at the end the following:

15 “(f)(1) The Secretary shall establish, in the office of  
16 the Assistant Secretary for Health, a permanent commis-  
17 sion responsible for broad oversight of the policy and per-  
18 formance of the Food and Drug Administration. The com-  
19 mission, which shall be subject to the provisions of sub-  
20 section (c) of this section, shall review the performance  
21 of individuals and groups in meeting the mission of the  
22 Food and Drug Administration and the development of  
23 appropriate agency policy to implement that mission and  
24 shall include outcomes measurements and performance as-  
25 sessments in evaluating agency activities. Such review

1 shall also include a comparison of the performance of the  
2 Food and Drug Administration with that of agencies per-  
3 forming similar functions for other countries and an eval-  
4 uation of the effect of the Food and Drug Administra-  
5 tion's performance on the competitiveness of the regulated  
6 American industries.

7       “(2)(A) The members of the commission shall include  
8 the nation's leading medical experts, medical society rep-  
9 resentatives, scientific and health policy authorities, and  
10 representatives from the trade associations for the regu-  
11 lated industries and from voluntary health associations.

12       “(B) Members of the commission shall serve at the  
13 discretion of the Secretary from year to year with no fixed  
14 term.

15       “(C) The Secretary shall pay members of the com-  
16 mission at an appropriate level commensurate with the  
17 services they provide.

18       “(3)(A) The commission shall issue a report to the  
19 Secretary and the Congress annually on the performance  
20 of the Food and Drug Administration. The Food and  
21 Drug Administration shall be given an opportunity to re-  
22 view and respond to the report before it is submitted to  
23 the Secretary and the Congress.

24       “(B) As part of its annual report under subparagraph  
25 (A), the commission shall recommend personnel and policy

1 changes to improve the performance of the Food and Drug  
2 Administration in order to meet its mission as set forth  
3 in subsection (d).”.

4 **SEC. 13. APPEALS.**

5 Section 903 (21 U.S.C. 393), as amended by section  
6 12, is amended by adding the following new subsection  
7 at the end thereof:

8 “(g)(1) The Secretary shall establish within the Food  
9 and Drug Administration a drug and biologics policy ap-  
10 peals committee consisting of the director and deputy di-  
11 rector of the center for drugs and the director and deputy  
12 director of the center for biologics. The appeals committee  
13 shall meet to hear and consider any dispute raised by an  
14 individual who wishes to contest a policy matter relating  
15 to drugs or biologics. The appeals committee shall meet  
16 to hear the individual within 15 days of receiving the re-  
17 quest from the individual and shall decide the matter with-  
18 in 10 days after the hearing.

19 “(2) The Secretary shall establish standing panels of  
20 qualified experts who are not employees of the United  
21 States Government or of any State or local government  
22 for the purpose of hearing appeals by individuals who have  
23 exhausted their informal appeals within the Food and  
24 Drug Administration and who wish to contest the action  
25 or failure to act by the Food and Drug Administration

1 in a particular matter. The Secretary shall establish an  
2 appeal procedure that assures immediate access to such  
3 a panel and prompt conclusions and recommendations by  
4 the panel. Following the conclusions and recommendations  
5 of the panel, the official of the Food and Drug Adminis-  
6 tration who reports to the Commissioner of Food and  
7 Drugs and is the director of the component responsible  
8 for regulation of the matter shall personally review the  
9 matter, in light of such conclusions and recommendations,  
10 and shall make a final decision within 15 days after receiv-  
11 ing the conclusions and recommendations. Such official  
12 may not delegate the requirement to review and make a  
13 final decision. The decision of that official shall imme-  
14 diately be implemented. If that official fails to make a de-  
15 cision within 15 days, or if the decision is not immediately  
16 implemented, the conclusions and recommendations of the  
17 panel shall be deemed to be the decision of the Food and  
18 Drug Administration and shall be implemented imme-  
19 diately. The failure of the Secretary to take action to im-  
20 plement that decision immediately shall constitute final  
21 agency action for purposes of judicial review.”.

22 **SEC. 14. EXPORT OF NEW DRUGS.**

23 Section 801(e) of the Federal Food, Drug, and Cos-  
24 metic Act (21 U.S.C. 381(e) is amended—

1           (1) in paragraph (1), by inserting after “under  
2           this Act” the following: “or in violation of section  
3           505 or section 351 of the Public Health Service  
4           Act”,

5           (2) in paragraph (1), by striking the last sen-  
6           tence, and

7           (3) by amending paragraph (2) to read as fol-  
8           lows:

9           “(2) Paragraph (1) does not apply to the export of—

10           “(A) any device—

11           “(i) which does not comply with an appli-  
12           cable requirement under section 514 or 515,

13           “(ii) which under section 520(g) is exempt  
14           from either such section, or

15           “(iii) which is a banned device under sec-  
16           tion 516, or

17           “(B) any drug (including a biological product)  
18           which does not comply with an applicable require-  
19           ment under section 505 or 512 or section 351 of the  
20           Public Health Service Act,

21           unless the device or drug is in compliance with the require-  
22           ments of paragraph (1). In the case of a device or drug  
23           for which an export notice is required under this para-  
24           graph, the Secretary may prohibit the export of such de-  
25           vice or drug if the Secretary determines that the possibil-

1 ity of the reimportation of the device or drug into the  
2 United States presents an imminent hazard to the public  
3 health and safety of the United States and the only means  
4 of limiting the hazard is to prohibit the export of the de-  
5 vice or drug.”.

6 **SEC. 15. EXPORT OF CERTAIN UNAPPROVED PRODUCTS.**

7 Section 802 (21 U.S.C. 382) is repealed.

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