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

IN THE HOUSE OF REPRESENTATIVES

JUNE 30, 1995

Mr. FOX of Pennsylvania (for himself, Mr. CLINGER, Mr. MCINTOSH, Mr. OXLEY, Mr. MILLER of Florida, Mr. BILBRAY, Mr. BLUTE, Mr. LATOURETTE, Mr. PETERSON of Minnesota, Mr. WELDON of Florida, Mr. FRISA, Mr. COX of California, and Mr. COOLEY) introduced the following bill; which was referred to the Committee on Commerce

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

1 shall be considered to be made to a section or other provi-
2 sion of the Federal Food, Drug, and Cosmetic Act.

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

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

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

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

14 “(2) encouraging the efficient development of
15 new products in the United States,

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

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

1 “(5) facilitating the flow of information to edu-
2 cate health professionals and the American public,
3 and

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

6 **SEC. 3. LIMITING THE REQUIREMENT FOR INVESTIGA-**
7 **TIONS USING PRODUCTS MANUFACTURED AT**
8 **A FULL-SCALE TESTING FACILITY; GUIDE-**
9 **LINES; HARMONIZATION.**

10 (a) FACILITIES.—Section 505 (21 U.S.C. 355) is
11 amended—

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

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

5 (b) GUIDELINES.—The Secretary, acting through the
6 Commissioner of Food and Drugs and after consultation
7 with the Institute of Medicine, shall develop guidelines for
8 the clinical testing required by subsections (b) and (i) of
9 section 505 of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 355).

11 (c) HARMONIZATION.—The Secretary shall take such
12 action as may be appropriate to harmonize the require-
13 ments of the Federal Food, Drug, and Cosmetic Act for
14 pre-clinical and clinical investigations with the require-
15 ments of similar laws in foreign countries through the
16 International Conference on Harmonization.

17 **SEC. 4. REGULATION OF BIOLOGICAL PRODUCTS.**

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

23 “(i) such biological product has been propa-
24 gated, manufactured, or prepared in accordance with
25 good manufacturing practices;

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

4 “(iii) each package of such biological product is
5 plainly marked with the proper name of the biologi-
6 cal product contained therein, the name, address,
7 and establishment number of the manufacturer, and
8 the date beyond which the contents cannot be ex-
9 pected to yield their specific results.

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

16 “(2)(A) The Secretary shall establish, by regulation,
17 requirements for product license applications. The Sec-
18 retary shall approve a product license application upon a
19 demonstration that there exists reasonable assurance that
20 the biological product which is the subject of the applica-
21 tion is safe and effective.

22 “(B)(i) The Secretary shall establish, by regulation,
23 standards for biological products subject to such stand-
24 ards under paragraph (1)(B), except that tissue, blood,
25 and blood components or derivatives (other than blood test

1 kits) shall be subject to standards established under para-
2 graph (4). Standards shall, as appropriate, reasonably as-
3 sure the safety, purity, and potency of the biological prod-
4 uct or class of biological products subject to such stand-
5 ard.

6 “(3)(A) A product license approved by the Secretary
7 under paragraph (2)(A) and regulations established by the
8 Secretary under paragraph (2)(B) may require that lots
9 or batches of a biological product be released only after
10 certification that such lots or batches have the characteris-
11 tics of safety, purity, and potency which the biological
12 product purports or is represented to possess.

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

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

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

4 “(4)(A) The Secretary shall by regulation establish
5 standards for tissue, blood, and blood components or blood
6 derivatives (other than blood test kits). Such standards
7 shall assure the safety and integrity of the tissue, blood,
8 and blood components or derivatives (other than blood test
9 kits). The Secretary shall solicit the submission of one or
10 more proposed standards, applicable to tissue, blood, and
11 blood components or derivatives (other than blood test
12 kits) and approved by the Secretary as appropriate for
13 purposes of this section, from professional and scientific
14 organizations. The Secretary shall publish such standards
15 as a notice of proposed rulemaking in accordance with
16 paragraph (2)(B)(ii).

17 “(B) The Secretary shall use professional and sci-
18 entific organizations and accrediting bodies used to assure
19 compliance with the standards of such organizations to as-
20 sist in the implementation of subparagraph (A) and to as-
21 sure that tissue, blood, and blood components or deriva-
22 tives (other than blood test kits) are processed in accord-
23 ance with good manufacturing practices established by the
24 Secretary under paragraph (6).

1 “(5) For purposes of this subsection, the term ‘tissue’
2 means a collection of human cells which are similar or the
3 intercellular substances surrounding them, or both,
4 which—

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

8 “(B) are procured, processed, stored, or distrib-
9 uted by methods to prevent the transmission of in-
10 fectious disease and to preserve or enhance clinical
11 usefulness;

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

14 “(D) may be combined with substances such as
15 excipients, fillers, or carriers that are not devices or
16 pharmacologically active;

17 “(E) if subjected to expansion, manipulation, or
18 other processing (which may include modification of
19 physical form or structure) before being trans-
20 planted or implanted, are not thereby substantially
21 altered in their inherent structural or functional
22 characteristics; and

23 “(F) achieve their principal intended purposes
24 through structural or functional support and not
25 systematic action;

1 but such term does not include vascularized human or-
2 gans.”.

3 **SEC. 5. GOOD MANUFACTURING PRACTICES.**

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

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

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

12 “(B) The Secretary shall by regulation establish good
13 manufacturing practices applicable to drugs subject to sec-
14 tion 505 of this Act and biological products (other than
15 blood) subject to section 351 of the Public Health Service
16 Act as follows:

17 “(i) One set of regulations shall apply only to
18 drugs and biological products which cannot be char-
19 acterized adequately by physical or chemical meth-
20 ods.

21 “(ii) A second set of regulations shall apply
22 only to drugs and biological products which can be
23 characterized adequately by physical or chemical
24 methods.

1 “(C) Regulations established under subparagraph
2 (B) shall establish requirements for submissions to the
3 Secretary of changes in manufacturing practices by the
4 applicant or holder. Such regulations shall provide as fol-
5 lows:

6 “(i) In the case of drugs and biological products
7 which can adequately be characterized by physical or
8 chemical methods, approval of manufacturing
9 changes shall be required prior to implementation of
10 such changes only if such manufacturing changes
11 are specified in regulations as substantially affecting
12 the safety or efficacy of such drugs and biological
13 products.

14 “(ii) In the case of drugs and biological prod-
15 ucts which cannot be characterized adequately by
16 physical or chemical methods, approval of such man-
17 ufacturing changes before implementation shall be
18 required—

19 “(I) in the case of a drug or a biological
20 product which is required under section
21 351(a)(1)(B) of the Public Health Service Act
22 to have a product license, only if such manufac-
23 turing changes are specified in regulations as
24 substantially affecting the safety and efficacy of
25 such drug or biological product; or

1 “(II) in the case of a biological product
2 which is subject to standards as determined
3 under section 351(a)(1)(B) of the Public
4 Health Service Act, only if such manufacturing
5 changes are specified in the regulations as sub-
6 stantially affecting the safety, purity, potency
7 (or, in the case of tissue, safety, and integrity)
8 of such biological products.

9 “(iii) Such regulations shall specify the types of
10 manufacturing changes that must be submitted in
11 writing to the Secretary (but not required to be ap-
12 proved prior to implementation). A request to make
13 such changes must be submitted by the applicant or
14 holder at least 30 days prior to implementation of
15 such changes. Such request shall be deemed ap-
16 proved on the 31st day after submission unless on
17 or before such day the Secretary disapproves such
18 request and notifies the applicant or holder in writ-
19 ing of such disapproval. Such notification shall in-
20 clude a complete statement of the reasons for dis-
21 approval and a statement of modifications to the re-
22 quest which, if made by the applicant or holder, will
23 allow approval of the request.

24 “(iv) A description of manufacturing changes
25 not covered by clauses (i) or (iii) shall be submitted

1 by the applicant or holder to the Secretary on an an-
2 nual basis.

3 “(D)(i) The Secretary shall, after notice and oppor-
4 tunity for public comment pursuant to section 553 of title
5 5, United States Code, establish not later than December
6 31, 1998, regulations to be used in determining whether
7 a drug or a biological product can adequately be character-
8 ized by physical or chemical methods.

9 “(ii) If the applicant disagrees with a determination
10 by the Secretary that the drug or biological product which
11 is the subject of an application cannot be adequately char-
12 acterized by physical or chemical methods, such applicant
13 may contest such determination by requesting an informal
14 hearing.

15 “(E) For purposes of subparagraphs (B) through
16 (D)—

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

19 “(I) changes in manufacturing procedures
20 generally applicable throughout the facility,
21 such as changes in recordkeeping procedures,
22 validation processes, methods of training of per-
23 sonnel, and methods of qualification of equip-
24 ment;

25 “(II) changes in equipment; and

1 “(III) changes in manufacturing proce-
2 dures of specific applicability to a biological
3 product;

4 “(ii) the term ‘holder’ means a person whose
5 drug application submitted under section 505 or
6 product license application submitted under section
7 351 of the Public Health Service Act has been ap-
8 proved; and

9 “(iii) the term ‘applicant’ means a person
10 whose application described under clause (ii) has
11 been submitted to, but not approved by, the Sec-
12 retary.”.

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

14 The last sentence of section 505(d) (21 U.S.C.
15 355(d)) is amended to read as follows: “As used in this
16 subsection and subsection (e), the term ‘substantial evi-
17 dence’ means evidence consisting of scientifically sound
18 data, including data from one well-controlled clinical inves-
19 tigation and confirmatory evidence (obtained either before
20 or after such investigation) on the basis of which experts
21 qualified by scientific training and experience to evaluate
22 the effectiveness of the drug involved could fairly and re-
23 sponsibly conclude, taking into account the entire knowl-
24 edge base on the drug’s effectiveness and safety, inter-
25 preted as a whole, that the drug will have the effect it

1 purports or is represented to have under the conditions
2 of use prescribed, recommended, or suggested in the label-
3 ing or proposed labeling of the drug.”.

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

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

7 “(o)(1) Any person who could submit or has submit-
8 ted an application for a new drug pursuant to subsection
9 (b)(1), other than an application described in subsection
10 (b)(2), may submit an application for approval pursuant
11 to this subsection.

12 “(2) Any person may submit to the Secretary an ap-
13 plication (including a supplemental application for a new
14 indication) for approval of a new drug, including approval
15 of a switch of a new drug from prescription to
16 nonprescription status, at any dose and for any indication
17 based upon an evaluation by a domestic nongovernmental
18 organization under clause (C) following licensing or ap-
19 proval of such new drug after the date of enactment of
20 the Life Extending and Life Saving Drug Act by any of
21 the following third party organizations:

22 “(A) The European Medicines Evaluation
23 Agency or any successor organization.

24 “(B) The United Kingdom Medicines Control
25 Agency or any successor organization.

1 “(C) Any competent governmental or non-
2 governmental organization established to evaluate
3 the safety and effectiveness of drugs which meets
4 any general criteria that the Secretary may by regu-
5 lation establish.

6 “(3) The application shall consist of the following ma-
7 terials:

8 “(A) The complete dossier or other submission
9 made to a third party organization described in
10 paragraph (2) (in this paragraph referred to as ‘the
11 third party organization’), including any amend-
12 ments or additions.

13 “(B) All correspondence, memoranda of meet-
14 ings and telephone discussions, and similar docu-
15 ments reflecting communications between the appli-
16 cant and the third party organization or persons
17 working with the third party organization prepared
18 or received by the applicant relating to the new
19 drug.

20 “(C) All analyses and other documents pre-
21 pared by or for the third party organization relating
22 to any aspect of the new drug that the third party
23 organization provides to the applicant upon request
24 and a letter authorizing the Secretary to obtain any
25 other such document directly from the third party.

1 “(D) A summary of adverse event information
2 obtained as the result of any marketing outside the
3 United States.

4 “(E) A copy of the labeling approved by the
5 third party organization and proposed United States
6 labeling that is consistent with the Secretary’s gen-
7 erally applicable labeling requirements.

8 “(F) An adequate summary of the documents
9 that constitute the application.

10 “(4) Within 7 days after receipt of the application,
11 the Secretary shall send the summary to each member of
12 a scientific review group established pursuant to section
13 904. Within 60 days after receipt of the application by
14 the Secretary, the scientific review group shall meet to
15 consider the application and to make its conclusions and
16 recommendations to the Secretary.

17 “(5) Within 180 days after receipt of the submission
18 by the Secretary (or if an application under subsection
19 (b)(1) was submitted before the submission under this
20 subsection, then within 180 days of receipt of the applica-
21 tion under subsection (b)(1) or 90 days of the receipt of
22 the submission under this subsection, whichever is later),
23 the Secretary, taking into account any conclusions and
24 recommendations of the scientific review group, shall ei-
25 ther (A) approve the application, (B) disapprove the appli-

1 cation if the Secretary demonstrates, based on the infor-
2 mation in the submission (and, if an application has been
3 filed under subsection (b)(1), on the information in such
4 application) that the drug is unsafe or ineffective, and (C)
5 if the application is disapproved, publish a notice of the
6 decision in the Federal Register. If the Secretary does not
7 publish a notice of disapproval in the Federal Register
8 within such 180 days, the conclusions and recommenda-
9 tions of the scientific review group regarding the applica-
10 tion shall be deemed to be the decision of the Secretary
11 and the Secretary shall implement them immediately. If
12 the Secretary does not publish a notice of disapproval in
13 the Federal Register within 90 days and no scientific
14 group has made conclusions or recommendations within
15 that period regarding the application, the application shall
16 be deemed to be approved and the Secretary shall imme-
17 diately approve the application. The failure of the Sec-
18 retary to take any such action shall constitute final agency
19 action for purposes of judicial review. The Secretary may
20 at any time take action to revoke the approval of an appli-
21 cation approved pursuant to this paragraph on the ground
22 specified in clause (B) using the procedures established
23 in subsections (e) through (h) of this section.

24 “(6) The Secretary shall continue to pursue inter-
25 national harmonization of drug regulation among nations

1 both through (A) adoption of uniform technical require-
2 ments and a registration dossier and (B) mutual recogni-
3 tion of marketing approval.”.

4 **SEC. 8. CLINICAL RESEARCH.**

5 Section 505(i) (21 U.S.C. 355(i)) is amended by add-
6 ing at the end the following: “A clinical study of a new
7 drug may begin after the Secretary has received from the
8 sponsor a notification containing information about the
9 drug and the clinical study. Such notification shall be re-
10 quired to contain only summaries of basic information,
11 certified by the applicant to be accurate, needed to assess
12 the safety of the clinical study and shall not be required
13 to contain detailed information on chemistry, manufactur-
14 ing, or controls or primary data tabulations or case report
15 forms or tabulations from animal or human studies. At
16 any time the director of the office within which the appli-
17 cation is being reviewed may issue to the sponsor in writ-
18 ing a clinical hold prohibiting the sponsor from conducting
19 the investigation and specifying the basis for the clinical
20 hold. The director of such office may issue a clinical hold
21 only upon a demonstration, based on specific information
22 available to the Secretary, that the drug represents an un-
23 reasonable risk to the safety of the persons who are the
24 subject of the clinical study, taking into account the condi-
25 tion for which the drug is to be investigated and the health

1 status of the subjects involved. Any response from the
2 sponsor to the director of such office requesting that the
3 clinical hold be removed shall receive a decision, in writing
4 and specifying the reasons therefor, within 15 days or the
5 clinical hold shall be deemed to be withdrawn. The director
6 may not delegate the authority to issue a clinical hold.

7 **SEC. 9. CONTENT AND REVIEW OF NEW DRUG APPLICA-**
8 **TION.**

9 (a) SUBSECTION (B)(1) APPLICATION.—Section
10 505(b) (21 U.S.C. 355) is amended by adding at the end
11 the following:

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

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

6 “(C) The Secretary shall establish standards for the
7 review of applications submitted under paragraph (1) re-
8 lating to promptness, technical excellence, lack of bias and
9 conflict of interest, and a knowledge of regulatory and sci-
10 entific standards which apply equally to outside reviewers
11 and to employees of the Secretary who review such appli-
12 cations. The Secretary shall conduct and maintain records
13 of training programs for outside reviewers and employees
14 of the Secretary who review such applications to assure
15 their compliance with good review practices and good re-
16 view standards and shall monitor their compliance with
17 such practices and standards, the requirements of section
18 708, and the statutory time limits for action.

19 “(D) Advice provided to a sponsor or applicant at its
20 request by a responsible Food and Drug Administration
21 employee regarding appropriate testing of a new drug
22 shall not be changed after such testing begins except with
23 the written agreement of the sponsor or applicant or by
24 a decision in writing after an informal hearing by the di-
25 rector of the office in which the drug is reviewed. The di-

1 rector may not delegate the authority to require such a
2 change.

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

9 “(F) No action by the center for drugs or the center
10 for biologics on any matter relating to a new drug or bio-
11 logic may at any time or under any circumstance be de-
12 layed because of the unavailability of information or action
13 by the field personnel or because of issues relating to the
14 integrity of data, except on the basis of evidence presented
15 to the applicant, followed by an informal hearing, that
16 data in that particular application are false.”.

17 (b) SUMMARIES.—Section 505(b)(1)(A) (21 U.S.C.
18 355(b)(1)(A)) is amended by inserting “(including de-
19 tailed summaries)” after “full reports and investigations”.

20 **SEC. 10. REVIEW BY INDEPENDENT TESTING ORGANIZA-**
21 **TIONS.**

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

24 “PRIVATIZATION OF APPROVAL FUNCTIONS

25 “SEC. 906. (a) The Secretary, acting through the
26 Commissioner of Food and Drugs, may establish and im-

1 plement a program under which the Commissioner will
2 contract, in whole or in significant part, with individuals
3 and laboratories certified under subsection (b) to conduct,
4 under such conditions as the Secretary may specify to as-
5 sure unbiased scientifically valid results, the following ac-
6 tivities and responsibilities of the Food and Drug Adminis-
7 tration in connection with the approval of drugs and de-
8 vices under sections 505 and 515 and with reviewing noti-
9 fications required under section 510(k) and making writ-
10 ten recommendations of initial classification under section
11 513(f)(1) of devices:

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

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

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

18 “(4) Preapproval manufacturing practice in-
19 spections to determine if applicable requirements are
20 being met.

21 “(5) Clinical reviews to determine if applicable
22 requirements are being met.

23 “(6) Any other function of the Food and Drug
24 Administration relating to the review and approval
25 of drugs or devices that the Secretary determines

1 can be adequately performed under contract with
2 qualified individuals and laboratories.

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

8 “(c) The Secretary shall provide that drugs and de-
9 vices which are subject to review under subsection (a) shall
10 be approved under sections 505 and 515 if the review de-
11 termines that the drugs and devices meet all applicable
12 approval requirements.

13 “(d)(1) Information otherwise protected from disclo-
14 sure to the public under section 301(j) or 520(c) may be
15 disclosed to—

16 “(A) contractors certified under subsection (b),
17 and

18 “(B) employees of such contractors,
19 if, in the opinion of the Secretary, such disclosure is nec-
20 essary for the satisfactory performance by the contractor
21 of work under a contract under subsection (a).

22 “(2) The Secretary shall, in writing, require as a con-
23 dition to the disclosure of information under paragraph
24 (1) that the person receiving such information take such
25 security precautions respecting the information as the Sec-

1 retary shall by regulation prescribe. Disclosure by such
2 person of such information to a person not authorized to
3 receive it shall constitute a violation of section 301(j) and
4 of section 1905 of title 18, United States Code.

5 “(e) The review of an application for approval of a
6 new drug or device under this Act or a biological product
7 under section 351 of the Public Health Service Act shall
8 not include the review of the environmental impact of such
9 drug, device, or biological product under the Environ-
10 mental Quality Improvement Act of 1970 (42 U.S.C. 4371
11 et seq.).”

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

16 (1) the use the Secretary has made under sec-
17 tion 906 of the Federal Food, Drug, and Cosmetic
18 Act of the authority to contract for individuals and
19 laboratories to perform duties of the Food and Drug
20 Administration, and

21 (2) any difficulties encountered in contracting
22 under such section 906.

23 **SEC. 11. RESEARCH ACTIVITIES.**

24 (a) ACTIVITIES.—Chapter IX, as amended by section
25 10, is amended by adding after section 906 the following:

1 “RESEARCH ACTIVITIES

2 “SEC. 907. Research activities of the Food and Drug
3 Administration relating to drugs, devices, and biological
4 products, which are authorized under section
5 903(b)(2)(D) and section 352 of the Public Health Service
6 Act, shall directly relate to the review and approval of
7 drugs, devices, and biological products. In conducting such
8 research activities, the Food and Drug Administration
9 may collaborate with the National Institutes of Health,
10 academic health centers, and other scientific institutions
11 and the drug and device industry.”.

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

15 “(e) Any research conducted by or for the Food and
16 Drug Administration shall be solely related directly to (1)
17 the regulatory mission or (2) professional staff develop-
18 ment related to that mission and shall be limited to the
19 minimum necessary to achieve such purposes.”.

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

21 Section 903 (21 U.S.C. 393), as amended by section
22 11(b), is amended by adding at the end the following:

23 “(f)(1) The Secretary shall establish, in the office of
24 the Assistant Secretary for Health, a permanent commis-
25 sion responsible for broad oversight of the policy and per-

1 formance of the Food and Drug Administration. The com-
2 mission, which shall be subject to the provisions of sub-
3 section (c) of this section, shall review the performance
4 of individuals and groups in meeting the mission of the
5 Food and Drug Administration and the development of
6 appropriate agency policy to implement that mission and
7 shall include outcomes measurements and performance as-
8 sessments in evaluating agency activities. Such review
9 shall also include a comparison of the performance of the
10 Food and Drug Administration with that of agencies per-
11 forming similar functions for other countries and an eval-
12 uation of the effect of the Food and Drug Administra-
13 tion's performance on the competitiveness of the regulated
14 American industries.

15 “(2)(A) The members of the commission shall include
16 the nation's leading medical experts, medical society rep-
17 resentatives, scientific and health policy authorities, and
18 representatives from the trade associations for the regu-
19 lated industries and from voluntary health associations.

20 “(B) Members of the commission shall serve at the
21 discretion of the Secretary from year to year with no fixed
22 term.

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

1 “(3)(A) The commission shall issue a report to the
2 Secretary and the Congress annually on the performance
3 of the Food and Drug Administration. The Food and
4 Drug Administration shall be given an opportunity to re-
5 view and respond to the report before it is submitted to
6 the Secretary and the Congress.

7 “(B) As part of its annual report under subparagraph
8 (A), the commission shall recommend personnel and policy
9 changes to improve the performance of the Food and Drug
10 Administration in order to meet its mission as set forth
11 in subsection (d).”.

12 **SEC. 13. APPEALS.**

13 Section 903 (21 U.S.C. 393), as amended by section
14 12, is amended by adding the following new subsection
15 at the end thereof:

16 “(g)(1) The Secretary shall establish within the Food
17 and Drug Administration a drug and biologics policy ap-
18 peals committee consisting of the director and deputy di-
19 rector of the center for drugs and the director and deputy
20 director of the center for biologics. The appeals committee
21 shall meet to hear and consider any dispute raised by an
22 individual who wishes to contest a policy matter relating
23 to drugs or biologics. The appeals committee shall meet
24 to hear the individual within 15 days of receiving the re-

1 quest from the individual and shall decide the matter with-
2 in 10 days after the hearing.

3 “(2) The Secretary shall establish standing panels of
4 qualified experts who are not employees of the United
5 States Government or of any State or local government
6 for the purpose of hearing appeals by individuals who have
7 exhausted their informal appeals within the Food and
8 Drug Administration and who wish to contest the action
9 or failure to act by the Food and Drug Administration
10 in a particular matter. The Secretary shall establish an
11 appeal procedure that assures immediate access to such
12 a panel and prompt conclusions and recommendations by
13 the panel. Following the conclusions and recommendations
14 of the panel, the official of the Food and Drug Adminis-
15 tration who reports to the Commissioner of Food and
16 Drugs and is the director of the component responsible
17 for regulation of the matter shall personally review the
18 matter, in light of such conclusions and recommendations,
19 and shall make a final decision within 15 days after receiv-
20 ing the conclusions and recommendations. Such official
21 may not delegate the requirement to review and make a
22 final decision. The decision of that official shall imme-
23 diately be implemented. If that official fails to make a de-
24 cision within 15 days, or if the decision is not immediately
25 implemented, the conclusions and recommendations of the

1 panel shall be deemed to be the decision of the Food and
2 Drug Administration and shall be implemented imme-
3 diately. The failure of the Secretary to take action to im-
4 plement that decision immediately shall constitute final
5 agency action for purposes of judicial review.”.

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

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

9 (1) in paragraph (1), by inserting after “under
10 this Act” the following: “or in violation of section
11 505 or section 351 of the Public Health Service
12 Act”,

13 (2) in paragraph (1), by striking the last sen-
14 tence, and

15 (3) by amending paragraph (2) to read as fol-
16 lows:

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

18 “(A) any device—

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

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

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

1 “(B) any drug (including a biological product)
2 which does not comply with an applicable require-
3 ment under section 505 or 512 or section 351 of the
4 Public Health Service Act,
5 unless the device or drug is in compliance with the require-
6 ments of paragraph (1). In the case of a device or drug
7 for which an export notice is required under this para-
8 graph, the Secretary may prohibit the export of such de-
9 vice or drug if the Secretary determines that the possibil-
10 ity of the reimportation of the device or drug into the
11 United States presents an imminent hazard to the public
12 health and safety of the United States and the only means
13 of limiting the hazard is to prohibit the export of the de-
14 vice or drug.”.

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

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

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