

105TH CONGRESS  
1ST SESSION

# H. R. 1411

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to facilitate the development and approval of new drugs and biological products, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 23, 1997

Mr. BURR of North Carolina (for himself, Mr. GREENWOOD, Mr. BARTON of Texas, Mr. KLUG, Mr. COBURN, and Mr. DEAL of Georgia) 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 and the Public Health Service Act to facilitate the development and approval of new drugs and biological products, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE, REFERENCE, AND TABLE OF**  
4       **CONTENTS.**

5       (a) SHORT TITLE.—This Act may be cited as the  
6       “Drug and Biological Products Modernization Act of  
7       1997”.

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1 (b) REFERENCE.—Except as otherwise specified,  
 2 whenever in this Act an amendment is expressed in terms  
 3 of an amendment to a section or other provision, the ref-  
 4 erence shall be considered to be made to that section or  
 5 other provision of the Federal Food, Drug, and Cosmetic  
 6 Act (21 U.S.C. 321 et seq.).

7 (c) TABLE OF CONTENTS.—The table of contents is  
 8 as follows:

- Sec. 1. Short title, reference, and table of contents.
- Sec. 2. FDA mission and annual report.
- Sec. 3. Streamlining clinical research on drugs and biological products.
- Sec. 4. The content and review of a new drug application.
- Sec. 5. Effectiveness determination.
- Sec. 6. Scientific review panels.
- Sec. 7. Marketing approval.
- Sec. 8. Accreditation of third parties.
- Sec. 9. Dispute resolution.
- Sec. 10. Good manufacturing practices.
- Sec. 11. Pilot and small scale manufacture.
- Sec. 12. Manufacturing changes.
- Sec. 13. Insulin and antibiotics.
- Sec. 14. Nonprescription drugs.
- Sec. 15. Information system.
- Sec. 16. Environmental impact review.
- Sec. 17. Application of State and Federal law to the practice of pharmacy  
 compounding.
- Sec. 18. Harmonization.
- Sec. 19. Informal agency statements.
- Sec. 20. Research and education; practice of medicine.
- Sec. 21. Delegation of authority.
- Sec. 22. Publication of notice of deviation.
- Sec. 23. Modernization of regulation of biological products.
- Sec. 24. Requirements for human tissue.
- Sec. 25. Access to unapproved therapies.
- Sec. 26. Radiopharmaceuticals.
- Sec. 27. Protection of confidential information.
- Sec. 28. National uniformity.
- Sec. 29. Centers for education and research on drugs, devices, and biological  
 products.

9 **SEC. 2. FDA MISSION AND ANNUAL REPORT.**

10 (a) MISSION.—Section 903 (21 U.S.C. 393) is  
 11 amended by redesignating subsections (b) and (c) as sub-

1 sections (c) and (d), respectively, and by adding after sub-  
2 section (a) the following:

3 “(b) MISSION.—The Food and Drug Administration  
4 shall protect the public health by ensuring that—

5 “(1) foods are safe, wholesome, and sanitary;

6 “(2) human and veterinary drugs are safe and  
7 effective;

8 “(3) there is reasonable assurance of safety and  
9 effectiveness of devices intended for human use;

10 “(4) cosmetics are safe; and

11 “(5) public health and safety are protected  
12 from electronic product radiation.

13 The Food and Drug Administration shall promptly and  
14 efficiently review clinical research and take appropriate ac-  
15 tion on the marketing of regulated products in a manner  
16 that does not unduly impede innovation or product avail-  
17 ability. The Food and Drug Administration shall partici-  
18 pate with other countries to reduce the burden of regula-  
19 tion, harmonize regulatory requirements, and achieve ap-  
20 propriate reciprocal arrangements.”

21 (b) ANNUAL REPORT.—Section 903 (21 U.S.C. 393),  
22 as amended by subsection (a), is amended by adding at  
23 the end the following:

24 “(e) ANNUAL REPORT.—The Secretary shall, simul-  
25 taneously with the submission each year of the budget for

1 the Food and Drug Administration, submit to the Com-  
2 mittee on Commerce of the House of Representatives and  
3 the Committee on Labor and Human Resources of the  
4 Senate an annual report which shall—

5           “(1) review the performance of the Food and  
6 Drug Administration in meeting its mission and the  
7 development of Food and Drug Administration poli-  
8 cies to implement such mission;

9           “(2) review the performance of the Food and  
10 Drug Administration in meeting its own perform-  
11 ance standards, including its own outcome measure-  
12 ments and statutory deadlines for the approval of  
13 products or for other purposes contained in this Act;

14           “(3) describe the staffing and resources of the  
15 Food and Drug Administration and list those per-  
16 sons and organizations accredited to conduct inves-  
17 tigations under sections 505(i) and 520(g), to review  
18 drugs under section 505, to make initial classifica-  
19 tion of devices under section 513, and to perform  
20 good manufacturing practice reviews under sections  
21 and 520(f); and

22           “(4) describe the goals, activities, and accom-  
23 plishments of the Food and Drug Administration in  
24 bilateral and multinational meetings that addressed  
25 methods and approaches to reduce the burden of

1 regulation, harmonize regulation, and to seek appro-  
2 priate reciprocal arrangements, list each such meet-  
3 ing, and list pending issues specifying those that are  
4 not consistent with or are contrary to the provisions  
5 of this Act.

6 “(f) GAO ANNUAL REPORT.—The Comptroller Gen-  
7 eral of the United States shall each January submit to  
8 the Committee on Commerce of the House of Representa-  
9 tives and the Committee on Labor and Human Resources  
10 of the Senate a report which compares—

11 “(1) the performance of the Food and Drug  
12 Administration in approving innovative drug, device,  
13 human tissue, and food products with that of agen-  
14 cies performing similar functions in countries listed  
15 in section 802(b); and

16 “(2) the resources used by agencies in such  
17 countries to approve such products.

18 In developing a methodology for the report, the Comptrol-  
19 ler General shall consult with representatives of the Sec-  
20 retary, the regulated industry, academic experts in the  
21 field, and experts knowledgeable about information in such  
22 other countries so that the approach accurately presents  
23 the information in a fair and balanced manner.

1 **SEC. 3. STREAMLINING CLINICAL RESEARCH ON DRUGS**  
2 **AND BIOLOGICAL PRODUCTS.**

3 Section 505(i) (21 U.S.C. 355(i)) is amended by add-  
4 ing “(1)” prior to the first sentence, by redesignating  
5 paragraphs (1), (2), and (3) as subparagraphs (A), (B),  
6 and (C), respectively, and by adding the following new  
7 paragraphs at the end thereof:

8 “(2) A clinical investigation of a new drug may begin  
9 30 days after the Secretary has received from the sponsor  
10 of the investigation a submission containing information  
11 about the drug and the clinical investigation as follows:  
12 The submission shall contain—

13 “(A) information on design of the investigation  
14 and adequate reports of basic information, certified  
15 by the applicant to be accurate reports, necessary to  
16 assess the safety of the drug for use in clinical inves-  
17 tigation; and

18 “(B) adequate information on the chemistry of  
19 the drug, manufacturing of the drug, controls avail-  
20 able for the drug, and primary data tabulations for  
21 the drug from animal or human studies, except that  
22 for phase I clinical investigations detailed informa-  
23 tion for drugs and well-characterized therapeutic,  
24 biotechnology derived drugs shall not be required un-  
25 less the director of the office responsible for the re-  
26 view of the drug makes a request within 30 days

1 after the submission regarding such detailed infor-  
2 mation in writing and specifies the reasons for the  
3 request.

4 “(3)(A) At any time, the Secretary may issue to the  
5 sponsor of an investigation a clinical hold confirmed in  
6 writing prohibiting the sponsor from conducting the inves-  
7 tigation and specifying the basis for the clinical hold. The  
8 Secretary may issue a clinical hold upon a demonstration,  
9 based on specific information available to the Secretary,  
10 that the drug to be investigated represents an unreason-  
11 able risk to the safety of the persons who are the subject  
12 of the clinical investigation, taking into account the quali-  
13 fications of the clinical investigators, information about  
14 the drug, and the design of the clinical investigation, the  
15 condition for which the drug is to be investigated, and the  
16 health status of the subjects involved.

17 “(B) Any response from the sponsor of an investiga-  
18 tion to the Secretary requesting that a clinical hold be re-  
19 moved shall receive a decision, in writing and specifying  
20 the reasons therefor, within 30 days after receipt of such  
21 response or the clinical hold shall be deemed to be with-  
22 drawn.

23 “(4)(A) As an alternative to the procedure estab-  
24 lished in paragraph (2), a Phase I or Phase II non-com-  
25 mercial clinical investigation may begin after an accredited

1 institution, accredited by the Secretary under subpara-  
2 graph (B) to conduct the specific type of investigation  
3 which is the subject of such research, has approved the  
4 investigation and the sponsor of the investigation has sub-  
5 mitted to the Secretary a notification setting forth the  
6 name and address of the sponsor, the identity of the drug,  
7 and the uses of the drug that the sponsor intends to inves-  
8 tigate. Data and information developed through such an  
9 investigation may be submitted in support of an applica-  
10 tion for approval of a new drug and shall be considered  
11 by the Secretary to the same extent as data and informa-  
12 tion developed through an investigation under paragraph  
13 (2). Paragraph (3) shall apply to such an investigation.

14       “(B) The Secretary shall establish and provide an op-  
15 portunity for public comment on the requirements and  
16 qualifications that an accredited institution, which may in-  
17 clude medical colleges and other organizations, shall meet  
18 to be eligible to approve an investigation for purposes of  
19 this paragraph.

20       “(5) The Food and Drug Administration shall have  
21 exclusive regulatory jurisdiction in the Department of  
22 Health and Human Services over the use of a new drug  
23 in any clinical investigation.”.

1 **SEC. 4. THE CONTENT AND REVIEW OF A NEW DRUG APPLI-**  
2 **CATION.**

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

5 “(4)(A) Within 1 year after the date of the enactment  
6 of the Drug and Biological Products Modernization Act  
7 of 1997, the Secretary, in order to minimize the burden  
8 of unnecessary information submissions and to better har-  
9 monize international regulatory requirements, shall, after  
10 consultation with patient advocacy groups and the regu-  
11 lated industry, publish in the Federal Register criteria for  
12 the type and amount of information relating to effective-  
13 ness to be included in an application for the approval of  
14 a new drug or a new use of an approved drug. In develop-  
15 ing the criteria, the Secretary shall consider any rec-  
16 ommendations of the International Conference on Harmo-  
17 nization of Technical Requirements for Registration of  
18 Pharmaceuticals for Human Use.

19 “(B) The Secretary shall establish standards for the  
20 review of applications submitted under paragraph (1) re-  
21 lating to promptness, technical excellence, lack of bias and  
22 conflict of interest, and a knowledge of regulatory and sci-  
23 entific standards which shall apply equally to outside re-  
24 viewers and to employees of the Secretary who review such  
25 applications.

1       “(C) Food and Drug Administration employees shall  
2 meet with a sponsor of an investigation or an applicant  
3 under an application for a new drug or a new use of an  
4 approved drug submitted under paragraph (1) within 30  
5 days of any reasonable request for a meeting by the spon-  
6 sor or applicant for the purpose of reaching agreement on  
7 the design and size of clinical trials. Minutes of any such  
8 meeting shall be exchanged. Advice provided to a sponsor  
9 or applicant at its request by a Food and Drug Adminis-  
10 tration employee, which is reduced to writing and made  
11 part of the administrative record by the sponsor or appli-  
12 cant or by the Food and Drug Administration, regarding  
13 appropriate testing of a new drug shall not be changed  
14 after such testing begins, except with the written agree-  
15 ment of the sponsor or applicant or by a decision in writ-  
16 ing, after an informal hearing, by the director of the office  
17 in which the drug is reviewed where such change is needed  
18 because there is a demonstrated need to protect the public  
19 health or a valid safety consideration.

20       “(D) The written decisions of the office responsible  
21 for the review of a drug on all aspects of scientific and  
22 medical matters relating to a new drug shall be binding  
23 upon, and may not directly or indirectly be changed by,  
24 the field personnel of the offices of compliance of the office  
25 responsible for the review unless in consultation with the

1 reviewing office, such field personnel demonstrate why  
2 such decision should be modified.

3 “(E) No action by the office responsible for the re-  
4 view of a drug on any matter relating to a new drug for  
5 which an application has been submitted under paragraph  
6 (1) may at any time, or under any circumstance other  
7 than a demonstrable extraordinary circumstance, be de-  
8 layed because of the unavailability of information from or  
9 action by field personnel unless the field personnel dem-  
10 onstrate to the office that such a delay is necessary to  
11 assure the marketing of a safe and effective drug.”.

12 (b) SECTION 505(j).—

13 (1) AMENDMENT.—Section 505(j) (21 U.S.C  
14 355(j) is amended by redesignating paragraphs (3)  
15 through (8) as paragraphs (4) through (9), respec-  
16 tively, and by adding after paragraph (2) the follow-  
17 ing:

18 “(3)(A) The Secretary shall establish standards for  
19 the review of applications submitted under paragraph (1)  
20 relating to promptness, technical excellence, lack of bias  
21 and conflict of interest, and a knowledge of regulatory and  
22 scientific standards which shall apply equally to outside  
23 reviewers and to employees of the Secretary who review  
24 such applications.

1       “(B) Food and Drug Administration employees shall  
2 meet with a sponsor of an investigation or an applicant  
3 under an application submitted under paragraph (1) with-  
4 in 30 days of any reasonable request for a meeting by the  
5 sponsor or applicant for the purpose of reaching agree-  
6 ment on the design and size of bioavailability or bioequiva-  
7 lence studies. Minutes of any such meeting shall be ex-  
8 changed. Advice provided to a sponsor or applicant at its  
9 request by a Food and Drug Administration employee,  
10 which is reduced to writing and made part of the adminis-  
11 trative record by the sponsor or applicant or by the Food  
12 and Drug Administration, regarding bioavailability or bio-  
13 equivalence studies shall not be changed after such testing  
14 begins, except with the written agreement of the sponsor  
15 or applicant or by a decision in writing, after an informal  
16 hearing, by the director of the office in which the drug  
17 is reviewed where such change is needed because there is  
18 a demonstrated need to protect the public health or a valid  
19 safety consideration.

20       “(C) The written decisions of the office responsible  
21 for the review of a drug on all aspects of scientific and  
22 medical matters relating to a new drug shall be binding  
23 upon the field personnel of the offices of compliance of  
24 the office responsible for the review unless in consultation

1 with the reviewing office, such field personnel demonstrate  
2 why such decision should be modified.

3 “(D) No action by the office responsible for the re-  
4 view of a drug on any matter relating to a new drug for  
5 which an application has been submitted under paragraph  
6 (1) may at any time, or under any circumstance other  
7 than a demonstrable extraordinary circumstance, be de-  
8 layed because of the unavailability of information from or  
9 action by field personnel unless the field personnel dem-  
10 onstrate to the office that such a delay is necessary to  
11 assure the marketing of a safe and effective drug.”.

12 (2) CONFORMING AMENDMENTS.—Section  
13 505(j) (21 U.S.C. 355(j) is amended—

14 (A) in paragraph (2)(A)(i), by striking  
15 “(6)” and inserting “(7)”;

16 (B) in paragraph (3), by striking “(4)”  
17 and inserting “(5)”;

18 (C) in paragraph (3)(I), by striking “(5)”  
19 and inserting “(6)”;

20 (D) in paragraph (6)(C), by striking “(5)”  
21 each place it occurs and inserting “(6)”.

22 **SEC. 5. EFFECTIVENESS DETERMINATION.**

23 Section 505(d) (21 U.S.C. 355(d)) is amended—

24 (1) by adding after the last sentence the follow-  
25 ing: “Substantial evidence may, where there is a

1 high level of confidence in the scientific validity of  
2 the results of an adequate and well-controlled inves-  
3 tigation, consist of data from an adequate and well-  
4 controlled investigation and adequate supportive sci-  
5 entific evidence (obtained before or after such inves-  
6 tigation).”;

7 (2) by adding at the end the following: “For  
8 purposes of the preceding sentence, a well-controlled  
9 investigation shall only include methods of control  
10 that are appropriate to the disease or condition for  
11 which a drug is intended as prescribed, rec-  
12 ommended, or suggested in its labeling. The Sec-  
13 retary may waive the requirement to conduct any  
14 well-controlled investigation, as defined in the pre-  
15 ceding sentence.”; and

16 (3) by inserting “(1)” after “(d)”, by redesign-  
17 ating clauses (1) through (7) as clauses (A)  
18 through (G), by striking “(1) through (6)” and in-  
19 serting “(A) through (G)”, and by adding at the end  
20 the following:

21 “(2) For purposes of paragraph (1)—

22 “(A) the Secretary shall, for the purpose of  
23 making an evaluation of a new drug for a serious or  
24 life-threatening condition, consider whether the ben-  
25 efits of the drug outweigh the known and potential

1 risks of the drug and the need to answer remaining  
2 questions about risks and benefits of the drug, tak-  
3 ing into consideration the severity of the diseases  
4 and the absence of no comparable or satisfactory al-  
5 ternative therapy; and

6 “(B) concurrent with the approval of a drug de-  
7 scribed in clause (i), the Secretary may seek agree-  
8 ment from the sponsor of such drug to conduct cer-  
9 tain postmarketing studies to delineate additional in-  
10 formation about such drug’s risks, benefits, and op-  
11 timal use.

12 “(3) For the purpose of making an evaluation of an  
13 application submitted for a new use of a previously ap-  
14 proved new drug, the Secretary shall consider whether the  
15 new use is supported by adequate valid scientific informa-  
16 tion from clinical investigation reports in peer reviewed  
17 medical and scientific journals, patient registries or com-  
18 pendia, and other sources recognized by the Secretary. In  
19 carrying out the preceding sentence, the Secretary may,  
20 as appropriate, consult with medical speciality societies.

21 “(4) For purposes of paragraph (1), the determina-  
22 tion of effectiveness shall not include any potential use not  
23 explicitly included in the labeling, except for public health  
24 reasons.

1 **SEC. 6. SCIENTIFIC ADVISORY PANELS.**

2 Section 505 (21 U.S.C. 355) is amended by adding  
3 at the end the following:

4 “(n)(1) For the purpose of providing expert scientific  
5 advice and recommendations to the Secretary regarding  
6 a clinical investigation of a drug or biological product or  
7 the approval for marketing of a drug or biological product  
8 under section 505, the Secretary shall establish panels of  
9 experts or use panels of experts established before the date  
10 of the enactment of this subsection, or both. Scientific ad-  
11 visory panels shall consider scientific issues and shall not  
12 include considerations of cost, economic aspects, compara-  
13 tive effectiveness, or legal matters.

14 “(2) The Secretary may delegate the appointment  
15 and oversight authority granted under section 904 to a  
16 director of a center or successor entity within the Food  
17 and Drug Administration.

18 “(3) The Secretary shall appoint to each panel estab-  
19 lished under paragraph (1) persons who are qualified by  
20 training and experience to evaluate the safety and effec-  
21 tiveness of the drugs and biological products to be referred  
22 to the panel and who, to the extent feasible, possess skill  
23 in the use of, or experience in, the development, manufac-  
24 ture, or utilization of, such drugs or biological products.  
25 The Secretary shall make appointments to each panel so  
26 that each panel shall consist of members with adequately

1 diversified expertise in such fields as clinical and adminis-  
2 trative medicine, engineering, biological and physical  
3 sciences, and other related professions. In addition, each  
4 panel shall include as nonvoting members a representative  
5 of consumer interests and a representative of interests of  
6 the drug and biological product manufacturing industry.  
7 Scientific, trade, and consumer organizations shall be af-  
8 forded an opportunity to nominate individuals for appoint-  
9 ment to the panels. No individual who is in the regular  
10 full-time employ of the United States and engaged in the  
11 administration of this Act may be a voting member of any  
12 panel. The Secretary shall designate one of the members  
13 of each panel to serve as chairman thereof.

14       “(4) Each member of a panel shall publicly disclose  
15 all conflicts of interest that member may have with the  
16 work to be undertaken by the panel. No member of a panel  
17 may vote on any matter where the member or the imme-  
18 diate family of such member could gain financially from  
19 the advice given to the Secretary. The Secretary may  
20 grant a waiver of any conflict of interest upon public dis-  
21 closure of such conflict of interest if such waiver contrib-  
22 utes to the ability of a panel to contribute to the public  
23 health, except that the Secretary may not grant a waiver  
24 for a member of a panel when the member’s own scientific  
25 work is involved.

1           “(5) The Secretary shall provide education and train-  
2   ing to each new panel member before such member partici-  
3   pates in a panel’s activities. Such education and training  
4   shall include a familiarization with certain requirements  
5   under this Act and any related regulation of the Secretary  
6   and the administrative process and procedures related to  
7   panel meetings.

8           “(6) Panel members (other than officers or employees  
9   of the United States), while attending meetings or con-  
10   ferences of a panel or otherwise engaged in its business,  
11   shall be entitled to receive compensation at rates to be  
12   fixed by the Secretary, but not at rates exceeding the daily  
13   equivalent of the rate in effect for grade GS–18 of the  
14   General Schedule, for each day so engaged, including trav-  
15   eltime. While so serving away from their homes or regular  
16   places of business, each member may be allowed travel ex-  
17   penses (including per diem in lieu of subsistence) as au-  
18   thorized by section 5703 of title 5, United States Code,  
19   for persons in the Government service employed intermit-  
20   tently.

21           “(7) The Secretary shall take whatever action is nec-  
22   essary to ensure that regular meetings are held by sci-  
23   entific advisory panels, at appropriate intervals and for a  
24   sufficient length of time, so that any matter to be reviewed  
25   by any such panel shall be presented to the panel not more

1 than 60 days after the matter is ready for review by the  
2 panel. Meetings of the panel may be held using electronic  
3 communication to convene the meeting.

4 “(8)(A) Any person whose drug is the subject of a  
5 scientific advisory panel shall have the same rights and  
6 responsibilities as the Secretary regarding—

7 “(i) the submission of written information to a  
8 scientific advisory panel;

9 “(ii) the participation of the persons at meet-  
10 ings of the panel; and

11 “(iii) access to data and information submitted  
12 to a scientific advisory panel (except for data and in-  
13 formation that are not available for public disclosure  
14 under section 552 of title 5, United States Code).

15 “(B) In a case in which a scientific advisory panel  
16 reviews an application submitted under section 505 or sec-  
17 tion 351 of the Public Health Service Act (including a pe-  
18 tition, notification, or other similar request), all related  
19 data and information that are not available for public dis-  
20 closure under section 552 of title 5, United States Code,  
21 shall be exchanged between the applicant and the Food  
22 and Drug Administration at the time the data and infor-  
23 mation are submitted to such panel but shall not otherwise  
24 be publicly disclosed.

1       “(C) Any meetings of a scientific advisory panel shall  
2 provide adequate time for initial presentations and for re-  
3 sponse to any differing views and shall encourage free and  
4 open participation by all interested persons.

5       “(9) Within 30 days after the date a scientific advi-  
6 sory panel makes its conclusions and recommendations on  
7 any matter under review by the panel, the Food and Drug  
8 Administration official responsible for the matter shall re-  
9 view the conclusions and recommendations of the panel,  
10 shall make a final decision on the matter, and shall notify  
11 the affected persons of the decision in writing and, if the  
12 decision differs from the conclusions and recommendations  
13 of the panel, shall include the reasons for the difference.

14       “(10) A scientific advisory panel under this sub-  
15 section shall not be subject to the annual chartering and  
16 annual report requirements of the Federal Advisory Com-  
17 mittee Act. Such a panel shall make an annual report of  
18 its activities to the Secretary.”.

19 **SEC. 7. MARKETING APPROVAL.**

20       (a) SECTION 505.—

21               (1) SUBSECTION (b).—Section 505(b) (21  
22 U.S.C. 355(b)), as amended by section 4(a), is  
23 amended—

24                       (A) in the first sentence of paragraph (1),  
25               by inserting immediately before the period the

1 following: “or and the Secretary may request a  
2 review of all or part of such application by an  
3 accredited person authorized to review applica-  
4 tions for marketing approval , upon concurrence  
5 of the sponsor, and the Secretary shall pay for  
6 such review with fees authorized by section  
7 736”; and

8 (B) by adding after paragraph (4) the fol-  
9 lowing:

10 “(5) The scope of review responsibilities of an accred-  
11 ited person authorized to conduct reviews of marketing ap-  
12 proval applications shall include the review of all or part  
13 of an application as requested by the Secretary . The ac-  
14 credited person shall submit a report of its review, includ-  
15 ing the basis for any recommendation to the Secretary.

16 (2) SUBSECTION (j).—Section 505(j)(1) (21  
17 U.S.C. 355(j)(1)) is amended by adding at the end  
18 the following: “The Secretary may request a review  
19 of all or part of such an application by an accredited  
20 person authorized to review applications for market-  
21 ing approval upon concurrence of the sponsor. The  
22 scope of review responsibilities of such an accredited  
23 person shall include the review of all or part of such  
24 an application as requested by the Secretary. The  
25 accredited person shall submit a report of its review,

1 including the basis for any recommendation to the  
2 Secretary.”.

3 (b) SECTION 735(7).—Section 735(7) is amended—

4 (1) by striking “applications for” and inserting  
5 “applications” and by inserting “for” after “(A)”,  
6 “(B)”, and “(C)”;

7 (2) by striking “and” at the end of subpara-  
8 graph (C),

9 (3) by striking the period at the end of sub-  
10 paragraph (D) and inserting “, and”, and

11 (4) by inserting the following after subpara-  
12 graph (D):

13 “(E) by outside organizations and individ-  
14 uals.”.

15 **SEC. 8. ACCREDITATION OF THIRD PARTIES.**

16 (a) AMENDMENT.—Subchapter A of chapter VII is  
17 amended by adding at the end the following:

18 **“SEC. 712. ACCREDITED PERSONS.**

19 “(a) IN GENERAL.—The Secretary shall, within 180  
20 days of the date of the enactment of this section, by regu-  
21 lation establish procedures for the accreditation of persons  
22 for the purposes of reviewing applications under section  
23 505(b), or under section 351 of the Public Health Service  
24 Act, providing written reviews to the Secretary for the

1 Secretary’s consideration, and making recommendations  
2 on whether or not such applications should be approved.

3 “(b) ACCREDITATION.—

4 “(1) PROGRAMS.—The Secretary shall provide  
5 for such accreditation through programs adminis-  
6 tered by the Food and Drug Administration, other  
7 government agencies, or by other qualified non-gov-  
8 ernment organizations.

9 “(2) ACCREDITATION.—

10 “(A) GENERAL RULE.—Within 180 days  
11 of the date of the enactment of this section, the  
12 Secretary shall establish and publish in the  
13 Federal Register requirements to accredit or  
14 deny accreditation to persons who request to  
15 perform the duties specified in subsection (a).  
16 The Secretary shall respond to a request for ac-  
17 creditation within 60 days of the receipt of the  
18 request. The accreditation of such person shall  
19 specify the particular activities under subsection  
20 (a) for which such person is accredited.

21 “(B) WITHDRAWAL OF ACCREDITATION.—

22 The Secretary may withdraw accreditation of  
23 any person accredited under this paragraph,  
24 after providing notice and an opportunity for an  
25 informal hearing when such person acts or fails

1 to act in a manner that is inconsistent with the  
2 purposes of this section or poses a threat to  
3 public health.

4 “(C) PERFORMANCE AUDITING.—To en-  
5 sure that persons accredited under this section  
6 will continue to meet the standards of accredi-  
7 tation, the Secretary shall—

8 “(i) make onsite visits on a periodic  
9 basis to each accredited person to audit  
10 the performance of such person; and

11 “(ii) take such additional measures as  
12 the Secretary determines to be appropriate.

13 “(D) ANNUAL REPORT.—The Secretary  
14 shall include in the annual report required  
15 under section 903(e)(2) the names of all accred-  
16 ited persons and the particular activities under  
17 subsection (a) for which each such person is ac-  
18 credited and the name of each accredited per-  
19 son whose accreditation has been withdrawn  
20 during the year.

21 “(3) QUALIFICATIONS.—An accredited person  
22 shall, at a minimum, meet the following require-  
23 ments:

24 “(A) Such person shall be an independent  
25 organization which is not owned or controlled

1 by manufacturer, supplier or vendor of drugs  
2 and which has no organizational, material, or  
3 financial affiliation with such a manufacturer,  
4 supplier, or vendor.

5 “(B) Such person shall be a legally con-  
6 stituted entity permitted to conduct the activi-  
7 ties for which it seeks accreditation.

8 “(C) Such person shall not engage in the  
9 development, manufacture, promotion, or sale  
10 of drugs.

11 “(D) Such person shall be operated in ac-  
12 cordance with generally accepted professional  
13 and ethical business practices and shall agree in  
14 writing that as a minimum it will—

15 “(i) certify that reported information  
16 accurately reflects data reviewed;

17 “(ii) limit work to that for which com-  
18 petence and capacity are available;

19 “(iii) treat information received,  
20 records, reports, and recommendations as  
21 proprietary information; and

22 “(iv) promptly respond and attempt to  
23 resolve complaints regarding its activities  
24 for which it is accredited.”.

1 (b) CONFORMING AMENDMENT.—Section 301 (21  
2 U.S.C. 321) is amended by redesignating the second para-  
3 graph (u) as paragraph (v) and by adding after that para-  
4 graph the following:

5 “(w) in the case of a drug, device, or food—

6 “(A) the submission of a report or rec-  
7 ommendation by a person accredited under section  
8 712 that is false or misleading in any material re-  
9 spect;

10 “(B) the disclosure by a person accredited  
11 under section 712 of confidential commercial infor-  
12 mation or any trade secret without the express writ-  
13 ten consent of the person who submitted such infor-  
14 mation or secret to such person; or

15 “(C) the receipt by a person accredited under  
16 section 712 of a bribe in any form or the doing of  
17 any corrupt act by such person associated with a re-  
18 sponsibility delegated to such person under this  
19 Act.”.

20 **SEC. 9. DISPUTE RESOLUTION.**

21 Chapter V is amended by adding after section 505  
22 the following:

23 “DISPUTE RESOLUTION

24 “SEC. 506. (a) In instances in which there is a sci-  
25 entific controversy between a regulated person and the  
26 Secretary regarding an obligation under this Act, and no

1 specific provision of this Act or regulations promulgated  
2 under this Act by the Secretary provides a right to review  
3 of the subject matter of the dispute, the Secretary, upon  
4 receipt of a request for review of the controversy from  
5 such a regulated person, shall refer the disputed issue—

6           “(1) to an existing (as of the date of the notifi-  
7           cation) scientific advisory panel having expertise re-  
8           lated to the issue; or

9           “(2) to a special Government employee, as de-  
10          fined in section 202(a) of title 18, United States  
11          Code, or to a non-governmental person qualified to  
12          mediate or arbitrate the substance of such impasse  
13          who is acceptable to the Secretary and the applicant.

14          “(b) The applicant and representatives of the Sec-  
15          retary may consult with the panel, special Government em-  
16          ployee, or non-governmental person on the matter re-  
17          ferred. The panel, special Governmental employee, or non-  
18          governmental person shall submit to the Secretary and the  
19          applicant a report containing recommendations (including  
20          a statement of reasons for the recommendations) regard-  
21          ing the matter not later than 60 days after the date of  
22          the referral, or not later than 90 days after the date of  
23          the referral if the panel, special Governmental employee,  
24          or non-governmental person considers the additional 30  
25          days to be necessary. Not later than 30 days after the

1 date of receiving the report, the Secretary shall, in writing,  
2 confirm or modify the recommendations received, provid-  
3 ing reasons and reference to data before the panel, special  
4 Governmental employee, or non-governmental person for  
5 any modification. If the Secretary fails to act on such a  
6 recommendation within 30 days of its receipt, the rec-  
7 ommendation of the panel, special Government employee,  
8 or non-governmental person shall be deemed to be the rec-  
9 ommendation of the Secretary.

10       “(c) Whenever the Secretary fails to complete a pre-  
11 market submission review under section 505 in a timely  
12 manner as prescribed by this Act and the regulations of  
13 the Secretary under this Act, the person who made the  
14 submission may request that the director of the office re-  
15 sponsible for the review (or any successor entity) evaluate  
16 the failure to timely complete the review of the submission  
17 and issue an explanation for such failure and a new date  
18 for completion of the review. Such director shall complete  
19 such an evaluation within 14 days of the date a request  
20 is made for it.

21       “(d) The Federal Advisory Committee Act shall not  
22 apply to any scientific advisory panel acting under this  
23 section.”.

1 **SEC. 10. GOOD MANUFACTURING PRACTICES.**

2 (a) AMENDMENT.—Section 501(a) (21 U.S.C.  
3 351(a)) is amended—

4 (1) by striking “(a)(1)” and inserting  
5 “(a)(1)(A)”;

6 (2) by redesignating subclauses (A) and (B) in  
7 clauses (2) and (4) as subclauses (i) and (ii), respec-  
8 tively; and

9 (3) by redesignating clauses (2) through (6) as  
10 clauses (B) through (F), respectively;

11 (4) by adding at the end the following:

12 “(2) All chemistry, manufacturing, and controls  
13 which comply with an approved new drug application  
14 under section 505 or a license application under section  
15 351 of the Public Health Service Act or with the opinion  
16 of an appropriate official in the component of the Food  
17 and Drug Administration responsible for the review of  
18 such chemistry, manufacturing, or controls and which is  
19 reduced to writing and made part of the administrative  
20 record shall be deemed to comply with current good manu-  
21 facturing practice. The Secretary shall not take action to  
22 delay or prevent the manufacture or marketing of a drug  
23 under section 505 or section 351 of the Public Health  
24 Service Act for failure to conform to current good manu-  
25 facturing practice unless there is reasonable probability of

1 harm to the public health or the Secretary determines in  
2 writing that the drug is—

3 “(A) not bioequivalent,

4 “(B) deviates from the specifications for the  
5 drug established in the approved new drug applica-  
6 tion from the specifications for the drug established  
7 by the manufacturer,

8 “(C) lacks adequate assurance that it will meet  
9 the represented sterility, or

10 “(D) has been rendered unsafe or ineffective.”.

11 (b) CONFORMING AMENDMENTS.—

12 (1) SECTION 303.—Section 303(g)(1)(B)(iii)  
13 (21 U.S.C. 333(g)(1)(B)(iii)) is amended by striking  
14 “501(a)(2)(A)” and inserting “501(a)(1)(B)(i)”.

15 (2) SECTION 304.—Section 304(d)(1) (21  
16 U.S.C. 334(d)(1)) is amended by striking  
17 “501(a)(3)” and inserting “501(a)(1)(C)”.

18 (3) SECTION 512.—Section 512(a)(1) (21  
19 U.S.C. 360c(a)(1)) is amended by striking  
20 “501(a)(5)” and inserting “501(a)(1)(E)”, section  
21 512(a)(2) (21 U.S.C. 360c(a)(2)) is amended by  
22 striking “501(a)(6)” and inserting “501(a)(1)(F)”,  
23 and section 512(a)(3) (21 U.S.C. 360c(a)(3)) is  
24 amended by striking “501(a)(5) or (6)” and insert-  
25 ing “501(a)(1)(E) or 501(a)(1)(F)”.

1           (4) SECTION 721.—Section 721(a) (21 U.S.C  
2     379e(a)) is amended by striking “501(a)(4)” and in-  
3     serting “501(a)(1)(D)”.

4           (5) SECTION 802.—Sections 802(b)(1)(D) and  
5     802(f)(1)(B) (21 U.S.C.382(b)(1)(D), 382(f)(1)(B))  
6     are each amended by striking “(a)(1), (a)(2)(A),  
7     (a)(3)” and inserting “(a)(1)(A), (a)(1)(B)(i),  
8     (a)(1)(C)” .

9     **SEC. 11. PILOT AND SMALL SCALE MANUFACTURE.**

10        Section 505(c) (21 U.S.C. 355(c)) is amended by  
11     adding at the end thereof the following:

12        “(4) A new drug manufactured in a pilot or other  
13     small facility may be used to demonstrate the safety and  
14     effectiveness of the drug and to obtain approval prior to  
15     scaling up to a larger facility, unless the Secretary dem-  
16     onstrates in writing and specifying in detail the reasons  
17     that a full scale production facility is necessary to ensure  
18     the safety or effectiveness of the drug.”.

19     **SEC. 12. MANUFACTURING CHANGES.**

20        Chapter VII (21 U.S.C. 371 et seq.) is amended by  
21     adding at the end thereof the following:

1           “SUBCHAPTER D—MANUFACTURING CHANGES

2   **“SEC. 741. MANUFACTURING CHANGES.**

3           “(a) IN GENERAL.—A change in the manufacture of  
4 a new drug or new animal drug may be made in accord-  
5 ance with this section.

6           “(b) CHANGES.—

7           “(1) VALIDATION.—Before distributing a drug  
8 made after a change in the manufacture of the drug  
9 from that established in the approved new drug ap-  
10 plication or new animal drug application or license  
11 application under section 351 of the Public Health  
12 Service Act, the applicant shall validate the effect of  
13 the change on the identity, strength, quality, purity,  
14 or potency as they may relate to the safety or effec-  
15 tiveness of the drug.

16           “(2) REPORTS.—The applicant shall report  
17 such changes to the Secretary and may distribute  
18 drugs made after the changes as follows:

19           “(A) Minor modifications in facilities,  
20 minor changes in personnel, or other minor  
21 manufacturing changes, which are of a type de-  
22 termined by the Secretary to have minimal po-  
23 tential to adversely affect the identity, strength,  
24 quality, purity, or potency as they may relate to  
25 the safety or effectiveness of a drug, may be

1           made at any time and shall be reported annu-  
2           ally with supporting data to the Secretary.

3           “(B) Major manufacturing changes, which  
4           are of a type determined by the Secretary to  
5           have a substantial potential to adversely affect  
6           the identity, strength, quality, purity, or po-  
7           tency as they may relate to the safety or effec-  
8           tiveness of a drug, shall be submitted to the  
9           Secretary in a supplemental application and  
10          drugs made after such changes may not be dis-  
11          tributed until the Secretary approves the sup-  
12          plemental application. Major manufacturing  
13          changes are (i) changes in the qualitative or  
14          quantitative formulation or the specifications in  
15          the approved marketing application (unless ex-  
16          empted by the Secretary); (ii) changes which  
17          the Secretary determines by regulation or guid-  
18          ance require completion of an appropriate  
19          human study demonstrating equivalence to the  
20          drug manufactured before such changes; and  
21          (iii) other changes which the Secretary deter-  
22          mines by regulation or guidance have a sub-  
23          stantial potential to adversely affect the safety  
24          or effectiveness of the drug.

1           “(C) All other manufacturing changes shall  
2           be reported to the Secretary in a supplemental  
3           application. Unless the Secretary notifies the  
4           applicant within 30 days that preapproval of  
5           the supplement is required, the applicant may  
6           distribute the drug before the application is ap-  
7           proved. The Secretary will subsequently approve  
8           or disapprove the supplemental application. The  
9           Secretary may determine types of manufactur-  
10          ing changes after which distribution of a drug  
11          may commence at the time of submission of the  
12          supplemental application.”.

13          (b) EXISTING LAW.—The requirements of the Fed-  
14          eral Food, Drug, and Cosmetic Act with respect to manu-  
15          facturing changes shall remain in effect for—

16                 (1) a period of 12 months after the date of the  
17                 enactment of this section, or

18                 (2) until the Secretary’s regulations implement-  
19                 ing section 741 of such Act take effect,  
20          whichever is sooner.

21          **SEC. 13. INSULIN AND ANTIBIOTICS.**

22          (a) CERTIFICATION OF DRUGS CONTAINING INSU-  
23          LIN.—

24                 (1) AMENDMENT.—Section 506 (21 U.S.C.  
25                 356) is repealed.

1 (2) CONFORMING AMENDMENTS.—

2 (A) Sections 301(i)(1) and 301(j)(1) (21  
3 U.S.C. 321(i)(1), 321(j)(1)) are each amended  
4 by striking “506, 507,”.

5 (B) Section 501(k) (21 U.S.C. 351(k)) is  
6 repealed

7 (C) Section 502(k) (21 U.S.C. 352(k)) is  
8 repealed.

9 (D) Sections 510(j)(1)(A) and  
10 510(j)(1)(D) (21 U.S.C. 360(j)(1)(A),  
11 360(j)(1)(D)) are each amended by striking  
12 “506, 507,”.

13 (E) Section 8126(h)(2) of title 38, United  
14 States Code, is amended by inserting “or” at  
15 the end of subparagraph (B), by striking “; or”  
16 at the end of subparagraph (C) and inserting a  
17 period, and by striking subparagraph (D).

18 (F) Section 1927(k)(2) of the Social Secu-  
19 rity Act (42 U.S.C. 1396r–8(k)(2)) is amended  
20 by striking “; and” at the end of subparagraph  
21 (B) and inserting a period and by striking sub-  
22 paragraph (C).

23 (b) CERTIFICATION OF ANTIBIOTICS.—

1           (1) AMENDMENT.—Section 507 (21 U.S.C.  
2           357), as in effect on the date of the enactment of  
3           this Act, is repealed.

4           (2) CONFORMING AMENDMENTS.—

5           (A) Section 201(aa) (21 U.S.C. 321(aa)) is  
6           amended by striking out “or 507”, section  
7           201(dd) (21 U.S.C. 321(dd)) is amended by  
8           striking “507,”, and sections 201(ff)(2)(B) and  
9           201(ff)(3) (21 U.S.C. 321(ff)(2)(B), 321(ff)(3))  
10          are each amended by striking “, certified as an  
11          antibiotic under section 507,”.

12          (B) Section 301(e) (21 U.S.C. 331(e)) is  
13          amended by striking “507(d) or (g),”.

14          (C) Sections 301(i)(1) and 301(j) (21  
15          U.S.C. 321(i)(1), 321(j)) are each amended by  
16          striking “507,”.

17          (D) Section 306(d)(4)(B)(ii) (21 U.S.C.  
18          335a(d)(4)(B)(ii)) is amended by striking “or  
19          507”.

20          (E) Section 502 (21 U.S.C. 352) is  
21          amended by striking subsection (l).

22          (F) Section 510(j)(1)(D) (21 U.S.C.  
23          360(j)(1)(D)) is amended by striking “507,”.

1 (G) Section 520(l) is amended by striking  
2 paragraph (4) and by striking “or Antibiotic  
3 Drugs” in the subsection heading.

4 (H) Section 525(a) (21 U.S.C. 360aa(a))  
5 is amended by inserting “or” at the end of  
6 paragraph (1), by striking paragraph (2), and  
7 by redesignating paragraph (3) as paragraph  
8 (2).

9 (I) Section 525(a) (21 U.S.C. 360aa(a)) is  
10 amended by striking “, certification of such  
11 drug for such disease or condition under section  
12 507,”.

13 (J) Section 526(a)(1) (21 U.S.C. 360bb) is  
14 amended by striking “the submission of an ap-  
15 plication for certification of the drug under sec-  
16 tion 507,” by inserting “or” at the end of sub-  
17 paragraph (A), by striking subparagraph (B),  
18 and by redesignating subparagraph (C) as sub-  
19 paragraph (B).

20 (K) Section 526(b) (21 U.S.C. 360bb(b))  
21 is amended by striking “, a certificate was is-  
22 sued for the drug under section 507,” each time  
23 it appears and by striking “, approval of an ap-  
24 plication for certification under section 507,”.

1           (L) Section 527(a) (21 U.S.C. 360cc(a)) is  
2 amended by inserting “or” at the end of para-  
3 graph (1), by striking paragraph (2), by redesi-  
4 gnating paragraph (3) as paragraph (2), and  
5 by striking “, issue another certificate under  
6 section 507,”.

7           (M) Section 527(b) (21 U.S.C. 360cc(b))  
8 is amended by striking “, if a certification is is-  
9 sued under section 507 for such a drug,” and  
10 “, of the issuance of the certification under sec-  
11 tion 507,”.

12           (N) Section 704(a)(1) (21 U.S.C. 374) is  
13 amended by striking “, section 507 (d) or (g)”.

14           (O) Section 735(1) (21 U.S.C. 379g(1)(C))  
15 is amended by inserting “or” at the end of sub-  
16 paragraph (B), by striking subparagraph (C),  
17 and by redesignating subparagraph (D) as sub-  
18 paragraph (C).

19           (P) Sections 5(b)(1)(A) and 5(b)(1)(B) of  
20 the Orphan Drug Act (21 U.S.C.  
21 360ee(b)(1)(A), 360ee(b)(1)(B)) are each  
22 amended by striking “or 507”.

23           (Q) Section 28(b)(2)(A)(ii)(II) of the In-  
24 ternal Revenue Code of 1986 is amended by  
25 striking “or 507”.

1 (R) Section 156(f)(4)(B) of title 35,  
2 United States Code, is amended by striking  
3 “507,” each place it occurs.

4 (S) Section 1927(k)(2)(A)(i) of the Social  
5 Security Act (42 U.S.C. 1396r–  
6 8(k)(2)(A)(ii)(II)) is amended by striking “or  
7 507”.

8 (c) EXPORTATION.—Section 802 (21 U.S.C. 382) is  
9 amended by adding at the end thereof the following:

10 “(h) EXPORTATION OF INSULIN AND ANTIBIOTICS.—  
11 Insulin and antibiotics may be exported without regard to  
12 the requirements in this section if the insulin and anti-  
13 biotics meet the requirements of section 801(e)(1).”.

14 **SEC. 14. NONPRESCRIPTION DRUGS.**

15 Chapter V is amended by adding after section 510  
16 (21 U.S.C. 360) the following:

17 “NONPRESCRIPTION DRUGS

18 “SEC. 511. All applications or petitions requesting  
19 that a drug be switched from prescription to nonprescrip-  
20 tion status and all other matters relating to nonprescrip-  
21 tion drugs shall be reviewed and acted upon solely by a  
22 single office in the Center for Drug Evaluation and Re-  
23 search or a successor entity, and that office shall report  
24 directly to the Director of the Center. A single scientific  
25 advisory panel may provide conclusions and recommenda-  
26 tions regarding any such matter.”.

1 **SEC. 15. INFORMATION SYSTEM.**

2 Chapter IX is amended by adding at the end the fol-  
3 lowing section:

4 **“SEC. 906. INFORMATION SYSTEM.**

5 “The Secretary shall establish and maintain an infor-  
6 mation system to track the status and progress of each  
7 application or submission (including a petition, notifica-  
8 tion, or other similar form of request) submitted to the  
9 Food and Drug Administration requesting agency action.  
10 The system shall permit access by the applicant.”.

11 **SEC. 16. ENVIRONMENTAL IMPACT REVIEW.**

12 Chapter VII, as amended by section 12, is amended  
13 by adding at the end the following:

14 “SUBCHAPTER E—ENVIRONMENTAL IMPACT REVIEW

15 **“SEC. 744. ENVIRONMENTAL IMPACT REVIEW**

16 “No action by the Secretary proposed to be taken  
17 pursuant to this Act shall require the preparation of an  
18 environmental assessment or environmental impact state-  
19 ment under the National Environmental Policy Act of  
20 1969 unless the Secretary finds that because of extraor-  
21 dinary circumstances the proposed action may have a sig-  
22 nificant effect, either directly or cumulatively, on the  
23 human environment.”.

1 **SEC. 17. APPLICATION OF FEDERAL LAW TO THE PRACTICE**  
2 **OF PHARMACY COMPOUNDING.**

3 (a) IN GENERAL.—Section 503 (21 U.S.C. 353) is  
4 amended by adding at the end the following:

5 “(h)(1) Sections 501(a)(2)(B), 501(f), 501(h),  
6 502(f)(1), 502(l), 502(o), 502(s), 502(t), 505, and sec-  
7 tions 510 through 520 shall not apply to a drug or device  
8 that is compounded by a licensed pharmacist or licensed  
9 physician or other licensed practitioner authorized by  
10 State law to prescribe drugs or devices or both—

11 “(A) on the order of such a licensed physician  
12 or other licensed practitioner for an individual pa-  
13 tient; or

14 “(B) in limited quantities, as determined by the  
15 principal State agency of jurisdiction which regulates  
16 the practice of pharmacy for that pharmacist, before  
17 receiving a valid order for an individual patient if  
18 the compounding of the drug or device is based on  
19 a history of receiving valid orders that have been  
20 generated solely within an established relationship  
21 between the pharmacist, and (i) the patient for  
22 whom the order will be given, or (ii) the physician  
23 or other licensed practitioner who will write such  
24 order.

25 Such sections shall not apply to a drug or device if such  
26 pharmacist or physician or other licensed practitioner does

1 no more than advertise or otherwise promote the  
2 compounding service and does not advertise or otherwise  
3 promote the compounding of a particular drug or device.

4 “(2) None of the provisions of this Act referred to  
5 in paragraph (1) shall apply to a bulk drug product or  
6 other drug, including an imported drug, that is intended  
7 for use by a licensed pharmacist or licensed physician or  
8 other licensed practitioner in compounding a drug or de-  
9 vice on the order of a licensed physician or other licensed  
10 practitioner for an individual patient, except to the extent  
11 that the provision relates directly to the quality, purity,  
12 potency, or identity of such drug.”.

13 (b) WITHDRAWAL OF PROPOSED RULE AND GUIDE-  
14 LINE.—The proposed rule of the Secretary of Health and  
15 Human Services concerning exceptions to the current good  
16 manufacturing practices for makers of positron emission  
17 tomography drug products and the draft guideline on the  
18 manufacture of positron emission tomography drug prod-  
19 ucts published in the Federal Register of February 27,  
20 1995 (at 60 FR 10517-10520 and 60 FR 10593-10594)  
21 are null and void and the Secretary of Health and Human  
22 Services may not propose another proposed regulation or  
23 guideline respecting the same matters covered by the pro-  
24 posed regulation and guideline described in this sub-  
25 section.

1 **SEC. 18. HARMONIZATION.**

2 Section 803 (21 U.S.C. 383) is amended by adding  
3 at the end the following:

4 “(c)(1) The Secretary shall participate in meetings  
5 with other countries to discuss methods and approaches  
6 to reduce the burden of regulation, harmonize regulatory  
7 requirements, and seek appropriate reciprocal arrange-  
8 ments. The Secretary shall, within 180 days of the date  
9 of enactment of this subsection, make public a plan that  
10 establishes a framework for achieving mutual recognition  
11 of good manufacturing practices.

12 “(2) The Secretary shall report to the Committee on  
13 Commerce of the House of Representatives and the Com-  
14 mittee on Labor and Human Resources of the Senate at  
15 least 60 days before executing any bilateral or multilateral  
16 agreement under paragraph (1).”.

17 **SEC. 19. INFORMAL AGENCY STATEMENTS.**

18 Section 701 (21 U.S.C. 371) is amended by adding  
19 at the end the following:

20 “(h)(1) The Secretary shall not rely upon informal  
21 agency statements, including guidance documents, policy  
22 statements, points to consider documents, or any other  
23 statements that have not been promulgated in accordance  
24 with the rulemaking requirements of chapter V of title 5,  
25 United States Code, to require any action be taken to sat-  
26 isfy a requirement of this Act.

1       “(2) The Secretary shall publish notice in the Federal  
2 Register of the availability to the public of each type of  
3 statement identified in paragraph (1). Additionally, the  
4 Secretary shall undertake to make available all such state-  
5 ments by electronic or other similar means.”.

6 **SEC. 20. EDUCATION AND RESEARCH; PRACTICE OF MEDI-**  
7 **CINE.**

8       Chapter IX, as amended by section 15, is amended  
9 by adding at the end the following sections:

10 **“SEC. 907. EDUCATION AND RESEARCH.**

11       “(a) EDUCATION.—The Secretary shall conduct  
12 training and education programs for the employees of the  
13 Food and Drug Administration relating to the regulatory  
14 responsibilities and policies established by this Act, includ-  
15 ing programs for scientific training, administrative process  
16 and procedure, and integrity issues.

17       “(b) RESEARCH.—The Secretary, acting through the  
18 Food and Drug Administration, may conduct or contract  
19 for scientific research only if it is directly related to the  
20 implementation of this Act.

21 **“SEC. 908. PRACTICE OF MEDICINE.**

22       “Nothing in this Act shall be construed to limit or  
23 interfere with the authority of a health care practitioner,  
24 licensed by law to administer drugs and devices, to pre-  
25 scribe or administer any legally marketed drug or device

1 to a patient for any condition or disease within a legiti-  
2 mate health care practitioner-patient relationship.”.

3 **SEC. 21. DELEGATION OF AUTHORITY.**

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

6 “(f) DELEGATION OF AUTHORITY.—The reference in  
7 sections 505(b)(4)(A), 505(b)(4)(C), 505(i)(2)(B),  
8 505(n)(1), 701(n), and 505(a)(4)(E) to the authority of  
9 a specific official or position in the Food and Drug Admin-  
10 istration to perform a particular function is an authority  
11 which shall be only exercised by such official or individual  
12 in such position and the authority to exercise such author-  
13 ity may not be delegated.”.

14 **SEC. 22. PUBLICATION OF NOTICE OF DEVIATION.**

15 Section 705 (21 U.S.C. 375) is amended by adding  
16 at the end the following:

17 “(c) The Secretary may make public or communicate  
18 to any person outside the Food and Drug Administration  
19 any information regarding a notice which informs a regu-  
20 lated person of a purported deviation from a requirement  
21 of this Act only after the Secretary has completed the in-  
22 vestigation of such deviation, except as provided in sub-  
23 section (b).”.

1 **SEC. 23. MODERNIZATION OF REGULATION OF BIOLOGICAL**  
2 **PRODUCTS.**

3 (a) IN GENERAL.—Section 351 of the Public Health  
4 Service Act (42 U.S.C. 262) is amended by striking “SEC.  
5 351. (a)” and all that follows through “barter, or ex-  
6 change the same.” and inserting the following:

7 “SEC. 351. (a)(1) Except as provided in paragraph  
8 (6), no person shall introduce or deliver for introduction  
9 into interstate commerce any biological product unless—

10 “(A) a license is in effect for the biological  
11 product; and

12 “(B) each package of the biological product is  
13 plainly marked with the proper name of the biologi-  
14 cal product contained therein, the name, address,  
15 and applicable license number of the manufacturer  
16 of the biological product, and the expiration date of  
17 the biological product.

18 “(2) The license required under paragraph (1)(A)  
19 shall, as determined by the Secretary, cover the biological  
20 product, any facility in which the biological product is  
21 manufactured, processed, packed, or held, or both the  
22 product and facility.

23 “(3)(A) The Secretary shall establish, by regulation,  
24 requirements for license applications for biological prod-  
25 ucts.

1       “(B) Except as provided in subparagraph (D), a li-  
2 cense application that covers a biological product shall be  
3 approved based upon a demonstration that—

4           “(i) the product that is the subject of the appli-  
5 cation is safe and effective in accordance with sub-  
6 sections (c) and (d) of section 505 of the Federal  
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355), or  
8 meets standards designed to ensure that the product  
9 is safe, pure, and where appropriate, potent; and

10          “(ii) the methods used in, and the facilities and  
11 control used for, the manufacture, processing, pack-  
12 ing, and holding of such product meet standards de-  
13 signed to ensure that the product meets the require-  
14 ments of clause (i).

15       “(C) A license application that covers a facility shall  
16 ensure that the product and the facility meet standards  
17 designed to ensure that the product meets applicable re-  
18 quirements of subparagraph (B).

19       “(D) A license application for blood or a blood com-  
20 ponent (including plasma) shall be approved based on a  
21 demonstration that the product meets standards designed  
22 to assure that such product is safe, pure, and where ap-  
23 propriate, potent, and that the facility in which the prod-  
24 uct is manufactured, processed, packed, or held meets

1 standards designed to ensure that such product is safe,  
2 pure, and where appropriate, potent.

3 “(4)(A) Requirements prescribed under paragraph  
4 (3) shall include a requirement for preapproval inspection  
5 under subsection (c).

6 “(B) A license shall be approved only on condition  
7 that the licensee agrees to permit inspection of the facility  
8 of the licensee in accordance with subsection (c).

9 “(5)(A) Except as provided in subparagraph (C), an  
10 approved license for a biological product may be revoked  
11 if the Secretary determines, on the record after providing  
12 an opportunity for a hearing in accordance with section  
13 554 of title 5, United States Code, that the requirements  
14 for approval as specified in paragraph (3) are no longer  
15 met with respect to such product, or that other public  
16 health reasons, prescribed by regulation, exist. No action  
17 to revoke a license based on the findings of an inspection  
18 shall be initiated prior to the submission and review by  
19 the Secretary of a written response submitted by the li-  
20 censee to a notice of inspection findings so long as such  
21 written response is received within 30 days after the date  
22 of receipt by the licensee of the findings. The revocation  
23 of any product license shall not prevent the continued use  
24 of any licensed biological product that has been sold and

1 delivered by the licensee unless the biological product is  
2 subject to recall under subsection (d).

3       “(B) If at any time before the Secretary has taken  
4 final action to revoke a license, the licensee requests an  
5 inspection by the Secretary to determine whether the li-  
6 censee is in compliance with applicable standards, the Sec-  
7 retary shall conduct an inspection within 30 days after  
8 the date of the request. If the inspection confirms that  
9 the licensee is not in compliance with applicable standards,  
10 the 30-day requirement for inspection shall not apply to  
11 any subsequent request by the licensee under this subpara-  
12 graph for inspection. If the inspection confirms that the  
13 licensee is in compliance with all applicable requirements,  
14 the Secretary shall withdraw any proposed action within  
15 30 days after the inspection.

16       “(C) If the Secretary determines that conditions exist  
17 that constitute a danger to health, the Secretary shall sus-  
18 pend the license, notify the licensee that the licensee’s li-  
19 cense is suspended, and require notification of the suspen-  
20 sion to any consignee. Within 30 days thereafter, the Sec-  
21 retary shall initiate the hearing process under subpara-  
22 graph (A).

23       “(6) The requirements of paragraph (1) do not apply  
24 to a biological product for which there is in effect an inves-

1 tigtational new drug application under section 505(i) of the  
2 Federal Food, Drug, and Cosmetic Act.”.

3 (b) DELETION OF ELA REQUIREMENT.—Section  
4 351(d) of the Public Health Service Act (42 U.S.C.  
5 262(d)) is amended—

6 (1) by striking “(d)(1)” and all that follows  
7 through “of this section.”;

8 (2) by redesignating paragraph (2)(A) as sub-  
9 section (d)(1);

10 (3) by redesignating subparagraph (B) as para-  
11 graph (2); and

12 (4) in paragraph (2) (as so redesignated), by  
13 striking “subparagraph (A)” and inserting “para-  
14 graph (1)”.

15 (c) LABELING.—Section 351(b) of the Public Health  
16 Service Act (42 U.S.C. 262(b)) is amended to read as fol-  
17 lows:

18 “(b) No person shall falsely label or mark any pack-  
19 age or container of any biological product or alter any  
20 label or mark on the package so as to falsify the label  
21 or mark.”.

22 (d) INSPECTION.—Section 351(c) of the Public  
23 Health Service Act (42 U.S.C. 262(c)) is amended by  
24 striking “virus, serum,” and all that follows through

1 “other product aforesaid” and inserting “biological prod-  
2 uct”.

3 (e) DEFINITION; APPLICATION.—Section 351 of the  
4 Public Health Service Act (42 U.S.C. 262) is amended  
5 by adding at the end thereof the following new sub-  
6 sections:

7 “(i)(1) For purposes of this section, the term ‘biologi-  
8 cal product’ means a virus, therapeutic serum, toxin, anti-  
9 toxin, vaccine, blood, blood component or derivative, aller-  
10 genic biologic product (except for topically applied aller-  
11 genic products used for the diagnosis of Type IV aller-  
12 gies), or arsphenamine or its derivative (or any other anal-  
13 ogous biological product) applicable to the prevention,  
14 treatment, or cure of diseases or conditions of human  
15 beings.

16 “(2) The Secretary shall promulgate regulations  
17 under section 513(d) of the Federal Food, Drug, and Cos-  
18 metic Act to provide for the regulation of diagnostic test-  
19 ing kits using topically applied allergenic products as de-  
20 vices within the meaning of section 201(h) of such Act.  
21 Such regulations shall take into account the following—

22 “(A) topically applied allergenic products used  
23 for diagnostic testing elicit a biological response, not  
24 a chemical response, on the body;

1           “(B) diagnostic testing kits using topically ap-  
2           plied allergenic products were commercially mar-  
3           keted prior to May 28, 1976;

4           “(C) diagnostic testing kits using topically ap-  
5           plied allergenic products are appropriately classified  
6           as class II devices pursuant to section 513(a)(1)(B)  
7           of such Act, without need for a review by or rec-  
8           ommendation from a classification panel under sec-  
9           tion 513(e) of such Act; and

10           “(D) clinical data are not required for purposes  
11           of determining substantial equivalence of diagnostic  
12           testing kits using topically applied allergenic prod-  
13           ucts under section 513(i) of such Act.

14           “(3) Not later than 12 months after the date of the  
15           enactment of this Act, the Secretary shall issue proposed  
16           regulations under paragraph (2). Not later than 24  
17           months after the date of enactment of this Act, the Sec-  
18           retary shall issue final regulations under paragraph (2).

19           “(j)(1) Sections 505(i), 903, and 904 of the Federal  
20           Food, Drug, and Cosmetic Act shall apply to all biological  
21           products, and references in such sections to new drug ap-  
22           plications shall be deemed to include product license appli-  
23           cations for biological products.

24           “(2) Requirements involving labeling or advertising  
25           for biological products shall be established in accordance

1 with sections 201(m) and 502(n) of the Federal Food,  
2 Drug, and Cosmetic Act.”.

3 (f) STRENGTHENING REGULATION OF BLOOD AND  
4 BLOOD PRODUCTS.—The Secretary of Health and Human  
5 Services, in order to strengthen and streamline the regula-  
6 tion of blood and blood products, shall, after consultation  
7 with patient advocacy groups and the regulated industry,  
8 develop the concept of a single license for the regulation  
9 of blood and blood products that would, as appropriate,  
10 cover multiple individual locations that fall under a single  
11 management. The Secretary shall report the progress on  
12 achieving a single license to the Committee on Commerce  
13 of the House of Representatives and the Committee on  
14 Labor and Human Resources of the Senate by March 31,  
15 1997.

16 **SEC. 24. REQUIREMENTS FOR HUMAN TISSUE.**

17 (a) IN GENERAL.—Section 201 is amended by adding  
18 at the end the following:

19 “(gg)(1) The term ‘human tissue’ means a collection  
20 of similar human cells which—

21 “(A) is intended for use in the diagnosis, cure,  
22 mitigation, treatment, or prevention of a disease or  
23 condition in man or for reproduction,

1           “(B) achieves its primary intended purpose  
2 through repair or replacement by structural support  
3 or cellular function and not systemic action,

4           “(C) may have been propagated or otherwise  
5 processed before use, and

6           “(D) may be combined with substances that are  
7 safe under conditions of intended use and not in-  
8 tended to provide a therapeutic effect.

9           “(2) The term human tissue does not include  
10 vascularized human organs, gene therapy, blood, blood  
11 components, milk, or human tissue combined with bio-  
12 materials.

13           “(3) Human tissue is not a drug, biological product,  
14 or device unless reclassified by the Secretary pursuant to  
15 355 of the Public Health Service Act.

16           (b) REGULATION OF HUMAN TISSUE.—Subpart 1 of  
17 part F of title III of the Public Health Service Act (42  
18 U.S.C. 262 et seq.) is amended by adding at the end the  
19 following section:

20                           “REGULATION OF HUMAN TISSUE

21           “SEC. 352A. (a)(1) Human tissue shall be subject to  
22 regulation under this section only if the Secretary pub-  
23 lishes a finding in the Federal Register, after a hearing  
24 before the Commissioner, that voluntary regulation under  
25 generally accepted scientific standards is inadequate to

1 protect the public health with respect to any particular  
2 type of human tissue or human tissue generally.

3 “(2) Human tissue shall not be subject to regulation  
4 as a drug, biological product, or device unless it is reclassi-  
5 fied under subsection (e).

6 “(b)(1) Any person subject to regulation under this  
7 section who recovers, processes, stores, or distributes  
8 human tissue for transplantation or implantation in the  
9 United States shall register in accordance with the reg-  
10 istration procedures established for drugs under section  
11 510 of the Federal Food, Drug, and Cosmetic Act. Such  
12 registration shall contain the name of the person, the loca-  
13 tion of the facilities of the person, a list of the types of  
14 human tissue recovered, processed, stored, or distributed  
15 by the person, and a brief description of the basic method  
16 or methods of processing of such tissue.

17 “(2) A registered person shall be deemed to be au-  
18 thorized to conduct human tissue recovery, processing,  
19 storage, and distribution activities identified in its reg-  
20 istration unless—

21 “(A)(i) the Secretary determines, upon inspec-  
22 tion, that such person fails to meet applicable oper-  
23 ating standards under subsection (e);

24 “(ii) the Secretary so notifies such person, ad-  
25 vises the person of the steps necessary to meet such

1 standards, and provides the person with a reason-  
2 able opportunity to establish compliance with the  
3 standards;

4 “(iii) the Secretary determines, after an oppor-  
5 tunity for an informal hearing, that the person has  
6 failed to establish such compliance within the appli-  
7 cable period and such failure constitutes a threat to  
8 the public health; and

9 “(iv) the Secretary suspends or revokes the au-  
10 thority to conduct such activities;

11 “(B) the Secretary determines, after an oppor-  
12 tunity for an informal hearing, that such person has  
13 failed to comply with any patient registry or other  
14 retrospective patient data requirement, and the Sec-  
15 retary suspends or revokes the authority to conduct  
16 such activities; or

17 “(C) the Secretary determines that such person  
18 presents an immediate or substantial danger to the  
19 public health, and the Secretary suspends or revokes  
20 the authority to conduct such activities.

21 “(c) The Secretary may establish operating standards  
22 for human tissue that shall be limited to the following gen-  
23 eral requirements for the recovery, processing, storage,  
24 and shipment of human tissue:

1           “(1) Requirements for infection control de-  
2           signed to prevent transmission of disease.

3           “(2) Requirements for processing practices that  
4           assure the safety of, and prevent damage to, human  
5           tissue.

6           “(3) Requirements for labeling and record keep-  
7           ing to identify the type of tissue and any added for-  
8           eign substance and to permit tracing.

9           “(d) A registered person may be required by the Sec-  
10          retary to maintain a patient registry or meet other retro-  
11          spective patient data requirements if, after notice and an  
12          opportunity for comment, the Secretary finds that such  
13          tissue has been commercially available within the United  
14          States for a period of less than 5 years and that such  
15          data requirement is necessary to protect the public health.

16          “(e)(1) The Secretary may reclassify a particular  
17          type of human tissue as a drug, biological product or de-  
18          vice if, after notice and an opportunity for comment, the  
19          Secretary finds that—

20                 “(A) the particular type of human tissue is—

21                         “(i) subject to a patient registry or other  
22                         retrospective data requirement under which the  
23                         collection of information has been required for  
24                         at least 5 years (or such other time period as

1           agreed to by the Secretary and the registered  
2           person); and

3           “(ii) the information received from such  
4           patient registry or other retrospective data re-  
5           quirement is insufficient to confirm the safety  
6           and clinical benefit from the use of such tissue;  
7           or

8           “(B) a particular type of human tissue should  
9           be reclassified because it presents an imminent haz-  
10          ard to public health.

11          “(2) The Secretary may reclassify a human drug, bio-  
12          logical product or medical device as human tissue if, after  
13          notice and an opportunity for comment, the Secretary  
14          finds that such previous classification is not necessary to  
15          protect public health.

16          “(3) The Secretary may reclassify a drug, biological  
17          product, device, or human tissue upon the petition of the  
18          sponsor of such drug, biological product, or device, or the  
19          registered person of such human tissue, if, after notice and  
20          an opportunity for comment, the Secretary finds that such  
21          reclassification is consistent with the protection of the  
22          public health.

23          “(f)(1) If the Secretary finds that a person violates  
24          any provision of this section or any regulations promul-  
25          gated thereunder, and the Secretary finds the violation

1 constitutes a significant risk to the public health, the Sec-  
2 retary may issue an order that such person cease distribu-  
3 tion of human tissue, or that human tissue recovered,  
4 processed, stored or distributed by such person be re-  
5 tained, recalled, or destroyed. After receipt of such an  
6 order, the person in possession of the human tissue shall  
7 not distribute or dispose of the human tissue in any man-  
8 ner inconsistent with the provisions of the order.

9       “(2) A person subject to an order under paragraph  
10 (1) may obtain an informal hearing regarding the order  
11 if the person requests such a hearing not later than 5 days  
12 after receiving the order. If the person makes such a re-  
13 quest within such period, the Secretary shall conduct the  
14 hearing not later than 30 days after receiving the request  
15 and shall issue an order not later than 15 days after the  
16 hearing is conducted. Such order shall be considered a  
17 final order of the Secretary.

18       “(g) Each registered person shall be subject to in-  
19 spection under section 704 of the Federal Food, Drug,  
20 and Cosmetic Act. The Secretary may, with the concur-  
21 rence of the registered person, authorize an inspection to  
22 be conducted by a person specifically accredited by the  
23 Secretary to conduct such inspection under section 712  
24 of such Act.

1       “(i) This section (including provisions regarding re-  
2 classification) shall apply with respect to cord blood to the  
3 same extent and in the same manner as this section ap-  
4 plies with respect to human tissue.”.

5       (c) TRANSITION—The requirements of the interim  
6 regulation promulgated by the Secretary of Health and  
7 Human Services on December 11, 1993, shall remain in  
8 effect until amended or withdrawn by the Secretary. Any  
9 changes to such regulations after the date of the enact-  
10 ment of this Act are subject to this Act and the amend-  
11 ments made by this Act.

12       (d) EFFECTIVE DATE.—Section 352A of the Public  
13 Health Service Act shall take effect on June 30, 1997.

14       (e) CONFORMING AMENDMENTS.—

15               (1) ADULTERATION PROVISION.—Section 501  
16 (21 U.S.C. 351) is amended—

17                       (A) in the first sentence, by striking “drug  
18 or device” and inserting “drug, device or  
19 human tissue”; and

20                       (B) by inserting at the end thereof the fol-  
21 lowing:

22       “(j) If it is human tissue and is recovered, processed,  
23 stored, or distributed by—

24               “(1) a registered person under section 352A of  
25 the Public Health Service Act whose failure to com-

1 ply with operating standards for human tissue con-  
2 sistent with such section constitutes a threat to the  
3 public health; or

4 “(2) a person who is required under such sec-  
5 tion to register but has failed to do so.”.

6 (2) MISBRANDING PROVISIONS.—Section 502  
7 (21 U.S.C. 352) is amended—

8 (A) in the heading for the section, by strik-  
9 ing “MISBRANDED” and all that follows and in-  
10 serting the following: “MISBRANDED DRUGS,  
11 DEVICES, AND HUMAN TISSUE”; and

12 (B) in the first sentence, by striking “drug  
13 or device” and inserting “drug, device or  
14 human tissue”.

15 (3) PROHIBITED ACTS.—Section 301 (21  
16 U.S.C. 331) is amended by inserting the following  
17 new section:

18 “(v) The adulteration or misbranding of any  
19 human tissue.”.

20 (4) SEIZURE.—

21 (A) Section 304 (a)(2)(D) (21 U.S.C. 334  
22 (a)) is amended by inserting “or human tissue”  
23 after “device.”

24 ((B) Section 304(d)(1) is amended by de-  
25 leting the “or” before “cosmetic” and inserting



1 Secretary as appropriate for expanded access under this  
2 section by the physician or patient making the request if—

3 “(1) in the case of a physician acting on behalf  
4 of a patient the physician has no comparable or sat-  
5 isfactory alternative therapy available to treat, diag-  
6 nose, or monitor the disease or condition; or

7 “(2) in the case of such a physician or patient,  
8 the risk to the physician or patient from the inves-  
9 tigational drug or device is not greater than the risk  
10 from the disease or condition.

11 “(b) A manufacturer or distributor may submit to the  
12 Secretary one or more expanded access protocols covering  
13 expanded access use of a drug described in subsection (a).  
14 The protocols shall be subject to the provisions of section  
15 505(i) for a drug and may include any form of use of the  
16 drug outside a clinical investigation, prior to approval of  
17 the drug for marketing, including protocols for treatment,  
18 use, emergency use, and uncontrolled trials and single pa-  
19 tient protocols.

20 “(c) A manufacturer or distributor may charge for  
21 an investigational drug under an expanded access proto-  
22 col, but the price of the drug or device may not be more  
23 than that necessary to recover the costs of manufacture,  
24 research, development, and handling for the drug or de-  
25 vice.

1       “(d) The manufacturer or distributor may inform na-  
2 tional, State, and local medical associations and societies,  
3 and voluntary health associations, about the availability  
4 of an investigational drug for expanded access use pursu-  
5 ant to this section but—

6               “(1) shall state that the drug is investigational;

7               “(2) shall not represent that the drug is safe or  
8 effective for any use; and

9               “(3) shall not otherwise promote or advertise  
10 the availability of the product for expanded access  
11 use.

12 **SEC. 26. RADIOPHARMACEUTICALS.**

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

15               “(4)(A) For purposes of paragraph (1), the  
16 safety and effectiveness of a radiopharmaceutical in-  
17 tended to be used for purposes of diagnosis or mon-  
18 itoring shall be determined by—

19                       “(i) weighing the probable benefit from the  
20 use of the radiopharmaceutical against any  
21 probable risk of injury or illness from such use;  
22 and

23                       “(ii) taking into account the appropriate  
24 use of the radiopharmaceutical in the practice  
25 of medicine, the level of pharmacological and

1 toxicological activity of the radiopharmaceutical,  
2 and the estimated absorbed radiation dose of  
3 the radiopharmaceutical.

4 “(B) In the case of a radiopharmaceutical in-  
5 tended to be used for purposes of diagnosis or mon-  
6 itoring, the indications for which such a  
7 radiopharmaceutical is approved under this section  
8 may refer to manifestations of disease (such as bio-  
9 chemical, physiological, anatomical, or pathological  
10 processes) common to or present in one or more dis-  
11 ease states or may refer to a diagnostic procedure  
12 used in the diagnosis of one or more diseases or con-  
13 ditions.

14 “(C) Within 180 days after the date of the en-  
15 actment of this paragraph, the Secretary shall, after  
16 consultation with patient advocacy groups, associa-  
17 tions, physicians licensed to use  
18 radiopharmaceuticals, and the regulated industry,  
19 issue guidelines pertaining to the evaluation, in ac-  
20 cordance with this paragraph, of the safety and ef-  
21 fectiveness of radiopharmaceuticals.

22 “(D) As used in this paragraph, the term  
23 ‘radiopharmaceutical’ means—

24 “(i) an article that is intended for use in  
25 vivo in the diagnosis, cure, mitigation, treat-

1           ment, or prevention of disease or a manifesta-  
2           tion of disease in man, and that exerts its pri-  
3           mary effect by the spontaneous disintegration  
4           of unstable nuclei with the emission of ionizing  
5           radiation; or

6                   “(ii) a reagent kit or nuclide generator  
7           that is intended to be used in the preparation  
8           of any such article.”.

9   **SEC. 27. PROTECTION OF CONFIDENTIAL INFORMATION.**

10          Section 301, as amended by section 8(b), is amended  
11   by adding after paragraph (w) the following:

12          “(x) The release to the public of confidential patient  
13   and donor identifying information from establishments li-  
14   censed or registered by the Secretary unless the release  
15   of such information is critical to a public health purpose.”.

16   **SEC. 28. NATIONAL UNIFORMITY.**

17          (a) Chapter VII is amended by adding at the end  
18   thereof the following:

19                “SUBCHAPTER D—NATIONAL UNIFORMITY

20                “SEC. 741. (a)(1) Except as provided in subsection  
21   (d)(1) or (e), no State or political subdivision of a State  
22   may establish or continue in effect any requirement—

23                   “(A) that relates to the regulation of a drug or  
24   cosmetic, and

1           “(B) that is not identical with a requirement of  
2           this Act, section 351 of the Public Health Service  
3           Act (42 U.S.C. 262), or the Fair Packaging and La-  
4           beling Act (15 U.S.C. 1451 et seq.), and the admin-  
5           istrative implementation of such Acts.

6           “(2) Except as provided in subsection (d)(2) or (e),  
7           no State or political subdivision of a State may establish  
8           any requirement after the date of enactment of this sec-  
9           tion or continue in effect any requirement established after  
10          such date—

11           “(A) that relates to the regulation of food, and

12           “(B) that is not identical with a requirement of  
13           this Act or the Fair Packaging and Labeling Act  
14           (15 U.S.C. 1451 et seq.) and the administrative im-  
15           plementation of such Acts.

16          “(b) For purposes of subsection (a)(1), a requirement  
17          that relates to the regulation of a drug or cosmetic shall  
18          be deemed to include any requirement that relates to the  
19          subject matter in any provision of this Act, section 351  
20          of the Public Health Service Act (42 U.S.C. 262), or the  
21          Fair Packaging and Labeling Act (15 U.S.C. 1451 et  
22          seq.), including any notification requirement for a drug  
23          or cosmetic that provides for a warning concerning the  
24          safety of the drug or cosmetic or any component or pack-  
25          age thereof, but shall not include any requirement that

1 relates to the practice of pharmacy or any requirement  
2 that a drug be dispensed only upon the prescription of  
3 a practitioner licensed by law to administer such drug.

4 “(c) For purposes of subsections (b)—

5 “(1) the term ‘warning’ with respect to a drug  
6 or cosmetic means any statement, vignette, or other  
7 representation which indicates, directly or by impli-  
8 cation, that the drug or cosmetic presents or may  
9 present a hazard to human health or safety; and

10 “(2) the term ‘notification requirement’ in-  
11 cludes any mandatory disclosure requirement that  
12 relates to the dissemination of information about a  
13 drug or cosmetic in any manner, such as labels, la-  
14 beling, posters, public notices, advertising, or any  
15 other means of communication.

16 “(d)(1) Upon application of a State, the Secretary  
17 may by regulation, after notice and opportunity for writ-  
18 ten and oral presentation of views, exempt from subsection  
19 (a)(1), under such conditions as the Secretary may im-  
20 pose, a State requirement which—

21 “(A) is justified by compelling and unique local  
22 conditions,

23 “(B) protects an important public interest that  
24 would otherwise be unprotected,

1           “(C) would not cause any drug or cosmetic to  
2           be in violation of any applicable requirement or pro-  
3           hibition under Federal law, and

4           “(D) would not unduly burden interstate com-  
5           merce.

6           “(2)(A) A State may establish a warning notification  
7           requirement for food that would otherwise violate sub-  
8           section (a)(2) if—

9           “(i) the warning is needed to address an immi-  
10          nent hazard to health that is likely to result in seri-  
11          ous adverse health consequences or death, and

12          “(ii) a petition for an exemption is submitted  
13          by the State no later than 7 days after the warning  
14          notification requirement is established and is not  
15          subsequently denied by the Secretary.

16          The Secretary shall take action on a petition no later than  
17          30 days after its submittal.

18          “(B) For purposes of subparagraph (A)—

19          “(i) the term ‘warning’ with respect to a food  
20          means any statement, vignette, or other representa-  
21          tion which indicates, directly or by implication, that  
22          the food presents or may present a hazard to human  
23          health; and

24          “(ii) the term ‘notification requirement’ in-  
25          cludes any mandatory disclosure requirement that

1 relates to the dissemination of information about a  
2 food in any manner, such as labels, labeling, posters,  
3 public notices, advertising, or any other means of  
4 communication.

5 “(e) An application described in paragraph (1) or a  
6 petition described in paragraph (2) of subsection (d) that  
7 demonstrates that a drug, cosmetic, or food during the  
8 period of its likely availability in the State will pose a sig-  
9 nificant public health threat from acute exposure shall be  
10 considered an urgent application or petition. If an order  
11 by the Secretary to grant or deny the requested authoriza-  
12 tion in an urgent application or petition is not made within  
13 30 days of receipt of the application or petition, the State  
14 may establish and enforce a temporary requirement. The  
15 temporary requirement shall be validated or terminated by  
16 the Secretary’s final order on the application or petition.

17 “(f) Nothing in this section shall be construed to  
18 modify or otherwise affect any action or the liability of  
19 any person under the product liability law of any State.”.

20 **SEC. 29. CENTERS FOR EDUCATION AND RESEARCH ON**  
21 **DRUGS, DEVICES, AND BIOLOGICAL PROD-**  
22 **UCTS.**

23 Chapter IX is amended by adding at the end the fol-  
24 lowing section:

1 **“SEC. 909. DEMONSTRATION PROGRAM REGARDING CEN-**  
2 **TERS FOR EDUCATION AND RESEARCH ON**  
3 **DRUGS, DEVICES, AND BIOLOGICAL PROD-**  
4 **UCTS.**

5 “(a) IN GENERAL.—The Secretary, acting through  
6 the Commissioner, shall establish a demonstration pro-  
7 gram for the purpose of making 1 or more grants for the  
8 establishment and operation of 1 or more centers to carry  
9 out the activities specified in subsection (b).

10 “(b) REQUIRED ACTIVITIES.—The activities referred  
11 to in subsection (a) are the following:

12 “(1) The conduct of state-of-the-art clinical and  
13 laboratory research for the following purposes:

14 “(A) To increase awareness of new uses of  
15 drugs, devices, or biological products and the  
16 unforeseen risks of new uses of drugs, devices,  
17 or biological products.

18 “(B) To provide objective clinical informa-  
19 tion to the following entities:

20 “(i) Health care practitioners or other  
21 providers of health care goods or services.

22 “(ii) Pharmacy benefit managers.

23 “(iii) Health maintenance organiza-  
24 tions or other managed health care organi-  
25 zations.

1                   “(iv) Health care insurers or govern-  
2                   mental agencies; and

3                   “(C) To improve the quality of health care  
4                   while reducing the cost of health care through  
5                   the prevention of adverse effects of drugs, de-  
6                   vices, or biological products and the con-  
7                   sequences of such effects, such as unnecessary  
8                   hospitalizations.

9                   “(2) The conduct of research on the compara-  
10                  tive effectiveness and safety of drugs, devices, or bio-  
11                  logical products.

12                  “(3) Such other activities as the Secretary de-  
13                  termines to be appropriate, except that the grant  
14                  may not be expended to assist the Secretary in the  
15                  review of new drugs.

16                  “(c) APPLICATION FOR GRANT.—A grant under sub-  
17                  section (a) may be made only if an application for the  
18                  grant is submitted to the Secretary and the application  
19                  is in such form, is made in such manner, and contains  
20                  such agreements, assurances, and information as the Sec-  
21                  retary determines to be necessary to carry out this section.

22                  “(d) PEER REVIEW.—A grant under subsection (a)  
23                  may be made only if the application for the grant has un-  
24                  dergone appropriate technical and scientific peer review.

1       “(e) AUTHORIZATION OF APPROPRIATIONS.—For the  
2 purpose of carrying out this section, there are authorized  
3 to be appropriated \$2,000,000 for fiscal year 1997 and  
4 \$3,000,000 for fiscal year 1998.”.

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