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To amend the Federal Food, Drug, and Cosmetic Act to create a new three-tiered approval system for drugs, biological products, and devices that is responsive to the needs of seriously ill patients, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 3, 2005

Mr. BROWNBACK (for himself and Mr. INHOFE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to create a new three-tiered approval system for drugs, biological products, and devices that is responsive to the needs of seriously ill patients, 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.**

4 This Act may be cited as the “Access, Compassion,
5 Care, and Ethics for Seriously Ill Patients Act” or the
6 “ACCESS Act”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) The necessity of placebo controlled studies
4 has been questioned on both scientific and ethical
5 grounds for seriously ill patients.

6 (2) The current standards of the Food and
7 Drug Administration for approval of drugs, biological
8 products, and devices deny the benefits of medical
9 progress to seriously ill patients who face mor-
10 bidity or death from their disease.

11 (3) Promising therapies intended to treat seri-
12 ous or life threatening conditions or diseases and
13 which address unmet medical needs have received
14 unjustified delays and denials of approval.

15 (4) Seriously ill patients have a right to access
16 available investigational drugs, biological products,
17 and devices.

18 (5) The current Food and Drug Administration
19 and National Cancer Institute case-by-case exception
20 for compassionate access must be required to permit
21 all seriously ill patients access to available experi-
22 mental therapies as a treatment option.

23 (6) The current emphasis on statistical analysis
24 of clinical information needs to be balanced by a
25 greater reliance on clinical evaluation of this infor-
26 mation.

1 (7) Food and Drug Administration advisory
2 committees should have greater representation of
3 medical clinicians who represent the interests of seri-
4 ously ill patients in early access to promising inves-
5 tigational therapies.

6 (8) The use of available investigational products
7 for treatment is the responsibility of the physician
8 and the patient.

9 (9) The use of combinations of available inves-
10 tigational and approved products for treatment is
11 the responsibility of the physician and the patient.

12 (10) The development and approval of drugs,
13 biological products, and devices intended to address
14 serious or life-threatening conditions or diseases is
15 often delayed by the inability of sponsors to obtain
16 prompt meetings with the Food and Drug Adminis-
17 tration and to obtain prompt resolution of scientific
18 and regulatory issues related to the investigation
19 and review of new technologies.

20 **SEC. 3. TIERED APPROVAL SYSTEM FOR DRUGS, BIOLOGI-**
21 **CAL PRODUCTS, AND DEVICES.**

22 Section 506 of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 356) is amended to read as follows:

1 **“SEC. 506. TIERED APPROVAL SYSTEM.**

2 “(a) IN GENERAL.—Notwithstanding any other pro-
3 vision of law, the sponsor of an investigational drug, bio-
4 logical product, or device may submit an application to
5 the Secretary for Tier I or Tier II approval in accordance
6 with this section.

7 “(b) TIER I APPROVAL.—

8 “(1) IN GENERAL.—

9 “(A) APPLICATION CONTENT.—A sponsor
10 of an investigational drug, biological product, or
11 device applying for Tier I approval of the prod-
12 uct shall submit to the Secretary an application
13 as described under section 505(b)(1) or
14 505(b)(2), section 351(a) of the Public Health
15 Service Act, or section 510(k) or 515(c)(1), as
16 applicable, which shall contain—

17 “(i) data and information from com-
18 pleted Phase I clinical investigations and
19 any other nonclinical or clinical investiga-
20 tions;

21 “(ii) preliminary evidence that the
22 product may be effective against a serious
23 or life-threatening condition or disease,
24 which evidence may be based on uncon-
25 trolled data such as case histories, infor-
26 mation about the pharmacological mecha-

1 nism of action, data from animal and com-
2 puter models, comparison with historical
3 data, or other preliminary information, and
4 may be based on a small number of pa-
5 tients; and

6 “(iii) an assurance that the sponsor
7 will continue clinical investigation to obtain
8 Tier III approval.

9 “(B) LIMITATION.—Tier I approval shall
10 be primarily based upon clinical evaluation, not
11 statistical analysis.

12 “(2) DETERMINATION BY SECRETARY.—

13 “(A) IN GENERAL.—Not later than 30
14 days after the receipt of an application for Tier
15 I approval, the Secretary shall either—

16 “(i) approve the application; or

17 “(ii) refer the application to the Accel-
18 erated Approval Advisory Committee.

19 “(B) RECOMMENDATION.—Within 90 days
20 after receipt of an application for approval, the
21 Accelerated Approval Advisory Committee shall
22 issue a recommendation to the Secretary on
23 whether the Secretary should approve the appli-
24 cation.

1 “(C) FINAL DECISION.—Within 30 days
2 after receipt of the recommendation from the
3 Accelerated Approval Advisory Committee, the
4 Secretary shall either approve the application or
5 shall issue an order setting forth a detailed ex-
6 planation of the reasons why the application
7 was not approved and the specific data that the
8 sponsor must provide so that the application
9 may be approved.

10 “(3) APPEAL.—If the Secretary does not ap-
11 prove an application for which the Accelerated Ap-
12 proval Advisory Committee recommended approval,
13 the sponsor of the application shall have the right to
14 appeal the decision to the Commissioner of Food
15 and Drugs. The Commissioner shall provide the
16 sponsor with a hearing within 30 days following the
17 nonapproval of the application and shall issue an
18 order within 30 days following the hearing either
19 concurring in the nonapproval or approving the ap-
20 plication. The Commissioner shall not delegate the
21 responsibility described in this paragraph to any
22 other person.

23 “(4) CRITERIA.—In making a determination
24 under paragraph (2), the Secretary shall consider
25 whether the totality of the information available to

1 the Secretary regarding the safety and effectiveness
2 of an investigational drug, biological product, or de-
3 vice, as compared to the risk of morbidity or death
4 from a condition or disease, indicates that a patient
5 (who may be representative of a small patient sub-
6 population) may obtain more benefit than risk if
7 treated with the drug, biological product, or device.
8 If the potential risk to a patient of the condition or
9 disease outweighs the potential risk of the product,
10 and the product may possibly provide benefit to the
11 patient, the Secretary shall approve the application.

12 “(5) PRODUCT LABELING.—The labeling ap-
13 proved by the Secretary for the drug, biological
14 product, or device—

15 “(A) shall state that the product is in-
16 tended for use by a patient whose physician has
17 documented in writing that the patient has—

18 “(i) exhausted all treatment options
19 approved by Secretary for the condition or
20 disease for which the patient is a reason-
21 able candidate; and

22 “(ii) unsuccessfully sought treatment,
23 or obtained treatment that was not effec-
24 tive, with an investigational drug, biologi-
25 cal product, or device for which such indi-

1 vidual is a reasonable candidate (which
2 may include consideration of the lack of a
3 source of supply or geographic factors);
4 and

5 “(B) shall state that every patient to
6 whom the product is administered shall, as a
7 mandatory condition of receiving the product,
8 provide—

9 “(i) written informed consent, as de-
10 scribed under part 50 of title 21, Code of
11 Federal Regulations;

12 “(ii) a written waiver of the right to
13 sue the manufacturer or sponsor of the
14 drug, biological product, or device, or the
15 physicians who prescribed the product or
16 the institution where it was administered,
17 for an adverse event caused by the prod-
18 uct, which shall be binding in every State
19 and Federal court; and

20 “(iii) consent for the manufacturer of
21 the product to obtain data and information
22 about the patient and the patient’s use of
23 the product that may be used to support
24 an application for Tier II or Tier III ap-
25 proval.

1 “(6) LIMITATION ON CONDITIONS.—Tier I ap-
2 proval may be subject to the requirement that the
3 sponsor conduct appropriate post-approval studies.

4 “(c) TIER II APPROVAL.—

5 “(1) IN GENERAL.—A sponsor of an investiga-
6 tional drug, biological product, or device applying for
7 Tier II approval shall submit to the Secretary an ap-
8 plication as described under section 505(b)(1) or
9 505(b)(2), section 351(a) of the Public Health Serv-
10 ice Act, or section 510(k) or 515(c)(1), as applica-
11 ble, which shall contain—

12 “(A) data and information that the drug,
13 biological product, or device has an effect on a
14 clinical endpoint or on a surrogate endpoint or
15 biomarker that is reasonably likely to predict
16 clinical benefit to a patient (who may be rep-
17 resentative of a small patient subpopulation)
18 suffering from a serious or life-threatening con-
19 dition or disease; and

20 “(B) an assurance that the sponsor will
21 continue clinical investigation to obtain Tier III
22 approval.

23 “(2) DETERMINATION BY SECRETARY.—

1 “(A) IN GENERAL.—Not later than 30
2 days after the receipt of an application for Tier
3 II approval, the Secretary shall either—

4 “(i) approve the application; or

5 “(ii) refer the application to the Accel-
6 erated Approval Advisory Committee.

7 “(B) RECOMMENDATION.—Within 90 days
8 after receipt of an application for approval, the
9 Accelerated Approval Advisory Committee shall
10 issue a recommendation to the Secretary on
11 whether the Secretary should approve the appli-
12 cation.

13 “(C) FINAL DECISION.—Within 30 days
14 after receipt of the recommendation from the
15 Accelerated Approval Advisory Committee, the
16 Secretary shall either approve the application or
17 issue an order setting forth a detailed expla-
18 nation of the reasons why the application was
19 not approved and the specific data that the
20 sponsor must provide so that the application
21 may be approved.

22 “(3) APPEAL.—If the Secretary does not ap-
23 prove an application for which the Accelerated Ap-
24 proval Advisory Committee recommended approval,
25 the sponsor of the application shall have the right to

1 appeal the decision to the Commissioner of Food
2 and Drugs. The Commissioner shall provide the
3 sponsor with a hearing within 30 days following the
4 nonapproval of the application and shall issue an
5 order within 30 days following the hearing either
6 concurring in the nonapproval or approving the ap-
7 plication. The Commissioner shall not delegate the
8 responsibility described in this paragraph to any
9 other person.

10 “(4) LIMITATION ON CONDITIONS.—

11 “(A) POST-APPROVAL STUDIES.—Tier II
12 approval may be subject to the requirement
13 that the sponsor conduct appropriate post-ap-
14 proval studies to validate the surrogate end-
15 point or biomarker or otherwise confirm the ef-
16 fect on the clinical endpoint.

17 “(B) RULE OF CONSTRUCTION.—Nothing
18 in this subsection shall be construed to permit
19 the Secretary to condition Tier II approval on
20 compliance with any other standards, including
21 any standard necessary to meet Tier III ap-
22 proval.

23 “(d) TIER III APPROVAL.—For purposes of this Act,
24 the term ‘Tier III approval’ means—

1 “(1) with respect to a new drug or new biological
2 product, approval of such drug or product under
3 section 505(b)(1) or 505(b)(2) or section 351 of the
4 Public Health Service Act, as the case may be; and

5 “(2) with respect to a new device, clearance of
6 such device under section 510(k) or approval of such
7 device under section 515(c)(1).

8 “(e) PROMOTIONAL MATERIALS.—Approval of a
9 product under either Tier I or II may be subject to the
10 requirements that—

11 “(1) the sponsor submit copies of all advertising
12 and promotional materials related to the product
13 during the preapproval review period and, following
14 approval and for such period thereafter as the Sec-
15 retary determines to be appropriate, and at least 30
16 days prior to the dissemination of the materials;

17 “(2) all advertising and promotional materials
18 prominently disclose the limited approval for the
19 product and data available supporting the safety and
20 effectiveness of the product; and

21 “(3) the sponsor shall not disseminate adver-
22 tising or promotional material prior to obtaining
23 written notification from the Secretary that the ad-
24 vertising or promotional material complies with this
25 subchapter.

1 “(f) EXPEDITED WITHDRAWAL OF APPROVAL.—The
2 Secretary may withdraw Tier I or Tier II approval using
3 expedited procedures (as prescribed by the Secretary in
4 regulations which shall include an opportunity for a hear-
5 ing) if—

6 “(1) the sponsor fails to conduct post-approval
7 studies with due diligence, considering all of the cir-
8 cumstances involved;

9 “(2) a post-approval study fails to verify clinical
10 benefit of the product for even a small patient sub-
11 population;

12 “(3) other evidence demonstrates that the prod-
13 uct is not safe or effective under the conditions of
14 use for even a small patient subpopulation; or

15 “(4) the sponsor disseminates false or mis-
16 leading promotional materials with respect to the
17 product and fails to correct the material promptly
18 after written notice from the Secretary.

19 “(g) ACCELERATED APPROVAL ADVISORY COM-
20 MITTEE.—

21 “(1) IN GENERAL.—In order to facilitate the
22 development and expedite the review of drugs, bio-
23 logical products, and devices intended to treat seri-
24 ous or life threatening conditions, the Secretary shall

1 establish the Accelerated Approval Advisory Com-
2 mittee.

3 “(2) DELEGATION.—The Secretary may dele-
4 gate authority for the Accelerated Approval Advisory
5 Committee to the Commissioner of Food and Drugs.
6 The Accelerated Approval Advisory Committee shall
7 be staffed and administered in the Office of the
8 Commissioner.

9 “(3) COMPOSITION.—

10 “(A) IN GENERAL.—The Committee shall
11 be composed of 11 voting members, including 1
12 chairperson and 5 permanent members each of
13 whom shall serve a term of 3 years and may be
14 reappointed for a second 3-year term, and 5
15 nonpermanent members who shall be appointed
16 to the Committee for a specific meeting, or part
17 of a meeting, in order to provide adequate ex-
18 pertise in the subject being reviewed. The Com-
19 mittee shall include as voting members no less
20 than 2 representatives of patient interests, of
21 which 1 shall be a permanent member of the
22 Committee. The Committee shall include as
23 nonvoting members a representative of interests
24 of the drug, biological product, and device in-
25 dustry.

1 “(B) APPOINTMENTS.—The Secretary
2 shall appoint to the Committee persons who are
3 qualified by training and experience to evaluate
4 the safety and effectiveness of the types of
5 products to be referred to the Committee and
6 who, to the extent feasible, possess skill in the
7 use of, or experience in the development, manu-
8 facture, or utilization of, such products. The
9 Secretary shall make appointments to the Com-
10 mittee so that the Committee shall consist of
11 members with adequately diversified expertise
12 and practical experience in such fields as clin-
13 ical medicine, biological and physical sciences,
14 and other related professions. Scientific, indus-
15 try, and consumer organizations and members
16 of the public shall be afforded an opportunity to
17 nominate individuals for appointment to the
18 Committee. No individual who is in the regular
19 full-time employ of the United States and en-
20 gaged in the administration of this chapter may
21 be a member of the Committee.

22 “(4) COMPENSATION.—Committee members,
23 while attending meetings or conferences of the Com-
24 mittee or otherwise engaged in its business, shall be
25 entitled to receive compensation at rates to be fixed

1 by the Secretary, but not at rates exceeding the
2 daily equivalent of the rate in effect for grade GS–
3 18 of the General Schedule, for each day so en-
4 gaged, including traveltime, and while so serving
5 away from their homes or regular places of business
6 each member may be allowed travel expenses (in-
7 cluding per diem in lieu of subsistence) as author-
8 ized by section 5703 of title 5, for persons in the
9 Government service employed intermittently.

10 “(5) ASSISTANCE.—The Secretary shall furnish
11 the Committee with adequate clerical and other nec-
12 essary assistance.

13 “(6) ANNUAL TRAINING.—The Secretary shall
14 employ nongovernmental experts to provide annual
15 training to the Committee on the statutory and reg-
16 ulatory standards for product approval.

17 “(7) TIMELINE.—The Committee shall be
18 scheduled to meet at such times as may be appro-
19 priate for the Secretary to meet applicable statutory
20 deadlines.

21 “(8) MEETINGS.—

22 “(A) OPPORTUNITIES FOR INTERESTED
23 PERSONS.—Any person whose product is spe-
24 cifically the subject of review by the Committee
25 shall have—

1 “(i) the same access to data and in-
2 formation submitted to the Committee as
3 the Secretary;

4 “(ii) the opportunity to submit, for re-
5 view by the Committee, data or informa-
6 tion, which shall be submitted to the Sec-
7 retary for prompt transmittal to the Com-
8 mittee; and

9 “(iii) the same opportunity as the
10 Secretary to participate in meetings of the
11 Committee.

12 “(B) ADEQUATE TIME; FREE AND OPEN
13 PARTICIPATION.—Any meetings of the Com-
14 mittee shall provide adequate time for initial
15 presentations and for response to any differing
16 views by persons whose products are specifically
17 the subject of the Committee review, and shall
18 encourage free and open participation by all in-
19 terested persons.

20 “(C) SUMMARIES.—At all meetings of the
21 Committee, the Secretary shall provide a sum-
22 mary to the Committee of all Tier I and Tier
23 II applications that the Committee did not con-
24 sider that were approved by the Secretary since
25 the last meeting of the Committee.

1 “(h) COMMENCEMENT OF REVIEW.—If the Secretary
2 determines, after preliminary evaluation of the data and
3 information submitted by the sponsor, that the product
4 may be effective, the Secretary shall evaluate for filing,
5 and may commence review of portions of, an application
6 for Tier I or Tier II approval before the sponsor submits
7 a complete application. The Secretary shall commence
8 such review only if the applicant provides a schedule for
9 submission of information necessary to make the applica-
10 tion complete.

11 “(i) INAPPLICABILITY OF PROVISIONS.—The fol-
12 lowing provisions shall not apply to Tier I or Tier II appli-
13 cations and approvals:

14 “(1) Chapter VII, subchapter C, parts 2 and 3
15 relating to fees for drugs, biological products, and
16 devices.

17 “(2) The provisions of the Drug Price Competi-
18 tion and Patent Term Restoration Act of 1984 that
19 authorize approval of abbreviated new drug applica-
20 tions and applications submitted under section
21 505(b)(2). Market exclusivity and patent term res-
22 toration of Tier I and Tier II approved drugs, bio-
23 logical products, and devices shall be determined
24 solely at the time of Tier III approval without re-
25 gard to prior Tier I or Tier II approval. Prior to

1 Tier III approval, the Secretary shall not approve
2 any application submitted under section 505(b)(2)
3 or section 505(j) that references a drug approved
4 under subsections (b) or (c) of this section.”.

5 **SEC. 4. ETHICS IN HUMAN TESTING.**

6 Chapter V of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 351 et seq.) is amended by adding at the
8 end of section 505(i) the following:

9 “(5) Notwithstanding any other provision of
10 law, the Secretary shall prohibit placebo-only or no-
11 treatment-only concurrent controls in any clinical in-
12 vestigation conducted under this chapter or, in the
13 use of the last-observation-carried-forward conven-
14 tion, in any clinical investigation conducted under
15 this chapter or section 351 of the Public Health
16 Service Act with respect to any life-threatening con-
17 dition or disease where reasonably effective approved
18 alternative therapies exist for the specific indica-
19 tion.”.

20 **SEC. 5. EXPANDED ACCESS TO INVESTIGATIONAL DRUGS**
21 **AND DEVICES.**

22 (a) IN GENERAL.—Chapter V of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
24 ed by adding at the end of section 561 the following:

1 “(f) EXPANDED ACCESS PROGRAM.—The Food and
2 Drug Administration shall establish a new program to ex-
3 pand access to investigational treatments for individuals
4 with serious or life threatening conditions and diseases.
5 In carrying out this expanded access program, the Sec-
6 retary shall publish and broadly disseminate written guid-
7 ance that—

8 “(1) describes such expanded access programs
9 for investigational drugs, biological products, and de-
10 vices intended to treat serious or life-threatening
11 conditions or diseases;

12 “(2) encourages and facilitates submission of
13 Tier I and Tier II applications and approvals; and

14 “(3) facilitates the provision of investigational
15 drugs and devices to seriously ill individuals without
16 unreasonable delay by recognizing that the use of
17 available investigational products for treatment is
18 the responsibility of the physician and the patient.

19 “(g) IMPLEMENTATION OF EXPANDED ACCESS PRO-
20 GRAMS.—

21 “(1) TRAINING OF PERSONNEL.—Not later
22 than 90 days after the date of enactment of this
23 subsection, the Secretary shall implement training
24 programs at the Food and Drug Administration with

1 respect to the expanded access programs established
2 under this section.

3 “(2) POLICIES, REGULATIONS, AND GUID-
4 ANCE.—The Secretary shall establish policies, regu-
5 lations, and guidance designed to most directly ben-
6 efit seriously ill patients.

7 “(h) DEVELOPMENT OF SURROGATE ENDPOINTS
8 AND BIOMARKERS.—The Secretary shall—

9 “(1) establish a program to encourage the de-
10 velopment of surrogate endpoints and biomarkers
11 that are reasonably likely to predict clinical benefit
12 for serious or life-threatening conditions for which
13 there exist significant unmet medical needs;

14 “(2) request the Institute of Medicine to under-
15 take a study to identify validated surrogate
16 endpoints and biomarkers, and recommend research
17 to validate surrogate endpoints and biomarkers, that
18 may support approvals for products intended for the
19 treatment of serious or life-threatening conditions or
20 diseases; and

21 “(3) make widely available to the public a list
22 of drugs, biological products, and devices that are
23 being investigated for serious or life-threatening con-
24 ditions or diseases and that have not yet received
25 Tier I or Tier II approval for marketing.”.

1 (b) CONFORMING AMENDMENT.—Section 561(c) of
 2 the Federal Food, Drug, and Cosmetic Act is amended
 3 by striking the heading and inserting “EXPANDED ACCESS
 4 TO INVESTIGATIONAL DRUGS AND DEVICES FOR SERI-
 5 OUSLY ILL PATIENTS”.

6 **SEC. 6. MODERNIZATION OF THE FOOD AND DRUG ADMIN-**
 7 **ISTRATION.**

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

11 **“SEC. 565. POLICIES RELATED TO STUDY EVALUATION IN-**
 12 **FORMATION.**

13 “(a) IN GENERAL.—

14 “(1) NONSTATISTICAL MEASURES.—The Sec-
 15 retary shall give equal weight to clinical judgment
 16 and statistical analysis in the evaluation of the safe-
 17 ty and effectiveness of drugs, biological products,
 18 and devices, and shall not disapprove a product ap-
 19 plication solely on the basis of a statistical analysis
 20 or the rigid use of the 95 percent confidence level
 21 convention. This policy shall apply—

22 “(A) in evaluating clinical study designs
 23 and endpoints; and

24 “(B) in making decisions with respect to
 25 product applications.

1 “(2) TYPES OF NONSTATISTICAL MEASURES.—

2 The policy established under paragraph (1), for the
3 purposes described in such paragraph—

4 “(A) shall include but not be limited to
5 such nonstatistical information as—

6 “(i) clinical evaluation information,
7 such as case history reports;

8 “(ii) scientific and clinical studies de-
9 signed to measure or define mechanisms of
10 action or molecular targeting;

11 “(iii) data from animal and computer
12 models; and

13 “(iv) comparison with historical data;
14 and

15 “(B) shall incorporate the use of—

16 “(i) evaluations of the adverse effect
17 of delaying the availability of an investiga-
18 tional drug to even a small subpopulation
19 of seriously ill patients; and

20 “(ii) scientific, observational, or clin-
21 ical studies designed and conducted to col-
22 lect well-documented information.

23 “(b) MEETINGS.—A meeting to address any pending
24 scientific, medical, regulatory, or other issue relating to
25 the development, investigation, review, or other aspect of

1 a drug, biological product, or device shall ordinarily be
2 held within 15 days of the receipt of a written request
3 for the meeting by the sponsor of the product, which may
4 be extended to 30 days for good cause. Such meetings
5 shall ordinarily be conducted in person, but may be con-
6 ducted by telephone or other form of communication if
7 both parties agree. In order to reduce the burden of meet-
8 ings, only those Food and Drug Administration employees
9 who are intended to actively participate in the discussion
10 shall attend a meeting. Minutes of a meeting shall be
11 promptly prepared and exchanged by both parties imme-
12 diately following the meeting and shall accurately summa-
13 rize what occurred at the meeting

14 “(c) RULE OF CONSTRUCTION.—The provisions of
15 chapter V and section 351 of the Public Health Service
16 Act shall be construed to incorporate the policy established
17 in this section.”.

18 **SEC. 7. MEMBERSHIP OF ONCOLOGY DRUGS ADVISORY**
19 **COMMITTEE.**

20 Membership of the Oncology Drugs Advisory Com-
21 mittee of the Food and Drug Administration shall consist
22 of no less than 2 patient representatives who are voting
23 members of the committee.

○